

News Release

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EMD Millipore Adds Protein Pegylation to Portfolio of Services for Biopharmaceutical Industry through Collaboration with celares GmbH

- **Services include feasibility studies, process and analytical development and scale-up**
- **Scales from milligram quantities to processes ready for CMO transfer**
- **Pegylation helps overcome pharmacological and physicochemical challenges and accelerates time to market of protein therapeutics**

Billerica, Massachusetts, July 27, 2015 – [EMD Millipore](#), the Life Science business of [Merck KGaA](#) of Darmstadt, Germany, today announced a collaboration with celares GmbH to provide pegylation services to customers developing protein-based therapeutics and biosimilars. The new service offering enabled by the collaboration includes feasibility studies, process and analytical development, and scale-up from milligram to gram quantities required for pilot and subsequent commercial scale.

Pegylation, the attachment of polyethylene glycol to a molecule, can significantly improve the pharmacological and physicochemical properties of peptide and protein therapeutics and reduce side effects. This well-recognized delivery system for biologics can enhance protein stability, bioavailability and solubility, overcoming common challenges in the development of these therapeutics.

“Whilst a widely used approach to improving drug delivery, a successful of pegylation strategy is dependent upon materials expertise and application experience,” said Andrew Bulpin, Executive Vice President of Process Solutions, EMD Millipore. “celares is a recognized leader in this area and through our collaboration, we are now able to expand

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our service offering to include conjugation, further helping our biopharmaceutical and biosimilar customers to optimize their protein therapeutics and to reduce their time to market.”

The new services will leverage EMD Millipore’s broad range of functionalized PEG products of different molecular weight and activation chemistry, as well as buffers, solvents and excipients, unit operations employed during the pegylation process and subsequent purification including tangential and normal flow filtration and chromatography.

“An optimized formulation can help a promising protein therapeutic reach the clinic and patients in need,” said Dr. Frank Leenders, Managing Director of Operations at celares GmbH. “Our expertise in pegylation combined with the experience and integrated products and unit operations from EMD Millipore will create customized solutions needed by the biopharmaceutical industry to maintain forward progress of promising drug candidates.”

For more information, please visit http://www.emdmillipore.com/US/en/small-molecule-pharmaceuticals/drug-delivery/activated-pegs/OVab.qB.KKsAAAFDc1JZXuRT_nav.

About EMD Millipore

EMD Millipore is the U.S. Life Science subsidiary of Merck KGaA, Darmstadt, Germany. As part of the global Life Science business of Merck KGaA, Darmstadt, Germany, EMD Millipore offers a broad range of innovative, performance products, services and business relationships that enable our customers' success in research, development and production of biotech and pharmaceutical drug therapies. Through dedicated collaboration on new scientific and engineering insights, and as one of the top three R&D investors in the life science tools industry, the Life Science business of Merck KGaA, Darmstadt, Germany, serves as a strategic partner to customers and helps advance the promise of life science. Headquartered in Billerica, Massachusetts, the global business has around 10,000 employees, operations in 66 countries and 2014 revenues of €2.7 billion.

For more information, please visit www.emdmillipore.com.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world’s oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name

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and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

For more information, please visit www.emdgroup.com.

About celares, Berlin, Germany

celares GmbH, Berlin, Germany, a privately owned company, is a recognized leader in the field of pegylation and chemical modification of biopharmaceuticals. The company provides high-quality customized services including feasibility studies, up-scaling and process development, as well as development and validation of required analytical methods. Furthermore, celares offers pilot batch production of pegylated and chemical modified biopharmaceuticals for in vivo testing and performs stability studies according to ICH guidelines. Based on long term experience and excellent scientific know-how, celares accelerates customers' development programs.