Cinfa Biotech
www.cinfabiotech.com

Developing a pegfilgrastim biosimilar to increase patient access to cancer care

In just four years, Cinfa Biotech's pegfilgrastim biosimilar has been developed, been tested, and received acceptance from the European Medicines Agency for review of a marketing authorization application to treat neutropenia.

The rising cost of cancer treatment has put the long-term use of biopharmaceuticals in the spotlight. Biosimilars, copies of off-patent biopharmaceuticals, offer healthcare systems a way to broaden patient access to medicines without compromising on quality, safety, or efficacy.

However, biosimilars are complex, large molecules that are challenging to characterize. To win approval, companies must present comprehensive data showing that the biosimilar is comparable to the reference biopharmaceutical. This limits participation in the sector to companies with deep expertise in biologic drug development, clinical studies, manufacturing, and quality control.

Cinfa Biotech meets all these demands. The company is the specialist biosimilar unit of Cinfa Group, a leading Spanish pharmaceutical firm. The group structure gives Cinfa Biotech the support of a large parent company with extensive, all-European infrastructure and capabilities in drug development. This constitution sets Cinfa Biotech apart from other biosimilar businesses and is the basis for its success.

In recent years, Cinfa Biotech used its resources to advance B12019, a biosimilar copy of Amgen's chemotherapy-induced neutropenia drug Neulasta, through clinical trials. B12019 and Neulasta are formulations of pegfilgrastim, a pegylated form of the granulocyte colony-stimulating factor analog filgrastim, which mitigates the negative effects of chemotherapy on the level of white blood cells.

Pegfilgrastim's vital role in cancer care has transformed Neulasta into a $4.6 billion-a-year drug. Cinfa Biotech is now poised to provide healthcare systems with an equally effective alternative.

The pegfilgrastim biosimilar program

The speed and success of the pegfilgrastim development program—which took only four years to deliver positive clinical data—are testaments to Cinfa Biotech's prowess. The company designed and executed an efficient program by complementing its own expertise with extensive regulatory advice and current scientific knowledge, resulting in a lean strategy built around two clinical trials and a comprehensive analytical and biofunctional dataset.

Both trials enrolled healthy volunteers, because differences between the immunogenicity of biosimilars and reference products are more sensitive to detection in this population. This increased the sensitivity of the trials and thereby reduced the number of trial participants needed to show that B12019 is comparable to Neulasta.

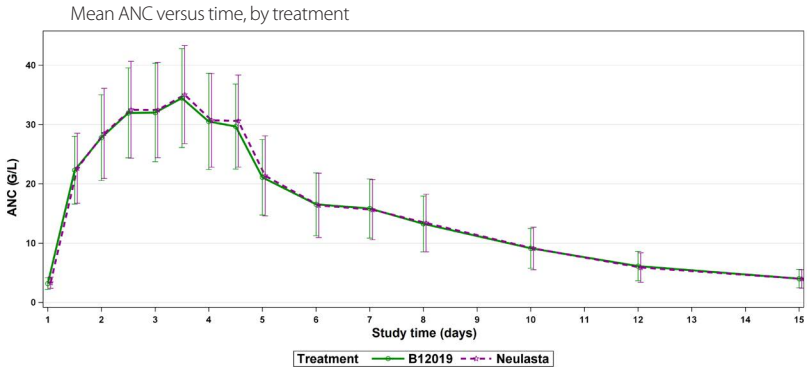

Fig. 1 | Results showing the pharmacodynamic (PD) comparability of 6 mg of B12019 versus 6 mg of Neulasta. Error bars indicate ±s.d. ANC, absolute neutrophil count; AUEC, area under the effect curve; CI, confidence interval; CV, coefficient of variation; G/L, giga per litre. Adapted with permission from ref. 1.

The first trial, in 172 participants, assessed the similarity between the pharmacokinetic/pharmacodynamic (PK/PD) properties of B12019 and Neulasta at the clinical dose of 6 mg. In the second trial, Cinfa Biotech administered a reduced, 3 mg dose to 96 volunteers to generate PD and immunogenicity data.

Data from the first trial showed that B12019 and Neulasta have comparable PK/PD and safety profiles, which demonstrated that B12019 is similar to Neulasta, a requirement for approval (**Fig. 1**).

The second trial confirmed the biosimilarity of B12019 to Neulasta and generated comparable safety and immunogenicity data.

No clinically meaningful differences in safety and immunogenicity were observed between the volunteers who received B12019 and those who received Neulasta in either trial.

When combined with analytical data showing the physicochemical comparability of the molecules and in vitro assessments of their biofunctional properties, the clinical trial results gave Cinfa Biotech the evidence to file for approval. The European Medicines Agency (EMA) accepted Cinfa Biotech's B12019 marketing authorization application (MAA) for review in September 2017.

If B12019 receives approval, Cinfa Biotech has the infrastructure and processes in place to supply the drug on a commercial scale. In preparation for launch, Cinfa Biotech has applied quality-by-design principles to establish and validate commercial-scale good manufacturing practice (GMP) processes for the B12019 drug substance and product at European facilities.

The facility has already produced a substantial number of batches to demonstrate the robustness of the process and quality of the finished product.

Cinfa Biotech is preparing for the approval of B12019 in Europe while working toward a development program designed to bring the drug to market in the US. The company is preparing interactions with the US Food and Drug Administration (FDA). Talks with potential partners are also under way.

The next steps

The progress of B12019 from idea to MAA in four years shows the potential of biosimilars and Cinfa Biotech's efficient development strategy. Such streamlined development requires deep expertise and a rigorous approach, which can lead to products that drive down the cost of treating cancer and other diseases.

Having completed development in Europe, Cinfa Biotech is closing in on the day it can make its biosimilar pegfilgrastim available through its license partners to more patients. That will be a landmark day for Cinfa Biotech, cancer patients, and efforts to control the costs of cancer care.

1. Gascón, P. et al. Perspectives on the future of pegfilgrastim biosimilars. *Generics and Biosimilars Initiative Journal (GaBI J.)* **6**(4), 185–187. https://doi:0.5639/gabij.2017.0604.040 (2017).

contact
Ruediger Jankowsky, Managing Director
Cinfa Biotech GmbH
Olloki, Spain/Munich, Germany
Phone: + 49 89 5454620
Email: info@cinfabiotech.com