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Shilpa Biologicals opens bioconjugation manufacturing site in Dharwad

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

Shilpa Biologicals, a full-service contract development and manufacturing organisation (CDMO), has announced the opening of a dedicated bioconjugation suite at its Dharwad site in Karnataka.

Located adjacent to the company's existing commercial biologics manufacturing facility, the suite is currently undergoing validation and is expected to begin onboarding client programmes 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 µg/m^3 – ensuring safe and compliant processing of even the most potent ADC payloads.

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 lyophilisation capacity of up to 65 kg. Complementary development laboratories will provide process development, analytical characterisation, 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.