

Cinfa Biotech begins US partnering and prepares US development for B12019, a proposed biosimilar to Neulasta[®] (pegfilgrastim)

Pamplona, Spain, 14 December 2017 – Cinfa Biotech S.L., the biosimilars company of Cinfa Group, today announced the start of US partnering and the preparation of US development for its drug candidate B12019, a biosimilar of Neulasta[®] (INN pegfilgrastim) to treat chemotherapy-induced neutropenia. In the first step, additional clinical data on B12019 were published during a poster presentation at the ASH Annual Meeting 2017. Early next year, the company will participate in the Biotech Showcase[®] conference, taking place on January 8-10, 2018 in San Francisco, USA.

During this event, Cinfa Biotech will meet with potential partners to discuss licensing options for the US market access for B12019. The B12019 Marketing Authorisation Application (MAA) for the European Union has been accepted for review by the European Medicines Agency (EMA) in September 2017.

“In hand with the EMA approval process, we are ramping up our partnering activities for the US market,” said Dr. Ruediger Jankowsky, Managing Director of Cinfa Biotech GmbH. *“In parallel, we are preparing interactions with the FDA to agree on the data package required for FDA approval of B12019.”*

About Cinfa Biotech

Cinfa Biotech is headquartered in Pamplona, Spain, with offices in Munich, Germany. Founded in 2013 and supported by the Cinfa Group, 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 B12019, a biosimilar version of Neulasta[®] (pegfilgrastim). The commercialisation models will be customised to the needs of partners and markets.

With 50 years' experience, Cinfa Group today employs over 1,800 people and reinvests an average of 90% of its annual profits in its portfolio companies, thereby driving their development and innovation. Cinfa Group's first subsidiary, Laboratorios Cinfa, has become a recognised leader in the Spanish pharmaceutical market. As part of the internationalisation strategy, the company also serves in currently over 50 countries and is further expanding.

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

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