Pharma Sources Insight

JANUARY 2021

Rolling Out the Vaccines

Advancing Oncology

A Brief Preview of 2021 in the Pharmaceutical Industry

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Pharma trends in China*

1. The 'Made in China 2025' initiative identifies biopharma and advanced medicinal products as one of 10 key sectors that the country will focus on.
2. Multinational companies continue to expand R&D operations in China. China's relatively lower cost base compared to developed markets globally is one of the attractions for these companies.
3. China's large pharmaceutical market and its strong growth potential provide an impetus for international pharmaceutical firms to develop medicines specifically for the country's domestic market.

*Fitch Solutions China Pharmaceuticals & Healthcare Report - Q1 2021

The Chinese Pharma Market is forecasted to grow at CAGR of

4.4%

between 2020 & 2024

reaching

CNY 1,3 trn

(USD176.1bn) by 2024

50,000+
pharmaceutical professionals

200,000 sqm
exhibition space

3,000+
exhibiting companies

100+
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ZHEJIANG JIANGBEI PHARMACEUTICAL CO.,LTD

Active Pharmaceutical Ingredients:

Simvastatin / Atorvastatin calcium trihydrate / Rosuvastatin calcium / Levetiracetam / Darunavir / Darunavir ethanolate / Efavirenz / Dabigatran etexilate mesylate / Sitagliptin phosphate monohydrate/

The Finished Pharmaceutical Products:

Started construction in the beginning of 2014

Constructed for the manufacture of tablet and capsule formulations

Capacity: 2 billion tablets per year

All products above are not availble in the patent covered areas

History of GMP inspection:

Authority	Time
EDQM	2007.09 & 2012.09
CFDA	2011.01 & 2015.01 & 2017.11 & 2019.10 & 2020.11
KFDA	2011.12
PMDA	2013.08
US FDA	2014.04 & 2016.05
German Authority	2015.07
WHO	2016.05 & 2018.08/11 & 2019.09
Russian FDA	2018.03
MHRA	2018.09

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JIANGBEI PHARMACEUTICAL

From the Editor

Dear Readers,

Does the pandemic of the COVID-19 virus change the world forever? Maybe in some way. But it definitely changed the directions of drug R&D in 2020 and here we are, at the starting point of 2021, with the approval of 6 vaccines in Europe, America, and Asia, making people expect a life without respirators, lockdowns, and a world that new drugs can soon get their way back to satisfy the unmet needs of the patients.

However, COVID-19 is not everything, we can never let the pandemic take control. As to Dr. Sarah Harding, one of the specialists, scientific and medical writers for PharmaSources.com, who stated in her article **"Advancing Oncology"**, many scientific discoveries in 2020 were "a little overlooked due to a world focus on COVID-19".

Therefore, in the January Pharma Sources Insight, on the one hand, we are going to have an overview of COVID-19 Pandemic in 2020, provided by Dr. Lin Zhang, a senior director of a health care industry company, with 10 years' experience once worked for U.S. FDA, on the other hand, it is more important to have a preview of the pharmaceutical industry in 2021. Meanwhile, Neeta Ratanghayra, a professional medical writer in the pharma and biotech sectors shares her viewpoints on Biosimilars in 2020.

Nevertheless, if one is interested in the new developments of COVID-19 vaccines in China and the World, Chinese-Produced Anticancer Drugs and global Regulatory Inspection Trends, he/she can still read them from "Notable Vaccines Against COVID-19 Making Promising Progress" by Deborah Seah, a science writer, also an editor who focuses on the discovery of biotechnology in the pharmaceutical field, and more articles by some of the Chinese pharma writers from CPhI.CN, the local B2B platform of PharmaSources.com and CPhI China.

From June to October 2020, three issues of Pharma Sources Insights have successfully caught the eyes of drug-makers from 78 countries of the 5 continents in the world. Luckily, we've been receiving feedbacks from Pharma Sources Insight readers who inquired how to subscribe to the E-compilation and even download the e-books in order to read off-line, now I am confident to say, the answer is right on the news section of PharmaSources.com (click "**subscribe**" and "**download**" to find out.)

What Pharma in 2021 will drive for? As PharmaSources.com will keep gathering passionate pharmaceutical contributors and creating quality content catering to the needs of the international pharma market, please stay with us. The future is in what we endeavor for, what we write on, what we know about and we don't.

Last but not least, thank you to all the readers who have been supportive of CPhI China, to the newly updated website PharmaSources.com and Pharma Sources Insight in 2020, thank you. Your companies and demands are the reasons why we take actions and move on...

Sincerely,
Editor in Chief
Pharma Sources Insight

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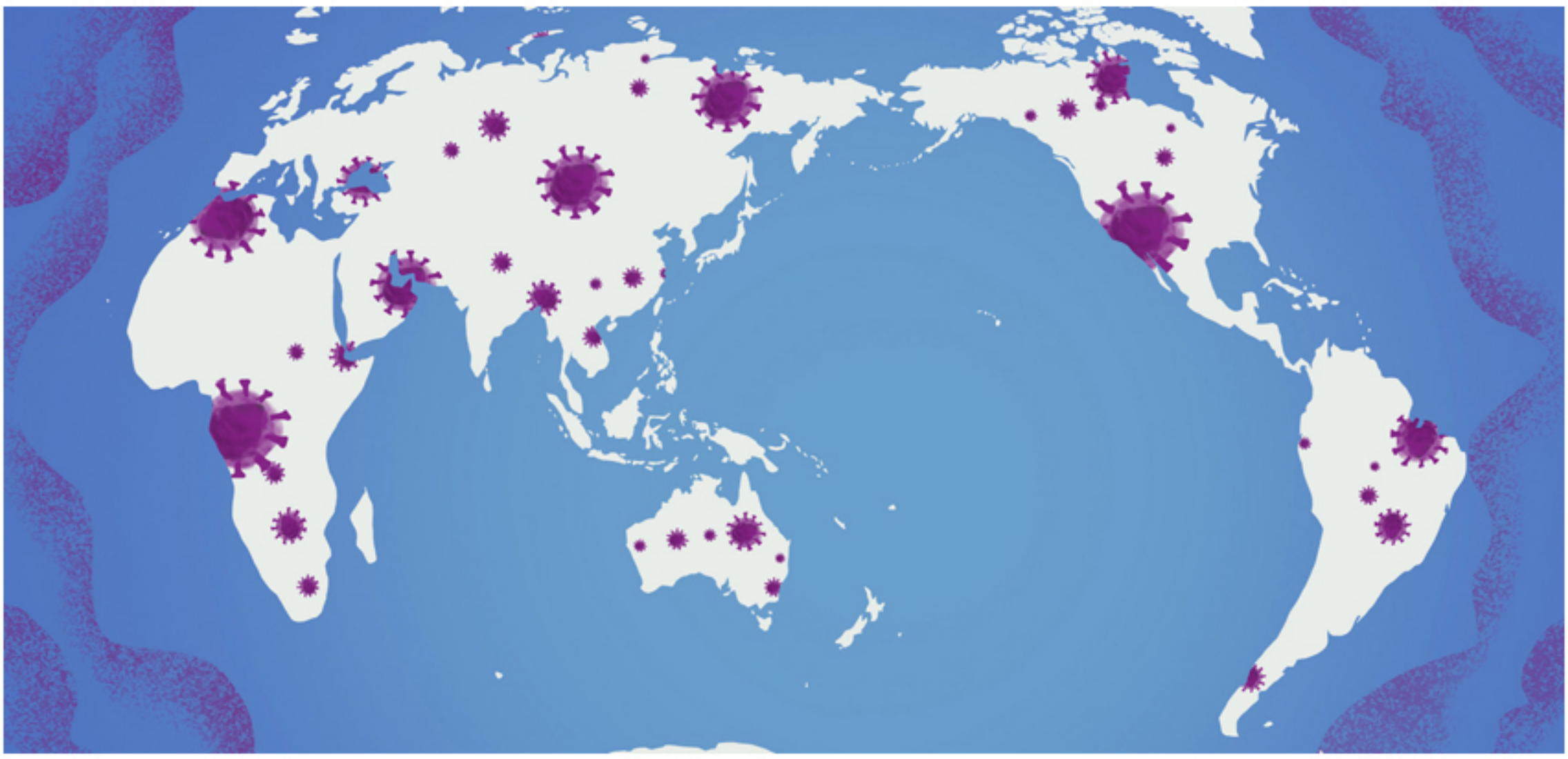
PHARMA IN CHINA JANUARY 2021

Analysis of the Regulatory Inspection Trends of China, the U.S. and the EU in the Pandemic Year and Outlook Therefor

By Zhulikou431

Keywords: GMP, Inspection, Trend



International GMP compliance inspections in the pharmaceutical industry decreased significantly in 2020 as affected by the COVID-19 pandemic. Due to the transportation restrictions and pandemic prevention policies of countries, the frequency of international inspections decreased. Regulatory authorities are using more written designs or remote assessments. Based on the inspection data of China, the U.S., and the EU in 2020, below is a review of the inspection trends in 2021 in the hope of providing a reference for pharmaceutical practitioners.

Part I: Summary and Analysis of FDA Inspection Data

The FDA's inspections on foreign enterprises significantly decreased in 2020 due to the impact of the pandemic. According to the data released so far, the FDA mainly focused on the compliance inspections on the U.S. pharmaceutical manufacturers. The latest data publicly available on FDA's official website shows that it issued six warning letters to Chinese enterprises in 2020, which was a lot fewer than the 15 warning letters in 2019, 19 warning letters in 2018, and 22 warning letters in 2017.

Table 1: Warning Letters Issued by the FDA to Chinese Enterprises in 2020

Company name	Product	Issuing date
Hangzhou Linkweier Daily Chemicals Co. Ltd.	CGMP / finished pharmaceuticals / adulteration	Mar. 13, 2020
Yibin Lihao Biotechnical Co., Ltd.	CGMP / APIs / adulteration	Feb. 13, 2020
Guangzhou Tianci Materials Technology Co., Ltd.	CGMP / APIs / adulteration	Jan. 23, 2020
Sunstar Guangzhou Ltd.	CGMP / finished pharmaceuticals / adulteration	Jan. 22, 2020
Zhuhai Aofute Medical Technology Co., Ltd.	CGMP / finished pharmaceuticals / adulteration	Jan. 9, 2020
Huaian Zongheng Bio-Tech Co., Ltd.	CGMP / finished pharmaceuticals / adulteration	Jan. 9, 2020

As seen from the warning letters, the GMP standard of some daily chemical and medical product enterprises needs to be improved, for example, deficiencies in the progress of quality management of the products. These deficiencies were common in warning letters to many companies, such as failure to conduct proper laboratory detections for each batch of drug products to determine whether they meet the final drug quality standards, including active ingredient and content identity, failure of detecting labeled active ingredients before releasing the drug products, and failure in the active ingredient identification and content determination of some products.

In 2020, the FDA issued more warning letters to Indian enterprises than to Chinese enterprises. However, further analysis shows that most of the site inspections involved in these warning letters occurred in 2019, namely, before the outbreak of the COVID-19 pandemic.

Part II: Data of EU Non-Compliance Reports (NCRs)

According to the data published in the EU GMP database, the EU issued four NCRs in 2020, involving countries including Switzerland, Austria, Poland, and India.

Table 2: EU NCRs in 2020

Report No.	Company name	Country	Inspection date	Issuing date
CH20-0566	Legacy Pharmaceuticals Switzerland GmbH	Switzerland	Aug. 28, 2020	Sept. 30, 2020
INS-482723-12976686	Lupuca Pharma GmbH	Austria	14-May-20	Jun. 30, 2020
IWPS.41.25.2020	Przedsiębiorstwo Produkcji Farmaceutycznej GEMI Nowakowski Grzegorz	Poland	Apr. 29, 2020	May.19, 2020
CH20-0177	DISHMAN CARBOGEN AMCIS LIMITED	India	Feb. 28, 2020	Apr. 20, 2020

Through analysis of the above NCRs, the main deficiencies include:Insufficient control over the air quality of clean rooms, incomplete verification of the air handling system, insufficient validation of sterile filtration operations, inadequate frequency of media fills (less than 2x/year) on some of the production lines, deviations occurred during the media fills were not coped with promptly, inadequate deviation management, etc., while the company's quality systems were functional, there was a lack of management supervision. Therefore, the company's sterile manufacturing management is considered not in compliance with GMP overall.

The company's manufacturing qualification license is limited. Based on the CAPA evaluation of the company, the manufacturing qualification license cannot be prolonged. Major systemic deficiencies that could not be resolved were in the areas of supplier qualification, change management, deviation management, qualification of equipment, validation of computerized systems, and good documentation practice.

Failure to take steps to prevent microbial and mold contamination and cross-contamination, use measures to properly investigate contamination during the progress of monitoring and quality control, equipment and plant were not properly cleaned and maintained. The manufacturer did not have adequate storage areas to ensure that the drugs were under control in the production processes.

The company's approach to material management, including the label traceability, storage conditions, dispensing and cleaning, pest control of raw materials, intermediates, solvents, and recovered solvents, was considered not in compliance with EU GMP. The company failed to lower the risks of cross-contamination in multipurpose facilities and was not aware of the necessary measures to be taken before introducing new chemical entities in the areas of sampling, distribution, and synthesis. The recycling of solvents was not properly managed and documented. Shortcomings were observed concerning cleaning validation and process validation. The critical and major deviations were not effectively resolved.

With the continuous development of the COVID-19 pandemic, the EU's cross-border inspections were also affected. As a result, the EU released guidance regarding distant assessments to encourage member states to actively take new assessment measures to ensure that pharmaceutical manufacturers comply with EU GMP, for example, Germany used distant assessments for Zhejiang Jingxin and eventually confirmed that Zhejiang Jingxin complied with EU GMP.

Part III: Summary of NMPA Inspection Data

The NMPA has an annual pharmaceutical product inspection plan outside of China every year. With the outbreak of the COVID-19, the CFDI under the NMPA did not release an inspection plan outside of China in 2020, and it might have made a plan on the new inspections based on the ones left from the previous year and combined risk assessment.

According to the NMPA announcement, the NMPA suspended the import of methoxyphenamine hydrochloride from Sanyo Chemical Laboratories Co., Ltd., and the drug administration at each port suspended the issuance of import customs clearance forms for the product in Aug. 2020. It was mainly because Sanyo Chemical Laboratories Co., Ltd. turned down the NMPA's onsite inspection of its methoxyphenamine hydrochloride production site. As a result, the enterprise was deemed as refusing the inspection according to the Provisions on the Administration of Overseas Inspection of Drugs and Medical Devices, and its production process was directly determined as not complying with the requirements of China's Good Manufacturing Practice for Drugs (2010 Revision).

Furthermore, the NMPA suspended the import, sale, and use of Nifuratel Tablets and Nifuratel Vaginal Tablets of POLICHEM S.R.L. in Sept. 2020. It was mainly because the overseas inspection conducted by the NMPA on the company found that the company failed to, as required, submit a rectification plan and carry out effective rectification on the deficiencies found of nifuratel products, and the actual technical process of the Nifuratel Vaginal Tablets product was not fully consistent with the declared process, which affected the key quality attributes of the product and did not meet the requirements in Good Manufacturing Practice for Drugs (2010 Revision) of China.

Meanwhile, many onsite inspections of CFDI in China were also affected due to restrictions of business trips within the country during the early stage of the COVID-19 outbreak. The CFDI, to close these gaps and keep the work, has actively cooperated with the inspection authorities of provincial administrations, to complete the inspection tasks of 2020 in various ways.

The CFDI released the Progress of the CFDI's Joint Inspection of Drug Registration in 2020 (by the end of November) on Dec. 7, 2020, which shows the updated data of inspections in China:

Inspection type		Number of inspections started	Number of inspections completed
Onsite inspection of pharmaceutical product registration	Clinical trial site inspection	321	220
	Registered production site inspection	392	275
Onsite inspection of consistency evaluation	Clinical trial data inspection	76	36
	Pharmaceutical development and production site inspection	163	120
Onsite inspection of chemical generic injection registration		8	6
Total		960	657

Part IV: Future Trend Preview

Through the summary and analysis of the data above, it is predicted that the inspections in and outside China will show the following characteristics in 2021:

Firstly, more agencies will complete compliance inspections through written designs or distant assessments, such as the FDA, the EU, and the WHO;

Secondly, the corresponding certificate validity periods of enterprises that pass written or distant assessments will be shortened, for example, the validity period is tentatively set as one year;

Thirdly, the CFDI's inspections on enterprises in China will remain regular;

Fourthly, the CFDI's overseas inspections will be based on written assessments in the first half of 2021 and gradually use onsite inspections in the second half of 2021.

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2、 *CFDI official website data*

3、 *EMA official website data*

4、 *FDA official website data*

5、 *WHO official website data*

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.

PHARMA IN CHINA JANUARY 2021

Biosimilars 2020: Low Approvals, but Significant Advances

By Neeta Ratanghayra

Keywords: Biosimilars, FDA, EMA, NMPA

2020 has been a tough year. The pandemic posed an array of challenges to the healthcare system and the global biopharmaceutical industry both rose to the challenges and seized opportunities.

Biosimilars offer the potential for more treatment options and affordable alternatives. Experts suggest that the broader adoption of biosimilars could lead to greater competition, ultimately reducing drug costs and enabling wider access to life-saving drugs.

Year 2020 - Low Approvals, but Significant Advances

The year 2020 saw just three biosimilar approvals from the United States Food and Drug Administration (FDA), while the European Medicines Agency (EMA) approved nine products.

Biosimilars Approved in 2020		
Food and Drug Administration (FDA)		
Biosimilar name	**Approval date**	**Reference product**
Hulio (adalimumab-fkjp)	Jul-20	Humira (Abbvie)
Nyvepria (pegfilgrastim-apgf)	Jun-20	Neulasta (Amgen)
Riabni (rituximab-arrx)	Dec-20	Rituxan (Genentech and Biogen)
European Medicines Agency (EMA)		
Biosimilar name	**Approval date**	**Reference product**
Livogiva (teriparatide)	Aug-20	Forsteo (Eli Lilly)

Aybintio (bevacizumab)	Aug-20	Avastin (Genentech/Roche)
Amsparity (adalimumab)	Feb-20	Humira (Abbvie)
Nepexto (etanercept)	May-20	Enbrel (Amgen)
Zercepac (trastuzumab)	Jul-20	Herceptin (Roche)
Equidacent (bevacizumab)	Sep-20	Avastin (Genentech/Roche)
Ruxience (rituximab)	Apr-20	MabThera (Roche)
Insulin aspart Sanofi (insulin aspart)	Jun-20	NovoRapid (Novo nordisk)

The number of biosimilars approved in 2020 were low, however there was great advances in clinical testing of new biosimilars, collaborations/deals, and exploring innovative ways to implement biosimilars as a cost-saving strategy.

Biosimilars in China – An Overview

The United States and Europe together account for more than 90% of biosimilars sales; however, there has been tremendous progress in the biopharmaceutical markets in East Asian countries such as China.

There is a huge unmet medical need for affordable biologics in China. Biosimilar drugs appear to be the best alternate solution for improving access to life-saving biologics.

In February 2019, China's National Medical Products Administration (NMPA) approved the country's first-ever biosimilar product, Hanlikang/HLX01 (rituximab), a monoclonal antibody developed by Henlius Biopharmaceutical. Hanlikang/HLX01 references Genentech and Biogen's Rituxan (rituximab) and is indicated for non-Hodgkin's lymphoma. This approval flagged off the biosimilar boom in China. The latest to join the list of approved biosimilars in China is adalimumab biosimilar, HLX03, developed by Henlius Biotech. The product was approved by NMPA on 7 December 2020.

Below is the list of biosimilars approved in China.

Biosimilars Approved in China		
Biosimilar name	**Approval date**	**Reference product**
Hanlikang - rituximab (Henlius Biopharmaceutical)	Feb-19	Rituxan (Genentech and Biogen)
QLELTLI - adalimumab (Bio-Thera Solutions)	Nov-19	Humira (Abbvie)
Ankeda – bevacizumab (Qilu Pharmaceutical)	Dec-19	Avastin (Genentech/Roche)
Byvasda - bevacizumab (Innovent Biologics)	Jun-20	Avastin (Genentech/Roche)
HLX02 - trastuzumab (Henlius Biopharmaceutical)	Aug-20	Herceptin (Roche)
SULINNO – adalimumab (Innovent Biologics)	Sep-20	Humira (Abbvie)
Halpryza – Rituximab Injection (Innovent/Lilly)	Oct-20	Rituxan (Genentech and Biogen)
HLX03 - adalimumab (Henlius Biopharmaceutical)	Dec-20	Humira (Abbvie)

Despite the late start, it has been reported that China has approved more than 200 clinical trials for biosimilars and this is reflected by an increasing pace of approvals and other activity starting in the later part of 2019.

Countering Biosimilar Disparagement and Misinformation

Despite the noted benefits and cost-saving opportunity, biosimilar use is still limited in some healthcare systems because they are not well understood by many health care professionals and patients. There are several different types of disparagement and misinformation related to biosimilars, which hampers their acceptance and market penetration.

As per an opinion piece published in the journal BioDrugs in 2020, disparagement and misinformation about biosimilars can be countered by balanced educational outreach across stakeholders, appropriate regulatory oversight, and use of enforcement powers already granted to government agencies.

Regulatory Challenges for Biosimilars 2020 - WHO Survey of 20 Countries

Despite progress with many aspects of the development of biologicals and especially biosimilars, the diversity of regulatory frameworks has presented significant challenges in many countries. A recent WHO survey, which included 20 countries, revealed four main challenges with biosimilars.

- *Unavailability or insufficient reference products in particular countries*
- *Lack of resources*
- *Problems with the quality of some biosimilars*
- *Difficulties with interchangeability and naming of biosimilars*

The authors recommended potential solutions, noting that resolving these challenges will require cooperation between regulatory authorities in different countries. Their proposed solutions included

- *Exchanging information on biologics with other regulatory authorities*
- *Avoiding unnecessary duplication of studies by accepting foreign-licensed and -sourced reference products*
- *Relying on approvals from other regulatory authorities or using joint review to facilitate approval of biosimilars*
- *Reassessing products approved before the biosimilar regulatory framework was in place*
- *Establishing regulatory oversight for good pharmacovigilance*

The Road Ahead

Experts suggest that the coming years will witness a modest level of biosimilar development. Each biologic has anywhere from one to three candidates in Phase 1 to preregistration, with many in discovery/preclinical development. Apart from this, most biologics with patent expiring in the next five years (2020to 2025) earn less than $100 million in sales per year, which may impede the commercial opportunity.

Another regulatory debate looming the biosimilar space is whether comparative efficacy trials must be required for approval of all biosimilar products. As per a study published in JAMA in October 2020, comparative efficacy trials for biosimilar products are as rigorous as and often larger, longer, and more costly than many pivotal trials for initial approval of new molecular entities, in contrast to trials for most small-molecule generic drugs, which compare plasma concentrations over time in healthy volunteers. This fact is vital for companies aiming to develop a biosimilar candidate, who should assure that their candidates, once approved, will still be relevant on the market and not be replaced by a next-generation version of the originator.

Biologics have transformed the way hard-to-treat patients are managed. Biosimilars can stimulate market competition and have the potential to expand patient access to life-saving biologics. However, the benefits of biosimilars will only be determined once they are more widely available in the market and used in clinical practice.

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1、 *Kang HN, Thorpe R, Knezevic I, et al. Regulatory challenges with biosimilars: an update from 20 countries [published online ahead of print, 2020 Nov 21]. Ann N Y Acad Sci. 2020;10.1111/nyas.14522.*

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Neeta Ratanghayra is a freelance medical writer, who creates quality medical content for Pharma and healthcare industries. A Master's degree in Pharmacy and a strong passion for writing made her venture into the world of medical writing. She believes that effective content forms the media through which innovations and developments in pharma/healthcare can be communicated to the world.

Chinese-produced Anticancer Drugs Granted Designations by the FDA in 2020

By Xiaobin

Keywords: Anticancer Drugs, Chinese-produced Drugs, FDA

As we wave goodbye to 2020 and embrace the arrival of 2021, it's time for us to review, sum-up, and outlook. In recent years, more and more Chinese-produced innovative drugs have gone global and received Fast Track designations from the FDA. Receiving the fast track designations means that the new drugs have shown potential to meet unmet medical needs in early trials, and the pharmaceutical companies can have more opportunities to communicate with the FDA to speed up the entire R&D process. Then, which are the Chinese innovative oncology drugs that have granted Breakthrough Therapy designations or Fast Track designations in 2020?

Pharmaceutical product: Sintilimab

Target: **PD-1**

Company: **Innovent**

The FDA granted an Orphan Drug designation to sintilimab (TYVYT) on Apr. 14, 2020, for the treatment of esophagus cancer, which was the third Orphan Drug designation obtained by TYVYT, followed by being granted the designation for peripheral T-cell lymphoma by the EMA and the designation for T-cell lymphoma by the FDA.

As an anti-PD-1 monoclonal antibody co-developed by Innovent and Eli Lilly and Company, sintilimab was approved for marketing in China in Dec. 2018 for the treatment of relapsed/refractory classical Hodgkin's lymphoma (r/r cHL) and has been included in the National Reimbursement Drug List of China. Furthermore, two new indication applications for the products: first-line treatment for non-squamous non-small cell lung cancer (NSCLC) and first-line treatment for non-squamous NSCLC in combination with gemcitabine have been accepted by the NMPA.

Pharmaceutical product: Sugemalimab (CS1001)

Target: **PD-L1**

Company: **CStone Pharmaceuticals**

CStone Pharmaceuticals announced in Oct. 2020 that sugemalimab received a Breakthrough Therapy designation from the U.S. FDA for the treatment of adult patients with relapsed or refractory extranodal natural killer/T-cell lymphoma (ENKTL).

As a fully human, full-length anti-PD-L1 monoclonal antibody, sugemalimab mirrors the natural G-type immunoglobulin 4 (IgG4) human antibody, which may reduce the risk of immunogenicity and toxicities in patients, showing a potentially unique advantage over similar drugs. According to the data presented at the 2020 annual meeting of the Chinese Society of Clinical Oncology (CSCO), the objective response rate (ORR) of 38 evaluable patients with ENKTL was 44.7%, with a complete response (CR) rate of 31.6%; the median duration of response (mDoR) was 16.8 months. The median overall survival (mOS) of the 43 patients who received study drug treatment was 19.7 months, and the 1-year OS rate was 55.5%.

Pharmaceutical product: KN026

Target: **HER2**

Company: **Alphamab**

Pharmaceutical product: KN046

Target: **PD-L1/CTLA-4**

Company: **Alphamab**

Alphamab Oncology announced on Dec. 23, 2020, that the combination therapy of the bispecific antibodies KN026 (anti-HER2 bispecific antibody) and KN046 (anti-PD-L1/CTLA-4 bispecific single domain antibody) independently developed by the company received an Orphan Drug designation from the FDA for the treatment of HER2-positive or low expressing gastric or gastroesophageal junction cancer.

This is the third Orphan Drug designation granted to Alphamab. According to early trial data, the objective response rate of KN046 in combination with KN026 in HER2-positive tumors was 64.3%, and the disease control rate 92.9%. Its phase Ⅱ pivotal clinical study (SEARCH-01) is in planning. Let's look forward to the new approach that KN046 plus KN026 will provide to address the unmet medical need in near future.

Pharmaceutical product: Disitamab vedotin (RC48)

Target: **HER2**

Company: **RemeGen**

The U.S. FDA granted a Breakthrough Therapy designation to disitamab vedotin in Sept. 2020 for the indication of second-line treatment of HER2-expressing (IHC 2+ or IHC 3+) locally advanced or metastatic urothelial cancer (UC). In Nov. 2020, disitamab vedotin received approval in the U.S. for the clinical trial of treating advanced or metastatic gastric cancer and gastroesophageal junction adenocarcinoma, and a Fast Track designation from the U.S. FDA for the treatment of gastric cancer. According to public data, RemeGen plans to initiate clinical studies of disitamab vedotin for the treatment of UC and gastric cancer in the U.S. in 2021.

Disitamab vedotin is a humanized anti-HER2 ADC conjugated with monomethyl auristatin E (MMAE) via a cathepsin cleavable linker, with an optimized drug-to-antibody ratio (DAR). It is the first independently developed ADC applied for production in China, with the marketing application included by the CDE in the priority review.

Pharmaceutical product: Toripalimab (JS001)

Target: **PD-1**

Company: **Junshi Biosciences**

Junshi Biosciences announced on Sept. 11, 2020, that toripalimab received the FDA's Breakthrough Therapy designation for the treatment of nasopharyngeal carcinoma, making it the first Chinese-produced anti-PD-1 monoclonal antibody that receives the FDA's Breakthrough Therapy designation. It was another registration development of toripalimab, followed by its receipt of the FDA's Orphan Drug designation in May 2020.

The approval was based on a Phase II open-label pivotal study involving 190 patients with advanced cases who have failed systemic treatment. The drug met the primary endpoint on the overall response rate. Furthermore, the patient enrollment for the phase III clinical study JUPITER-02 of toripalimab injection in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) has completed.

Pharmaceutical product: Plinabulin

Target: **GEF-H1**

Company: **BeyondSpring**

BeyondSpring announced in Sept. 2020 that the U.S. FDA granted a Breakthrough Therapy designation to plinabulin concentrated solution for injection in patients with non-myeloid malignancies for the prevention of chemotherapy-induced neutropenia (CIN).

As a guanine nucleotide exchange factor (GEF)-H1 activator, plinabulin achieves early protection of white blood cells in the bone marrow by reversing a chemotherapy-induced-block in the bone marrow, and maintaining the normal levels of neutrophils, and reduces the occurrence of early CIN by a mechanism of action different from that of G-CSF (granulocyte colony-stimulating factor).

Pharmaceutical product: Zanubrutinib

Target: **BTK**

Company: **BeiGene**

As a Chinese-produced innovative drug, zanubrutinib is a highly selective BTK inhibitor independently developed by BeiGene. It received the FDA's accelerated approval in Nov. 2019 as a second-line treatment of mantle cell lymphoma (MCL) in adults who have received at least one prior therapy.

Zanubrutinib was officially approved for marketing by the U.S. FDA in Dec. 2019 for the treatment of R/R MCL in adults who have received at least one prior therapy, making it the first new

anticancer drug developed in China and approved for marketing by the FDA based on clinical studies in Chinese patients.

Zanubrutinib was approved in June 2020 in China through priority review for MCL in adults who have received at least one prior therapy and chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in adults who have received at least one prior therapy. Furthermore, the marketing applications of zanubrutinib have been accepted in Europe and Israel.

Pharmaceutical product: Sulfatinib

Target: VEGFR, FGFR, CSF-1R

Company: Hutchison MediPharma

The U.S. FDA granted two Fast Track designations to sulfatinib in Apr. 2020 for the treatment of both advanced and progressive pancreatic neuroendocrine tumors ("NET") and extra-pancreatic (non-pancreatic) NET in patients who are not amenable to surgery.Surufatinib is a small molecule oral tyrosine kinase inhibitor, and the mechanism of action is to block tumor angiogenesis by inhibiting vascular endothelial growth factor receptor (VEGFR) and fibroblast growth factor receptor (FGFR), inhibit colony-stimulating factor-1 receptor (CSF-1R) and promote the body's immune response against tumor cells by regulating tumor-associated macrophages. The dual mechanism of action of tumor angiogenesis blocking and immunoregulation may make it very suitable for possible combinations with other immunotherapies. According to the data from the SANET-ep phase III clinical study, surufatinib reduced the progression of relevant disease or mortality by 67% and was generally well tolerated.

Pharmaceutical product: Fruquintinib

Target: VEGFR

Company: Hutchison MediPharma

Fruquintinib received a Fast Track designation from the U.S. FDA in Jun. 2020 for the treatment of metastatic colorectal cancer (mCRC). A Phase III study of fruquintinib for the treatment of patients with mCRC, FRESCO-2, has been registered and initiated in the U.S., Europe, and Japan, with patient enrollment planned at approximately 130 study centers in 10 countries.

Pharmaceutical product: Penpulimab (AK105)

Target: PD-1

Company: Akeso/Chiatai Tianqing

On Oct. 27, Chiatai Tianqing, an enterprise of Sino Biopharmaceutical, and Akeso announced the joint development and commercialization of the anti-PD-1 monoclonal antibody penpulimab for the third-line treatment of metastatic nasopharyngeal carcinoma, which has received a Fast Track designation from the U.S. FDA.

Penpulimab's Fc receptor and complement-mediated effector are completely removed by mutations of Fc region; it also has a slower antigen-binding off rate. These features have made penpulimab more effective in blocking the activity of the PD-1 pathway and maintain stronger T-cell anti-tumor activity, therefore it has the potential to become an anti-PD-1 drug that can achieve better clinical efficacy.

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PHARMA IN CHINA JANUARY 2021

A Brief Preview of 2021 in the Pharmaceutical Industry

By Lin Zhang

Keywords: 2021, Pharmaceutical Industry, Trend

2020 has been a difficult year for everyone, and the pharmaceutical industry has been also affected by the new coronavirus (COVID-19) pandemic and related phenomena. Many things have happened in regards to global health. First, the COVID-19 pandemic has presented significant challenges, scientists have put many traditional clinical trials on hold, and has changed the focus to developing a vaccine or medication for the coronavirus. For the next months and maybe even years, COVID-19 will remain a central aspect of our lives and also a central topic in the pharmaceutical industry. The second main trend is the increased adoption of digital solutions that can also play a role in how 2021 is likely to shape up.

To date, COVID-19 caused a major shakeup in the drug industry, making it quicker and easier to trial drugs. CEOs and C-level executives of pharmaceutical companies have their own predictions regarding 2021 trends. Many recognize the COVID-19 situation as both a crisis and an opportunity for improving clinical research, as well as something that has revealed the need to better address and treat other deadly illnesses and develop new safe, and effective options. A faster and more efficient process of drug development is in demand in the market, and technology is likely the way to get there.

Scientific technology is becoming more popular. **Artificial intelligence (AI)** is growing in demand in the pharmaceutical industry and is projected to have a huge growth burst in 2021. We expect to see huge demand and rapid growth of AI technology next year. It is likely that pharmaceutical companies will be employing more AI in different ways to accelerate their processes. For instance, using digital trials, robotics, and the internet of things, and other new approaches, it's possible to cut down the time and costs of drug development. Recovering from the pandemic is also likely to be an important task for many companies in 2021. (1)

AI in particular is becoming more and more popular since the COVID-19 pandemic started. Its available roles are expanding quickly. Some companies have fully embraced it for patient recruitment, data collection, finding undiagnosed patients, trial matching, predicting clinical drug outcomes, participant drop-out, and many more factors, which can significantly speed up clinical trials, medication improvement, and more. In addition, monitoring technology can become a useful source for gathering data that can be interpreted using AI, for example, staying alert for signs of trouble or adverse reactions. Therefore, making and developing smart tech for the health field is an increasingly lucrative task (2) and can streamline processes.(3) In the future, it is likely that AI will be used even more extensively, especially for things that take too long or that are hard to detect using a human perspective. It has been reported that AI market in drug discovery alone is estimated to reach $6.6 billion in 2021. (4)

In addition to AI, other **digital solutions like smart wearables** and **blockchain** have also become more popular and are gaining traction in the industry. One trend involves wearables, which can provide doctors with better data, or smart speakers that can be used for improving adherence to a medication regime or smart pets that can be used for patients with dementia who cannot care for a real animal. Furthermore, blockchain technology is also becoming integrated into pharmaceutical industries for simplifying transactions and keeping data more secure.

Also, COVID-19 has accelerated changes in the pharmaceutical industry, pushing for faster and more **efficient procedures**. It has forced companies to adopt technology as a matter of daily practice, and it seems unlikely that this is turning back. The pandemic made these processes, that were already taking place, move faster, and forced the industry to implement quick changes. Even though the pandemic has negatively impacted many, this can be seen as a silver lining, as it pushed the industry to make changes and set in motion digital trends that are likely to continue. Even companies that have been resistant to work-from-home or the implementation of digital tools have been forced to accept these as a part of the new normalcy. The trends are unlikely to get fully reversed, and it seems probable that in 2021, companies will keep moving ahead with the technological changes they have already started. (5)

Additionally, other potential trends have been rising in popularity and are likely to become even more popular in 2021, for instance, **medical marijuana**, as the associated legislation and existing literature changes and grows. Marihuana has also been the subject of much research recently that suggests it might have medical potential (3) which is becoming more accepted and is getting legalized across different countries. (As of 2020, 35 states have implemented medical marijuana programs for patients in the U.S.).

2020 has been a challenging year for everyone, but the pharmaceutical industry has been especially affected, in positive and negative ways, due to the need to seek and produce vaccines and medications. Speedy **vaccine development** in 2020 could potentially lead to accelerated timelines for other therapeutics in the future. As vaccines are reaching the public, it becomes particularly relevant, and in 2021, the demands on the pharmaceutical industry are likely to grow.

One silver lining of the COVID-19 pandemic is that it has accelerated the rate of change for the pharmaceutical industry and life sciences fields in general. Many companies will continue to focus on COVID-19. The need for vaccines and medication for COVID-19 is not going away any time soon. It is also worth noting that the long-term effects of the virus are not yet well-known, but there will likely be some requiring support from the industry in the form of medication. The industry will need to better adapt to the existing demands and grow faster, but most importantly, smarter AI and technology seems to be the way of the future, as they have been changing the approach to drug development, testing, and many other things.

The year 2021 will likely be another pivotal year for the life sciences field at large, and drug developers in particular with many different opportunities for development and growth.

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A Brief Overview of COVID-19 Pandemic in 2020

By Lin Zhang

Keywords: COVID-19, SARS-CoV-2, Pandemic

2020 has been a challenging year across the globe. SARS-CoV-2, the virus that causes COVID-19 and is believed to originate from bats, quickly spread into a global pandemic. During this outbreak of COVID-19, the world is frightened with an unpredictable and hasty impact of the infection, and the data is changing day by day. As of December 29, 2020, almost a year later, the coronavirus COVID-19 is affecting 218 countries and territories around the world with over 79,931,215 confirmed cases, including 1,765,265 deaths, according to WHO. (1)

The most common clinical features of COVID-19 infection are fever (more than 80% cases), cough (more than 60% cases), fatigue (more than 35% cases), sputum production (more than 30% cases), and shortness of breath (more than 15% cases). Respiratory distress syndrome, septic shock, metabolic acidosis, coagulation dysfunction, and multiple organ failure are noted as the main complications of COVID-19. (2)

COVID-19 took the world by storm, requiring an unprecedented response from governments and healthcare institutions from across the world. It became an international threat, leading many pharmaceutical companies, organizations, and laboratories to begin studying it to understand this virus and treat it successfully. With both good and bad developments, the pandemic has prompted the development of fast diagnostic tools and treatment options.

R/D Progress for COVID-19 in 2020

2020 saw major pharmaceutical companies, like Pfizer, direct their efforts at understanding the virus and creating the tools to manage it. Specifically, research has addressed diagnostics, treatments, drug repurposing, vaccination, and protection measures against the disease. The progress and the rate of said progress have been amazing, much faster than expected, especially in regards to the vaccine. Usually, successful develop-

ment of a new vaccine requires years of research and testing before reaching the clinic, but in this pandemic crisis of COVID-19, scientists embarked on a race to produce safe and effective coronavirus vaccines in record time. As per the available data, scientists are currently testing 64 vaccines in clinical trials on humans, and 19 have reached the final stages of testing. At least 85 preclinical vaccines are under active investigation in animals. (3)

COVID-19 Diagnostic Progress in 2020

In order to control COVID-19, various emerging technologies have been implemented to confirm its presence by the pharmaceutical and biotech industries and organizations.

One of the first issues was developing a quick diagnostic tool for the COVID-19. Currently, the most common diagnostic tools were the real-time reverse transcription-polymerase chain reaction (RT-PCR). RT-PCR method was based on detection of genes that are unique to SARS- CoV-2. (4) This was managed rather quickly for the diagnosis of COVID-19.

In addition, infrared (IR) sensors and thermal scanning have been used as diagnostic auxiliaries. Thermal cameras allow detection of increase temperature and can monitor individuals and crowds or large gatherings who may present symptoms.

Another diagnostic option is the Nucleic Acid Amplification test or NAAT, which can confirm COVID-19 through a nasal swab or a blood sample in real-time. However, it can be associated with false negatives due to limited sensitivity. (5)

Now, tests have become more available, and across the world individuals with symptoms can access one with a good general degree of accuracy. Testing has been an important part of the strategy for containing the virus, however, the problem with false negatives has not been fully resolved. (6)

COVID-19 Treatment Progress in 2020

Medical science has progressed very quickly, even faster than expected during the COVID-19 pandemic. Effective therapeutics include antiviral drugs (Remdesivir and Favilavir), the protease inhibitors (Lopinavir/ritonavir (LPV/RTV), cytokine inhibitors (IL-6 inhibitors, such as Tocilizumab), monoclonal antibodies (Leronlimab, the CCR5/chemokine receptor 5 inhibitor), convalescent plasma and corticosteroids (corticosteroids should only be used in COVID-19 induced lung injury in the setting of a clinical trial). (7) These medications have shown promising results. (8) In particular, the most promising development has been in the field of vaccines. By December 2020, vaccinations already started across the world, and vaccine candidates reported high rates of success after only a few months of development. Vaccines appear as the most promising strategy as well, however, other than this, there also appears to be some positive news for antibody treatments. Eli Lilly and Regeneron have received limited approval for their COVID-19 treatments. (9)

Medical interventions have helped reduce deaths almost in half. China reported some measure of success using drugs like interferon.(10) Dexamethasone is the first drug to be shown to improve survival in COVID-19. (11)

Currently, there are over 300 potential treatments, and over 200 potential vaccines being developed and researched.(12) Three vaccines are approved, and another 80 are being studied at the moment. (3)

Current Problems

At the moment, there are viable vaccines that are already being used. However, there are some concerns and problems still to be addressed. Firstly, the vaccinations will likely take time to reach everyone and to have a complete effect on global health. This appears to be the best long-term strategy and there is a low risk of anaphylaxis after receiving the vaccine. However, a bigger issue is the concerns people might have and their unwillingness to accept a vaccine that is perceived to be dangerous, in particular, those who believe in conspiracy theories surrounding the virus and the treatment as well. (13)

Furthermore, distribution, production, and storage all present their own issues, as, for instance, some of the vaccines require

specific conditions, like temperature, to stay viable, that could influence on-time delivery and vaccination for COVID-19. The logistics associated with a massive vaccination present challenges for vaccine manufacturers, distributors, and local governments. As the process is only just beginning, it remains to be seen how it will continue, but early results seem promising.

Future Perspectives

COVID-19 is not going to magically end with the end of 2020. It is likely to remain a problem throughout 2021 as well, while the vaccine is being distributed and applied, as contagions keep happening. However, there is also good reason to be more optimistic, as there are more solutions and a better understanding of the virus and how it should be treated. Still, it will remain a challenge for some time.

The COVID-19 pandemic highlighted the incredible speed of scientific responses, as the vaccine appeared within just a year of the virus being discovered. However, the pandemic also showed that a more serious threat, a virus that is deadlier, could have a huge impact on humanity, and there is a need to be prepared for such a situation.

The research focused on COVID-19 continues and will likely remain a priority. This especially concerns possibilities for treatment and improvement of the vaccines. A better understanding of the treatment options could help save the lives of people who are already infected with the disease.

COVID-19 has been a real challenge, and it has put to the test many aspects of modern society, from healthcare, pharmaceutical research, and diagnostics to policies and public health approaches. It has forced the world to work harder and faster and has also made everyone pay more attention to health. The long-term impacts are not yet fully clear, but they will definitely be significant.

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Chinese Vaccines Going Global amid Receipt of the COVID-19 Vaccines Worldwide

By Xiaoyaowan

Keywords: Vaccine, COVID-19, China

The COVID-19 pandemic has circulated again recently in Europe and America, with the number of new confirmed cases hitting new highs in countries represented by the UK and the U.S., which has objectively put forward higher requirements for pandemic prevention and control. Urgently in demand, the development of COVID-19 vaccines has been accelerated, and many vaccines have been approved to be vaccinated worldwide. This is expected to relieve the current anti-pandemic pressure and reverse the pandemic to some extent.

R&D Progress of COVID-19 Vaccines in the World

According to the public information at present, more than 40 COVID-19 vaccines have entered the clinical stage worldwide, of which 17 have entered/completed phase III clinical trials, 8 are in phase II clinical trials, and 18 are in phase I/II clinical trials.

17 COVID-19 Vaccines that have Entered Phase III Clinical Trials

Developed by	Technical route
Wuhan Institute of Biological Products	Inactivated virus vaccine
Beijing Institute of Biological Products	Inactivated virus vaccine
Sinovac Biotech	Inactivated virus vaccine
CanSinoBIO	Adenovirus-vectored vaccine
University of Oxford/AstraZeneca	Adenovirus-vectored vaccine
Moderna NIH/NIAID	mRNA-based vaccine
Pfizer/BioNTech	mRNA-based vaccine
Nowavax	Protein subunit vaccine
Gamaleya Research Institute	Adenovirus-vectored vaccine

Janssen Pharmaceutical	Adenovirus-vectored vaccine
Bharat Biotech from India	Inactivated virus vaccine
Medicago from Canada	Adenovirus-vectored vaccine
Zhifei Biological	Recombinant protein vaccine
Vektor from Russia	Adenovirus-vectored vaccine
CureVac	mRNA-based vaccine
Chinese Academy of Medical Sciences	Inactivated virus vaccine
Kazakhstan Research Institute for Biological Safety Problems	Inactivated virus vaccine

Source: Organized according to public data

Depending on the technical route, the current COVID-19 vaccine varieties in the world include inactivated virus vaccines, adenovirus-vectored vaccines, mRNA-based vaccines, and protein subunit vaccines. Each technical route has advantages and disadvantages: inactivated virus vaccines have the simplest process, however, the immunizing potency is relatively low; adenovirus-vectored vaccines are well tolerated while the anti-adenovirus antibodies in some people can cause the vaccines to fail; mRNA vaccines can be produced fastest, although they are easy to be degraded.

An Overview of Vaccines Approved for Marketing Worldwide

A total of six COVID-19 vaccines have been approved for marketing worldwide by Jan. 12, 2021, separately, BNT162b2 and mRNA-1273 under the Emergency Use Authorization (EUA) in the U.S., AZD1222 under the EUA in the UK, an inactivated COVID-19 vaccine conditionally marketed by Sinopharm CNBG in China, an inactivated vaccine from India under the EUA in India, and "Sputnik V" approved for marketing in Russia.

The entire development process of a vaccine normally takes 8 to 10 years, with a statistical success rate of only about 20%. According to public data, only six vaccines have been successfully developed and marketed in contrast to 44 newly discovered infectious disease pathogens in the past 50 years, with a success rate of less than 14%. However, the severe global situation of the COVID-19 pandemic since 2020 has prompted the development and approval of COVID-19 vaccines to be greatly accelerated. The COVID-19 vaccines approved for use in China, the U.S., and the UK are all marketed conditionally or under the EUA, and the subsequent monitoring data still need to be taken into consideration for approval.

It should be noted that no valid clinical trial data have been made available for the inactivated vaccine approved under the EUA in India and the "Sputnik V" approved for marketing in Russia, thus their efficacy is doubtful.

Inactivated COVID-19 Vaccine of Sinopharm CNBG

An inactivated virus vaccine is a vaccine that can cause the virus to lose its infectivity and replication ability through physical or chemical treatment while retain the virus's activity to trigger an immune response in humans. Inactivated vaccines are vaccine products with prototype viruses entirely inactivated, retain almost all the antigens and epitopes of the viruses, and can target the conserved epitopes of viruses to reduce the possibility of virus escape.

The inactivated COVID-19 vaccine of Sinopharm CNBG received approval from the National Medical Products Administration of China (NMPA) at the end of Dec. 2020 for conditional marketing. According to the interim analysis data results of phase III clinical trial, the vaccine had good safety after vaccination, and after two injections of the immunization procedure, all vaccine recipients had high-titer antibodies, with a neutralizing antibody-positive conversion rate of 99.52%. The protective efficacy of the vaccine against the disease caused by the novel coronavirus infection (COVID-19) reached 79.34%, and the data results met the relevant WHO technical standards and the relevant standard requirements in the Guidelines for the Clinical Evaluation of Prophylactic Vaccines against COVID-19 (Trial) issued by the NMPA.

Chinese Vaccines Going Global amid the Receipt of COVID-19 Vaccines Worldwide

The Joint Prevention and Control Mechanism of the State Council of China held a press conference on the recent pandemic prevention and control and vaccination on Jan. 9, according to which, the cumulative number of people reported to have been vaccinated in China reached 7.383 million, plus the key populations vaccinated earlier in different provinces, leading to a total of more than 9 million vaccinated.

Besides China, some countries have also started to conduct COVID-19 vaccination in succession. According to statistics by Jan. 8, 2021, COVID-19 vaccines received worldwide reached 17.3 million doses, involving 18 countries, with the main brands of COVID-19 vaccines involved being Pfizer BioNTech,

Sinopharm CNBG, Sinovac Biotech, and Sputnik V; some rich countries with small populations already had vaccination rates of more than 10%, such as the United Arab Emirates (UAE).

It is noteworthy that the COVID-19 vaccine administered in the UAE is the inactivated virus vaccine from Sinopharm CNBG. And besides the UAE, many countries including Bahrain, Egypt, Morocco, and Brazil have received/are planning to receive COVID-19 vaccines from China. According to the Phase III clinical trial data of Sinovac's COVID-19 vaccine announced in Brazil on Jan. 8, it achieved a 78% effective rate and 100% effectiveness in severe cases.

Compared with mRNA vaccines that require long-term storage at -70°C, Chinese vaccines require milder storage conditions and do not have harsh requirements for cold chain and other facilities, leading to a lower overall cost and easy acceptance by most countries. And there is another way for other countries to obtain Chinese vaccines: direct production locally by obtaining licenses and conducting cooperation. This "cooperative production" method with Chinese characteristics can shorten the transportation distance of vaccines, further reduce vaccine transportation and storage costs, and facilitate local production and vaccination in other countries.

From the perspective of global population distribution, developing countries, which account for 80% of the population, have the most urgent demand for vaccines under the impact of this pandemic, and most of these countries do not have the overall strength of COVID-19 vaccine development and industrialization. The Chinese-produced COVID-19 vaccines take on the role of global public goods and will soon provide strong support for the safety protection of these countries.

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COVID-19

JANUARY 2021

Notable Vaccines Against COVID-19 Making Promising Progress

By Deborah Seah

Keywords: COVID-19, Vaccines, Progress

The year 2020 has proven to be a defining year for the medical and biopharmaceutical fields across the world. Since the first half of the year, many countries across the world have been plagued with the COVID-19 pandemic. With countries now facing second and third waves of COVID-19 outbreaks and the total number of cases across the world reaching close to 60 million at the point of writing this article, biopharmaceutical companies race against time to search for a safe and efficacious vaccine that could help combat against the COVID-19 disease.

The last few months of 2020 has seen much promise in the area of vaccine clinical trials against COVID-19. A number of biopharmaceutical companies have announced success in their Phase 3 clinical trials. These results bring hope to the potential of a vaccine against COVID-19 in the near future. At the time of writing, there are 60 COVID-19 vaccines in the clinical development stage and 172 in the pre-clinical development stage. This article will provide a summary of the notable biopharmaceutical companies that have released results from its Phase 3 clinical trial for the COVID-19 vaccine and national regulatory approval across the world. The information in this article is based on clinical trial results released as of December 2020 and companies mentioned here are not ranked in any order.

Moderna. Inc.

Vaccine Candidate: mRNA-1273, LNP-encapsulated mRNA

Vaccine Platform: RNA

Dosage: 2 doses, one at 0 and 28 days

Since the reveal of the genetic sequence of the novel coronavirus by the Chinese authorities on 11 January 2020, Moderna quickly kick-started its quest towards development of a vaccine against COVID-19. Within days, on 13 January 2020, Moderna finalised the sequence for mRNA-1273 with the intention of the National Institute of Allergy and Infectious Disease (NIAID) to begin Phase I studies for mRNA-1273 against SARS-CoV-2. Following the success of Phase I and Phase II, Phase III clinical trial study of mRNA-1273 began promptly on 27 July 2020, in collaboration with NIH (National Institutes of Health) and BARDA (Biomedical Advanced Research and Development Authority).

The Phase III study completed an enrollment of 30,000 participants on 22 October 2020. On 16 November 2020, Moderna released an announcement that its Phase III study has met primary efficacy endpoints based on first interim analysis. Together with this, the first interim analysis that included 95 participants with confirmed cases of COVID-19 found to show statistically significant vaccine efficacy of 94.5 percent. Having scaled up its manufacturing for preparation of the COVID-19 vaccine, Moderna mentioned in a media release that by the end of 2020, it expects almost 20 million doses of the vaccine ready to ship to the U.S.

The Moderna COVID-19 vaccine was approved by the US Food and Drug Administration on 18 December 2020 for emergency use authorization which allows the distribution in the US for use in individuals 18 years of age and older.

AstraZeneca and Oxford University

Vaccine Candidate: AZD1222, ChAdOx1 nCoV-19

Vaccine Platform: Non-Replicating Viral Vector

Dosage: 2 doses, one at 0 and 28 days

On 30 April 2020, AstraZeneca and Oxford University announced an agreement for the collaboration to develop and distribute the recombinant adenovirus vaccine aimed at preventing COVID-19 infections.

The vaccine candidate, AZD1222/ ChAdOx1 nCoV-19 was developed by Oxford University's Jenner Institute, together with the Oxford Vaccine Group. It is a replication-deficient chimpanzee viral vector based on a weakened version of the adenovirus that causes infections in chimpanzees and contains the genetic material of SARS-CoV-2 spike protein. Following a vaccination, the viral vector will produce surface spike protein, allowing the immune system to produce antibodies to fight against COVID-19 should it infect the body later.

Interim data from its Phase I/II trial demonstrated strong immune responses in all participants. These results were announced on 20 July 2020. This Phase I/II COV001 trial, led by Oxford University, found that AZD1222 was well tolerated coupled with robust immune responses against SARS-CoV-2. The blinded, multi-centre, randomised controlled Phase I/II trial with 1,077 healthy adult participants, aged 18-55 years. Results published in The Lancet also confirmed a single dose of AZD1222 resulted in a four-fold increase in antibodies to the SARS-CoV-2 virus spike protein in 95 percent of participants one month after injection. In all participants, a T-cell response was induced, peaking by day 14, and maintained two months after injection.

On 30 August 2020, AstraZeneca released a statement on the enrolment of 30,000 adults aged 18 and over to assess safety, efficacy and immunogenicity of AZD1222 in the U.S. This Phase III randomised, double-blind, placebo-controlled multi-centre study tested participants two doses of either AZD1222 or a saline control, four weeks apart, with twice as many participants receiving the potential vaccine than the saline control.

The Phase III trials were paused for a month from September to October 2020 due to unexplained illness that occurred in the UK Phase III trial. Following resumption, interim data analysis announced on 23 November 2020 from Phase III trials in UK and Brazil demonstrated the vaccine to be highly effective in preventing COVID-19 with primary endpoints met and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine. There were a total of 131 COVID-19 cases in the interim analysis. Interim analysis of the four randomized controlled trials conducted in Brazil, South Africa and the UK were published in the Lancet on 8 December 2020.

The vaccine by AstraZeneca and Oxford University has received regulatory approval by the UK medical regulators on 30 December 2020.

BioNTech and Pfizer

Vaccine Candidate: BNT162b2, 3 LNP-mRNAs

Vaccine Platform: RNA

Dosage: 2 doses, one at 0 and 28 days

In a media release on 9 November 2020, Pfizer and BioNTech announced its first interim analysis from the Phase 3 clinical trial study of its COVID-19 vaccine. Based on the announcement, the vaccine candidate was found to be more than 90 percent effective in preventing COVID-19 in participants without evidence of prior SARS-CoV-2 infection.

The Phase 3 of the clinical trial began on 27 July 2020, enrolling a total of 43,538 participants, according to the interim Phase 3 results, no serious safety concerns were observed. Of all the participants, 38,955 of which received a second dose of the vaccine on 8 November 2020. Following the release of these results, the study continued to collect safety and efficacy data for the final analysis. Based on current projections we expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. Pfizer and BioNTech plan to submit data from the full Phase 3 trial for scientific peer-review publication.

On 2 December 2020, the BNT162b2 vaccine received the world's first authorization for a vaccine against COVID-19. Regulatory agency in the UK, Medicines & Healthcare Products Regulatory Agency (MHRA) granted this temporary authorization for emergency use. This decision was based on data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95 percent in participants without prior SARS-CoV2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose.

This mRNA vaccine by Pfizer and BioNTech later received

authorization on 22 December 2020 in the European Union (EU), granting conditional marketing authorization and representing a milestone in a joint global effort to advance the first authorized mRNA vaccine. The vaccine has now been granted a conditional marketing authorization, emergency use authorization or temporary authorization in more than 40 countries worldwide, including all 27 EU member states.

As part of the agreement between Pfizer and BioNTech to provide global commitment to help address the COVID-19 pandemic, the two companies project an approximate 1.3 billion doses of the vaccine to be manufactured by the end of 2021.

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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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COVID-19 JANUARY 2021

Rolling Out the Vaccines

By Sarah Harding

Keywords: COVID-19, Vaccine, Pandemic

The UK became the first country to approve the Pfizer/BioNTech vaccine on 2nd December last year, swiftly followed by the US, the EU, and other countries countries across the world. The Oxford-AstraZeneca vaccine was also approved on 30th December (in the UK), providing a less expensive and easier-to-handle option. Although the approval of the latter was surrounded by questions concerning trial data and design, the overall news of both vaccines was greeted with delight, as people began to see an end to the pandemic that blighted 2020.

To many, it meant that 2021 would be a happy new year with a return to pre-COVID 'normality' restored. Experts continued to warn that it would be several months before the effects of a mass immunization program were felt, but there was a general impression from the public media that things would be 'better by the spring', or even 'over by Easter'. Clearly, we all wanted a little good news. However, while suggestions of imminent normality might have made great headlines, I think they showed a lack of understanding of how long this process is going to be.

Taking the UK as an example (because this is where I live, so I have paid most attention to the UK situation), priority is being given to frontline health workers and people aged over 80 years. The following priority groups will then receive the vaccine: over 75s; over 70s; clinically extremely vulnerable people; over 65s; other people with underlying health conditions; over 60s; over 55s and over 50s. According to the BBC (ONS population mid-2019 estimates, BBC research), these priority groups in the UK total more than 25 million people – close to 40% of the country's population. They all need two doses (within 12 weeks of the first). The remaining 60% of the population can then get in line.

By 27th December, a total of 944,539 people had received their first vaccine dose – about 1.5% of the UK population. Clearly,

the rate of vaccination needed to be a significantly increased, so the UK government announced they would work to a target of 2 million per week, with the latest announced aim of giving 13 million of the most vulnerable people a first dose by mid-February…. It remains to be seen if this target will be achieved but, currently, plans appear to be hampered by a global shortage of glass vials to package up the vaccines, long waits for safety checks and the process of ensuring there are enough vaccinators.

The key learning here, I think, has been that while the UK government was great at securing sufficient quantities of the Pfizer/BioNTech and Oxford-AstraZeneca vaccines to ensure everyone in the country can get their two doses, the tactics of how those doses are going to be delivered is still not quite resolved. I have every confidence that our leaders will find a solution but, with the benefit of hindsight, addressing tactics as well as strategy would seem to be an area that other countries might like to bear in mind when planning their own COVID-19 vaccination programs.

(A second learning is that if you're in the business of making glass vials for pharma, you're in for a boom year!)

It is not yet known whether compliance with the double-dose requirement is going to be a problem. Currently, it is thought that the first dose provides 70 to 90% protection from the virus (depending on the vaccine chosen, and probably on a variety of inter-individual factors that have not yet been figured out). The second dose is required to achieve full protection of 95 to 100%. I would confidently predict that the very elderly and extremely vulnerable groups will comply fully with the double-dosing requirement, but I suspect many younger people (when their turn eventually comes) will need to be persuaded to return for the second jab.

Even that, of course, assumes that they turn up to get the first one.

Last year, when considering the possibilities of A Post-pandemic Future, we discussed the fact that COVID-19 appeared to be providing an opportunity to extend acceptability for technologies that were until recently viewed with a certain level of mistrust by the public. As concern about the virus (and the perception of 'risk') was high, technologies such as vaccines, CRISPR and nanoparticles in pharma were seeing an upsurge in their acceptance. To the best of my knowledge (i.e. from what I have read in the public media), people in the highest priority group who have so far been offered the vaccine have all eagerly received it. However, anecdotally, among groups of people who are less vulnerable, and for whom the benefit-risk advantage is less immediately apparent, the usual concerns over vaccine safety are being voiced.

By early January 2021, the number of allergic reactions world-wide to the COVID-19 vaccine was reported to be about one in 100,000 people. This compares unfavourably with the usual rate of one per one million, but health authorities across the world are still urging everyone to take the vaccine, as the benefits for individuals as well as countries (for herd immunity) outweigh the risk. At the time of writing, there is no way of predicting how these concerns will affect uptake of the vaccine, but I think this will be an interesting factor to watch.

Meanwhile, there are suggestions that the effects of the vaccine are already being felt. Although the UK has seen a surge in COVID-19 cases and deaths in the first weeks of 2021, it has been reported that proportional cases among people aged over 80 have significantly reduced – this has been attributed to protection provided already by the first doses of the vaccines given to this highest priority age group in December last year. Soon, elderly people living in nursing homes, who have had no face-to-face contact with their families for the past ten months, will be able to hug their grandchildren. Our children will be able to return to school again, and maybe by late summer I will be able to have the 'big' birthday party that I've been anticipating/dreading for the past 3 years…. although perhaps a couple of months late!

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.

Tofflon

Sterile Solvent Crystallization

API Systems

Most APIs are not heat-resistant, so non-final sterile APIs are the most common in real production. The production of non-final sterile APIs usually includes solvent based crystalline sterile APIs, freeze-dried sterile APIs and spray drying sterile APIs. The sterile APIs produced by solvent crystallization have the advantages of high quality, less impurities and good stability. Although the crystallization and drying processes are different, they are mainly transformed from non-sterile to sterile by sterilization and filtration, and keep aseptic during the whole drying and subsequent crushing, mixing and packing process after transformation. This article is a case study of a sterile solvent crystallization API systems. This production line is mainly used for the production of sterile drugs, to ensure consistent compliance of core process from solution preparation, crystallization, filtration and washing to final product pulverizing and dispensing with the design concept of product quality, environmental and personnel safety, in line with the development trend of high-end pharmaceutical production processes.

Features of Workshop Layout

The production workshop is divided into Class A area (explosion-proof area) and Class C area (non-explosion-proof area) based on the fire risks of materials, which are partitioned by the explosion-proof wall.The integrated design has reduced the explosion-proof area. The modular design of the thermal medium and vacuum system are placed in the non-explosion-proof area to save upfront investment and daily operating costs.

The core process module and the solvent are separated by a wall only, which allows a short conveying distance of materials through the pipeline to avoid material loss due to pipeline residue.

The cleanroom environment is required to be controlled at the level C only, which has effectively reduced the cost of auxiliary facilities, personnel clothes changing, cleanroom environmental monitoring, daily energy consumption, etc.

Studying and Sharing cGMP Update - Best Practices – Latest Technologies for Drug Manufacturing Science

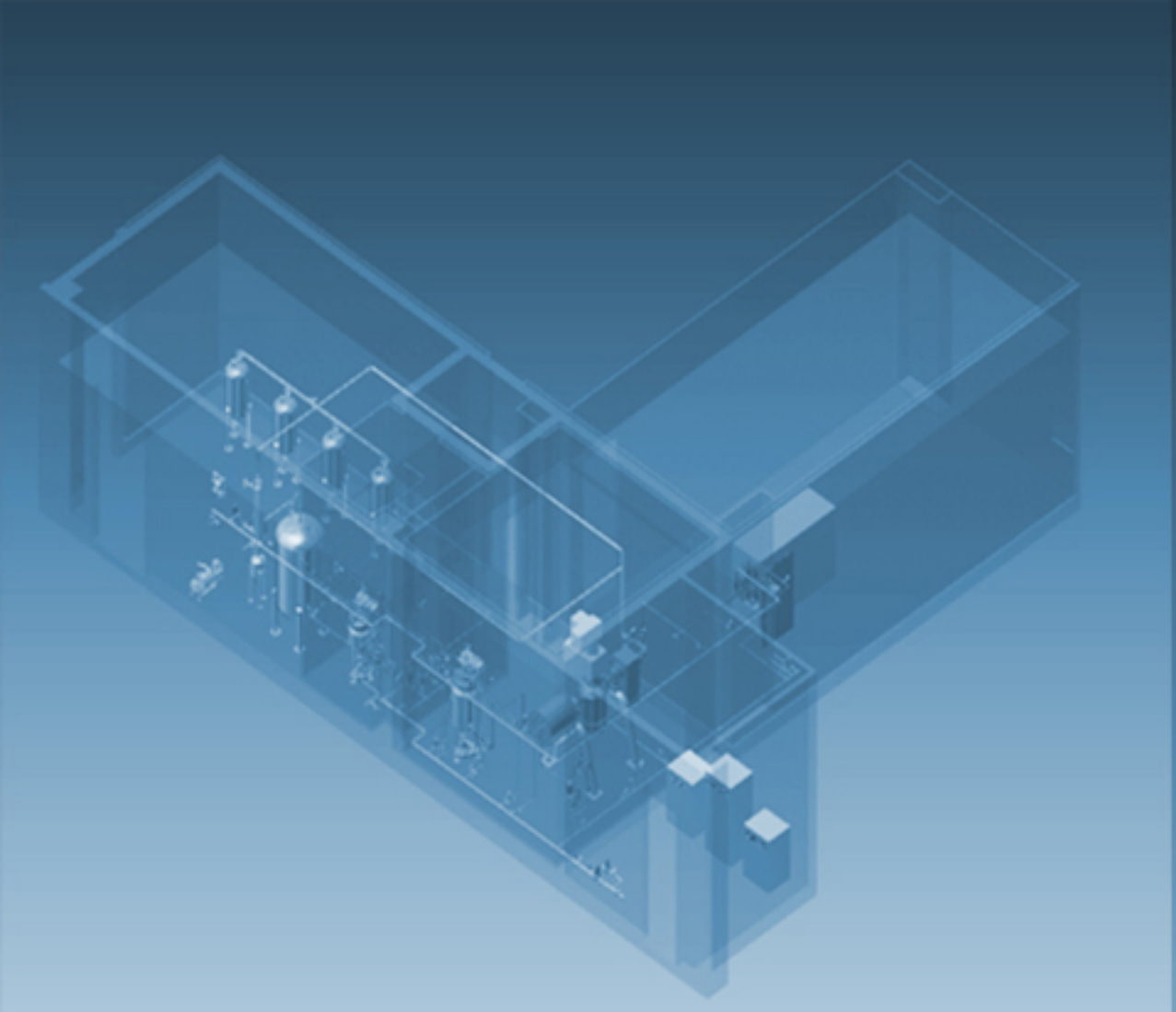

Fig.1Workshop Layout

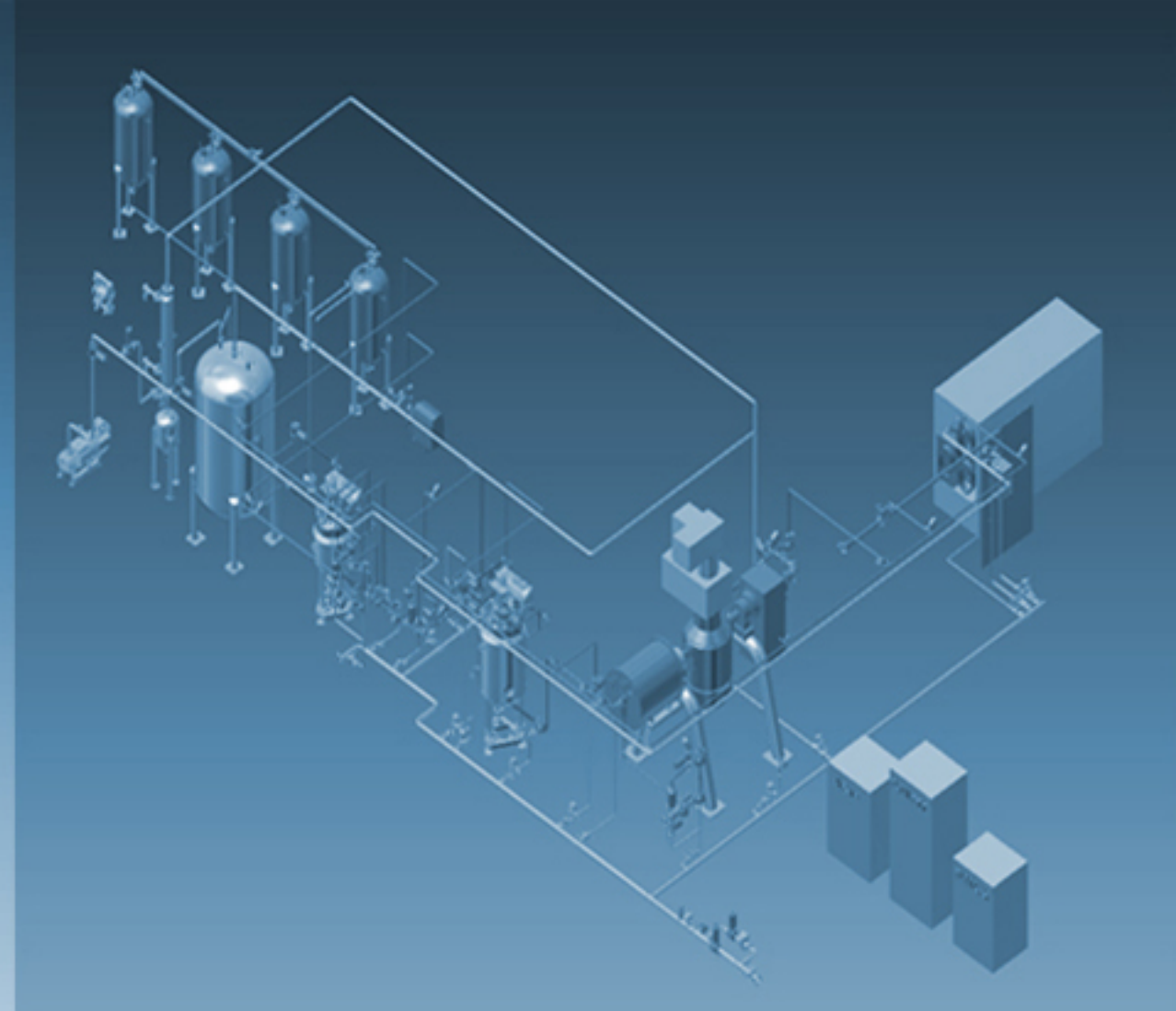

Fig. 2 Process Module Diagram

Process Module Design

The reasonable layout, based on the upstream and downstream processes, is arranged to minimize the material conveying distance and avoid material loss during the transfer to the greatest extent.

The modular design of process pipelines, tanks, and pump sets has reduced the intensity of fieldwork. The process tubes are arranged on the pipe racks to ensure integrity and aesthetics. The equipment piping can be connected to the main pipe in the vicinity. Thus, the overall modular pipe arrangement is highly concise, beautiful and easy to maintain.

These factors were considered in the design process such as the orientation of public utilities, room return air and others. What's more, overall consideration is given to the equipment module and room design, to avoid the risk of interference and winding after equipment entry and improve the integration of equipment and workshop.

Integrated design is adopted for the jet mill and isolator, which, on the one hand, can reduce the intermediate material transfer process and risks considering the sterility of discharging and dispensing; on the other hand, it also considers the sterile protection in the removal and assembly of some parts of jet mill during its cleaning and sterilization process.

Optimized process steps and rational equipment selection

Based on the respect for the process, ration equipment design is performed to reduce the equipment input cost and material exposure risk greatly. The traditional recrystallization process is as follows: crystallization in the crystalline tank - filtration and washing by centrifuge or suction filter - removing solids - drying. However, In our system, Pressure Filter Dryer (PFD), a new sterile solvent crystallization machine with characteristic structural, was ingeniously used to prevent the risks caused by traditional open operation or discontinuous transfer of units (such as the transfer among centrifuge, drying oven and pulverizer) effectively, reduce the input cost for the related process equipment (equivalent to the function of centrifuge and dryer), and avoid the personnel safety hazard due to material exposure or material loss due to the multi-step and multi-device transfer.

In the PFD model selection, Tilting PFD is selected for this project. Under the same conditions of materials and solvents, the discharge rate is 10% higher than the traditional PFD, and the drying time is shortened by 30%, which has effectively improved the production efficiency and yield, helping customers save production and time costs.

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INDUSTRY INSIGHT JANUARY 2021

Advancing Oncology

By Sarah Harding

Keywords: 2020, Oncology Vaccine, WHO

With so much going on last year, you might be forgiven if you missed a ground-breaking announcement in November 2020 about the **'Galleri blood test'**. This new technology, which is now being piloted in the UK in a program to detect more than 50 types of cancer with just one test, could revolutionize oncology screening for the masses. The test was developed by GRAIL, a healthcare company working to detect cancer at an early stage, when it can be cured. If the pilot program is successful, it will allow the detection of many types of cancer that are difficult to diagnose early, such as head and neck, ovarian, pancreatic, esophageal and some blood cancers. By enabling the detection of these early cancers, the program has the potential to increase survival rates by a factor of up to ten times.

This could be one of the important advances made in oncology in recent years. In other years, it might have made headlines across the globe. Just imagine being able to detect such a large range of cancers, with one simple blood test, before any symptoms show!

Another significant advance in oncology in 2020 was the progression of **oncology vaccines**. Generally designed to promote tumor specific immune responses, these agents elicit an immune response that induces protection against specific molecules (antigens) expressed on tumor cells. There are currently no vaccines that can prevent cancer from developing, but some agents have shown promise in the treatment of patients with selected cancers. This is a huge area of investigation, with a variety of avenues providing scope for productive research. Among agents being evaluated for potential vaccines are peptides, proteins, antigen presenting cells, tumor cells and viral vectors. For example, in May 2020, scientists from the Chinese Academy of Sciences announced the development of a new oncology vaccine based on self-healing polylactic acid microcapsules, which can activate the immune system and inhibit tumor development.

Also last year, a breakthrough was announced with a **new vaccine** that has the potential to treat a wide variety of blood cancers and malignancies. The vaccine, which is comprised of

human antibodies fused with tumor-specific protein, was developed by a team based at The Translational Research Institute in collaboration with The University of Queensland, Australia. Clinical trials are now ongoing, following successful outcomes in preclinical studies, and it is hoped that the vaccine may eventually be used to treat blood cancers, such as myeloid leukemia, non-Hodgkin's lymphoma, multiple myeloma, and pediatric leukemias, as well as solid malignancies such as breast, lung, renal, ovarian and pancreatic cancers, and glioblastoma.

Another significant advance has been the progression of **personalized cancer vaccines**. This approach uses a patient's own cancer cells to develop a vaccine intended to teach the immune system how to recognize and destroy that cancer. The field is still young, but using antigens produced by a patient's own cancer cells promises to yield successful treatments for a range of cancer types. For example, in November 2020, the University of Arizona (USA) reported encouraging preliminary data from a clinical trial evaluating the safety and effectiveness of a personalized mRNA vaccine in combination with pembrolizumab (a humanized antibody used in cancer immunotherapy) for patients with multiple cancer types, including head and neck cancers. The encouraging preliminary results have led the research team to expand the study to include a further 40 patients.

> **"As with many scientific discoveries in 2020, these advances were a little overlooked due to a world focus on COVID-19."**

As I hope I have shown with the few examples chosen above, oncology is an active and exciting area of research. Testament to the strength of the field, oncology drugs represented the lion's share of the FDA's new drug approvals in 2020, with 21 novel agents approved. Nevertheless, I think it's fair to say that, as with many scientific discoveries in 2020, these advances were a little overlooked due to a world focus on COVID-19.

Our focus on the pandemic was understandable. **However, while COVID-19 is thought to have caused around 1.9 million deaths worldwide so far, the World Health Organization (WHO) estimates that, in 2018, an estimated 9.6 million people died of cancer worldwide**. In other words, by current estimates, it looks as if cancer might kill about five times as many people as COVID-19.

This makes me – and apparently a lot of other people – very worried by reports that cancer research, screening and treatment are being disrupted by the COVID-19 pandemic.

- *There are widespread concerns that screening programs have been disrupted, with many people worried about likely increases in the rates of undetected cancers.*
- *In an article in Nature Reviews last year, a group of researchers expressed concerns that the pandemic was disrupting oncology clinical trials.*
- *In November 2020, Cancer Research UK highlighted a "crisis in funding" and "irreparable damage" to their work without government intervention and support. The statement claimed that, as funding had been diverted from oncology to focus on the pandemic, a crisis in oncology research was looming.*

Taking a long-term view, diverting resources from oncology to COVID-19 seems a little like running into a burning building to escape a street full of lava – either way, you're going to get burnt.

When we have beaten COVID-19 (and I believe that we will), cancer will still be here, and we still need to beat that too.

About the Author:

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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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