Piramal Pharma Solutions, a contract development and manufacturing organization (CDMO) and San Francisco-based biotech Bolt Biotherapeutics have signed a production agreement in which Piramal will be handling the manufacturing of Bolt’s Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC), BDC-1001.

Bolt Biotherapeutics’ Platform Technology, exclusively licensed from Stanford University, is applicable to a broad spectrum of antibodies targeting tumor antigens expressed on all types of cancer and consists of Immune-Stimulating Antibody Conjugates (ISAC), a new class of immuno-oncology therapeutics, that harnesses the ability of innate immune stimulants to convert cold tumors into immunologically hot tumors, thereby illuminating tumors to the immune system and allowing them to be invaded by tumor-killing cells.[1]

**BDC-1001**

In *preclinical studies*, researchers at Bolt demonstrated profound antitumor efficacy for BDC-1001, the company’s lead HER2-targeted ISAC therapeutic program when administered as a monotherapy.

Treatment results in activation of the innate immune system that subsequently generates an adaptive immune response leading to complete and durable T-cell mediated clearance of large tumors. These
preclinical studies also showed that BDC-1001 produces an immunologic memory – the immune system retained the ability to attack tumors even after the Boltbody was no longer present in the body, even protecting against tumors that had lost HER2 expression.[1]

BDC-1001, Bolt’s first Boltbody™ has entered clinical development and is currently being evaluated a first-in-human phase I/II study in patients with human epidermal growth factor receptor (HER2-) expressing solid tumors.

**Agreement**

Under the terms of the agreement, Piramal manufactures Bolt’s BDC-1001 ISAC for the ongoing Phase I/II clinical study in cancer patients.

Piramal will apply its integrated drug development model to Bolt’s BDC-1001. The program includes formulation development and ISAC development and manufacturing at Piramal’s Grangemouth, UK site. Following the manufacturing phase, the materials are further processed into lyophilized, sterile fill-finish vials at Piramal’s Lexington, Kentucky (USA) site.

This seamless integration across two of Piramal’s manufacturing facilities, which is expected to shorten delivery timelines and expedites distribution to the clinic, is part of the company’s patient-centric philosophy.

“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,” said Peter DeYoung, Chief Executive Officer, Piramal Pharma Solutions.

“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,” he added.

**Reliable partner**

“We’re 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,” noted Nathan Ihle, Vice President CMC & Quality for Bolt Biotherapeutics.

A spokesperson for Piramal confirmed that the first cycle of trial drugs manufacturing has been successfully completed through Piramal’s integrated program. Additional cycles are in progress, as are further developments that will benefit future indications and new clinical programs.

Both Biotherapeutics was founded by Edgar G. Engleman, M.D., Director, Immunology & Immunotherapy of Cancer Programs, Stanford Cancer Institute and Bolt Biotherapeutics founder and board member.

**Clinical trials**

A First-in-human Study Using BDC-1001 in Advanced and HER2-Expressing Solid Tumors – NCT04278144

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