Cinfa Biotech receives positive CHMP opinion for Pelmeg® (pegfilgrastim), a proposed biosimilar to Neulasta®

Munich, Germany, 21 September 2018 – The biosimilar company Cinfa Biotech today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorization for Pelmeg® (B12019), a proposed biosimilar to Neulasta® (pegfilgrastim), for the treatment of chemotherapy-induced neutropenia.

"The positive CHMP opinion for our proposed pegfilgrastim biosimilar product Pelmeg® is an important milestone in our effort to provide patients with high-quality and affordable treatment options," said Dr. Ruediger Jankowsky, Managing Director of Cinfa Biotech GmbH. "This recommendation reflects the high quality of our data and validates our approach for the further development of our product pipeline."

The marketing authorization application was submitted in September 2017 and is supported by a comprehensive set of biosimilarity data from analytical, biofunctional and clinical studies comparing Pelmeg® and Neulasta®. The clinical development program included two studies, which confirmed the analytical and biofunctional similarity of Pelmeg® and Neulasta® in highly sensitive clinical study settings.

The European Commission (EC) will review the CHMP's positive opinion. If adopted, the EC will grant a centralized marketing authorization, which will be valid in all member countries of the EU.

About Cinfa Biotech

Cinfa Biotech has offices in Munich, Germany and Pamplona, Spain. Founded in 2013, the Company is creating a pipeline of biosimilar drugs for a range of indications to address the growing need for affordable therapies based on proven science, quality, safety and efficacy. A complete team of experts with decades of in-depth experience is conducting product development, clinical studies, manufacturing and quality control, according to the highest European standards. Cinfa Biotech's first product candidate is Pelmeg® (B12019), a biosimilar version of Neulasta® (pegfilgrastim).

For more information, please visit: http://www.cinfabiotech.com

Contact:

Cinfa Biotech GmbH

Nymphenburger Strasse 3c

80335 Munich, Germany

Phone +49 89 54 54 62 0

Email: info[at]cinfabiotech.com

For press enquiries:

MC Services AG

Julia von Hummel, Shaun Brown

Phone: +49 89 210 228-0

Email: cinfabiotech[at]mc-services.eu