Pharmatech Helps Innovent Biologics with Basis of Design for New Biosimilars Manufacturing Facility in China

The Associated Press

HAYWARD, Calif.--(BUSINESS WIRE)--Nov 1, 2012--, a compliance consulting firm serving companies in the pharmaceutical, biotech and medical device industries, was selected by Innovent Biologics to provide facility design and compliance support for their new biosimilars manufacturing facility in Suzhou, China.

Because of their detailed understanding of biopharmaceutical manufacturing processes, quality systems and international requirements, Pharmatech Associates was engaged by Innovent to prepare a meeting with the UK Medicines and Healthcare Products Regulatory Agency (MHRA). Pharmatech will engage the agency on Innovent’s behalf to obtain comments on the Basis of Design (BoD) for the new manufacturing facility and to discuss compliance aspects.

Innovent has initiated construction of the new Suzhou campus near Shanghai, China. In addition to laboratories and offices, the campus will house a commercial manufacturing plant with 6X12000 L bioreactors, and a pilot plant with 2x300L and 2x1000L bioreactors for production of clinical testing materials. Both plants are designed to comply with international requirements for cGMPs, as defined by the European EMA and the USFDA, and with China sFDA cGMP regulations.

“As a global leader in compliance, pharmaceutical and biopharmaceutical manufacturers rely on us to meet their design and compliance requirements quickly and effectively,” said Bikash Chatterjee, President and CTO of Pharmatech Associates. “We enable them to receive regulatory pre-approval of their new or renovated facilities, by establishing the technical approach and design parameters that will speed time-to-market for the project, and ultimately, ensure the highest quality pharmaceutical end-product.” About Pharmatech Associates Pharmatech Associates, Inc. (founded in 1995) consults to the pharmaceutical, biotech, medical device manufacturing and other regulated life sciences industries. Headquartered in the San Francisco Bay Area, Pharmatech advises clients that range in size from startups to large multi-national corporations on projects in North America, Asia, and Europe.

About Innovent Biologics Innovent Biologics is a privately held biopharmaceutical company dedicated to the development and manufacturing of monoclonal antibodies to be marketed in China and worldwide.

Innovent is funded by the venture arm of Fidelity, Lilly Ventures, and Suzhou bioBay. Innovent’s founders and senior management team have over 70 years of combined experience in the discovery, development and manufacture of biologics worldwide and were involved in the launch of such products as Bexxar, Conbercept,

Natrecor, Oncorine, Recombivax HB, and others.

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