Cinfa Biotech presents additional clinical data for pegfilgrastim biosimilar candidate B12019 at the 59th ASH Annual Meeting

Cinfa Biotech starts US partnering discussions

Pamplona, Spain, 2 November 2017 – Cinfa Biotech S.L., the biosimilars company of Cinfa Group, today announced that it will present additional data from the clinical development program of its lead development candidate B12019, a biosimilar version of Neulasta® (INN: pegfilgrastim) to treat chemotherapy-induced neutropenia. The new data will be presented during a poster presentation at the 59th American Society of Hematology (ASH) Annual Meeting 2017 in Atlanta, USA, from December 9-12, 2017.

The poster 1002 titled: "*Comparability of Pharmacodynamics and Immunogenicity of B12019, a Proposed Pegfilgrastim Biosimilar to Neulasta®"* will be presented on Saturday, December 9, from 5:30 to 7:30 p.m. EST in Hall A2 on level 1, Building A; an abstract is now available at http://www.hematology.org/Annual-Meeting/

Based on scientific advice from EMA, the clinical development program for B12019 included a pivotal and a supportive clinical study. Pharmacokinetic (PK) and pharmacodynamic (PD) comparability between Neulasta and B12019 in the pivotal study had been previously shown (Blood 2016 128:5079). The data to be presented at the ASH Annual Meeting 2017 are from the supportive study. They provided, together with the data from the pivotal study, the clinical basis for the marketing authorization application that was accepted for review by the EMA, as reported in October 2017.

The supportive study investigated the immunogenicity and PD comparability of B12019 and Neulasta at a reduced dose of 3 mg. This dose is considered to be more sensitive to detect potential differences in PD between B12019 and Neulasta as compared to the clinical dose of 6 mg. The study confirmed the comparability in PD and immunogenicity of B12019 with Neulasta at the reduced dose.

Dr. Ruediger Jankowsky, Managing Director of Cinfa Biotech, commented: "*We are proud to present new data of our clinical development program at the ASH Annual Meeting. The recent MAA acceptance in Europe and the robust B12019 development data provide an excellent basis for finalizing the partnering activities in Europe and to initiate partnering activities in the US."*

The Company will also attend the life science partnering conference BIO-Europe®, Berlin, Germany, November 6 – 8, 2017.

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 in clinical development 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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