EXECUTIVE INSIGHTS
BIOSIMILARS IN CHINA

The Next Frontier

Abstract

Combining rapidly increasing demand, coming off blockbuster biologics' patents, more structured and comprehensive regulations, and closing technology gap, we are expecting that the Chinese biosimilar market will enjoy tremendous growth over the next 5-10 years and reach Rmb33 bn by 2025.

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Biosimilars in China: The Next Frontier

On February 22, 2019, China's National Medical Products Administration (NMPA) approved China's first biosimilar, Rituximab, which was developed by Shanghai Henlius Biopharmaceutical ("Henlius"). While the approval process took many years, as Henlius commenced work on Rituximab in April 2010 and started Phase 1a in 2Q2014[1], we believe that this initial approval will serve as a launchpad for the Chinese biosimilar market and will likely be followed by more biosimilar approvals in 2019.

Unlike generic drugs - considered equivalent or exact copies of the original "innovator" product, biosimilars are "highly similar" to an already approved biologic product. The lack of clear definition on what constitutes "highly similar" leads to regulatory uncertainties and delay in commercialization.

While the first biosimilar, Sandoz's Omnitrope, was approved in 2006 in Europe, it took another 7 years for larger biosimilar molecules, such as monoclonal antibodies (mAbs) to enter the market - again in Europe in June 2013, with biosimilar versions of Infliximab. Meanwhile, it was not until 2015 that the first biosimilar was approved in the US, and the North American market continues to be affected by delays and false starts, resulting in few biosimilar approvals.

We believe China's late arrival on the global scene will be an advantage, as both regulators and industry players benefit from the experience and lessons learned by their European and American peers. In fact, we believe China's timing is impeccable for the following reasons:

- the need for innovative therapies in China – particularly in areas such as oncology – has never been greater,
- a large number of blockbuster biologics are coming off patent between 2019 and 2025,
- the Chinese government is looking for alternatives to curb rising expenses from branded/originator drugs and is establishing a robust regulatory framework,
- Chinese manufacturers are closing the gap with global peers in terms of R&D expertise and investments.

We expect the combination of these factors to propel the Chinese biosimilar market to Rmb33 bn by 2025. Time to buckle our seatbelts and get on the biosimilar fast lane.

Unmet Need for New Therapies Creates Large Market Opportunity

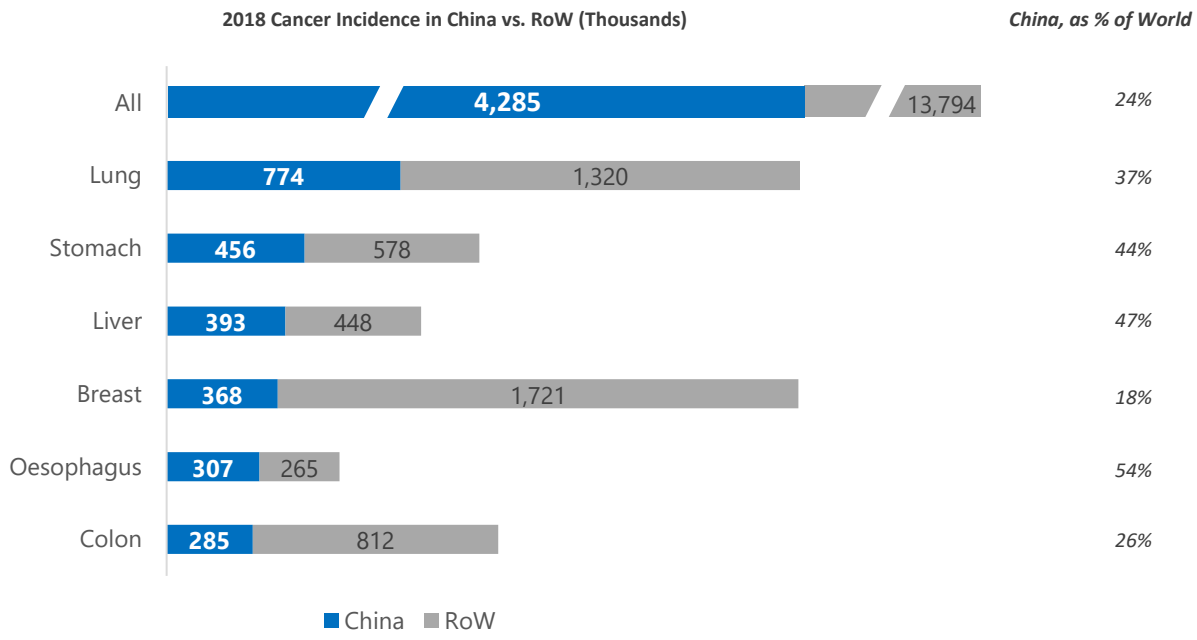
In 2018, China represented about a quarter of all cancer incidences, and over 40% of the world's total for several categories, including stomach, liver and esophagus. In addition, China's oncology population is increasing at a faster pace than in the US, and the trend is unlikely to

[1] Shanghai Henlius Biotech's IPO application with HKSE

slow in the foreseeable future, partly due to the aging population, and changing lifestyle and dietary habits.

According to the National Coalition of Cancer Research and Frost & Sullivan, the incidence of cancer is expected to grow at a 2.6% CAGR from 2017 to 2022 in China, far outpacing the 0.8% expected in the US. By 2022, China's oncology patients will reach 4.8 mm[2]. In addition, cancer mortality in China does not show any sign of moderation: in 2018, 2.6 million Chinese are estimated to have lost their fight against cancer and this figure is expected to approach 3 million by 2023[3].

Figure 1: China's Cancer Incidence, in the Global Context[4]



While therapies exist, their availability has historically been limited in China. Out of 55 oncology drugs launched globally from 2012 to 2016, only 9 were available in China in 2017. The lack of available medication is particularly acute within advanced therapies, such as biologics and mAbs. While 8 of the top 10 global bestsellers in 2017 were biologic drugs, only 2 of China's top 10 selling drugs (excluding traditional Chinese medicines) were biologics and none were oncology drugs[5]. Moreover, China's mAbs sales in 2018 represented less than 2% of the global total (only $2.0 bn out of over $110 bn of global mAbs sales)[6].

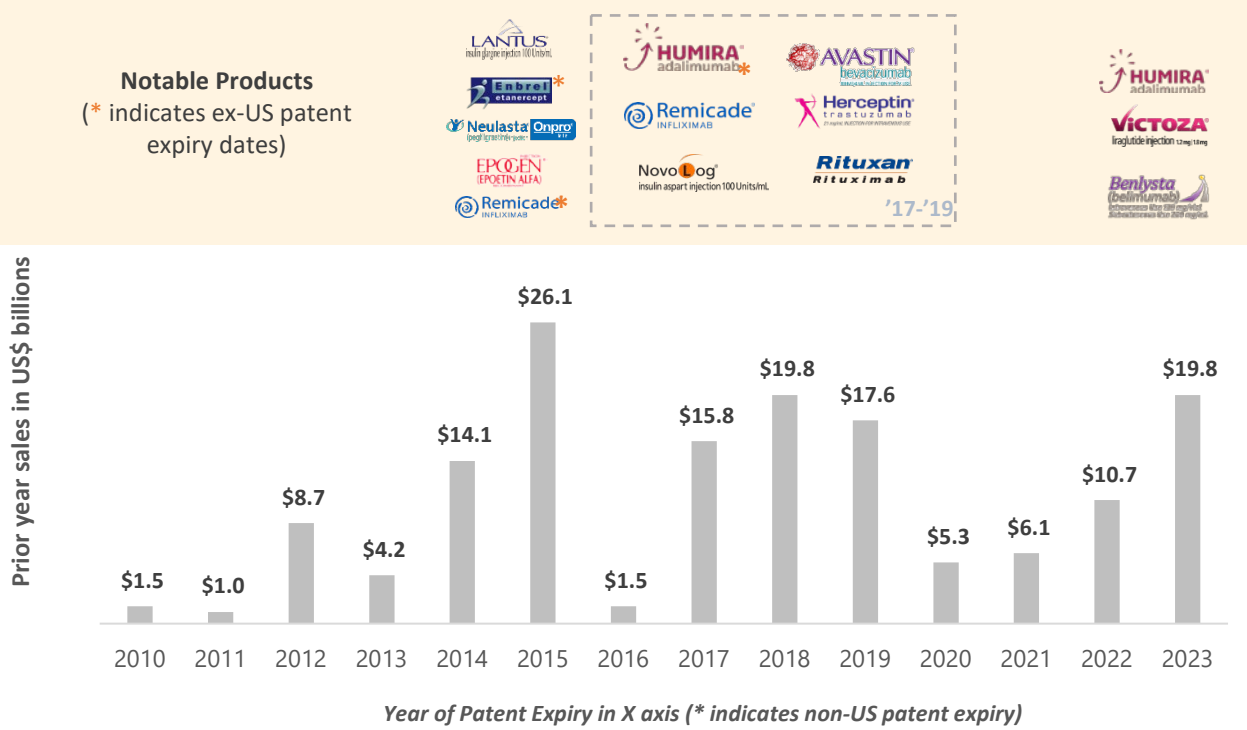
[2] Innovent Biologics' IPO prospectus, October 18, 2018
[3] ibid
[4] Cancer Tomorrow, World Health Organization
[5] Shanghai Henlius Biotech's IPO application with HKSE and Innovent Biologics' IPO prospectus, referencing Frost & Sullivan
[6] Shanghai Henlius Biotech's IPO application

Blockbuster Biologics Coming off Patent

Credit Suisse recently estimated that roughly $113 bn of the $299 bn (based on 2022 sales) in annual global biological sales would no longer have patent protection by 2023[7], opening the door for a wave of new biosimilar entrants. While blockbusters, including Lantus and Neulasta, lost their patents over the past couple of years, even more patents are scheduled to phase out in the near future, including the US patent for the world's best-selling drug, Humira.

The busy patent expiry schedule constitutes a compelling opportunity for biosimilar manufacturers around the world and we believe that Chinese producers are well positioned to rise to the occasion.

Figure 2: Global sales in the year before patent expiry of biologics[8]



Besides Rituximab, Henlius is conducting Phase 3 studies on several biosimilars such as Trastuzumab, Adalimumab and Bevacizumab[9]. In addition, a growing number of Chinese players, including Innovent Biologics (Innovent), Qilu, Bio-Thera, Zhejiang Hisun and SinoXCelltech are aggressively advancing their biosimilar clinical studies. In this article, we focus on 6 mAbs star products that account for roughly 63% of the $86 billion of sales from mAbs

[7] Credit Suisse, "Keeping up with the Biosimilars," Nov. 29, 2018
[8] Credit Suisse PharmaValues Database and Credit Suisse Analysis, IDG Capital estimates
[9] Shanghai Henlius Biotech's IPO application with HKSE

among the top 200 global drugs, and 4 potential dark horses (relatively less crowded) to visualize the current competition landscape. Please refer to Appendix I for details.

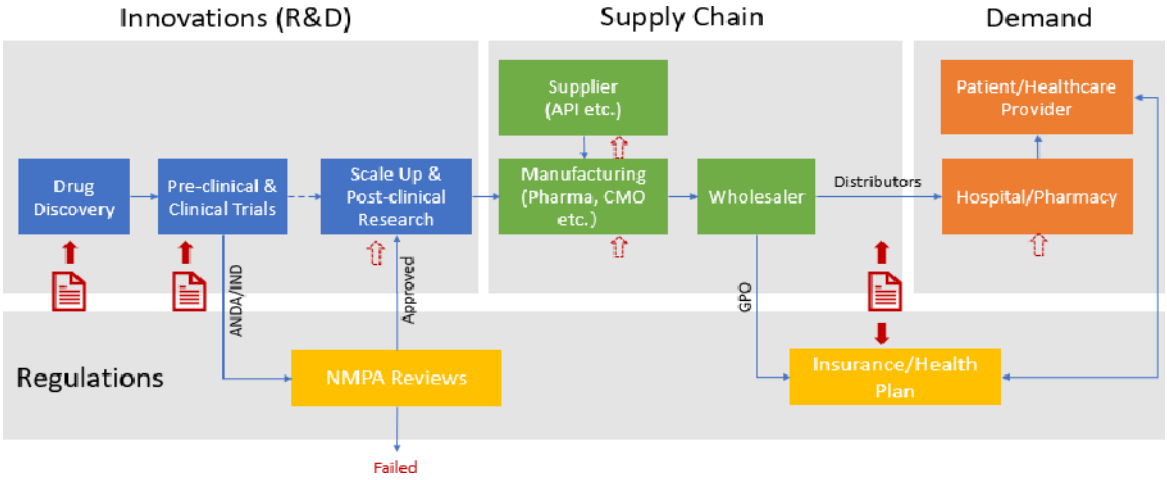
Improved Regulatory Environment in China

A critical factor in Europe's early adoption of biosimilars was its more favorable regulatory environment. For example, Northern Europe has world leading biosimilar adoption rates, helped by its local tendering systems and national policies encouraging physician-led switching. In addition, the EMA was the first agency to establish regulatory guidelines for "similar biological medicinal products" (i.e. biosimilars) as early as 2005.

The US responded in 2009 with the Biologics Price Competition and Innovation Act (BPCIA), which provided a regulatory approval pathway for biosimilars – the 351(k) route of the Public Health Service (PHS) Act. However, the pace of adoption of biosimilars has been underwhelming in the US, with the first biosimilar only approved in 2015, or 24 years after the innovator product hit the market. As a result, only 2% of biosimilar sales come from the US (87% come from Europe), while 59% of global biologic sales come from the US.

Facing a rapid increase in healthcare expenses, China is looking for solutions and taking a proactive approach to solving this problem including developing alternatives to expensive brand drugs (including the recent GPO/4+7 tender trial). Considering the significant improvements achieved in the Chinese pharmaceutical regulatory environment over the past few years, we believe that generics and biosimilars offer attractive solutions.

Figure 3: Current regulation coverage structure [10]



Specifically, the current biosimilar framework relies on the "Guidelines on Development and Evaluation of Biosimilars (draft)," released by China's NMPA on February 28, 2015, which defines "biosimilar" (生物类似药) as "therapeutic biological product that is similar

[10] TWG

to the approved RLD in terms of quality, safety, and efficacy," and requests the amino acid sequence of the biosimilar to be the same as that of the RLD.

Building upon the 2015 guidelines, the current regulations for R&D and registration of biosimilars in China includes three design points and key evaluation considerations:

1. "Considerations of Clinical Research Design and Evaluation of Biosimilar of Bevacizumab Injection" announced on July 19, 2017,
2. "Key Considerations of Clinical Research Design and Evaluation of Biosimilar of Trastuzumab Injection (draft for comments)" announced on October 31, 2017, and
3. "Key Considerations of Clinical Research Design of Biosimilar of Adamumab (draft for comments)" announced on September 18, 2018.

In the past two years, the Chinese government has also released two lists of "Priority Drugs" (48 drugs in the first list and 30 in the second list) with urgent clinical needs in order to encourage pharmaceutical companies to bring more innovative products to the market. The lists focus on new drugs for the treatment of rare diseases that have already been or are actively being marketed in United States, the European Union or Japan but have not been made available in China, as well as new drugs for the prevention and treatment of life-altering or life-threatening diseases for which no effective treatments have been made available, or, those drugs with obvious clinical advantages[11]. If there is no ethnic difference in the clinical study, sponsors of these drugs can submit the clinical trial data obtained overseas and directly apply for the drug listing registration. The CDE will accelerate the approval process by establishing priority review and approval procedures. Notably, the list includes a number of biologics, among them Humira (Adalimumab) and Levemir (Insulin Detemir), a clear sign that the Chinese government is supporting the development of such molecules.

The regulations of R&D and the registration pathway for biosimilars in China will continue to become more structurally sound, clear, and transparent in the foreseeable years.

Large R&D Investments by Chinese Manufacturers

From 2013 to 2017, the biologics NDAs approved by NMPA increased from 6 to 29 and the number of biologics INDs soared from 78 to 227 (with oncology candidates accounting for 42% of this total)[12]. While Henlius' Rituximab was the first biosimilar approved in China, the pipeline of biosimilars in Phases 1 or 3 is already quite extensive. Taking Bevacizumab as an example, we

[11] Center of Drug Evaluation, NMPA (2018). *关于征求境外已上市临床急需新药名单意见的通知*. Beijing: CDE
[12] NMPA, per Innovent Biologics' IPO prospectus, October 18, 2018

are aware of at least 9 Chinese manufacturers at advanced stages of development (Phase 3 or NDA).

Such developments are made possible by the significant investments in R&D incurred by Chinese manufacturers over the past 5 to 8 years. For instance, Innovent disclosed that its R&D expenses surged from Rmb385 mm in 2016 to Rmb612 mm in 2017, and Rmb1.2 bn in 2018. Over the past 7.5 years, Innovent has developed a pipeline of 20 drug assets, including 3 biosimilars.

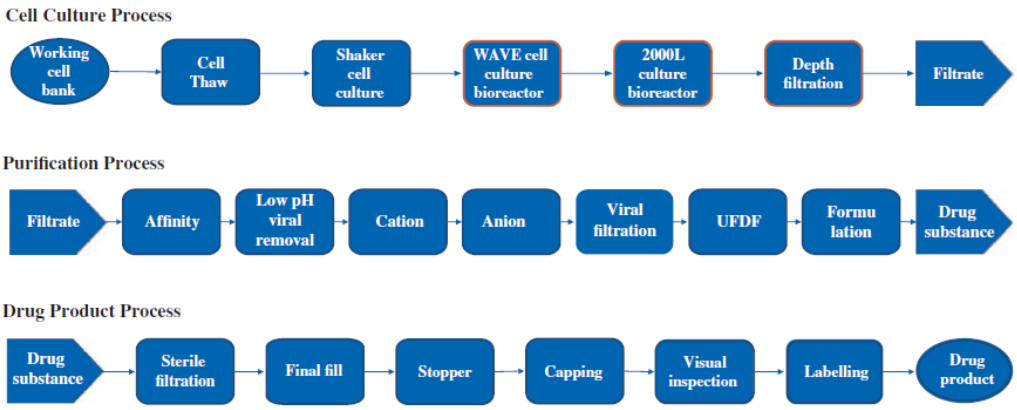
Challenges Remain

While we are optimistic about China's biosimilar prospects, we note that most Chinese companies have, so far, been focused on the research, development and regulatory aspects of the biosimilar process. With significant progress made in these fields, resources must now shift to the development of strong manufacturing and distribution infrastructure essential for the successful launch of biosimilars.

Manufacturing

The biologics and biosimilar manufacturing processes have little in common with the production of small molecules. For example, the molecular mass of Rituximab is about 144,000 Daltons, while aspirin, a well-known small molecule, "weighs" only 180 Daltons. In addition to their molecular complexity, biologics and biosimilars are also manufactured from living organisms, rendering their mass production, and associated quality controls, incredibly more demanding. In its 2018 IPO filing, Innovent indicated that large biologics manufacturing facilities require upward of US$200-700 mm to build, compared with US$30-100 mm for small molecule facilities of similar scale.

Figure 4: Illustrative biosimilar manufacturing process (from Henlius)[13]



[13] Shanghai Henlius Biotech's IPO application with HKSE

We are concerned that manufacturing operations may turn into major hurdles for many of the biosimilar producers. In addition, biosimilar contract manufacturing organization (CMO) options are limited and likely to be scarce for the next few years. Several local contract research organizations (CROs) have developed divisions devoted to biologics and biosimilars. However, their facilities are frequently pilot-scale designed for preclinical or clinical trial usage, and have not yet demonstrated their abilities to handle full-scale commercial GMP production.

In addition to the constrained availability of suitable facilities, we believe that many of the existing biologics plants in China suffer from a productivity deficit and require significant investments to bring their production yields on par with international peers.

Distribution

Once the biosimilars have been developed, approved by regulators and produced at

commercial scale, they still need to be distributed to hospitals and patients. Scott Gottlieb, the former FDA Commissioner, recently indicated that "there are always things we can do to make the pathway more efficient, to lower the cost of development (...) but the impediments are really on the commercial side and the physician acceptance side."[14]

The experience of several European countries and the US shows that the success of the biosimilar market is closely linked to the creation of a strong commercial ecosystem that informs physicians and patients of this new therapeutic class and ensures the availability of drugs through an efficient supply chain.

Currently, China's marketing and distribution system still lacks transparency. If we look at the prescription drug model, rebates and other reward systems can heavily influence physicians' decision-making, and potentially increase the risk of overcharging end-users/patients.

Future Perspectives

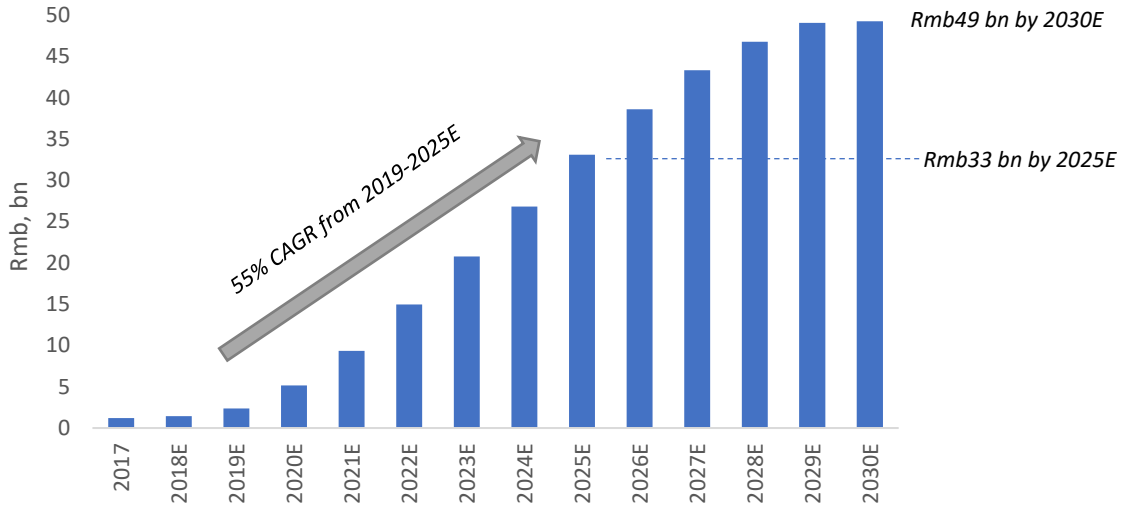
After almost tripling between 2013 and 2017, China's biologics market is expected to grow at a 17% CAGR through 2022, with most of this expansion coming from mAbs (expected to grow at a CAGR of over 40% through 2022)[15]. With more approvals on the way, we expect the Chinese biosimilar market to enjoy tremendous growth over the next 5-10 years and reach Rmb33 bn by 2025 (with a 55% CAGR between 2019 and 2025), partly driven by Bevacizumab, Etanercept, Trastuzumab and Adalimumab, each with biosimilar sales above Rmb4 bn. By 2030, we expect the market to expand to Rmb49 bn - we note that alternate sources exhibit 2030 estimated revenues that are about 20% higher.

[14] Biopharmadive article, "Unblinded: Scott Gottlieb on biosimilars' precarious moment and the gene therapy boom," March 12, 2019

[15] Frost & Sullivan, per Innovent Biologics' IPO prospectus, October 18, 2018

Although we expect the arrival of biosimilar alternatives to boost volumes, we also believe that market competition will be acute by 2025. Markets for "first generation" biosimilars, such as Bevacizumab, will rapidly become crowded, leading to significant price cuts. Winners will need to develop their own competitive advantages, particularly low manufacturing costs and efficient distribution networks.

Figure 5: Projected Sales from China Biosimilar Market (Rmb, bn)[16]



For China to enjoy the full benefits of biosimilars, two critical factors need to be addressed.

First, we believe the government has a leading role to play at several key levels, starting with the inclusion of biosimilars into the National Reimbursement Drug List (NDRL). In the most recent 2017 NDRL, 5 oncology biologics (4 mAbs) were added including, branded Rituximab and Bevacizumab. We expect an acceleration of the number of biologics added to future NDRLs, and subsequently, the addition of biosimilars as well. Since the current focus is on standardizing manufacturing and distribution, more guidance and rules are on the way to provide further structure in the establishment of the entire ecosystem at large. Once this structure is in place, we expect that accessibility and affordability will be determined by market demand, albeit still characterized by China's unique style of state-involvement.

Second, market participants need to be informed and educated about the benefits of biosimilars, through improved access to up-to-date knowledge and training in both technical and regulatory science. The biosimilars that are currently developed in China need further improvement to match the brand name drugs in terms of titer, bioreactor scale, capacity, and in some cases quality. However, participants in China's biosimilar market will still need to expend significant resources over the next few years to inform and educate distributors, hospitals and doctors. Shortcuts and a "race to the bottom" in terms of cost-cutting and

[16] IDG Capital estimates

margin-compression would be costly and detrimental over the long-run, and ultimately delay true innovation. We believe building a healthy environment for biosimilar businesses is critical, especially for an industry likely to be valued at almost 50 billion RMB in the not-so-distant future.

Appendix I—Key Biosimilars Profiles

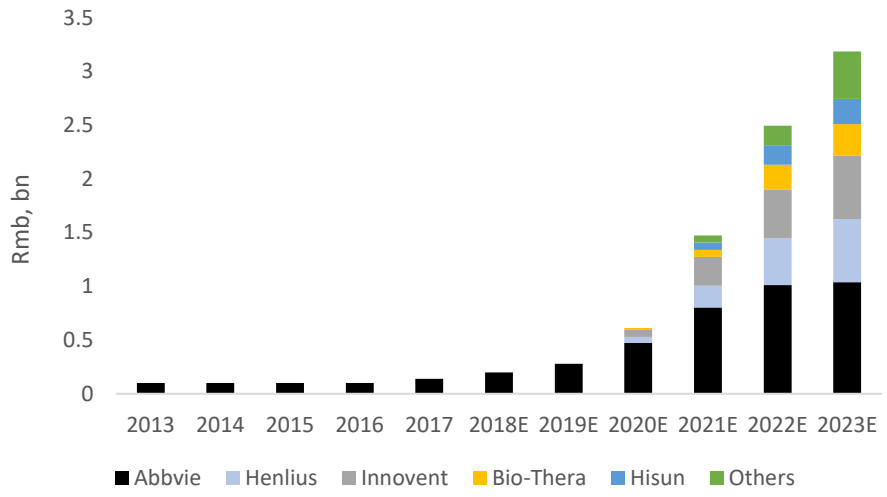
Humira (Adalimumab)

Abbvie's Humira, approved by the FDA on December 31, 2002 and primarily used to treat rheumatoid arthritis and ankylosing spondylitis, is the bestselling drug in the world with global sales of $18.4 billion in 2017. Humira entered the Chinese market in February 2012, though sales remain underwhelming (about $30 million annually), primarily due to its high cost and limited marketing success.

In the US, two Adalimumab biosimilars have since been approved by the FDA, Amjevita from Amgen and Cyltezo from Boehringer Ingelheim, and four biosimilars have been approved in Europe. According to public information, there are more than 20 Chinese companies actively developing Adalimumab biosimilars. Four enterprises, namely Henlius (复宏汉霖), Innovent (信达生物), Bio-Thera (百奥泰) and Hisun Pharma (海正药业) are currently leading the way (as of February 26, 2019, all four had entered the registration stage and fast-track review).

With the rapid emergence of Chinese domestic biosimilar drugs at lower prices, we expect the use of Adalimumab to increase dramatically.

Figure 6: Estimated Adalimumab Sales in China (Rmb, bn)[17]



Rituxan (Rituximab)

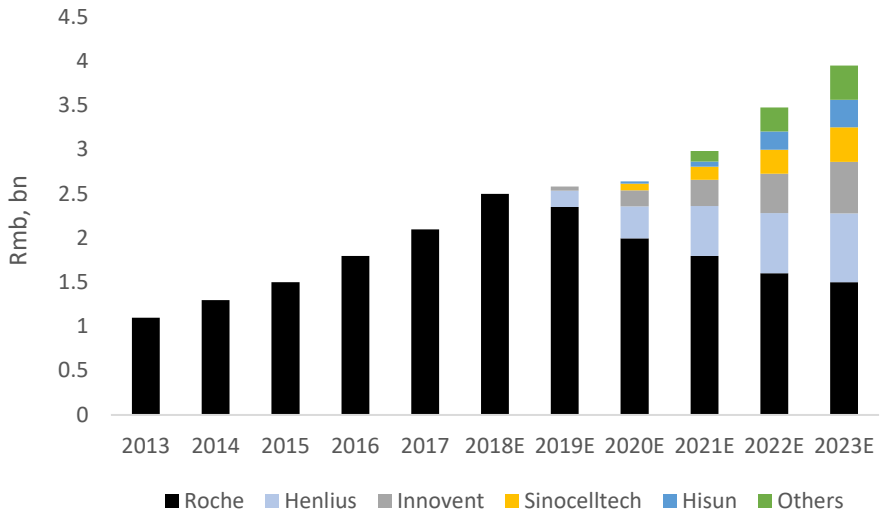
Rituxan was originally developed by Roche and approved by the FDA in 1997. Its main indications are for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis. On April 21, 2008, Roche's Rituxan officially entered the Chinese market.

[17] IDG Capital estimates

In January 2018, Henlius (复宏汉霖)'s recombinant human-mouse chimeric anti-CD20 monoclonal antibody injection, which is indicated for the treatment of non-Hodgkin's lymphoma and rheumatoid arthritis, was selected for priority review, and was subsequently approved by NMPA on February 22, 2019, becoming the first biosimilar drug approved in China.

IBI301 (anti-CD20 mAb), jointly developed by Innovent (信达生物) and Eli Lily, was accepted for review by NMPA on November 13, 2018 and additional biosimilars from Sinocelltech (神州细胞工程有限公司) and Hisun Pharma (海正药业) have entered phase III clinical trials.

Figure 7: Estimated Rituximab Sales in China (Rmb, bn)[18]



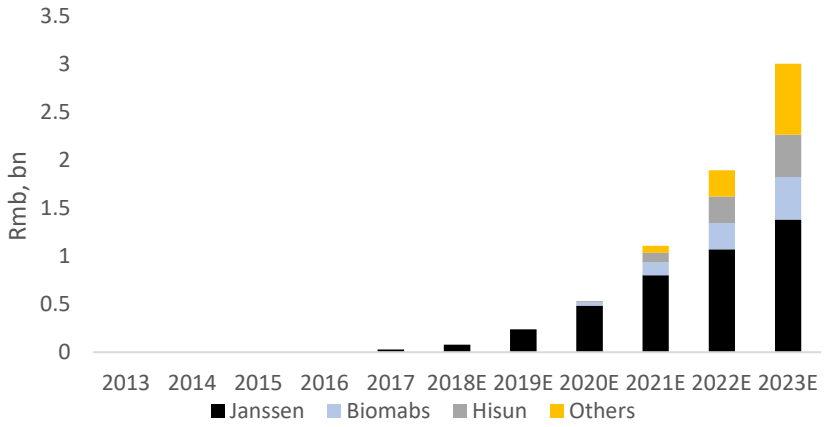
Remicade (Infliximab)

Remicade, developed by Janssen and approved by the FDA in August 1998, is used in the treatment of several indications, including rheumatoid arthritis, ulcerative colitis and Crohn's disease. To date, the US FDA has approved two biosimilars of Infliximab, Inflectra from Pfizer and Renflexis from Samsung Bioepis (the EMA has greenlit 3 biosimilars). On May 17, 2017, Remicade was officially approved by NMPA.

A few Chinese manufacturers are currently developing Infliximab biosimilars, including CMAB-008 from Shanghai Biomabs (上海百迈博制药) - applied for marketing authorization in Shanghai - and HS626 from Hisun Pharma (海正药业) - in phase III clinical trials, while other competitors are still in early clinical stages.

[18] IDG Capital estimates

Figure 8: Estimated Infliximab Sales in China (Rmb, bn)[19]



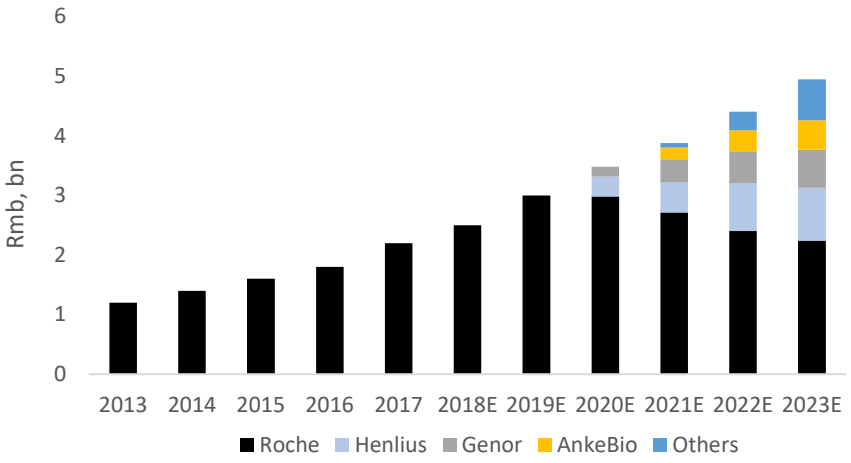
Herceptin (Trastuzumab)

Developed by Roche/Genentech and approved by the FDA in September 1998, Herceptin's main indications include the treatment of breast cancer, metastatic gastric cancer, and metastatic esophageal and gastric junction cancer with overexpressing HER2. With total sales of $7.4 billion in 2017, Herceptin ranked fifth in the world's best-selling drugs, and is one of China's best-selling anti-cancer drugs.

To date, two Trastuzumab biosimilars, Mylan/Biocon's Ogivri and Samsung Bioepis' Ontruzant, are on the market in the US. Trastuzumab was approved by NMPA on September 5, 2002.

While Sunshine Guojian Pharma (三生国健药业) submitted an application of recombinant human anti-HER2 monoclonal antibodies for injection (赛普汀) early on, the application was withdrawn in clinical self-examination. HLX02 from Henlius (复宏汉霖), Genor Biopharma (嘉和生物药业) and AnkeBio (安科生物) have all entered Phase III clinical trials in China.

Figure 9: Estimated Trastuzumab Sales in China (Rmb, bn)[20]



[19] IDG Capital estimates
[20] IDG Capital estimates

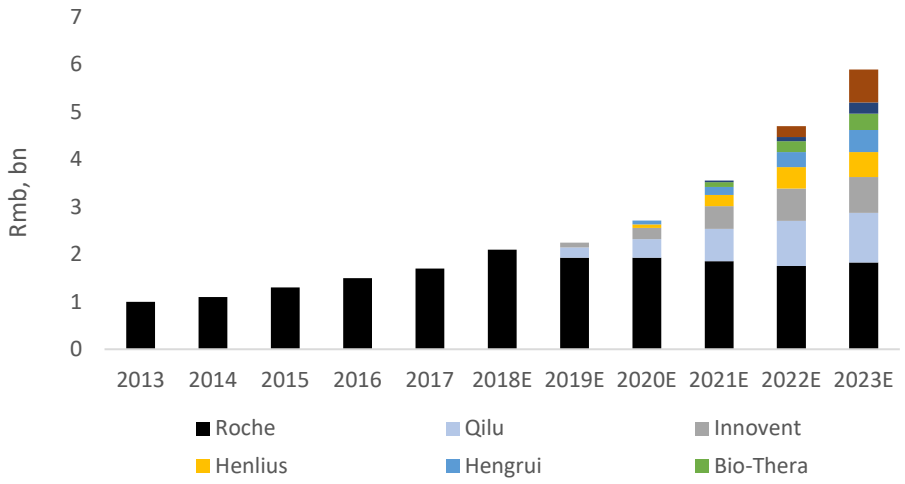
Avastin (Bevacizumab)

Developed by Genetech/Roche and approved by the FDA in February 2004, Avastin is used for the treatment of colorectal, lung, glioblastma, kidney, cervical and ovarian cancers.

In September 2017, the US FDA approved the first Bevacizumab biosimilar, Amgen's Mvasi (Bevacizumab-awwb). However, Mvasi is not marketed yet, due to patent restrictions. In China, Roche launched Avastin in February 2010 and the drug has been on the NDRL since July 2017.

At present, Qilu Pharma and Innovent are the most advanced in the development of bevacizumab biosimilars in China. QL1101 from Qilu Pharma has been accepted for NMPA review, and in January 2019, Innovent announced that the NMPA had accepted its NDA filing for IBI305. Meanwhile, Fosun Pharma, Hengrui Pharma, Beijing Mabworks Biotech and four more competitors are also conducting Phase III clinical trials.

Figure 10: Estimated Bevacizumab Sales in China (Rmb, bn)[21]



Enbrel (Etanercept)

Enbrel was originally developed by Amgen, as the fusion protein of recombinant human TNF-α receptor and human IgG-Fc. It was approved by the FDA in November 1998 and is mainly used for the treatment of rheumatoid arthritis. So far, the FDA has approved only one biosimilar: Sandoz's Erelzi.

"Copycats" appeared early in China. Yisaipu from CP Guojian Pharma was marketed in 2005. In addition, Qiangke from Celgen Biopharma and Anbeno from Hisun Pharma have also been approved. However, these products are neither real biosimilars of Enbrel, nor do they meet the standards or definition of the current guidance on biosimilars. They are, instead, biological drugs developed in accordance with Enbrel's design ideas.

[21] IDG Capital estimates

Appendix II--New Discovered Biosimilars With Large Potential

Levemir (Insulin Detemir)

Levemir, the long-acting Insulin Detemir used to treat both type I and type II diabetes, was developed by Novo Nordisk and approved by the FDA in 2005. Levemir was approved for sale in China in 2014 and made available via the import route. Sales of Levemir in China reached Rmb2 billion in 2018. [22]

There are currently several Chinese firms working on biosimilars, including Hangzhou Zhongmeihuadong Pharmaceutical, Hangzhou Jiuyuan Gene Engineering Co., Ltd., Tonghua Dongbao Pharmaceutical, Chia Tai Tianqing Pharmaceutical Group, and Zhuhai United Laboratories Co., Ltd. Each of these firms has been approved to conduct clinical research. Zhuhai United and Chia Tai Tianqing's programs are the most advanced and have already entered clinical trials.

Victoza (Liraglutide)

Novo Nordisk's non-insulin liraglutide Victoza, is used in the treatment of type II diabetes. Victoza was approved for sale in China in 2011 and made available via import.

There are currently 10 Chinese firms working on a biosimilar, including Hangzhou Jiuyuan Gene Engineering Co., Ltd., Hybio Pharma, Chengdu Shengnuo Biopharm, Tonghua Dongbao Pharma, Jiangsu Wanbang Pharma, Chia Tai Tianqing Pharma, Guangdong HEC Pharma, Zhuhai United Laboratories, Chongqing Peg-bio Biotech, and Beijing E-town International. Each of these firms have been approved to conduct clinical research. We believe that Chengdu Shengnuo Pharma's program is the most advanced, having completed clinical trials and moved into registration batch manufacturing.

While sales of Novo Nordisk's Victoza® have grown rapidly since entering China's market in 2011, volume and scale have not quite reached the levels expected. According to data from PDB, a sampling of China's domestic hospitals, in 2011 liraglutide sales were at 480,000 RMB and by 2016 sales reached 2,960,000 RMB, reflecting a CAGR of 128.5%. However, while Victoza's® global sales reached upward of 29,000,000 USD in 2016, China's market only accounted for 0.15% of that figure. [23]There are different reasons why Victoza's® China sales are significantly lower, but [high] pricing has been one of the major factors.

Lucentis (Ranibizumab)

Developed by Roche/Genentech (Novartis has exclusive commercial rights outside of the US) and approved by the FDA in 2006, Lucentis is a blood vessel growth inhibitor. Currently, the approved indications for ranibizumab include diabetic macular edema (DME, 2006), secondary

[22] NMPA Southern Medicine Economic Research Institute
[23] PDB

macular edema due to retinal vein occlusion (RVO-ME, 2010), wet-age-related macular degeneration (wet-AMD, 2012) and diabetic retinopathy (DR, 2015).

Shanghai United Cell Biotechnology Co., Ltd. is currently developing a biosimilar for Lucentis in China and has applied for approval to conduct clinical research, while Huadong Medicine Co., Ltd. is approaching the clinical phase of product development.

Lucentis was approved for sale in China in 2012 and made available via the import route. According to PDB, 2018 sales of Lucentis in China were more than Rmb0.5 billion.

NovoRapid (Insulin Aspart)

Developed by Novo Nordisk and approved by the FDA in 2000, NovoRapid is a rapid-acting insulin-aspart injectable used for the treatment of diabetes. NovoRapid was approved for sale in China in 2002 and made available via import.

There are currently seven firms working on a biosimilar, including Jilin Jinsheng Pharmaceutical Co., Ltd., Beijing Shuanglu Pharmaceutical Co., Ltd., Liaoning Boao Biopharmaceutical Co., Ltd., Zhuhai United Laboratories, Gan & Lee Pharmaceutical Co., Ltd., Tonghua Dongbao Pharma, and Hisun Pharma.

Besides the before-mentioned products, mAbs such as Nimotuzumab, Toripalimab (JS001), Golimumab, Omalizumab, Ikuzumab, Emicizumab, Epratuzumab, and Tocilizumab are proactively going through R&D process or will soon be marketed.

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About The WhiteOak Group (TWG):

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THE WHITEOAK GROUP

TWG is a full-service, global regulatory consulting firm that specializes in global drug regulatory strategy and practice. We help organizations to navigate the world's regulatory regimens as they cross borders, in particular marketing generic and innovative drugs in US and China.

TWG's team are of senior former FDA reviewers, compliance officers, and project managers that have an average of 20 years of experience in positions providing technical and regulatory support for the entire product development life cycle as well as investigational and marketing application submission preparation. More specifically, we provide comprehensive, integrated, efficient, and effective regulatory strategies to reduce development timelines and accelerate the movement of new products to commercialization. Our regulatory and development strategies services are characterized by thorough understanding of scientific, technical, and regulatory requirements, and attention to details.

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