

Simtra BioPharma Solutions and MilliporeSigma Announce Strategic Alliance for Antibody Drug Conjugates Drug Substance and Drug Product Manufacturing Services

Proven leaders in biologics manufacturing are aligning their strengths to deliver a more efficient and cost-optimized drug development supply chain, worldwide

Alliance aims to expedite time to market for ADCs and bioconjugates

PARSIPPANY, N.J, June 11, 2025 – Simtra BioPharma Solutions, a leading contract development and manufacturing organization (CDMO) specializing in sterile injectables, today announced that it has formed a five-year strategic alliance with the Life Science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada. The partnership brings together the strengths of two leaders and creates a turnkey offering for biopharmaceutical companies seeking ADC and bioconjugation, linker/payload manufacturing, drug product formulation development and fill-finish capabilities.

“By bringing together two experts in the ADC value chain, biopharmaceutical companies should benefit from shorter timelines and less complexity, allowing them to focus their efforts on drug discovery,” said Franco Negron, CEO of Simtra BioPharma Solutions. “Harmonizing our processes with designated program management from start to finish will give customers greater confidence that their product will be delivered on time and to the highest quality standards—ultimately accelerating the delivery of life-changing therapies to patients who need them most.”

Manufacturing ADCs is complex as it involves combining three different components: a monoclonal antibody, a cytotoxic payload, and a linker – each with its own production challenges – into a single, stable, and effective therapeutic. This new alliance creates a seamless development and contract manufacturing value chain with the bulk drug substance conjugated by MilliporeSigma directly transferred to Simtra for drug product fill/finish. Customers will receive streamlined support with designated project managers at each of the partners’ sites working closely together to ensure smooth transfers and expedite timelines.

The ADC pipeline is experiencing strong growth with an increasing number of biopharma companies developing assets in this space, and currently more than 70% of these drugs are manufactured by CDMOs. A Roots Analysis study showed the market for ADC manufacturing is \$1.79 billion today, but is expected to grow to \$7 billion by 2035, or a compound annual growth rate of 13%. Early success of ADCs, such as treatments for HER2-positive breast cancer, have helped demonstrate the significant potential of ADCs as a cancer treatment option. However, most biopharmaceutical companies today must seek out multiple manufacturing partners to develop antibodies, high-

potency active pharmaceutical ingredient/cytotoxic payloads, and linkers, perform the conjugation and purification step and complete fill-finish.

“Patients can’t wait. With over 200 new ADCs in active clinical trials, it is critical that we work to speed up the manufacturing process, reduce the risk of knowledge or time-loss during handoffs, and enable our clients to advance their programs,” said Benjamin Hein, Head of Life Science Services, Life Science business of Merck KGaA, Darmstadt, Germany. “Connecting the bioconjugation and fill-finish steps will be a value-add for our clients, ultimately meeting their ambitious timelines and allowing the broadest number of patients to benefit in the fastest and safest possible way.”

To learn more about the alliance: www.simtra.com/the-power-of-two-the-ease-of-one

To learn more about Simtra BioPharma Solutions, visit: www.simtra.com

To learn more about Millipore® CDMO services by MilliporeSigma visit: www.sigmaaldrich.com/adc-cdmo

About Simtra BioPharma Solutions

As the premier, independently owned Contract Development Manufacturing Organization with more than 65 years of sterile injectable manufacturing expertise, Simtra BioPharma Solutions offers world-class cGMP sterile fill and finish, technical expertise, quality service, and a uniquely collaborative approach to support our customers’ strategic objectives.

Biotech and pharmaceutical companies partner with us when they need to take their molecule to market, whether launching an innovation globally, improving a formulation, or proactively mitigating risk to grow their business.

Our teams of tenured experts deliver tailored, flexible solutions to help our customers consistently fulfill their product goals at the highest quality, so they get in the hands of the patients who need them most.

For more information, visit www.simtra.com.

About the Life Science business of Merck KGaA, Darmstadt, Germany

The Life Science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has more than 26,000 employees and more than 55 total manufacturing and testing sites worldwide, with a portfolio of more than 300,000 products focused on scientific discovery, biomanufacturing and testing services. Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and electronics.

Around 62,000 employees work to make a positive difference to millions of people’s lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the

most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2024, Merck KGaA, Darmstadt, Germany, generated sales of € 21.2 billion in 65 countries. The company holds the global rights to the name and trademark “Merck” internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company’s technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company. For more information about Merck KGaA, Darmstadt, Germany, visit www.emdgroup.com. Follow MilliporeSigma on [Twitter](#) @MilliporeSigma, on [Facebook](#) @MilliporeSigma and on [LinkedIn](#).

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