Pharma Sources Insight

DECEMBER 2021

Quantum Revolution in Drug Discovery

Has COVID-19 been Injecting Cash into Pharma?

Quantum Computing in Pharma

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Dear Readers,

As of today, COVID-19 has swept most countries and areas in the world with over 246 million cases of Coronavirus Disease and nearly 5 million deaths reported, according to WHO.

Statistics show that, as the result of the pursue to develop effective vaccines to protect people from the virus, there are 21 vaccines now in use, 82 vaccines in total are in Phase 2 and Phase 3 trials, and another 10 vaccines are being monitored in the wider population after being approved. If you are interested in vaccine R&D, you might find it useful to read **"Where Are the Oral COVID-19 Vaccines Stand Now" (Page 10) by Dr. Lin Zhang and Demand for High-End COVID-19 Vaccines to Drive Growth of Excipients Market (Page 16) by Shem Oirere.**

Meanwhile, treatments are still "developed to finetune the right cocktail of medications to treat patients with COVID-19", according to **Deborah Seah**, in the article **"Progress of Research on Key COVID-19 Treatments"(Page 13).**

Here comes a question mark, **"Has COVID been Injecting Cash into Pharma?" (Go to Page 6 to find out!)**

Inspired by the success of mRNA vaccines, **"the Application of mRNA Technology has Become a Hot Field in China" (Page 28)**. In China, a series of incentive policies such as centralized procurement, MAH system have encouraged the pharmaceutical companies to embark on a race of new drug development and innovation. In December Issue, on the one hand, we are going to look at **"Sustainable Development Capacity Building of Pharmaceutical Enterprises from the Perspective of R&D Expenditure" (Page 22).** On the other hand, what catches our attention is how **"Innovative Drugs of Chinese Pharmaceutical Companies have Obtained Overseas Authorization and Developed Rapidly" (Page 26).**

To drug discovery nowadays, speed is everything. Technology development, for instance, **Quantum Computing**, provides an enormous potential of not falling behind at the starting line for the pharmaceutical industry. Quantum seems to have permeated to every corner in the advance of science, and pharma is with no difference. In **Industry Insight,** Dr. Sarah Harding will introduce **"How is Quantum going to impact pharma?" and "Why is it better than normal computing?" (Curious to know? Turn to Page 31 now).**

The year 2021 will come to an end, but our exploration in the pharmaceutical industry will not. Gathering elite writers to produce high-quality pharma content, PharmaSources will continue its effort to update developments and trends in the Chinese Pharmaceutical Industry and provide a link for the world pharmaceutical industry to connect with sources of Chinese pharmaceutical products.

Last but not least, our sincerest thanks to the strong support of PharmaSources contributors and the dearest readers of PSI. Thank you for hearing us!

Sincerely,
Editor in Chief
Pharma Sources Insight

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HAS COVID-19 BEEN INJECTING CASH INTO PHARMA

By Sarah Harding

Keywords: COVID-19 Pandemic, Pharmaceutical Companies, Stock Exchange

The impact of COVID on our lives and economies can, in many sectors, only be described as seismic. Casualties include the commercial property market, the hospitality and entertainment industries, and disruptions to supply chains have led to effects on a range of manufacturing and retail businesses. It seems like eons ago (in fact it was just last year, in the early days of the global pandemic) that I wrote about ***Supply Chain Disruption Going Viral***, and considered how troubles in China were affecting many global pharma manufacturers' abilities to make key ingredients. There were widespread concerns at the time that the pharma industry – often considered to be as 'recession proof' as an industry can be – would see significant financial challenges in the months ahead.

I was therefore quite curious, when asked to write something on this topic, to discover how the pharma industry had actually fared. Has pharma weathered the [cytokine] storm, or are pharma companies accumulating debt faster than they can say "coronavirus pandemic"?

Ill people buy medicines

It seems an obvious thing to say, but ill people buy medicines. Panic buying in the UK at the start of the COVID pandemic wasn't limited to toilet paper – I distinctly remember finding it impossible to lay my hands on a packet of paracetamol for several weeks. Right from the start, people stocked up on preventative and curative products, in the hope that they would be able to stave off the worst infections.

On the other hand, it must be acknowledged that cut-backs and reduced access to other medical services led to shortfalls in other areas. I wrote in February this year about my concerns that, as we turned our gaze from other illnesses in our quest to "beat the virus", we might approach a point at which more people died from other diseases, as a result of inaccessibility, than from COVID itself. Yet it was still saddening to read, a couple of months later, that a large systematic review covering 20 countries revealed a 33% decrease in healthcare utilization.[1] This could well be expected to have had an impact

on diagnoses, drug prescriptions, uptake and purchasing during the pandemic.

Naturally, once COVID-specific products became available, people clamoured for access. Governments of developed countries pre-ordered millions of doses of [at the time unproven] vaccines, or battled to keep batches on home soils for domestic use.

Injections of cash

According to a Forbes article published in July 2021,[2] US giant Pfizer now expects to generate $33.5 billion from COVID vaccine sales alone in 2021. This is around 30% higher than the original estimate of $26 billion, with the new projections being based on the 2.1 billion doses of the Pfizer/BioNTech vaccine that the company expects to manufacture and deliver by the end of the year. As Pfizer's partner, BioNTech is benefiting from Pfizer's financial resources, global manufacturing capacity, and regulatory expertise. The company's mRNA technology was critical to the success of the vaccine, and that success is expected to drive BioNTech's fortunes in the coming years. However, some analysts argue that – because the company doesn't have to split profits with a partner – US pharmaceutical and biotechnology company Moderna is likely to make the most money from its own COVID vaccine, over the long run.

In August, an article in Reuters[3] estimated that Pfizer, BioNTech and Moderna have together locked up over $60 billion in sales of COVID vaccines over 2021 and 2022 – by my calculation, that's 4% of the total global pharma spend in 2019. Sales agreements already in place include supply of the initial two doses of their vaccines, as well as billions of dollars in potential boosters as wealthy nations plan to deliver winter booster shots "in a market that could rival the $6 billion in annual sales for flu vaccines for years to come."[3]

In contrast, AstraZeneca's pledge to 'not profit' from their COVID vaccine, which was co-developed with the UK's Oxford University, resulted in comparatively lower earnings. AstraZeneca's COVID vaccine is reported to have generated $1.2bn in the first half of 2021,[4] with sales tripling in the second quarter compared with the first, but the 2021 total income from the vaccine is unlikely to come anywhere near that of the other three companies presiding over the Western COVID market (Pfizer, BioNTech, Moderna). In an industry in which being the 'first to market' has always provided an inarguable revenue advantage, one can only guess whether AstraZeneca's C-suite executives are seeing their situation as a bitter pill to swallow, or as a masterly stratagem to position themselves as the beating ethical heart of pharma.

Johnson & Johnson, which developed the fourth vaccine available to the Western market, has experienced manufacturing problems at a contractor's facility, and concerns about blood clotting have caused a temporary halt in the vaccine's administration in the US. However, as J&J were also selling their COVID vaccine at cost during the pandemic, these issues are reported to be of minimal concern to investors.

Although several COVID vaccines have reached the market, Gilead's remdesivir remains the only antiviral that has been approved by the US Food and Drug Administration (FDA) for the treatment of COVID. Despite scientists at the World Health Organization saying the drug has "no meaningful effect" on mortality or the need for ventilation, the company saw a 26% rise in fourth-quarter 2020 revenue, driven by sales of remdesivir. Earlier this year, Gilead forecasted 2021 sales of up to $3 billion for the drug.

Rise and fall

These wins have been faithfully reflected on the stock exchange. Shortly after Gilead announced their 2021 forecast, shares of the company were up 2.5% in extended trading. Subsequently, shares of Pfizer hit a record high in August 2021, for the first time in more than 20 years, as shares of the COVID vaccine makers surged amid rising cases in the US. The 4.9% percentage gain was the stock's biggest one-day rise since November 2020, when Pfizer released positive data for its COVID vaccine. This is a particularly impressive gain, when you consider that Pfizer's size makes it difficult for any product to substantially change its stock price. Shareholders must be particularly relieved at the successful impact of the COVID vaccine, as it compensates for recent clinical setbacks with

some other products, and the loss of key patents for several drugs later this decade.

Predictably, AstraZeneca shareholders have not been as roundly rewarded. Still pending approval by the FDA, AstraZeneca vaccine sales have been predominantly within Europe, despite an unfortunate supply dispute with the European Commission. That dispute is now resolved, but AstraZeneca's share price remains under pressure following discontinuation of their amyotrophic lateral sclerosis drug trial, due to lack of efficacy. Without profits from their COVID vaccine to buoy them through this choppy period, analysts are advising that AstraZeneca stock isn't a buy right now.[5]

Who to watch?

With only one anti-viral on the market, numerous companies are racing to develop an effective treatment for COVID. Examples include:

- *Merck's molnupiravir tablet is currently in Phase III trials and the company expects to have data by the end of 2021 – this oral product exerts its antiviral action through the introduction of copying errors during viral RNA replication.*

- *Pfizer is also carrying out late-stage trials of two antiviral products – a tablet that can be taken at home, and an intravenous infusion for hospitalised patients suffering from more serious symptoms – both of which are said to work by preventing the replication of the virus by blocking activity of the COVID protease.*

- *Synairgen is developing an inhaled interferon that acts by suppressing the production of interferon beta, which plays a role in activating the wider immune response and preventing the virus from replicating.*

Such is the interest and urgency for such therapies that the FDA has created a special emergency program for possible COVID treatments, called the Coronavirus Treatment Acceleration Program (CTAP). Similarly, the European Medicines Agency (EMA) is interacting with developers of potential COVID treatments to hasten products to market. Programs such as these – driven by the FDA and EMA – will ensure that promising medicines reach patients as soon as possible; they will of course also ensure that the companies developing them receive a return on their investments as soon as possible.

At the end of 2019, before the availability of COVID vaccines and treatments, the total global pharmaceutical market was valued at around $1.27 trillion. Most analysts appear to be suggesting CAGR of around 7% going forward, with COVID cited as a factor underlying some – but not all – of that market growth in the near future. It seems reasonable to conclude that pharma has survived the pandemic intact, with minimal impact of the financial challenges we feared.

The pharma industry has also recovered from some of its pre-pandemic reputational issues, as consumers have turned to big pharma for solutions, giving the industry an important opportunity to improve public engagement and trust.

I can't help thinking that AstraZeneca, in particular, and their non-profit pledge with Oxford University, have helped with that. Compared with a damning report published in September 2019,[6] which revealed deep public mistrust and criticisms of high drug costs, truly socially responsible pledges – like not profiting from a global pandemic – have surely made the public realise that it's not all bad.

It's not often I get to say this, so I'm going to type this very slowly, and relish the moment… it actually makes me quite proud to be British.

Worth Reading:

How Much Money Do Pharmaceutical Companies Really Make From COVID-19 Vaccines?

Read More

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About the Author:

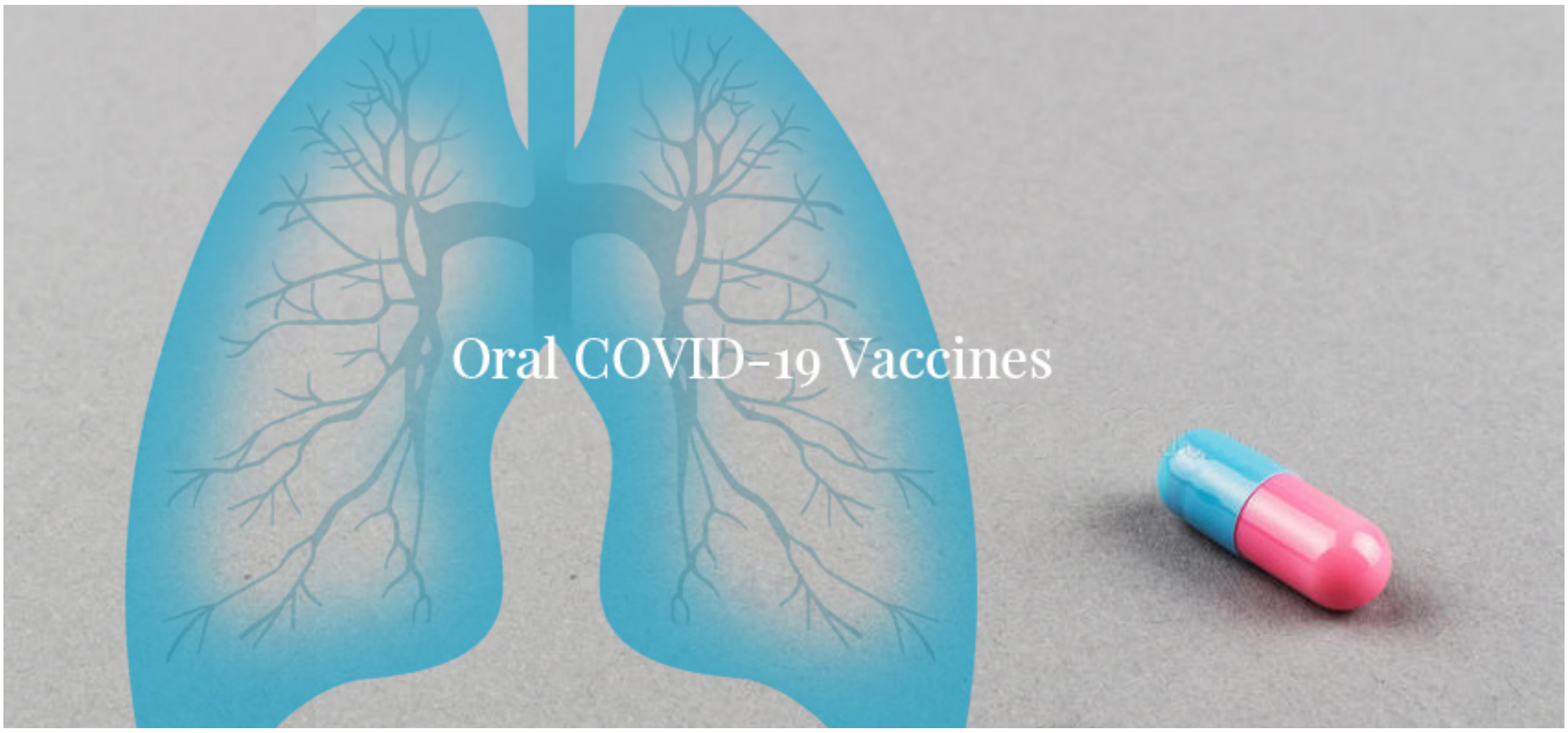
Sarah Harding, PhD

Sarah Harding worked as a medical writer and consultant in the pharmaceutical industry for 15 years, for the last 10 years of which she owned and ran her own medical communications agency that provided a range of services to blue-chip Pharma companies. She subsequently began a new career in publishing as Editor of Speciality Chemicals Magazine, and then Editorial Director at Chemicals Knowledge. She now focusses on providing independent writing and consultancy services to the pharmaceutical and speciality chemicals industry.

WHERE ARE THE ORAL COVID-19 VACCINES STAND NOW?

By Lin Zhang

Keywords: Coronavirus, COVID-19, Oral Vaccine



The novel coronavirus, SARS-CoV-2, has led to an unprecedented international health crisis and is continuing its spread across the world, with more than 218 million confirmed cases of COVID-19, including more than 4.5 million deaths, reported to the WHO as of 3 September 2021. (1)

More than one year into the pandemic, the vaccines for the COVID-19 have been developed in record time as a potentially effective prophylactic strategy. However, despite the amazing progress, there is a strong demand for more options that are more accessible, easier to store, and more effective vaccines. In developing countries, the critical issue is a lack of access to vaccines, or no infrastructure and personnel to deliver the injections en masse. In developed countries, the key issue is the lack of willingness to get vaccinated, an aversion to needles, and a lack of trust for the vaccines and injections in general. To date, with 40.4 % of the world population fully vaccinated, more options are sorely needed. (2)

Oravax - oral virus-like particle (VLP) COVID-19 vaccine

The good news is that an oral virus-like particle (VLP) COVID-19 vaccine by Oravax, an Israeli pharmaceutical Oramed is being tested in preclinical studies against COVID-19 variants including the Delta variant. Study data demonstrated that the oral COVID-19 vaccine promoted both systemic immunity through Immunoglobulin G (IgG), the most common antibody in blood and bodily fluids that protects against viral infections, and Immunoglobulin A (IgA), which protects the respiratory and gastrointestinal tracts against infection. (3)

Based on existing technologies, the scientists have designed synthetic particles that mimic three key structures of the coronavirus pathogen: the spike protein, the envelope protein, and the membrane protein, that includes more elements than the currently approved vaccines, which should enable the pill to better protect against current and future variants of the COVID-19 virus. As we know that the current vaccines in circulation focus on the spike protein, so adding more of these

can help boost the overall effectiveness of vaccines.

How will the oral vaccine work? A challenge is the difficulty ensuring that the vaccine survives the acidic environment, Oramed believes they can create a capsule that is strong enough to withstand the stomach acid as necessary since the company has previously had experience working with protective coating for insulin with Avram Hershko, a Nobel-winning biochemist, showing that it is possible to create capsules.(4) Oramed hopes to use the same technology for the oral VLP COVID-19 vaccine development.

Oravax claims oral COVID-19 vaccine is safe, efficacious, and well-tolerated at normal to high doses, and generates high titers of neutralizing antibodies, which can potentially be more effective against current and future variants of the COVID-19 virus. The VLP vaccine can also be used both as a standalone vaccine and a booster for people who have been previously vaccinated for COVID-19.(3)

The oral VLP COVID-19 vaccine is poised to begin clinical trials during the second quarter of 2021, first in Israel, then in additional clinical sites in multiple countries, including the United States, Europe, and Mexico. The clinical study protocol has been approved by the Institutional Review Board (IRB) at Ichilov Hospital in Tel Aviv Sourasky Medical Center, Israel's leading multidisciplinary healthcare institution, and is now pending approval from the Israeli Ministry of Health. GMP manufacturing for the oral vaccine is underway. As with other vaccines, the trials will move in phases to show success, safety, and efficacy. If the trials prove successful, Oravax hopes to seek emergency approval in countries that are facing vaccine deficits, in particular, developing countries. (5)

Oral vaccines come with a variety of advantages. They can be taken at home and reduce the need for medical professionals who have to administer them, an especially big concern in developing countries. In developed countries, oral vaccines offer an advantage for people who fear needles. Oral vaccines cut out the need for freezing equipment for transportation and storage and eliminates bio-hazardous waste problem. Take together, the oral vaccines may offer relative advantages concerning safety, efficacy, compliance, ease of manufacturing and administration with fewer side effects. (4)

Oral coronavirus vaccine of Israeli team

Currently, a number of research groups throughout the world are now also working intensively to create oral vaccines against COVID-19 besides Oravax. With a similar approach, another Israeli team from the MIGAL Galilee Research Institute's biotechnology group began development on what they hoped would be an oral coronavirus vaccine in February 2020. The scientists said they were primed to develop their vaccine within a few months. (6)

Vaxart's oral recombinant COVID-19 vaccine tablet

Vaxart, a US-based clinical-stage biotechnology company has recently been cleared by the U.S. Food and Drug Administration (FDA) for its drug application for an oral recombinant COVID-19 vaccine tablet, that has moved to the Phase-I clinical trial (NCT04563702).(7) It is an S-only vaccine based on an orally administered adenoviral-vector-based vaccine (VXA-COV2-1) expressing a SARS-CoV-2 antigen and dsRNA adjuvant that is expected to produce higher serum antibodies. (8)

iosBio's oral vaccine

Another oral vaccine candidate under development by a UK-based company iosBio (previously known as Stabilitech) is OraPro-COVID-19TM.(9) It uses a non-replicating viral-vector that expresses the 'S' protein and is used as a thermally stable capsulated form, which meant there is no need of refrigeration which could be a major problem with many other vaccine candidates that need a lower temperature for storage and deployment, especially in developing countries.

Oral capsules of Chan Soon-Shiong Research Institute

In addition, the Chan Soon-Shiong Research Institute in El Segundo, California is also testing oral capsules as an alternative and, perhaps, a more effective alternative to COVID vaccines. The researchers point out another advantage, the possibility of storing the pills at room temperature. Currently, the oral vaccine is under testing with healthy volunteers. (10)

Pfizer's oral solutions for COVID-19

More recently, Pfizer is also getting into the game of oral solutions for COVID-19. It is currently testing an oral medication for COVID in various clinics, including the Austin Regional Clinic, to see whether the oral medication being used can reduce symptoms for high-risk and low-risk individuals. While not a vaccination, it is meant to see whether the oral solution can reduce symptoms and prevent the onset of COVID-19

symptoms among household members. (11)

West Virginia University's approach on nasal mist as a vaccine

There is another approach, West Virginia University scientists are working on a nasal mist as a vaccine, similar to a flu vaccine that can also be offered nasally. Administering vaccines nasally could encourage the development of strong antibody responses. (12) This is a type of research undertaken alongside oral vaccines and might serve as a complement to the oral solutions.

Oral solutions might be combined with nasal solutions for greater efficacy. A study from University of Tokyo researchers has found that oral bacteria-combined intranasal vaccine can protect individuals from COVID-19. Moreover, data showed that oral bacteria-combined intranasal vaccine protects from influenza virus and SARS-CoV-2 infection. (13)

As of August 31, 2021, there have been 297 COVID-19 vaccine candidates in both clinical and pre-clinical development worldwide,(14) only 8 studies are for oral COVID-19 vaccine. (15) Based on current progress, the COVID-19 oral or nasal vaccine is closer to being a reality, offering more vaccination opportunities for developing and developed countries, but it still needs to undergo clinical trials and receive all the proper approvals. We urgently expect a safe and effective oral COVID-19 vaccine to the market as early as possible.

About the Author:

Lin Zhang

Lin Zhang, Ph.D., senior director of a health care industry company in the United States. With the experience in clinical medicine, biotechnology, health industry and other fields, he is responsible for the research and development of plant medicine, functional food and health products. He was a clinician and worked for the National Cancer Institute, FDA and the National Cancer Center of Japan for many years.

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Worth Reading:

Small Molecule and Great Potential: Oral Small Molecule COVID-19 Pharmaceutical Chemicals

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PROGRESS OF RESEARCH ON KEY COVID-19 TREATMENTS

By Deborah Seah

Keywords: COVID-19 Treatments, Molnupiravir, Remdesivir

At the point of writing the COVID-19 pandemic is nearing its two-year run with more than four million deaths and a total of 219 million cases worldwide. Scientists across the world are still scrambling to better understand this virus that struck the world in the beginning of the year 2020. Vaccination against COVID-19 has been the focus of many governments since the approval and manufacture of new COVID-19 vaccines in early 2021. Treatments however are still being worked on and developed to finetune the right cocktail of medications to treat patients with COVID-19. Given the range of symptoms, the patient's age, as well as underlying health condition, COVID-19 patients can experience different severities of symptoms. Most COVID-19 patients with mild symptoms are able to recover at home without having to be admitted to the hospital. For such patients it is usually recommended for them to be quarantined for 14 days depending on the measures set by the government. To help ease the symptoms of COVID-19 patients should try to get enough rest, stay well hydrated, and take medications to relieve fever, aches, and pains as prescribed by a medical doctor.

Based on the World Health Organization (WHO) close to 80% of COVID-19 patients usually recover from the disease without the need for hospital treatment. Unfortunately for the remaining 20% it is a different story. Out of those with COVID-19 15% become seriously ill and would require respiratory support from oxygen tanks. The remaining 5% who are critically ill will need intensive care. Those who are of higher risk of severe disease require more advanced respiratory support such as ventilation. Currently treatment of COVID-19 has been to counter the symptoms or to help reduce the severity of the symptoms. But there is light at the end of the tunnel as the research and development of a COVID-19 treatment is underway and some promising results from various trials have shown that a treatment is not far behind. The following will discuss the treatments that have been studied to curb the progression of COVID-19 in people.

Molnupiravir

Early October 2021, MSD also known as Merck in the

United States (U.S.) and Canada together with Ridgeback Biotherapeutics announced promising interim results from its Phase 3 trial for molnupiravir, an investigational oral antiviral medicine. From the analysis it was found that administering molnupiravir to patients significantly reduced the risk of hospitalization or death.

“With these compelling results, we are optimistic that molnupiravir can become an important medicine as part of the global efforts to fight the pandemic and will add to MSD’s unique legacy of bringing forward breakthroughs in infectious diseases when they are needed most. Consistent with MSD’s unwavering commitment to save and improve lives, we will continue to work with regulatory agencies on our applications and do everything we can to bring molnupiravir to patients as quickly as possible,” said Robert M. Davis, chief executive officer and president, MSD.

After the release of the interim analysis of the Phase 3 trial, MSD announced on October 11, 2021 that it has submitted an application for Emergency Use Authorization (EUS) to the U.S. Food and Drug Administration (FDA) for molnupiravir for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization. Agreements have also been drawn between countries such as Singapore and the U.S. for the supply of molnupiravir if it is authorized or approved for use.

Editor's Note:

According to Merck & Co., Inc., known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics, on November 4, 2021, Merck and Ridgeback’s Molnupiravir has been authorized for the treatment of mild-to-moderate COVID-19 in adults with a positive SARS-CoV-2 diagnostic test and who have at least one risk factor for developing severe illness in UK, while applications remain under review by other regulatory authorities, including U.S. Food and Drug Administration and the European Medicines Agency.

Dexamethasone

Traditionally used to treat a wide range of conditions due to its anti-inflammatory and immuno-suppressant effects, dexamethasone is a corticosteroid that was found to benefit critically ill COVID-19 patients. Dexamethasone was tested in the United Kingdom’s national clinical trial called RECOVERY. Results from the trial demonstrated a lower mortality among the patients who were administered dexamethasone.

According to the WHO, COVID-19 patients who need oxygen ventilators showed reduced mortality by about one third after treatment with dexamethasone. For patients who only require oxygen support the mortality was reduced by one fifth. Based on the WHO recommendations such corticosteroids should be given orally or intravenously for the treatment of patients with severe and critical COVID-19. On top of that, for patients with less severe COVID-19 WHO recommends against the use of dexamethasone or other corticosteroids for treatment.

Remdesivir

Remdesivir is a nucleotide analog invented by Gilead Sciences, Inc. It has broad-spectrum antiviral activity in both in vitro and in vivo demonstrated in animal models against multiple emerging viral pathogens.

On November 20, 2020 the WHO issued a conditional recommendation for the use of remdesivir in hospitalized patients with COVID-19, regardless of disease severity. This was announced as a result of data reviewed by a panel of professionals from the WHO Solidarity Trial as well as three other randomized controlled trials consisting of data from over 7000 patients.

Remdesivir has been approved or authorized for temporary use as a COVID-19 treatment in almost 50 countries worldwide. There are also multiple ongoing international Phase 3 clinical trials to evaluate the safety and efficacy of Remdesivir for the treatment of COVID-19, in different patient populations, formulations, as well as combinations with other therapies.

Tocilizumab

Tocilizumab is an intravenous anti-inflammatory monoclonal antibody used to treat rheumatoid arthritis. It is manufactured by Swiss drugmaker, Roche.

FDA issued an emergency use authorization (EUA) for Actemra (tocilizumab) for the treatment of hospitalized adults and

pediatric patients 2 years of age and older with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Actemra is not authorized for use in outpatients with COVID-19.

In clinical trials of hospitalized patients with COVID-19, tocilizumab in addition to routine care, which included corticosteroids, was shown to reduce the risk of death through 28 days of follow-up and decrease the amount of time patients remained hospitalized. The risk of patients being placed on ventilators through 28 days of follow-up was also decreased.

Convalescent plasma

Convalescent plasma is blood plasma from a person who has recovered from an infection. It contains antibodies against the infection such as SARS-CoV-2 and may help a patient with COVID-19 recover faster. It is sometimes used to complement initial treatments with steroids and antiviral medications.

Despite some evidence of its effectiveness in treating patients with COVID-19, studies have shown that it does not reduce the risk of intubation or death in hospitalized patients with COVID-19.

About the Author:

Deborah Seah
Science Writer

Deborah Seah is a contributing writer for a column on PharmaSources.com, Discovering Biotechnology. The column explores innovative technologies in the world of biotech and evaluates its impact on our future. She is also an editor for a monthly science and technology magazine, Asia-Pacific Biotech News.

Prior to her career in writing she worked as a research associate at a plant genetics laboratory of a multinational agriculture company. Following that she also had experience in a medical diagnostics start-up as a medical technologist.

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New Progress of Key Chinese COVID-19 Drugs under Research

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DEMAND FOR HIGH-END COVID-19 VACCINES TO DRIVE GROWTH OF EXCIPIENTS MARKET

By Shem Oirere

Keywords: High-end Vaccines, COVID-19 Vaccines, Excipients Market

The COVID-19 pandemic has infected 247 million people and killed five million others as of November 01, 2021 the situation still looks grim due to the high infection rates, the prolonged SARS-CoV-2 virus incubation period and persistent shortage of mature treatments or protective jabs. (1)

Although there is an increase in manufacture and distribution of new biopharmaceuticals, drug products, vaccines, and efforts to re-purpose older pharmaceutical drugs to effectively tackle the deadly COVID-19 globally, demand, especially for vaccine continues to rise hence triggering spike in the production and supply of appropriate excipients for the stabilization of biologics and vaccines during processing and storage.

For example, with only 77 million people having been vaccinated in Africa, the region is in need of nearly 275 million COVID-19 vaccines to enable it meet its target of fully immunizing 40% of the continent's nearly 1.2 billion people. *(ibid)*

This number of immunized people in Africa is an equivalent of 6% of the continent's population compared to more than 40% vaccinated in nearly 70% of high-income countries. *(ibid)*

For pharmaceutical companies such as Johnson & Johnson, Moderna, AstraZeneca and Pfizer, some of the leading vaccine suppliers globally, the demand for millions of COVID-19 vaccine doses could translate into an expanded order book for excipients such as thimerosal, stabilizers, diluents, gels and antibiotics.

A case in point is the recent realization that fatty droplets or lipid nanoparticles, are suitable in protecting the active ingredient messenger RNA (mRNA) and help it easily enter cells. The realization paved way for the commercial production of the mRNA COVID-19 vaccine, which was the first mRNA product to receive approval from Food and Drug Administration (FDA) in the US and now the most widely used vaccine globally according to US biotechnology firm Biopharma PEG Scientific Inc. (2)

The use of lipid nanoparticles in the mRNA COVID-19 vaccine

has a direct impact on the demand for excipients such as solid lipids, liquid lipids (oils), surfactants, and surface modifying agents that support the stabilization mRNA during its processing and subsequent storage. *(ibid)*

"In mRNA vaccines, the mRNA is encapsulated in lipid delivery technology, which provides protection for the mRNA and safely delivers it to human cells where it can be released and the vaccine can take effect," says Biopharma PEG.

Apart from COVID-19 vaccine production, demand for excipients is expected to grow as the global generic drugs market expands with reports projecting the market size to hit $533 billion by the end of this year according to US-based market research firm BCC Research. (3)

The anticipated growth of the generic market is driven by "pharmaceutical drugs facing patent expiry, the pressure to control healthcare costs, the rise of biosimilar drug technologies, and high-growth market activity in emerging regions." *(ibid)*

Furthermore, Aztrazenica, the manufacturer of COVID-19 Vaccine AstraZeneca, says currently "demand for generics is high". This is due to the products being "lower priced because generic manufacturers are largely spared the costs of research and development and market development." (4)

At least 85.3% of the prescriptions dispensed in the US in 2020, were generics an indication of how the products would drive the future market growth for excipients. *(ibid)*

However, generic drug manufacturing as a driver in the growth of the global excipients market continues to grapple with the unresolved issue of how switching branded to generic pharmaceutical drugs is impacting the global healthcare system.

The US' FDA proposes more tests to confirm the effectiveness levels of some excipients on for example their efficiency in aiding drug absorption alimentary canal. (5)

"Therefore, laboratory studies are needed to understand the potential differences in excipients contained in brand name versus generic drug products," FDA says.

Elsewhere, the global excipients market received a major boost in September 2021 when the International Pharmaceutical Excipients Council Federation promulgated the revised IPEC Good Distribution Practices Audit Guide for Pharmaceutical Excipients to support a seamless supply chain management and control of pharmaceutical starting materials. (6)

The Guide, which consolidates and revises IPEC Europe's GDP Audit guideline (2011) and IPEC-Americas GDP Audit Guide for North American distribution of pharmaceutical excipients (2011), "provides a comprehensive tool for companies auditing the supply chain of pharmaceutical excipients."

"Several incidents in the past were caused by a lack of supply chain security and inappropriate handling of pharmaceutical excipients," IPEC said in a statement.

The revised guidelines, which has the support of excipient regulators, users, manufacturers and distributors "serves as a valuable tool to help the auditor conduct a complete audit of all relevant GDP principles for pharmaceutical excipients." *(ibid)*

The document outlines the role of various excipient value chain players such as "re-processors, re-packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer." *(ibid)*

The release of the excipient GDP principles coincides with a projected global pharmaceutical sales growth. AstraZeneca estimates the growth at 3.8% in 2020 with the international healthcare spending expected increase at an annual rate of 4.2% from 2019 to 2024.

With an anticipated increase in global demand for healthcare, particularly in Africa, the Commonwealth of Independent States, the Indian subcontinent and Latin America, pharmaceutical drug production is expected to grow as would the rate of excipient consumption.

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About the Author:

Shem Oirere

Shem Oirere graduated from the University of South Africa with a bachelor's degree in International Relations and Diplomacy, and also holds a Diploma in Journalism from the London School of Journalism. He previously worked for the Kenya Times, Nation Media Group and The People Daily over a twenty-year span as a business writer and Sub-editor. He wishes to share a view of the scenes behind Africa's latest pharma market trends with the rest of the world.

Global R&D Trend DECEMBER 2021

FROM PEGAN DIET TO FUNCTIONAL MEDICINE AND BOTANIC REMEDY

By Lin Zhang

Keywords: Pegan Diet, Functional Medicine, Botanic Remedy

There are many different diets offered today. A Mediterranean-style diet has been widely studied, and a new concept is the so-called pegan diet, which is combined paleo and vegan two words and led to a new hybrid model, the pegan diet, which is gaining worldwide attention. (1)

As the name suggests, the Pegan Diet concept is a hybrid diet, combining the paleo diet and the vegan diet (although it goes a step beyond this). Paleo is focused on whole foods that are like those that our ancestors ate, for example, fruits, meats, nuts, while a vegan diet involves only plant-based foods, excluding dairy and meat. The pegan diet is less strict than vegan and encourages the practitioner to eat about 75% of plant-based foods and 25% of animal-based foods, but fully forbids dairy and gluten. (2)

The roots of this diet can be traced to a 1985, S. Boyd Eaton and Melvin Konner published a landmark paper in the New England Journal of Medicine titled "Paleolithic Nutrition: A Consideration of Its Nature and Current Implications," and this work postulated that an increase in the prevalence of chronic disease among modern humans is the result of a dietary composition that was not compatible with both our genetic ancestry and natural metabolic function. (3) This laid a foundation for the paleo diet that tries to focus on foods that are like those that people could eat since the beginnings of their evolution. At the same time, another camp has been promoting a vegetarian and, more recently, a fully vegan diet on grounds of both ethics and health, suggesting that the optimal human diet should be plant-based.

As a hybrid model, what are the health benefits of the pegan diet? It is not as well-tested as other diets because it's a relatively new approach. However, it has some strong advantages. The pegan diet emphasizes nutrient-rich fruits, vegetables, and healthy fats, which is generally good for health and can have a variety of positive effects on the body. It may also help prevent chronic disease, promote heart health, and reduce inflammation, in particular, the cardiovascular and digestive systems. (4)

The findings from one study indicated that only 12% of Americans are metabolically healthy. 75% of us are overweight, 42% are obese, and one in two Americans have pre-diabetes or type 2 diabetes. (5) The pegan diet appears to be especially good for people with metabolic and chronic health conditions. Therefore, individuals with diabetes or pre-diabetes might find this diet more helpful.

As the pegan diet creator, Dr. Mark Hyman said: “we now know that food is medicine—perhaps the most powerful drug on the planet—with the power to cause or cure most disease”. (6) In accordance with this, food has been called “Functional Medicine, Eat Your Medicine” which is the science of creating health, of creating resilience, and making your system an inhospitable place for disease to support longevity, energy, mental clarity, happiness, and much more as well as uncovers and addresses the root cause of chronic disease through the power of functional medicine (foods)—the only way to actually cure and reverse chronic diseases. (7)

According to the US Centers for Disease Control and Prevention (CDC), chronic diseases are defined broadly as conditions that last one year or more and require ongoing medical attention or limit activities of daily living or both. It is well established that chronic diseases such as cardiovascular diseases, diabetes, and cancer are global epidemics in developed countries. CDC data shown these chronic diseases are the leading causes of death and disability in the United States. They are also leading drivers of the nation’s $3.8 trillion in annual health care costs. (8)

Traditional functional medicines used for centuries often have tangible physiologic and therapeutic value. Therefore, dietary contributions to health and chronic conditions, such as obesity, metabolic syndrome, cancer and cardiovascular disease, are of universal importance. Functional medicine will be forged through our understanding of how each of these dietary variables influence metabolism and their relationship to genetic individuality for many chronic diseases.

For instance, in a recent large collaborative study, the impact of this Mediterranean/Pegan-type diet approach on 1098 individuals was evaluated using deep phenotyping through metagenomic sequencing, as well as fasting-and post-prandial cardiometabolic blood biomarkers. The study results, which were published in ***Nature Medicine*** in 2021, demonstrated that application of this diet had a favorable influence on intestinal microbiome composition and was associated with healthy cardiometabolic biomarkers. (9)

Another study from Chinese group demonstrated that 27 commonly used wild food-medicine plants were recorded and analyzed. These botanical species can be classified into 8 categories: treatment of the damp-heat syndrome, digestive diseases, urologic diseases, arthropathy, respiratory diseases, gynecological diseases, snake or insect bites, and uses as a tonic. (10)

Specifically, today, more than 8000 phytochemicals have now been identified in functional foods and botanical agents (11) , some of them with anti-viral and immune-boosting herbs and spices have been used as part of the Functional Medicine approach to the SARS-CoV-2 virus indicates they may have a role in the pre-exposure and early phase of COVID-19. These botanicals included but not limited to Ginger, Garlic, Turmeric, Rosemary, Chili pepper, and Oregano, (5) as well as Curcumin, Quercetin, Zinc acetate, citrate, picolinate, or glycinate; zinc gluconate, N-Acetylcysteine (NAC), Vitamin A, C, D, Melatonin, Elderberry (Sambucus nigra), Green tea or epigallocatechin gallate (EGCG), Resveratrol, Beta-glucans, Medicinal mushrooms and Licorice root (standardized to glycyrrhizin). (12) Likewise, these agents can be considered as functional medicine, botanic remedies, immunoadjuvants, protease inhibitors, angiotensin-converting enzyme II (ACE2) modulators, zinc ionophores, and anti-inflammatory agents for promising prevention approaches and therapeutic (functional medicine and botanical) interventions.

Therefore, some functional food aforementioned potentially can be developed as botanic medicine for the prevention and treatment of chronic diseases and change patients’ lives and improve their quality of life.

Notably, these recommended interventions are only intended to identify functional medicine and botanical agents that may boost your immune system. It is not meant to recommend any treatments, nor have any of these been proven effective against the COVID-19. For up-to-date information of prevention and treatment on COVID-19 pandemic, please refer to the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention at www.fda.gov and www.cdc.gov, respectively.

About the Author:

Lin Zhang

Lin Zhang, Ph.D., senior director of a health care industry company in the United States. With the experience in clinical medicine, biotechnology, health industry and other fields, he is responsible for the research and development of plant medicine, functional food and health products. He was a clinician and worked for the National Cancer Institute, FDA and the National Cancer Center of Japan for many years.

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ANALYSIS ON THE SUSTAINABLE DEVELOPMENT CAPACITY BUILDING OF PHARMACEUTICAL ENTERPRISES FROM THE PERSPECTIVE OF R&D EXPENDITURE

By Zhulikou431

Keywords: R&D Expenditure, Sustainable Development Capacity, Pharmaceutical Enterprises

From the data of semi-annual reports released by major companies, we now focus on the R&D investment of pharmaceutical companies instead of the highly anticipated revenue data. Whatever the huge gap of R&D investment amount between Chinese head pharmaceutical companies and the international leading pharmaceutical companies in the past, according to the annual report data of listed Chinese pharmaceutical companies, the recent few years have seen a continuous increase of R&D expenses, but most of the expenses are invested in the field of biopharmaceuticals and a few head chemical pharmaceuticals.

Among multinational pharmaceutical companies, we can see that Roche ranks first in R&D expenditure with an investment of USD 7.75 billion (the R&D expenses account for 23.86%). According to Roche's annual report data and the list of R&D investment of global pharmaceutical companies, we can see that in recent years, Roche's expenditure on R&D has been ranked first in the world: in 2017, it was 11.8 billion US dollars, ranking first in the world; in 2018, it was 10.8 billion US dollars, ranking first in the world; in 2019, it was as high as 12.31 billion US dollars, accounting for 19.0% of its total revenue. In 2020, the R&D investment of Roche was 13 billion Swiss francs (about 13.85 billion US dollars), ranking first in the world and accounting for 22.2% of R&D investment. From the above data, it can be seen that Roche, as a representative company of multinational pharmaceutical companies, invests a lot in R&D, and its R&D expenditure ranks first for many years. The core idea of this business strategy is to attach importance to R&D, pursue the development of new products, and increase strength for the sustainable development of enterprises and strong control over the market.

The Pharmaceutical industry is a knowledge-intensive industry, and R&D innovation is the central theme of pharmaceutical companies and the fundamental security for sustainable vitality. R&D investment is not only an important factor to measure the strength and potential of R&D innovation, but also one of the main influencing factors to affect pharmaceutical R&D output, while the R&D level determines the international competitiveness of the whole industry. In recent years, the global R&D expenditure of the pharmaceutical industry has maintained steady growth, and global drug R&D has increasingly heated up. According to incomplete statistics, the global drug R&D expenditure reached USD182 billion in 2019. New molecular drugs are constantly appearing in the disease areas of cancer, diabetes, cognitive impairment, rare diseases, inflammation, and others. Biomedicine has entered a high-speed development stage. Diagnostic techniques and therapies are closely combined and complement each other. The monoclonal antibody, immunotherapy, cell therapy, gene therapy, stem cell therapy, and other technologies and drugs are constantly emerging and gradually maturing. New progress has been made in the fundamental frontier disciplines of medicine. Especially in the severe situation of COVID-19 from 2020 to 2021, the fact that advent of test kits, preventive

drugs (vaccines), and therapeutic drugs has further proven the significance of strengthening the construction of fundamental frontier disciplines.

Looking back at the R&D investment of domestic pharmaceutical companies, people in the industry feel pressure. Let alone the huge gap of R&D investment amount between Chinese head pharmaceutical companies and the international leading pharmaceutical companies in the past, according to the annual report data of listed Chinese pharmaceutical companies, the recent few years have seen a continuous increase of R&D expenses of pharmaceutical companies in China, but most of the expenses are invested in the field of biopharmaceuticals and a few head chemical pharmaceuticals. For a long time, the major products in the Chinese pharmaceutical industry have always been generic drugs and traditional Chinese medicines, and biopharmaceuticals are in the ascendant. In recent ten years, Chinese biopharmaceuticals have entered the fast lane of development. On the whole, although the R&D investment of pharmaceutical companies is on the rise with the heating up of biomedicine, centralized procurement of generic drugs, and encouraging policies for innovative drugs, there is still a big gap between Chinese and global R&D investment in drugs.

First of all, the TCM R&D orientation of the Chinese pharmaceutical enterprises, as a traditional sector of the Chinese pharmaceutical industry, is not very clear, and the TCM innovation is still at the stage of dosage form improvement and process optimization with the product innovation lagging behind. From the recently published semi-annual report, we can see that in the first half of this year, the R&D investment of more than 70 listed traditional Chinese pharmaceutical enterprises accounted for less than 1% of the revenue, and only a dozen of them exceeded 5%. The best ones are Kanion Pharmaceutical (the R&D investment is about 217 million yuan, which accounts for 12.25% of the revenue), and Guilin Sanjin (the R&D investment is about 104 million yuan, which accounts for 11.87% of the revenue). Besides the lack of investment in R&D, the backwardness in the field of traditional Chinese medicine can also be reflected in pharmaceutical equipment and analytical resources, the quality and ability training of technicians, and the strategic layout of pharmaceutical enterprises, which are obviously insufficient compared with international famous pharmaceutical companies and the fierce competition pattern in the 21st century.

In the field of chemical medicine and biopharmaceuticals, the top five Chinese pharmaceutical companies which invest the most in R&D in 2020 are BeiGene (8.452 billion yuan), Hengrui Medicine (4.989 billion yuan), CSPC (2.89 billion yuan), Sino Biopharm (2.853 billion yuan) and Fosun Pharma (2.795 billion yuan). Next, we will focus on analyzing the R&D investment of these pharmaceutical companies in the first half of 2021.

BeiGene

BeiGene is a biotechnology company focusing on the research, commercialization, and production of innovative cancer drugs. In the first half of 2021, BeiGene achieved a total product revenue of USD 245 million, a year-on-year increase of 107.95%. At the same time, in the first half of 2021, the R&D expenditure was USD 677 million, up by 14.66% year-on-year, which was mainly due to the expansion of the company's global development institutions, clinical and preclinical candidate drugs, and continued efforts to internalize research and clinical trials. It is reported that BeiGene currently has about 50 kinds of drugs and candidate drugs in the commercial stage or clinical development stage, including 10 approved drugs, 2 drugs to be approved, and more than 30 drugs in the clinical development stage. From the above data, it can be predicted that the next 5-10 years will be the intensive harvest period of BeiGene.

Hengrui Medicine

The main businesses of Hengrui Medicine involve drug R&D, production, and sales, and its main products cover many fields such as anti-tumor drugs, surgical anesthesia drugs, contrast media, special infusion, cardiovascular drugs, etc. In the first half of 2021, Hengrui Medicine achieved a revenue of 13.298 billion yuan, a year-on-year increase of 17.58%. At the same time, the R&D investment in the first half of the year was 2.581 billion yuan, up nearly 40% year-on-year. This amount accounted for 19.41% of sales revenue, hitting a new high.

Hengrui Medicine is a representative enterprise of medical innovation in China and is now in the harvest period. The

number of innovative drugs under development by Hengrui Medicine ranks among the top in China. At present, 8 innovative drugs such as Imrecoxib, Apatinib, Mecapegfilgrastim, Pyrotinib, Camrelizumab, Remimazolam Tosilate, Risperidone, and Herombopag have been approved for marketing. The company also has dozens of innovative drugs in clinical trials stages, which supports undergoing post-marketing clinical research and continuous innovation and development in the fields of anti-tumor drugs, surgical drugs, endocrine therapy drugs, cardiovascular drugs, anti-infective drugs, and rheumatism immunity drugs.

In addition, in the first half of the year, Hengrui Medicine obtained marketing approvals for 5 innovative pharmaceutical preparations and 9 generic drugs preparations, clinical approvals for 41 drugs and consistency evaluation approvals for 10 varieties, completed the application for consistency evaluation of 2 products, and carried out more than 240 clinical projects at home and abroad. At the same time, 131 new domestic patent applications and 39 new international PCT applications were submitted. 64 domestic authorizations and 59 overseas authorizations were obtained. In the first half of 2021, Hengrui faced various pressures, and the market also gave feedback on layoffs and policy adjustments of Hengrui many times. However, according to the comprehensive strength, the adjustment cycle of Hengrui will not be very long. It is estimated that Hengrui Medicine will once again become the leading enterprise in China's pharmaceutical industry in the second half of 2021 or the first half of 2022.

CSPC

In the first half of 2021, CSPC achieved a sales revenue of 13.82 billion yuan, up 9.8% year-on-year, and the net profit was 3.06 billion yuan, up 32.3% year-on-year. The R&D expenses reached a new high of 1.61 billion yuan, up 11.0% year-on-year.

CSPC is one of the largest production bases of antibiotics and vitamins in the world. For many years, it has been adhering to innovative development. The key to its sustainable development is that the main point of development has transferred from raw medicine to innovative drugs. Now, CSPC has transformed into one of the most innovative pharmaceutical companies. At present, the company has 300 projects under research, including over 40 small molecule innovative drugs, over 40 macromolecular innovative drugs, and over 30 new preparations. It mainly covers 6 treatment areas including anti-tumor, immunity and respiration, psychiatric nerve, metabolism,

cardiovascular and cerebrovascular system, and anti-infection. 29 products are in the pending registration review approval stage, 40 products are undergoing clinical trials (including 33 innovative drugs and 7 new preparations), 5 products are undergoing bioequivalence trials, and 11 products and clinical trial indications are in the pending clinical approval.

In addition, CSPC has established eight innovative drug technology platforms, among which, the nanomedicine technology platform has a systematic product layout, including nanoliposomes, albumin nano preparations, polymeric micelles, and a number of core delivery technologies. The company has also established a platform for mRNA vaccines and small nucleic acid drugs. Great progress has been made in the mRNA vaccines for many major infectious diseases and small nucleic acid drugs for genetic diseases and metabolic diseases.

In the next five years, more than 30 innovative drugs and new preparations are expected to go on the market in CSPC, including multivalent mRNA vaccines against SARS-CoV-2 mutants and small nucleic acid drugs administrated once every six months, all of which are blockbuster products with global patents. As a local pharmaceutical group grown from Shijiazhuang, Hebei Province, it is not easy for CSPC to achieve the above achievements. If CSPC wants to hold the leading position and continue to develop and expand internationally, invest flexibly and actively, and continuously strengthen R&D control, this is a field that shall be considered deeply.

Sino Biopharm

In the first half of 2021, Sino Biopharmaceutical Limited achieved a revenue of 14.354 billion yuan with a year-on-year increase of 13.5%, hitting a record high. The net profit attributable to the parent company was 8.48 billion yuan, a year-on-year increase of 583.6%. In terms of R&D investment, the total amount of Sino Biopharmaceutical Limited in the first half of 2021 was about 1.88 billion yuan, up 15% year-on-year

and accounting for 13.1% of the total revenue.

Sino Biopharmaceutical Limited is a pharmaceutical company specializing in the R&D, production, and sales of biopharmaceuticals and pharmaceutical chemicals. In the first half of 2021, it maintained double-digit growth in five core areas, namely, anti-tumor, parenteral nutrition, cardiovascular and cerebrovascular diseases, respiratory diseases, and orthopedics. Antitumor drugs became the largest business sector of Sino Biopharmaceutical Limited, with the growth rate of seven varieties exceeding 50%. The company's existing pipelines have great market potential. In particular, the strong tumor and respiratory pipelines are the core track of global new drug R&D. In addition, in recent years, the R&D investment of Sino Biopharmaceutical Limited has continuously increased, and 50% of the projects entering the clinical stage are self-developed varieties. More than 60 new products marketed after 2018 have contributed more than 80% to sales growth, and their share of sales revenue has exceeded 40% and is still growing rapidly.

Fosun Pharma

In the first half of 2021, Fosun Pharma achieved an operating income of 16.952 billion yuan, a year-on-year increase of 20.85%. At the same time, the R&D investment was 1.954 billion yuan, a year-on-year increase of 15.69% and accounting for 11.53% of business income. Among them, the R&D expenses were 1.562 billion yuan, a year-on-year increase of 29.73%.

Fosun Pharma is one of the leading biopharmaceuticals in China and has made great achievements in monoclonal antibodies, CARTs, and vaccines. In recent years, Fosun Pharma has devoted itself to promoting innovative R&D and accelerated the implementation of innovative technologies and launching of products to meet the unmet clinical needs and improve drug accessibility. At present, there are 240 projects under research, including innovative drugs, generic drugs, biosimilar drugs, and consistent evaluation of generic drugs. There are 72 innovative drugs among them.

Fosun Pharma has a strong ability to integrate resources within the group. Internationalization and flexible investment ability are the other two strengths of Fosun Pharma. If Fosun Pharma wants to turn R&D projects into achievements and hold its head position in the fierce competition, it still needs to pay attention to the continuous control of internal R&D resources and stabilization of the R&D core team.

Summary

From the data above, we can summarize that:

- Although the national drug administration agencies and local governments continue to issue policies to promote Traditional Chinese Medicine, it is difficult to change the situation that the Traditional Chinese Medicine industry is difficult to expand due to product characteristics.

- The strong enterprises will be stronger is increasingly obvious. From the annual report of the first half of 2021, it is difficult to rank in the leading place in China without a profit of about 2 billion yuan.

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About the Author:

Zhulikou431

Zhulikou431, as a senior engineer, PDA member, ISPE member, ECA member, PQRI member, senior aseptic GMP expert, has deep knowledge in aseptic process development and verification, drug development and registration, CTD document writing and review, regulatory audit, international certification, international registration , quality system construction and maintenance, as well as sterile inspection, environmental monitoring and other fields. In recent years, he has focused on the analysis of trends in the macro pharmaceutical field and the risk management of pharmaceutical enterprise mergers and acquisitions projects.

INNOVATIVE DRUGS OF CHINESE PHARMACEUTICAL COMPANIES HAVE OBTAINED OVERSEAS AUTHORIZATION AND DEVELOPED RAPIDLY

By Xiaoyaowan

Keywords: License In/Out, Chinese Pharmaceutical Companies, Innovative Drugs

In March 2007, Chipscreen licensed the global development rights of Chidamide, a product under research, to HUYA of the United States at a price of USD 28 million. This transaction represents that Chinese local pharmaceutical companies have embarked on a new journey to authorize innovative drugs in overseas markets.

In recent years, with the continuous improvement of the overall R&D environment of innovative drugs in China and the constant advancement of the innovation capability of local pharmaceutical companies, innovative drugs independently developed by China have gained increasing attraction and recognition in the international market. After years of accumulation, the pipelines of Chinese innovative drugs under research are gradually abundant, and the products under research are maturing gradually. The overall number of innovative drug projects authorized in the overseas market is increasing. According to statistics, before 2014, there were 4 innovative drugs authorized in overseas markets, and the number has increased to 65 up to now.

Chinese Pharmaceutical Companies Entering the Market, Overseas Authorized Innovative Drugs are Multi-target Distributed

There are 37 local pharmaceutical enterprises that are overseas licensors of innovative drugs in China, including innovative biopharmaceutical companies represented by Innovent and BeiGene; large Chinese pharmaceutical companies that have been internationalized for many years, such as Hengrui Medicine; and traditional pharmaceutical companies that have transformed into making innovative drugs, represented by I-Mab Biopharma and Luye Pharma.

The innovative drug types authorized in overseas markets include small-molecule, monoclonal-antibody, and double-antibody drugs. From the target distribution of authorized innovative drugs overseas, broad-spectrum targets such as VEGF and PD-1/PD-L1 occupy a dominant position. The enterprises of these externally authorized innovative drugs involve Bio-Thera, Betta Pharmaceuticals, Innovent, Hengrui Medicine, etc. In terms

of targets for specific disease fields such as BTK, EGFR, and HER2, pharmaceutical companies including Allist, BeiGene, and Remegen have authorized relevant innovative drug varieties.

From the current development trend, the innovative drug targets authorized by Chinese pharmaceutical companies are gradually laid out and extended in many disease fields, and the types of innovative drugs under research are becoming increasingly rich.

In 2020, the Number of Overseas Authorizations by Chinese Local Pharmaceutical Companies Reached a New High

Thanks to the support of Chinese pharmaceutical policies, and with the help of investment and financing fields for the R&D of the innovative drug, Chinese local pharmaceutical companies have put greater focus on their R&D and innovation in recent years. Since 2017, the number and the average number of innovative drugs authorized by Chinese local pharmaceutical companies have gradually increased.

In 2020, 18 Chinese local pharmaceutical companies have finished their authorizations in overseas markets of 23 innovative drug projects, which has reached a new high. Such therapeutic areas as anti-tumor, ophthalmology, psychiatry, non-alcoholic steatohepatitis, diabetes, and COVID-19 are incorporated. There is a historical record in terms of the number of overseas authorizations. The targets of the innovative drugs include VEGF, PD-1, BTK, EGFR, CD47, etc. and the drug types involve small-molecule, monoclonal-antibody, ADC, double-antibody drugs, etc.

It is worth noting that in 2020, the transaction volume of two overseas authorizations exceeds USD 1 billion. The total transaction amount of PD-1 monoclonal antibody CS1001 authorized by Cstone Pharmaceuticals to EQRx reached USD 1.3 billion, and the total transaction amount of monoclonal antibody antitumor drug Lemzoparlimab authorized by I-Mab Biopharma to Abbvie reached USD 2 billion. **In 2021, the transaction of authorization is active and the amount of a single transaction hit a new record.**

In 2021, Chinese local pharmaceutical companies were still active in external authorization transactions, maintaining the good development momentum in 2020. According to the authorization transactions disclosed by biopharmaceutical companies, the total transaction amount was as high as RMB 29.5 billion. Certain therapeutic fields, such as tumors, rare diseases, immune diseases, COVID-19, and multiple sclerosis, are incorporated.

At the same time, the transaction amount reached a new high, and the performance of Chinese licensors was great. In January 2021, BeiGene and Novartis entered into a cooperation agreement on the development rights of PD-1 monoclonal antibody tislelizumab in many countries, with a total transaction amount of USD 2.2 billion. In September, Remegen reached a cooperation agreement with Seagen on its ADC drug - disitamab vedotin, which is intended to be used for the treatment of gastric cancer. The total transaction amount of USD 2.6 billion, including the down payment of 200 million US dollars and a milestone payment of USD 2.4 billion, sets a new record for overseas authorization of Chinese pharmaceutical companies in innovative drugs.

In addition to the above two transactions exceeding USD 2 billion, the authorized transaction amount of Junshi Biosciences in February and Innocare Pharma in July both exceeded USD 1 billion.

With the further improvement of Chinese innovation strength, Chinese local innovative pharmaceutical companies will gradually integrate into the global market of innovative drugs, and their R&D capabilities will gradually be recognized by the international market. In the future, the transaction on the overseas authorization of innovative drugs will be more active and frequent, and the number of transaction projects is expected to reach new heights. The hard power to participate in international competitions will become much stronger.

About the Author:

Xiaoyaowan

Xiaoyaowan, a pharmaceutical industry practitioner, a word carrier in the We-media era focusing on changes of the pharma industry.

SUPPORTED BY CAPITAL, THE APPLICATION OF MRNA TECHNOLOGY HAS BECOME A HOT FIELD IN CHINA

By Xiaoyaowan

Keywords: Financing, mRNA, COVID-19 Vaccines

In the middle of August, 2021, Abogen Biosciences announced that it had completed the third round of financing with a total amount exceeding 700 million US dollars, which set a new record for single financing before the IPO of Chinese biopharmaceutical companies. In April this year, Abogen Biosciences announced that it had completed the second round of financing totaling 600 million yuan, which was mainly used for the development of mRNA innovative drugs. Adding this round of financing with a total amount of more than 700 million US dollars, Abogen Biosciences's leading position will be further enhanced in the field of mRNA in China.

Preliminary Attempt of mRNA Technology in the Field of COVID-19 Vaccine

With the outbreak of global COVID-19, mRNA technology has been applied for pandemic prevention and control. In December 2020, the world's first mRNA COVID-19 vaccine developed by Pfizer/BioNTech obtained emergency use authorization from FDA, and the vaccination can be available worldwide. In the middle of August this year, FDA officially approved the marketing application of it, which is used to protect people aged 16 and above from the infection of COVID-19.

Since vaccination, the mRNA vaccine has been available in 120 countries and regions worldwide. The successful application of the mRNA COVID-19 vaccine makes mRNA technology ascend to the frontier in the field of medicines. In late February 2021, the mRNA vaccine was ranked among the "Top 10 Breakthrough Technologies" selected by MIT Technology Review.

In China, the mRNA COVID-19 vaccine (ARCoV), jointly developed by Abogen Biosciences, Academy of Military Medical Sciences, and Walvax, was officially approved for clinical trials by National Medical Products Administration in June 2020, becoming the first mRNA vaccine approved for clinical trials in China. At present, Phase I and Phase II clinical research of the mRNA vaccine has been completed. On July 21, 2021, this mRNA vaccine registered Phase III clinical trial in the Chinese Clinical Trial Register, which is the first Phase III clinical trial in China for domestic mRNA vaccine.

It is worth noting that besides the mRNA COVID-19 vaccine, other pipelines of Abogen Biosciences, such as the mRNA herpes zoster vaccine, are going to enter the IND stage.

Supported by capital, The Field of mRNA Innovative Drugs Becomes Hot

As one of the Top 10 Breakthrough Technologies in 2021, mRNA technology has stepped onto the historical stage since the outbreak of the COVID-19 pandemic. It started with vaccines, but its significance is much more than that. It also shows great potential in other fields, such as tumor immunity and rare disease treatment. The primary attempt of the mRNA COVID-19 vaccine once again ignited the industry's expectation

for this technology, which is favored by the market with capital support.

Financing Events in the Field of mRNA Innovative Drugs in China Since July 2021		
Manufacturer	Financing time	Financing scale
Abogen Biosciences	August 2021	700 million US dollars
Innorna	July 2021	Amount not disclosed
Immorna	July 2021	800 million yuan
Kactus	July 2021	Over 100 million yuan
Proxybio	July 2021	Tens of millions of yuan

Source: public data

According to incomplete statistics, since July this year, five financing projects have been carried out in the field of mRNA innovative drugs in China, including Abogen Biosciences, Innorna, Immorna, Kactus and Proxybio. The largest one was the financing of Abogen Biosciences in August, with a total amount exceeding 700 million US dollars.

Overview of Domestic Independent-developed mRNA Innovative Drugs Enterprises

The ravages of SARS-CoV-2 made the whole world realize the great potential and commercial value of mRNA technology, and also greatly accelerated the commercialization process of this technology. At present, most of the domestic enterprises developing mRNA innovative drugs were established in recent years and are still in the primary stage. According to statistics, there are 9 innovative enterprises focusing on the R&D of mRNA drugs in China, mainly including StemiRna, Abogen Biosciences, Immorna, RNAcure, and so on. StemiRna is the first mRNA pharmaceutical company in China, and other companies were established (or entered into the mRNA field) after 2018.

Overview of Independent-developed mRNA Innovative Drugs Enterprises in China				
Full name of company	Delivery technology	Technology source	Technical advantage	Potential application area
Abogen Biosciences	LNP	Independent R&D	The protein expression is 2.5-4 times that of other companies. Dynamic precision mixing technology of teammates	Vaccine; Tumor immunotherapy
Innorna	LNP	Independent R&D	With ionizable phospholipid library	Vaccine; Tumor immunotherapy
Immorna	LNP	Independent R&D	It can reduce the dosage and toxicity of LNP	Vaccine; Tumor immunotherapy; Rare diseases
LIVERNA	LNP	Independent R&D	One-step synthesis and stable process; high consistency among batches	Vaccine
Rhegen	Targeted delivery	Independent R&D	Targeted mRNA delivery without vector	Drugs for cancer, infectious diseases and rare diseases
Longuide	LLLRNA	Independent R&Dment	Low carrier cost; Low toxicity	Vaccine; Tumor immunotherapy

Source: public data

Among these domestic enterprises, Abogen Biosciences has held the technical details of the whole process and took the leading position of mRNA COVID-19 vaccine developing in China. Innorna designed and built thousands of ionizable phospholipid libraries, and devoted itself to finding the optimal solution of LNP to complete mRNA delivery through selecting different application scenarios. Immorna is committed to developing innovative drugs based on the mRNA platform, and its self-replicating mRNA core platform technology is in the lead internationally. It has a wide range of potential application fields, including tumor therapeutic drugs, personalized tumor vaccines, infectious disease vaccines, rare disease treatment, and many other fields; LIVERNA has its own mRNA production and drug delivery platform. In the middle of March this year, the mRNA COVID-19 vaccine developed by LIVERNA has obtained the Permission for Drug Clinical Trail issued by National Medical Products Administration, becoming the third domestic mRNA COVID-19 vaccine after Abogen Biosciences and StemiRna. Rhegen is developing 9 kinds of preventive mRNA vaccines, conducting 7 Phase I studies, and also developing targeted delivery technology without vectors. Longuide owns the patent of mRNA nano-delivery technology and conducts extensive and in-depth research on the COVID-19 vaccine.

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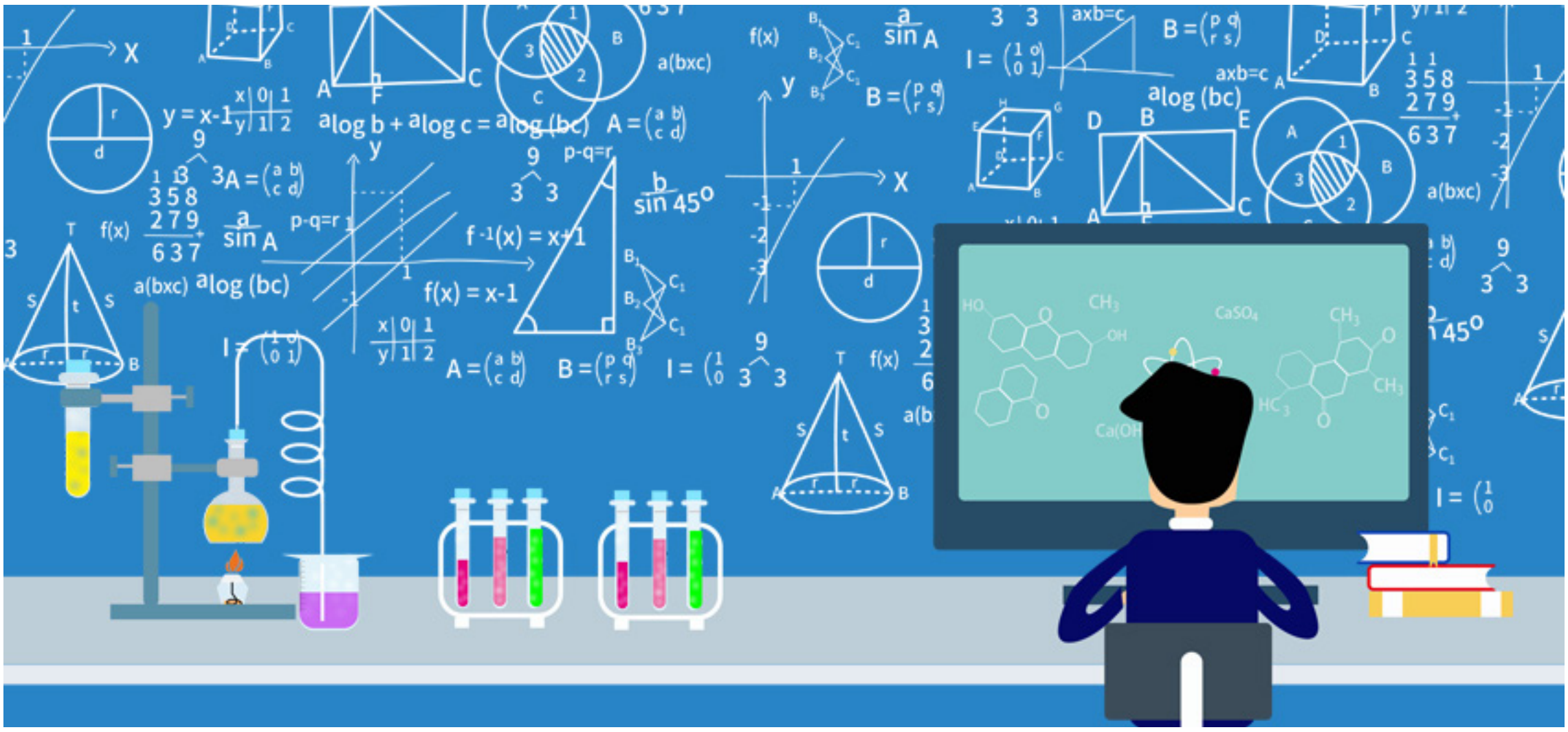
Industry Insight DECEMBER 2021

QUANTUM COMPUTING IN PHARMA

By Sarah Harding

Keywords: Quantum Computing, Normal Computing, Pharma R&D



The topic of quantum computing just keeps on cropping up. There doesn't seem to be any sector that isn't enthralled by the potential that the quantum revolution will bring – and pharma is no different. But what is quantum computing? Why is it so much better than 'normal' computing? And how is it going to impact pharma… really?

What is quantum computing?

You might have heard of quantum mechanics. This relatively young branch of physics deals with the mathematical description of the physical properties and nature of atoms and subatomic particles. However, very strange things can happen at the subatomic level, so in order to simulate these properties, scientists needed to make calculations that can handle uncertainty.

Classic computers – even very large, co-called 'super computers' – are not very good at dealing with uncertainly. Classic computers use binary data – millions of bits in combinations of ones and zeroes or, to put it another way, in combinations of ons and offs.

But the universe doesn't work in terms of just being on or off. Our existence and our environment are fluid – uncertain – and classic computers are unable to hold, compare and analyze simultaneous complex, uncertain real-world problems.

Therefore, in 1980, US physicist Paul Benioff offered the first theoretical possibility of a quantum computer. Instead of bits, quantum computers would use qubits. That means that the combinations used could be more than just on or off. Qubits could also be in 'superpositions' where they are both on and off at the same time, or somewhere on a spectrum between the two.

Why is it better than normal computing?

Estimates suggest that quantum computers are about 100 million times faster than any classical computer available today. **As well as solving problems faster, that means they would require significantly smaller physical and energy footprints than current super computers.**

However, it's about more than just speed. **Thanks to their ability to deal with 'uncertainty', quantum computers can generate highly complex simulations that would not be possible with classical computers.** They can simulate quantum properties in molecules, for example, or complicated molecular reactions. With qubits, quantum computers can create vast multidimensional spaces in which to represent very large problems. Algorithms are then used to find solutions in this space, and translate them back into forms we can use and understand.

To put it more simply, the best analogy I have found is this:[1] if you asked a classical computer to find its way out of a maze, it will try every single branch in turn, ruling them all out individually until it finds the right one. A quantum computer can go down every path of the maze at once. It can hold uncertainty 'in its head' and find a faster, better solution by analyzing multiple uncertainties, all at the same time.

Quantum computers could be applied wherever a large, uncertain, complicated system needs to be simulated. That could be anything from predicting the financial markets, to improving weather forecasts, or modelling the behaviour of individual electrons.[1] Quantum computing has the potential to disrupt entire industries, from finance to cybersecurity, to healthcare and beyond.

How is this going to impact pharma?

While quantum computing may benefit the entire pharma value chain, from discovery, through development, and across production and delivery, its primary value is expected to lie in R&D.[2]

As stated previously by Brian Martin, Head of Artificial Intelligence in R&D information Research at AbbVie,[3] "For most problems in computational chemistry for drug development, classical computing is sufficient, but there are situations where there are limitations. What we haven't been able to do [until] now as an industry is pinpoint among those computationally limited problems which ones are amenable to resolution by quantum computing."

Given its focus on molecular formations, pharma as an industry is a natural candidate for quantum computing. Quantum computers are especially well suited to molecular simulations – all molecules are based on quantum mechanics, so quantum computing should be able to predict and simulate the structure, properties and behaviors of drug molecules. This should enable computational tools for drug design and discovery, and for providing a 'tool set' of molecules that might be best suited to solving a particular medical problem. This could involve the design and optimization of protein therapeutics, or predictive algorithms to generate human-relevant data.

In summary, within pharma R&D, quantum computing could significantly enhance:[2]

- Disease understanding and hypothesis development
- Target finding
- Hit generation and identification
- Lead generation
- Optimization of candidate properties
- Pharmacokinetic and toxicity predictions
- Dosing and solubility optimization
- Patient identification and stratification
- Pharmacogenetic modelling
- Casualty analysis for side effects
- Data management.

Beyond R&D, quantum computing could bring further value in terms of improving production processes, with optimization of catalytic processes or product formulations, quality monitoring and predictive maintenance.[2] Logistics and supply chains could be improved with better routes and networks, or dynamic inventories and procurement approaches. Quantum computing could even help with advanced forecasting for market demand, patient understanding, tailored or personalized care, patient engagement, and automatic treatment recommendations.

In summary, pharma is a perfect case for quantum computing. In particular, it will help researchers find the molecules most likely to succeed, dramatically reducing the current 90% fail rate of drugs reaching the clinical trial phase. Such is the promise of quantum computing in pharma, that in 2019 the heads of digital research technology at some of the world's top drug companies formed QuPharm, the Pharma Quantum Computing Working Group, to share the risks and rewards of quantum computing in pharma.[3]

So is pharma about to be disrupted?

Despite all of the excitement, we still have a while to wait before quantum computers can do all the things they promise. Right now, the best quantum computers have about 50 qubits. That's enough to make them incredibly powerful, but they are not yet reliable – they have extremely high error rates. Even once those reliability issues are resolved, it will take time to develop commercial quantum computers, and to apply the technology in commercially useful ways.

Any company that has undergone a digital transformation will know how painful and time-consuming such initiatives

can be. While the effort is invariably worth the input, in terms of improved efficiencies, better productivity, enhanced connectivity and visibility, and so on, just consider – if a digital transformation using just classic computers can be challenging, **how much more challenging could it be to transform from classic to quantum systems?**

Michael Guilfoyle, Vice President – Consulting at the ARC Advisory Group[4] is an expert in digital transformations. The move to quantum computing seems to me like the supreme digital transformation, so I asked him what he thought.

"Given that quantum computing is still neither well understood nor commercially viable, it's worth taking a step back for a moment when thinking about practical applications and the timeline for achieving them," he advised. "People always want to make digital transformation about data and technology, but it's about neither, really. At its heart, successful digital transformation – whether it's quantum computing or any other technology – relies on people that are very good at identifying business outcomes and then uncovering the problems that impede those outcomes. Once that is done, then the technology and data become important, as they are the keys to how those problems get solved and the outcomes ensured."

He's right, of course. The promise of quantum computing is astounding. However, before organizations lay the foundations for quantum-based systems, they need to first consider any changes they might need to make. A clear understanding of goals, and a pathway for how quantum computing will help reach those goals, is critical, as is a realistic appreciation of the impact the transition will have on people, products and processes.

If you're dreaming of quantum pharma, odds are that one day, in the not too distant future, your dreams will start to come true. It will take a while before the first commercial quantum computers are widely available, and it will take longer still before the impact on pharma is seen. However, that gives you time to figure out exactly what you want quantum to do, and how to uncover the problems that stand in your way to achieving those goals. With that exercise complete, you'll have a far better chance of being at the head of the line when it comes to finally realizing the value of quantum computing in pharma.

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About the Author:

Sarah Harding, PhD

Sarah Harding worked as a medical writer and consultant in the pharmaceutical industry for 15 years, for the last 10 years of which she owned and ran her own medical communications agency that provided a range of services to blue-chip Pharma companies. She subsequently began a new career in publishing as Editor of Speciality Chemicals Magazine, and then Editorial Director at Chemicals Knowledge. She now focusses on providing independent writing and consultancy services to the pharmaceutical and speciality chemicals industry.

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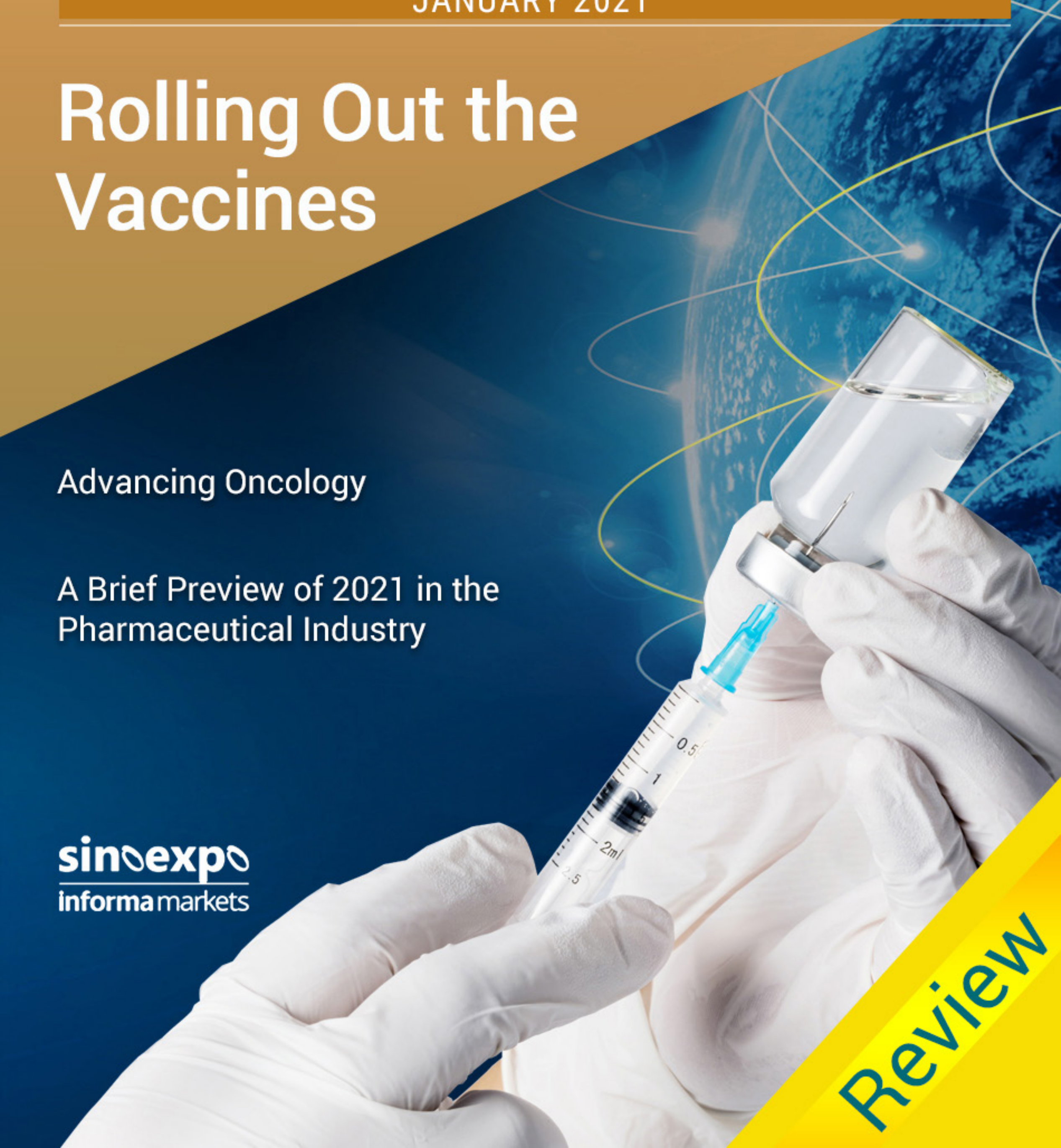

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