Xellia Pharmaceuticals Reaches Agreement with FDA on Modifications to Consent Decree for Newly-Acquired Cleveland Site

Copenhagen, Denmark – 25 April 2016 – Xellia Pharmaceuticals ('Xellia'), a specialty pharmaceutical company focusing on providing important anti-infective treatments against serious and often life-threatening infections, has entered into a Modified Consent Decree with the US Food and Drug Administration (FDA) for its recently acquired manufacturing facilities in Cleveland, Ohio.

The modified decree sets out the process with which Xellia must comply in order to commence manufacturing activities at the site. Reaching an agreement with the FDA on the modified decree is an important step in the Company's plan to resume operations in the new manufacturing units at the site.

The original Consent Decree for the Cleveland site was entered into by the FDA and the previous owner, Ben Venue Laboratories, Inc., (BVL) in January 2013. BVL subsequently ceased manufacturing in December 2013.

Xellia acquired major parts of the site in November 2015 and is investing significantly in the facilities to commence manufacturing of sterile injectable anti-infective products by the end of 2017. The Company is working closely with the FDA to ensure a timely and controlled start-up at the facility.

Once up and running, the Cleveland site will considerably increase Xellia's production capacity for sterile injectable products in the US. It will operate alongside the Company's existing sterile injectables production plant in Raleigh, North Carolina.

Carl-Åke Carlsson, CEO, Xellia said: "The Modified Consent Decree is the result of a constructive dialogue between Xellia and the FDA and is an important step in our plan to resume manufacturing at the Cleveland site.

"We are making considerable progress at the site and have already established an experienced team of more than 50 employees. Our focus is on recruitment and training of the new organization to drive operations and ensure GMP compliance at the site. We anticipate having a workforce of 170 new employees at the site by the end of 2017."

The US is an important market for Xellia, generating over 40% of total sales in 2015. By developing the Cleveland site, the Company will be well positioned to meet the growing needs of its US customers, alleviate supply shortages for vital anti-infectives, and enable future pipeline expansion.

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For more information, please contact:

Xellia Pharmaceuticals
Carl-Åke Carlsson, CEO
Tel: +45 32 64 55 00

Niels Lynge Agerbæk, General Manager, Xellia Cleveland
Tel: +1 440 359 2055

Instinctif Partners (media relations)
Jen Lewis / Eileen Paul / Melanie Toyne-Sewell
Tel: +44 (0)1260 296 500
Email: xellia@instinctif.com

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 1,000 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.