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The FDA authorizes Cenexi to produce ProvayBlue® (methylene blue) for the USA

Cenexi, a French CDMO specializing in the formulation, analytical development, and manufacture of complex molecule drugs, has announced that it has been authorized by the FDA (Food and Drug Administration) to produce ProvayBlue®, a drug from the French pharmaceutical company Provepharm, packaged in vials at the Hérouville-Saint-Clair site, for the USA. This authorization is a major first for the Normandy site.

The first three batches of ProvayBlue® in vials will be provided to Provepharm in Q1 2022. ProvayBlue® has also been manufactured in the form of ampoules at Cenexi's Fontenay-sous-Bois site, since 2016. The FDA inspected this site and also declared it compliant with its requirements.

"This new production in Hérouville-Saint-Clair is proof of Cenexi's and Provepharm's partnership of trust", **said Christophe Durand, CEO of Cenexi**. It also reflects the success of our strategy of offering to manufacture our customers' product portfolio in the Group's various plants. This agility makes it possible to quickly provide patients with innovative therapies."

"This is the second time that a Cenexi site has been FDA approved through ProvayBlue®", said Damien Holly, Technical Operations Manager at **Provepharm.** Fontenay was the first site, for ampoules, and now, Hérouville, for vials. We have just obtained our own FDA approval for our unit that manufactures the active ingredients used in the composition of our drugs. Thanks to our partnership with Cenexi, we control the security of the supply chain for these products."

About Cenexi

Cenexi, a major French CDMO operating in Europe with 1,500 employees and some €200 million in turnover (2021), is experiencing steady growth with four production sites (Fontenay-sous-Bois, Osny, and Hérouville-Saint-Clair in France and Braine-I'Alleud in Belgium) and a center of expertise dedicated to new product introduction.

Created in 2004, the Cenexi Group is positioned on the very dynamic international market for drugs with major therapeutic indications, drawing on its spirit of innovation and its extensive expertise in the manufacture and development of products.

The Group's new management team has revitalized the company, in particular, by strengthening its sterile expertise which already represents 70% of its business.

Cenexi has the facilities to produce many pharmaceutical forms and has strong expertise in cytotoxic, hormonal, and narcotic drugs.

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