



NEWS RELEASE

Novasep opens €11M new antibody-drug conjugate (ADC) bioconjugation unit

ADCs, used in innovative treatments against cancer, will be produced in Le Mans, France to serve international markets

Lyon, France, February 23, 2017 – Novasep, a leading supplier of services and technologies for the life sciences industry, announces that its new €11M bioconjugation facility is now operational. The greenfield facility was erected within 20 months on Novasep's Le Mans site in France.

The 2,000m² facility features two flexible GMP production suites equipped with 10L to 400L vessels to support both clinical and commercial manufacturing of antibody-drug conjugates. The stand-alone facility is purpose-built and offers R&D services, QC and scale-up laboratories.

Novasep has been a leading contract service provider in the ADC arena for more than 10 years; the new unit completes Novasep's ADC manufacturing platform already featuring ADC payloads, drug linkers and monoclonal antibody commercial scale production capabilities.

"We designed the facility to ensure smooth and robust scale-ups and address the ADC-specific analytical and process challenges." Rachel de Luca, General Manager of Le Mans site said. "Our team has a long experience in applying DoE to chemical synthesis and bioprocessing and efficiently develop conjugation and purification steps on a wide range of ADC platforms. Furthermore, the site has established good manufacturing practices meeting the Quality and SHE standards applied to the production of anti-cancer compounds, confirmed by a long track of successful FDA inspections."

ADCs are particularly complex to produce because they are composed of a biological part – the monoclonal antibody, and a chemical part - the linker and the highly potent payload. The conjugation is the critical process step where both parts are assembled.

Although only two drugs have reached the market so far, the pipeline of ADC-based drugs in development is rich and promising. Many research platforms are being developed to control and improve further the activity of ADC drugs through alternative strategies of linkage, site specificity and new payloads. More generally, this approach addresses the patients' demand for more targeted therapies having lower side effects.

Dr Michel Spagnol, CEO and Chairman of Novasep, declared: "We are delighted to inaugurate this new unit which reflects Novasep's strong know-how and expertise. Our Group continues to strengthen its position and pursue its investment strategy to delivering service excellence to its worldwide clients, at the forefront of innovative therapies which can change the life of patients."