Xellia starts commercial production and distribution of premix bag products from its Cleveland facility

Vital life-saving medicines can now be produced locally in Cleveland, USA, for the US market

Copenhagen, Denmark, and Cleveland, Ohio, USA, 29 November 2023 - Xellia Pharmaceuticals ('Xellia'), a global leader in the manufacturing of specialty anti-infective treatments and critical care therapies, has received approval by the US FDA for the manufacture of its first premix bag products at its facility in Cleveland, Ohio, USA. Production has commenced and the first commercial batches have been released.

The Xellia team has worked closely with the FDA to bring the whole Cleveland facility into operation, gaining approval for the commercial manufacturing of its first injectable drug products in March 2020 and now for its first premix bags, following regular inspections. The approval from the FDA means that Xellia can now produce its first premix bags at its site in the US, for the US market.

Our unwavering dedication to excellence propels us to continually enhance our facilities, ensuring the integration of cutting-edge technologies. The Group has made significant investments in upgrading the manufacturing capabilities and growing its dedicated team at Cleveland, creating an advanced facility to provide a reliable, consistent supply of specialty anti-infectives and critical care therapies across the US. This milestone further strengthens our goal to demonstrate excellence in innovative development and state-of-the-art manufacturing to meet the demands for anti-infective and critical care therapies for patients around the world.

Xellia is one of the very few pharmaceutical manufacturers with the established technology to deliver aseptically filled premix bag capability. Healthcare providers are showing a preference for premixes as they aid in promoting safe medication administration practices and timeliness to treat patients, as demonstrated in Xellia's recent study with the Virginia Mason Institute.

The Cleveland site operates alongside Xellia's other manufacturing plants in Copenhagen, Denmark; Budapest, Hungary; and Taizhou, China, as part of its vertical integration strategy and wholly owned supply chain. The network provides a secure supply and one-stop shop for both active pharmaceutical ingredients (APIs) and finished dosage form (FDF) products for customers globally.

Michael Kocher, CEO at Xellia Pharmaceuticals, said:
"This FDA approval and the release of our first commercial batches from the Cleveland site are significant milestones for Xellia. It is the culmination of eight years of hard work by the team to establish our state-of-the-art manufacturing capabilities there. We are one of very few manufacturers with the ability to produce aseptically filled premix products and are proud to now be able to do so in the US for US customers, with all the safety and speed of use benefits that they provide. This moment perfectly aligns with our dedication to make essential anti-infective medicines accessible to patients especially on a regional basis."

John Stewart, SVP Global Product Supply at Xellia Pharmaceuticals, added:
"Premix products are proven to help healthcare professionals do their work safely and more efficiently and we are pleased to be able to produce these value-added products at our Cleveland facility for our US customers. This is a great step forward in our strategy to enable the commercial production of our full product capabilities at Cleveland. Many thanks to the cross-site and cross-functional efforts to make this happen."

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For more information, please contact:

Xellia Pharmaceuticals
Hanne Junggreen, Communication and Brand Management
+45 32 64 55 00

Instinctif Partners (International media relations)
Melanie Toyne-Sewell / Tim Field / Feaven Abidta
+44 (0) 20 7457 2020
xellia@instinctif.com

About Xellia Pharmaceuticals

Xellia Pharmaceuticals is a specialty pharmaceutical company and a global leader in providing anti-infective treatments and other critical care therapies for serious and often life-threatening conditions. Xellia has an extensive history in developing, manufacturing, and commercializing anti-infective products, including Active Pharmaceutical Ingredients (APIs) as well as Finished Dosage Forms, where the majority are injectable drug products.

As an organization, Xellia is committed to providing security and consistency of supply of critical care therapies. Through a global vertically integrated supply chain, the Company continuously works to improve supply security through multiple sources of in-house production of its APIs and drug products, and in conjunction through working alongside Xellia's R&D centers of excellence. Through innovation and with the patient in focus, Xellia is building a pipeline of value-added critical care therapies which aim to enhance patient care by providing convenience and ease of use for healthcare professionals.

Headquartered in Copenhagen, Denmark, Xellia has a global footprint with R&D, manufacturing and commercial operations across Europe, Asia, the Middle East and North America. Xellia Pharmaceuticals is wholly owned by Novo Holdings A/S and employs a dedicated team of more than 1,800 people.

Further information about Xellia can be found at: www.xellia.com
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