BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Piramal Pharma Solutions announces integrated development programme with Bolt Biotherapeutics

29 July 2020 | News

PPS is handling production of Boltâ??s Boltbodyâ?¢ Immune Stimulating Antibody Conjugate (ISAC), BDC-1001, currently in a first-in-human Phase 1/2 clinical study for treatment of cancer patients



Piramal Pharma Solutions, a leading contract development and manufacturing organization (CDMO), has announced that it is providing US based Bolt Biotherapeutics (Bolt) with the supply of both the BDC-1001 ISAC drug substance and the drug product for Bolt's ongoing Phase 1/2 clinical study in cancer patients.

The Piramal Pharma Solutions (PPS) team is applying its integrated drug development model to Bolt's BDC-1001 for the treatment of patients with HER2-expressed solid tumors.

The program encompasses formulation development and ISAC development and manufacture at PPS' Grangemouth, UK site.

The drug substance is then processed into lyophilized, sterile fill-finish vials at PPS's Lexington, KY, U.S. site.

This seamless integration across two PPS sites, which shortens delivery timelines and expedites distribution to clinic, is an example of PPS' patient-centric philosophy.

According to Peter DeYoung, Chief Executive Officer, Piramal Pharma Solutions, "Bolt's technology platform has demonstrated significant, positive data in preclinical models, including the development of immunological memory against tumors, and is now in a human clinical trial. The manufacturing of ISACs utilizes essentially the same process as antibody drug conjugate (ADC) manufacturing, enabling us to capitalize on our deep expertise in this space. Our ability to produce these novel ISACs and package them for clinical trials in one efficient, integrated process compresses the timeline of the development of Bolt's drug. We remain committed to our patient-centric approach and are proud to partner with an industry-leader like Bolt to help reduce the burden of disease on patients."

Nathan Ihle, VP CMC & Quality for Bolt Biotherapeutics, added, "Bolt is a leader in ISAC technology, and our partnership with Piramal Pharma Solutions is important to bring our technology to the clinic. Piramal's experience in the manufacture of commercial ADCs provides Bolt with a reliable partner for the development of BDC-1001."

The first cycle of drug substance to drug product manufacturing has been successfully completed through PPS' integrated program. Additional cycles are in progress, as are further developments that will benefit future indications and new clinical programs.