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Free, bi-monthly newsletter for China's BioBusiness, BioScience, Regulatory and Clinical News; tracking news/trends in the China biopharmaceutical/pharmaceutical biologics industry

BioPlan Publications

[Updated! 2nd Edition! China Top 60 Biopharmaceutical Manufacturing Directory](#)

New, comprehensive directory, review and analysis of the top biopharmaceutical facilities in China. Rank and profile of facilities are based on current capacity, staffing, commercial and clinical products, and future build-out plans.

The [directory](#) also highlights upcoming facilities, and includes data on key marketed and clinical trial products.



BioBusiness in China

EpimAb Biotherapeutics closed a USD \$25M Series A round, led by Suzhou's Oriza Seed Capital. The co., which is building a pipeline of immuno-oncology candidates, expects to start its first clinical trial in 2018. *Source: Various, April 2017*

Suzhou Ribo Life Science entered a broad collaboration with U.S.-based Ionis Pharma to develop RNA therapeutics. The agreement has multiple parts: Ribo in-licensed China rights for two Ionis second-gen antisense candidates, one in metabolic disease and the other a cancer drug, and it optioned a third; Ribo will also use Ionis' ssRNAi technology to discover additional drugs. Ribo will make an undisclosed upfront payment to Ionis and also grant equity to Ionis. *Source: Various, April 2017*

Tianjin CanSino Biologics, a vaccine developer, raised USD \$65M in its latest funding round. The co. is currently testing four products in Phase I to III clinical trials in North America, Africa and China respectively. It also has three IND submissions awaiting CFDA trial approvals. *Source: Various, April 2017*

Cellular Biomedicine formed a strategic collaboration with GE Healthcare Life Sciences China to co-develop an automated autologous cell preparation system for

immunotherapy/stem cell manufacturing. To develop the processes, the two co.'s will build a joint lab inside CBMG's new Zhangjiang GMP facility in Shanghai. *Source: Various, April 2017*

Beijing's Creat Group, an investment firm working in financial services, plasma drugs, manufacturing and mineral resources, acquired Germany's Biotest AG, a plasma co., for USD \$1.3B. Creat agreed to a five-year agreement that will keep Biotest's corporate seat in Dreieich, Germany, maintain the Biotest corporate name and increase employment equal to management's business plan. *Source: Various, April 2017*

Shanghai's CRO Newsummit Biopharma, a unit of Zhejiang Yatai Pharma, in-licensed rights for a novel antibody targeting Hepatitis C virus from MRC Technology of the UK. MRC said the novel molecule was humanized by MRC Tech scientists, and originated in the lab of Prof. Arvind Patel, of the MRC-University of Glasgow Centre for Virus Research. *Source: Various, March 2017*

Qilu Pharma of Jinan signed an agreement for China's co-development and marketing of a ALT-L2, a biosimilar to Roche's Herceptin, which is used to treat breast and gastric cancers, and developed by Korea's Alteogen. The molecule is ready to start a Phase III trial in Canada. Alteogen will transfer the technology for the drug to Qilu. *Source: Various, March 2017*

Innovent Biologics will partner with Korea's Hanmi Pharma to co-develop and co-commercialize a targeted, immuno-oncology bispecific drug candidate. The two co.'s expect the molecule to be ready for clinical development in 2019. Hanmi will lead the antibody's development and commercialization outside China, while Innovent will be responsible for manufacturing, along with China development and commercialization. The two firms will share development costs and profits, though details were not disclosed. *Source: Various, March 2017*

GeneQuantum Healthcare raised USD \$5.8M to advance its development of novel antibody drug conjugates toward IND filings. Founded in 2013, GeneQuantum says its proprietary next-generation Ligase Dependent Conjugation (LDC) technology allows the co. to conjugate anti-tumor cytotoxins and site-specific antibodies with a much larger therapeutic window. *Source: Various, March 2017*

C-Bridge Capital and Tasly Holding, a TCM company, will partner to invest USD \$150M in two young China biopharmas, Shanghai's Tianjing Biopharma and Tianjin's Tianzhenshi Biotechnology, which will be merged into a single entity as part of the investment. The merged co.'s will jointly hold twelve antibody drug candidates. *Source: Various, March 2017*

Bio-Facilities Planned in China

Xuchang Biologics Industry Park recently started construction in Xuchang, Henan. The first phase of the park will be focused on manufacturing of amino acids, fructose, etc.; second

and third phase will be focused on construction of biologics manufacturing plants. The construction is projected to be completed within 3-5 years. *Source: Various, Feb 2017*

Teruisi Pharma is building a mAb production plant in Huzhou, which the co. claims to be the first US/EU cGMP compatible plant in China. The phase I construction is projected to cost approx. USD ~\$77M. *Source: Various, Feb 2017*

BeiGene will form a USD \$330M JV with Guangzhou GET Technology Development to build a Guangzhou biologic drug manufacturing facility. BeiGene will contribute USD \$30M to the JV, and Guangzhou GET will invest USD \$150M in a combination of direct equity investment and a convertible shareholder loan, and the JV will raise another USD \$150M in commercial loans. Some of the funds may be used to support China biologic drug development, and construction of the new facility will begin this year. *Source: Various, Feb 2017*

U.S.-based Just Biotherapeutics will use prefabricated clean rooms made by U.S.-based G-CON for its first commercial manufacturing site being built in Hangzhou. Just Hangzhou (Just China) is a partially owned subsidiary of Just Bio. *Source: Various, Feb 2017*

Shanghai's Zai Lab will expand into biologic drug manufacturing through a partnership with GE Healthcare. The two co.'s will cooperate on a facility in Suzhou's BioBay Park, already under construction, which will initially produce clinical-trial-level supplies of biologic drugs. In BioBay, Zai has started building the 4,200-square meter large molecule cGMP plant. The co. is also close to completing construction on a 5,000-square meter small molecule manufacturing facility. GE's equipment will be used in the biologics facility. *Source: Various, April 2017*

Sichuan-based Baili Pharmaceutical announced it completed phase I construction of the ADC-mAb manufacturing base in Chengdu Medical Park. The co. claims the phase I construction includes pilot-scale and commercial scale product plants for antibodies with 6,000 square meters of space. The co. plans to invest USD \$100M in the phase II construction of the site, which is projected to be completed in 2020. The manufacturing facility is established with GE equipment. *Source: Various, April 2017*

Regulatory and Clinical in China

South Korea-based Celltrion received CFDA approval to begin clinical trials of Remsima, a biosimilar to Johnson & Johnson's arthritis treatment Remicade. Remsima has the distinction of being the first foreign antibody biosimilar approved for an efficacy/safety test in China, according to Celltrion, which filed for trial approval in January 2014. *Source: Various, May 2017*

Beijing-based Yisheng Biopharma announced its YS-ON-001, a large molecule drug candidate against cancer, started a Phase I clinical trial in Singapore. The product was granted orphan drug status by FDA in October, 2016. *Source: Various, May 2017*

MSD's HPV vaccine (Gardasil), approved by CFDA, will be launched in the China market. The first HPV vaccine approved in China was GSK's Cervarix. *Source: Various, May 2017*

Beijing-based Eastern Biotech announced its recombinant humanized anti-VEGF mAb for treatment of age-related macular degeneration was granted IND approval by CFDA to start clinical trials in China. CDSCO will seek to align India's pharma GMP regulations with those of WHO (not major market countries, e.g., US or EU, GMP regulations). *Source: Various, May 2017*

BeiGene, a Beijing oncology company, dosed its first patient in a pivotal China Phase II trial of its PD-1 candidate in patients with relapsed or refractory classical Hodgkin lymphoma (cHL). The co., which has administered the PD-1 drug to more than 400 patients, has been approved to test the drug in Australia, New Zealand, the U.S. and Taiwan. *Source: Various, Apr 2017*

Genor Pharma announced it kicked off its Phase I clinical trial of GB222, a biosimilar of Bevacizumab. *Source: Various, Apr 2017*

China's FDA is proposing a new rule to speed up China's approval of novel foreign drugs. Under the new rules, if a drug's IND is already approved in another country, it would be exempted from filing a China IND/CTA request before starting China clinical trials. *Source: Various, Mar 2017*

CFDA and the National Health and Family Commission of PRC announced for-profit stem cell co.'s can be qualified vendor of cells used in cell therapy. The move is regarded as paving the way for commercialization of stem cell therapy in China. *Source: Various, Mar 2017*

JHL Biotech dosed the first patient in a European trial of JHL1101, a biosimilar of Roche/Genentech's rheumatoid arthritis treatment MabThera/Rituxan. JHL partnered with Sanofi giving Sanofi rights to commercialize JHL1101 in China (though no trials have been announced) in late 2016. Sanofi paid USD \$21M upfront and invested USD \$80M in JHL stock for the rights in a deal valued at USD \$257M. *Source: Various, Mar 2017*

U.S.-based Kite Pharma reported very positive topline results from a U.S. Phase III trial of its lead CAR-T immunotherapy in patients with chemorefractory B-cell non-Hodgkin lymphoma (NHL). Fosun Pharma and Kite announced a USD \$95M JV in early 2017 to develop the candidate in China, and Kite will complete its NDA filing of the CAR-T therapy in the U.S. during Q1 and in Europe later this year. *Source: Various, Mar 2017*

Upcoming Biomanufacturing Meetings

[Phar-East Asia's Pharma & Biotech Festival 2018](#) – 1-2 March 2018, Singapore

[ChinaBio Partnering Forum 2018](#) – 25-26 April 2018, Kempinski Hotel Suzhou, Suzhou, China

[World Congress on Advanced Pharmacy and Industrial Research 2018](#) – 20-22
August 2018, Beijing, China

Articles

[Trends in Biopharma Contract Manufacturing in China and India](#); Pharmaceutical Outsourcing; June 2017, V. Xia and R. Rader

[2 part series - Chinese & Indian Expectations For GMP Biologics Exports - A Comparative Assessment](#); BioProcess Online; July 2017, V. Xia, L. Yang, E. Langer

[Chinese And Indian GMP Biologics Exports: Surveying The Current Landscape](#); BioProcess Online; June 2017, V. Xia, L. Yang, E. Langer

[China Biopharma: Is a Wave of GMP Exports in Our Future?](#); PharmaFocus Asia; May 2017, V. Xia, L. Yang, E. Langer

Comments/Suggestions/Resources

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BioPlan Associates, Inc. | 1-301-921-5979 | info@bioplanassociates.com | www.bioplanassociates.com

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