

Kemwell Biopharma Selected to Manufacture the Monoclonal Antibody Drug Substance For a US Phase 3 Clinical Trial



NEWS PROVIDED BY
Kemwell Biopharma →
Jun 05, 2018, 10:49 ET

BANGALORE, India, June 5, 2018 /PRNewswire/ -- Kemwell Biopharma, a biologics contract development and manufacturing service provider, announced today that it has signed a contract to manufacture and supply drug substance using its state-of-the-art mammalian cell culture plant in India for Phase 3 clinical trials that will be conducted in the US by its customer for a BLA filing.

[Continue Reading](#)



India's largest biologics CDMO

Analytical | Formulation Development | Process Development | Clinical and Commercial Manufacturing



www.kemwellbiopharma.com

Kemwell's state-of-the-art drug substance facility for monoclonal antibodies

Kemwell provided the customer with a fully integrated solution including technology transfer, process optimization, scale-up, manufacturing of toxicology materials and cGMP manufacturing of drug substance clinical materials, and release testing for the on-going Phase 1 trials in the US.

"We are very excited in taking the project to the next stage and supporting our customer for their Phase 3 supplies and the BLA filing in the US. As we are seeing a great increase in large molecules in the pipelines of biopharma companies, we believe Kemwell is ideally suited to provide high quality development and manufacturing services at significantly lower costs to support a fast track to GLP tox studies and cGMP clinical and commercial supplies," says Kemwell's Chairman, Anurag Bagaria.

Kemwell has a strong team of senior scientists trained in USA with an in-depth knowledge and technical expertise on the development of new biological entities (NBE's), biosimilars and bio-betters. Their biotechnology capabilities include process development and manufacturing of drug substances and drug products for toxicology supplies in 80L scale bioreactors, as well as for cGMP clinical and commercial manufacturing in 400L and 2000L bioreactors with corresponding downstream processing, fill & finish in liquid and lyophilized vials and integrated quality management.

Kemwell Biopharma Pvt Ltd is located in Bangalore, India and is a pure play contract development and manufacturing service provider for biopharmaceuticals. Kemwell's state-of-the-art facility is one of the largest available capacities for contract manufacturing of monoclonal antibodies and protein therapeutics derived from mammalian cell culture in India.

Contact: Karan Bagaria, 196632@email4pr.com, +91-80-26982400

Read more about Kemwell on www.kemwellbiopharma.com

SOURCE Kemwell Biopharma

Related Links

<http://www.kemwellbiopharma.com>