Xellia Pharmaceuticals Commences Packaging and Distribution Operations at Cleveland Site after Successful FDA Inspection

Significant milestone in achieving ultimate goal of commencing manufacturing of sterile injectable products at the site during 2018

Copenhagen, Denmark – 14th November 2016 – Xellia Pharmaceuticals ('Xellia'), a specialty pharmaceutical company focusing on providing important anti-infective treatments against serious and often life-threatening infections, has received notice from the US Food and Drug Administration (FDA) allowing the Company to commence packaging and distribution of drug products at its Cleveland, Ohio facilities.

The notice follows a successful cGMP inspection by the FDA conducted under the procedures of the Modified Consent Decree that Xellia entered into with the FDA in April 2016. Xellia acquired the Cleveland site in November 2015. This notice demonstrates the significant progress that Xellia has made in bringing the Cleveland site back to compliance. The Company can now initiate certain commercial activities at the newer part of the Cleveland site that involves labelling, secondary packaging and distribution of drug products manufactured at other sites.

As well as investing significantly in equipment upgrades and the facility design, Xellia has hired an experienced team of over 90 employees. This will be expanded to a staff of around 170 employees over the next twelve months as the Company prepares to start the production of sterile anti-infective injectable products during 2018. Xellia is working closely with the FDA to ensure this is achieved.

Carl-Åke Carlsson, CEO, Xellia said: "The permission by the FDA to commence packaging and distribution of drug products at this site is a huge achievement for the Cleveland team on our journey towards resuming sterile product manufacturing. It is testimony to the expertise and dedication of our employees who have worked tirelessly to achieve compliance at the site.

"Once up and running, this facility will significantly increase our production capacity for sterile injectable products in the US, meeting the growing needs of our customers and helping to alleviate supply shortages for vital anti-infectives. We have already received considerable interest in our contract manufacturing services from both existing customers and new prospects."

Xellia Cleveland will operate alongside the Company's existing sterile injectables production plant in Raleigh, North Carolina and Copenhagen, Denmark. The US is an important market for Xellia, generating over 40% of total sales in 2015.

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About Xellia

Xellia Pharmaceuticals is a specialty pharmaceutical company focused on providing important anti-infective treatments against serious and often life-threatening infections. With over 100 years of experience Xellia is a leading developer, manufacturer and trusted supplier of fermented and semi-synthetic Active Pharmaceutical Ingredients (APIs) and Injectable Finished Dosage Forms (FDFs) to the pharmaceutical industry. The Company has growing sales in more than 70 countries to over 500 customers across the healthcare industry. Headquartered in Copenhagen, Denmark, Xellia has global facilities including operational and manufacturing capabilities in Denmark, USA, Hungary and China, and currently employs over 1,200 people.

Xellia is a leading supplier of vancomycin and colistimethate sodium (CMS) which together combat life-threatening, multi-drug resistant bacterial infections across Gram-positive and Gram-negative species. Xellia is also developing novel antibiotics effective against MDR Gram-negative bacteria in a development project with SINTEF Materials and Chemistry (Trondheim) and the Statens Serum Institut (Copenhagen), supported by a grant from the Research Council of Norway.

Since July 2013, Xellia has been wholly owned by Novo A/S, the holding Company of the Novo Group.

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