



## **US Court Lifts Modified Consent Decree Entered into by FDA and Xellia's Cleveland Facility**

**Copenhagen, Denmark, and Cleveland, Ohio, USA, 29 April 2024** - Xellia Pharmaceuticals ('Xellia'), a global leader in the manufacturing of specialty anti-infective treatments and critical care therapies, announces that the US Court has vacated the Modified Consent Decree imposed on Xellia's Cleveland, Ohio facility in 2016.

The original Consent Decree for the manufacturing site was entered into by the US Food and Drug Administration (FDA) and the previous site owner, Ben Venue Laboratories, Inc. (BVL) in January 2013. Consent Decrees are site specific and do not relate to the owner. As a result, when Xellia acquired the site in November 2015, the Company entered an associated Modified Consent Decree with the FDA.

The Modified Decree sets out the processes with which Xellia must comply to conduct manufacturing activities at the Cleveland site. Since entering the Decree, Xellia's site has been regularly inspected by FDA to determine compliance with rules and regulations.

In March 2024, Xellia received a VAI (Voluntary Action Indicated) classification, a milestone demonstrating a 'continued state of compliance', based on repeated positive feedback from inspections. On the back of this classification, the US Court of Law has vacated the Modified Consent Decree.

**Michael Kocher, CEO at Xellia Pharmaceuticals, said:**

*"Our team in Cleveland has done an excellent job of navigating the FDA's inspections over the years, providing prompt and comprehensive responses to observations and information requests. The team's perseverance has been rewarded with the lifting of the Decree, which is great news for Xellia. Our sincere thanks to everyone at the Cleveland site."*

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## **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.

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 1,700 people.

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

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