



## **Xellia Pharmaceuticals' site, Cleveland, Ohio, passes FDA inspection of Injectable Drug Manufacturing Methods, Facilities, Processes & Controls**

*Cleveland site to manufacture Xellia's aseptic injectables for the US market*

**Copenhagen, Denmark, 26 March 2020** - Xellia Pharmaceuticals ('Xellia'), a specialty pharmaceutical company focusing on providing important anti-infective treatments against serious and often life-threatening infections, has received inspection sign-off from the US Food and Drug Administration (FDA) enabling the Company to commence manufacturing of drug products at its Cleveland, Ohio site.

Since acquiring the Cleveland site in 2015, Xellia has made significant investment to create a modern, world-class facility that will allow the Company to continue to provide a reliable and consistent supply of its vital anti-infective products across the US. Xellia has worked closely with the FDA to resume activities at the site, and in January 2020, the FDA performed a comprehensive cGMP inspection of the facility. The Agency notified Xellia of the successful outcome of this inspection this month, confirming that the FDA has found the methods, facilities, processes and controls used by Xellia to manufacture, process, pack, hold and distribute drugs at Phases IV and V to be in conformity with the Federal Food, Drug and Cosmetic Act.

Xellia can now initiate commercial manufacturing of drug products at the Cleveland site and will use the facilities to maximize production of aseptic injectables. The increased capacity will be used to grow and scale Xellia's own pipeline with dedicated production lines for its established and innovative anti-infective injectable drug products. Xellia will also use the site to widen its offering of CMO services for third-party injectables.

Xellia Cleveland will operate alongside the Company's existing sterile injectable production plant in Copenhagen, Denmark.

Carl-Åke Carlsson, Xellia's CEO said: *"Passing the FDA inspection marks a major milestone for us, enabling us to manufacture our established and innovative anti-infective injectable products at the site. We have invested substantially in the Company's manufacturing and commercial capabilities in the US over recent years. We firmly believe in the importance of consistent and reliable manufacturing of critical medicines locally in the US for use by US physicians for their patients."*

Up until now, the focus at the Cleveland site was on packaging, labelling and distributing drug products manufactured at other Xellia facilities, following the first FDA inspection at the facility in 2016.

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**About Xellia Pharmaceuticals**

Xellia Pharmaceuticals (“Xellia”) is a specialty pharmaceutical company developing, manufacturing and commercializing anti-infective treatments against serious and often life-threatening bacterial and fungal infections.

With over 100 years of experience, Xellia is a world-leading trusted supplier of several important established anti-infective drugs, comprising active pharmaceutical ingredients as well as injectable products. Continuing the Company’s evolution, Xellia is generating an innovative pipeline of value-added anti-infective medicines intended to enhance patient care, 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 and North America and is investing significantly to expand its sales and manufacturing capabilities within the United States. Xellia is wholly owned by Novo Holdings A/S and employs a dedicated team of over 1,700 people.

Further information about Xellia can be found at: [www.xellia.com](http://www.xellia.com).