BioBusiness in China

JHL Biotech (Japan), a bioprocessing supplier co. and CMO, opened the world's first modular KUBio (from GE) biopharma manufacturing facility fitted-out with single-use bioprocessing technology in Wuhan, China, for manufacture of biosimilars. *Source: HealthCareBusiness Daily News, May 10, 2016*

CSPC Pharmaceutical Group concluded a potential USD $106 MIL deal licensing a "complex a generic oncology drug" to Watson Labs., now part of Allergan, with Watson obtaining all rights outside of China. *Source: FiercePharma, May 4, 2016*

Innovent Biologics (Suzhou) entered into a potential USD $120 MIL partnership with EpimAb Biotherapeutics (Shanghai) for development of EpimAb's Fabs-In-Tandem Immunoglobulin (FIT-Ig) bispecific antibody products. *Source: FiercePharma, June 8, 2016*

Shanghai Fosun Pharmaceutical (Group) Co. Ltd. acquired a 96% stake in India's Gland Pharma Ltd. (owned by KKR and Co.) for USD $1.35 BIL. Such foreign investments in India's pharma industry are rare, particularly from Chinese co.'s. *Source: Google News, July 29, 2016*

"Biotechnology" areas have received about 5% of Asian venture capital investment, and three Chinese R&D centers were identified as among top 10 global leaders, according to a study published by KPMG and CB Insights. *Source: Gen. Eng. & Biotech. News, May 30, 2016*

Novartis opened a USD $1 BIL R&D facility in Shanghai with 1,300 staff, with this the co.'s 3rd major R&D center; and the first pharma developed by Novartis Chinese researchers is about to enter trials. *Source: Fortune, June 2, 2016*

TNK Therapeutics, a subsidiary of California-based Sorrento Therapeutics formed a partnership with Shenyang Sunshine Pharmaceutical Co. for development of TNK's chimeric antigen receptor T cell (CAR-T) cell therapy technology in China. *Source: San Diego Union-Tribune, June 8, 2016*

Sanofi S.A. linked with Shanghai-based Hummingbird Bioscience for access to its Rational Antibody Development platform. *Source: FierceBiotech, April 22, 2016*

BioScience in China

"50% of the top global innovators in pharmaceuticals are based in China, in terms of the number of new inventions credited to companies, universities or other centers in 2015," according to a *2016 State of Innovation report* from Thomson Reuters. *Source: BioSpace, May 16, 2016*

Researchers at the Academy of Military Sciences reported isolation of "integration factor complex" gene INTS10, which can activate the body's innate immune function and suppress replication of the hepatitis B virus (HBV). *Source: People's Daily Online, June 8, 2016*

Researchers at the Guangzhou Institute of Biomedicine and Health formed functional human stem cells by purifying cells from urine. *Source: CNN, April 28, 2016*

A Phase I trial with CAR-T cell therapy, developed by Innovative Cellular Therapeutics (ICT), in collaboration with First Affiliated Hospital of Zehjiang University, showed 90% complete remission rate in patients with relapsed/refractory B lymphoblastic leukemia. *Source: Seeking Alpha, May 6, 2016*

Researchers at the Beijing Institute of Genomics and BGI-Shenzhen developed a cell-free protein expression system to produce isotope-labeled peptides for use in targeted peptide quantitation assays. *Source: GenomeWeb, June 3, 2016*

An Ebola virus-like protein (VLP) Ebola vaccine with PIKA adjuvant, developed jointly by Jilin Jian Yisheng Biopharma and the U.S. Army Medical Research Institute of Infectious Diseases, showed positive results in earlier trials. *Source: FiercePharma, July 17, 2016*

California-based BioDuro, LLC completed a 92,000 sq. ft. expansion of its "fully integrated drug discovery and development" facility in Shanghai. *Source: BioDuro PR, Sept. 6, 2016*

Regulatory and Clinical in China

Companies found falsifying data will receive a three years' probation before any application from that co./facility will be considered, according to the CFDA. Also, those involved will be "blacklisted." *Source: FDA News, Sep. 1, 2016*

Draft CFDA pharma regulations with nearly 150 changes are being circulated for comment. Major changes include that pharmas should provide clinical advantage, with new products with no or minor changes discouraged. *Source: FDANews, Aug. 15, 2016*

CFDA is experiencing difficulties retaining knowledgeable staff, as the industry offers them much higher salaries. A highly regimented work environment, e.g., no Internet access, has not helped. Over 1/3rd of pharma evaluation staff have left in the past 3 years. *Source: Reuters, May 22, 2016*

CFDA cut in half its inspections of domestic pharma manufacturing facilities in 2015, according to newly-released data. Among 221 inspections, only 4% failed, with most problems related to data integrity. *Source: BioPharma Dive, June 9, 2016*

CFDA granted full approval to Cervarix, human papillomavirus (HPV) vaccine, from GlaxoSmithKline (GSK). GSK will now have to convince Chinese physicians and consumers that HPV vaccination is needed. *Source: FiercePharma, July 18, 2016*

CFDA has a backlog of over 21,000 pharma product applications waiting to be processed. In 2014, it took an average of 42 months to approve drugs in some classes (vs. average of 10 months for FDA). *Source: CRIENGLISH.com, June 8, 2016*

Chinese authorities are “cracking down” on parents protesting substandard vaccines, including making a large number of arrests. *Source: Time, April 21, 2016*

Cuba and China (PRC) are forming a strategic collaboration, which will include exchanges of R&D staff. *Source: CRIENGLISH.com, May 3, 2016*

The National Development and Reform Commission is expected to start "large-scale and systematic" antitrust probes concerning pharma distribution, particularly pricing, in China. Foreign co.’s could well be the primary targets. *Source: China Daily, May 5, 2016*

A biosimilar version of Xolaire from Mabtech Ltd. (China), licensed from Sorrento Therapeutics, showed success in a Phase 2/3 clinical trial in China for treatment of asthma and urticaria. *Source: Seeking Alpha, May 16, 2016*