

News Release

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MilliporeSigma to Manufacture Elypta's Liquid Biopsy Kits

Liquid biopsy kits aim to improve accuracy of cancer diagnosis

Burlington, Massachusetts, February 18, 2020 – <u>MilliporeSigma</u> today announced that it has been selected by Swedish molecular diagnostics firm <u>Elypta</u> as the contract manufacturer for Elypta's clinical diagnostic liquid biopsy kits. The kits analyze metabolites deregulated in several cancer types, making diagnoses more accurate.

"Both small and large diagnostic and clinical testing kit manufacturers struggle to find high quality, reliable contract manufacturing organizations like MilliporeSigma," said Jean-Charles Wirth, head of Applied Solutions at MilliporeSigma. "The kits that we will produce together with Elypta use a bio-fluid sample to detect and analyze biological markers to evaluate disease and determine treatment options for cancer. This collaboration underscores our commitment to accelerate the pathway to commercialization of this important diagnostic product."

The kits, which will be manufactured at MilliporeSigma's facility in St. Louis, Missouri, will initially be made available for research use only. They are intended for mass spectrometry systems and will allow qualified researchers to measure the full spectrum of human glycosaminoglycans in body fluid samples.

"Having MilliporeSigma as a supplier helps us to commercialize Elypta's test without significant manufacturing investments and will accelerate time to market," said Karin Mattsson, vice president of Research & Development at Elypta.





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"MilliporeSigma's history in IVD product custom manufacturing is well reflected in their current efforts with our kits and we have great confidence in their quality and manufacturing capabilities. We expect to have RUO kits ready for the market in 2020."

MilliporeSigma, which has more than 30 years' experience in the diagnostics space, has been working with Elypta toward the customization of assay kits. Elypta plans to qualify the kits for in-vitro diagnostics use in the United States and European Union following completion of clinical validation studies, including one evaluating performance in surveillance of kidney cancer recurrence.

MilliporeSigma's Applied Solutions business unit focuses on diagnostic, testing and industrial customers and provides products and solutions that streamline processes, lower costs and deliver reliable results.

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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 some 21,000 employees and 59 manufacturing sites worldwide, with a portfolio of more than 300,000 products focused on scientific discovery, biomanufacturing and testing services. Udit Batra is the global chief executive officer of MilliporeSigma.

Merck KGaA, Darmstadt, Germany completed its \$17 billion acquisition of <u>Sigma-Aldrich</u> in November 2015, creating a leader in the \$125 billion global life science industry.

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 56,000 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 advancing gene-editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices − the company is everywhere. In 2018, Merck KGaA, Darmstadt, Germany generated sales of €14.8 billion in 66 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 EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 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.