BIO Boston 2025

Shilpa Biologicals opens bioconjugation manufacturing site for fully integrated ADC development

New bioconjugation services to complete the CDMO's end-to-end capabilities across payload, linker, and MAb

21/05/25, India: Shilpa Biologicals – a full-service contract development and manufacturing organization (CDMO) – announces the opening of a dedicated bioconjugation suite at its Dharwad site [India]. Located adjacent to the company's existing commercial biologics manufacturing facility, the suite is currently undergoing validation and is expected to begin onboarding client programs by September 2025.

This latest expansion positions Shilpa Biologicals among a select group of global CDMOs capable of providing clinical and commercial-scale manufacturing across all three-core antibody-drug conjugate (ADC) components – payloads/linkers, monoclonal antibodies, and bioconjugation — and within a single, integrated campus.

The new suite is backed by one of the industry's largest payload and linker libraries, with a multi-ton high-potency active pharmaceutical ingredient (HPAPI) capacity. In fact, the CDMO currently manufactures approximately 40% of the oncological HPAPIs in use today from its USFDA-approved facilities. It's 10 cGMP HPAPI suites are equipped to handle compounds with occupational exposure limits (OELs) below 0.01 $\mu g/m^3$ – ensuring safe and compliant processing of even the most potent ADC payloads.

Announced ahead of **BIO Boston** [June 16-19] – where next generation ADC targets are widely expected to be one of the key areas of innovation and investment – Shilpa is anticipating strong interest from clinical stage biotechs seeking a single, specialized ADC partner.

The new multi-client bioconjugation suite is built to support the manufacture of ADCs and other advanced bioconjugates progressing through the pipeline, and includes 200L single use bioconjugation reactors and a lyophilization capacity of up to 65 kg. Complementary development laboratories will provide process development, analytical characterization, and both early and late-stage scale-up capabilities. For final dose requirements, Shilpa's Hyderabad site is equipped with multiple isolator-based fill-finish lines dedicated to cytotoxic products.

Shilpa biologicals, Chief Executive Officer Dr. Sridevi Khambhampaty commented; "We are seeing an unprecedented wave of ADC innovation entering clinical development — yet only a handful of CDMOs globally offer true end-to-end capabilities. Our co-located ADC services — spanning payloads, linkers, antibodies, and bioconjugation — are generating significant industry interest, especially from US and European biotech companies seeking a single, reliable partner to support their journey from discovery to commercial launch.

Shilpa's team of dedicated onco-scientists brings deep expertise across a range of moieties and will support innovators at every development stage. Khambhampaty added, "What truly sets us apart is our ability to combine integrated manufacturing with next-generation technologies including cytotoxic and peptide-based payloads, enhanced DAR strategies, and novel conjugation platforms. By combining these within a single CDMO we can improve the therapeutic window and increase the probability of clinical success for our partners."

Notes to editors

About Shilpa Biologicals Pvt Ltd

Shilpa Biologicals is a fully integrated biopharmaceutical company with a therapeutic focus on immunology, oncology and ophthalmics. The company's disruptive technology platforms enable patient access to high-quality, cutting-edge biopharmaceuticals in the global markets. The company currently has a pipeline of biosimilars at various stages of development including one commercialized product in the Indian market. The company is also catering to the growing demand from its global customers for high quality developmental and manufacturing work from its facility in Dharwad, Karnataka.

For media enquiries, please contact:

Alex Heeley or Nidhi Narain De Facto Communications

T: +44 (0) 203 735 8165 / +44 (0) 7834 785 764

E: n.narain@defacto.co.uk / a.heeley@defacto.co.uk