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# Pfizer Throws In China Biosimilar Towel, Divests Site To WuXi

Changing Market To Blame?

by Brian Yang

After an earlier frenzy around local production and supply, policies to encourage generics, and fast-evolving procedural streamlining, Pfizer's \$350m ambition to develop and make cheaper biologics in China has come to an abrupt halt with the sale of its manufacturing site in a deal with services heavyweight WuXi Apptec.

Just five years ago, <u>Pfizer Inc.</u> was in an upward swing to develop and manufacture several biosimilars in China, the potentially largest market for the follow-on biologics, especially for cancer. But now its ambitions seem to be largely tamed.

The US drug maker has announced it has agreed to divest its biologics manufacturing site in the eastern city of Hangzhou to <u>WuXi Biologics</u>, a contract manufacturing and development organization and subsidiary of major Chinese services group <u>WuXi AppTec Co., Ltd.</u>

Pfizer has established a total of four manufacturing facilities in China - in Dalian, Suzhou, Wuxi and Hangzhou - and the Hangzhou site is particularly significant as it acts as the firm's first Global Biotechnology Center in Asia. "It will ensure the local production of high-quality, affordable biosimilar medicines that will benefit patients both in China and throughout the world," Pfizer had noted on its website.

Clinical study data compiled by Informa's Citeline and Pharmaprojects show that Pfizer has two anticancer biosimilar trials ongoing in China, both for its version of bevacizumab, a biosimilar to Roche's Avastin. One is for monotherapy use and the other is in combination with carboplatin and paclitaxel.



A Pfizer spokesperson told *Scrip* that the divestment move was not easy. "After a comprehensive review of the biosimilars market and the company's global manufacturing network, Pfizer has made a difficult decision to halt its biosimilars programs in China and to sell 100% of its equity interest in Pfizer Biologics (Hangzhou) Co. Ltd." The company stressed it remains committed to China and to continue to realize its purpose – which it sees as breakthroughs that change patients' lives.

One source familiar with the matter told *Scrip* that the US firm had been looking for some time to sell the manufacturing site. Recent regulatory changes in China have also posed a new challenge to the biosimilar manufacturing sector.

## **Fading Frenzy**

Pfizer's Hangzhou site, touted as a state-of-the-art facility, opened to much fanfare in 2018, when multinationals large and small were rushing to establish production sites in China's Jiangsu or Zhejiang provinces, encouraged by local governments' tax incentives. Emerging local biotech firms such as *BeiGene*, *Ltd*. also set up production sites in Suzhou during the heyday of the manufacturing localization frenzy.

But this has since faded, despite the Chinese government's series of policies to encourage generics and its plan to include

# China Lays Out Requirements For Biosimilar Extrapolation

By Brian Yang

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In what could be a blow to some aspiring developers eyeing the nascent but growing biosimilars market in China, new rules lay out when extrapolation of approved indications of reference biologics will be allowed, meaning this will not be automatic.

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biosimilars in volume-based procurement schemes, which have slashed product prices in many cases.

The decisive factor that led to Pfizer's move to sell the Hangzhou biologics site appears to be the wider changing biosimilars market landscape in China. Original local biosimilar developers such as *Innovent Biologics, Inc.* and *Shanghai Henlius Biotech Co. Ltd.* are now turning to innovative new drugs and leaping into the fray of immuno-oncology with anti-PD-1 and -PD-L1 antibodies.

Both Innovent and Henlius started their corporate journeys with goals to develop and market biosimilars to large-selling anticancer biologics in China, where the market for such cost-effective products was expected to overtake the US to become the largest in the world.

But Innovent has now largely transformed itself into a new drug developer, while Henlius has devoted equal attention to both biosimilars and new biologics to be used in combination with the



#### biosimilars.

Several latecomer biosimilar developers in China are also transforming to become new drug originators. *AffaMed Therapeutics*, a biosimilar startup backed by C-Bridge Capital, for instance, has emerged, as has EverInsight, another C-Bridge-supported startup focusing on novel CNS and ophthalmology treatments.

AffaMed previously licensed the rights to ranibizumab (a biosimilar to Lucentis) and aflibercept (Eylea) from <u>Samsung Bioepis Co., Ltd.</u>

### **WuXi Expansion**

Meanwhile, for its part WuXi Biologics is moving quickly in China to expand its late-stage manufacturing capabilities amid surging demand.

Pfizer's acquired  $50,000 \text{ m}^2$  facility includes drug substance (DS) capacity comprising  $2 \times 2,000 \text{L}$  single-use bioreactors expandable to  $4 \times 2,000 \text{L}$  (MFG20) and drug product (DP) capacity for vial filling (DP9) and prefilled syringes (DP10).

It will "address the surging manufacturing demands for late-stage and commercial projects due to the success of our Win-the-Molecule strategy. Globally, DS and especially DP capacities are in urgent need now," noted Chris Chen, CEO of Hong Kong-listed WuXi Biologics.

"It takes us time to build them [the ex-Pfizer facilities], so it bodes well for WuXi Biologics to acquire them [instead of building them]," one spokesperson told *Scrip*. "Pfizer's Hangzhou site is known for quality and high standards, which will be a good fit."

WuXi plans to offer industry-competitive compensation to attract the staff working at the Pfizer site, which number in the hundreds, the person added.