



Xellia Pharmaceuticals Reports 2021 Business Update and 2022 Outlook

Copenhagen, Denmark, 25 April 2022 - Xellia Pharmaceuticals ('Xellia' or the 'Group'), a global leader in the manufacturing of specialty anti-infective treatments, reports on its business update for the year ending December 31, 2021 and outlook for 2022.

Carl-Åke Carlsson, CEO and President, Xellia Pharmaceuticals, commented:

"During 2021, Xellia maintained a strong focus on its purpose - to help save patient lives by leading the fight against infections. We launched new products in new markets, collaborated with long-running and new customers and business partners, and continued investments in infrastructure projects such as our US manufacturing site in Cleveland, Ohio.

"As expected, 2021 has been a challenging year with several external factors impacting financial performance, but we are pleased to report significant progress in both our global anti-infective business and our US injectable business in 2021; the ramp-up of sales of VANCO READY® has been a particular highlight.

"Through these successful and fast-growing business segments, we foresee further growth in 2022 to place us in a stronger position for the longer term. We look forward to forming new partnerships, and to utilizing our full manufacturing capacity and capabilities to reach more customers, hospitals and patients around the world in the coming year."

2021 Full Year Overview

Global Anti-Infective Business

Xellia is a leading, trusted supplier of several important and established anti-infective drugs, comprising active pharmaceutical ingredients as well as injectable drug products.

As many of Xellia's products remain on the World Health Organizations' Model Lists of Essential Medicines and the US Food and Drug Administration Drug and Biologic Essential Medicines List, Xellia has expanded its geographic reach to ensure global access to these vital critical-care medicines. During 2021, Xellia's global anti-infective business continued to make the Group's products available across new markets through local partnerships, with 35 product launches across 9 countries.

As one of the only European integrated manufacturers of several key critical anti-infectives, Xellia has a vital role in ensuring a sustainable and competitive supply of these important medicines to customers and patients across the world. In 2021, Xellia continued its efforts and investments to expand capacity, to meet demand and maintain the high manufacturing and quality standards at its manufacturing sites. In line with this, the underlying priority of the year was to uphold a reliable and consistent supply of its critical-care medicines through the COVID-19 pandemic, during which Xellia continued to work with suppliers and customers across multiple regions to ensure the ability to react to changes in demand and ensure no supply chain disruption.

Another key area of focus in 2021 and beyond is to expand the indications for Xellia's key anti-infective products through working with partners to increase healthcare professionals' access to medicines to treat patients in need. A good example of the effectiveness of this strategy is Xellia's partnership with Zambon SpA ('Zambon') which extended its agreement for the supply of colistimethate sodium (CMS) in Europe for use with its I-neb[®] - Zambon's non-cystic fibrosis bronchiectasis (NCFB) Adaptive Aerosol Delivery System, following the positive results of its Phase 3 study in September 2021. Xellia is working with other partners to support clinical trials of its products to achieve the Group's long-term ambition of making its products available to more patients worldwide.

US Injectable Business

In continuing the Group's evolution, Xellia has been building a growing US injectable business with a specialty focus, delivering its innovative ready-to-use (RTU) premix bags for the US hospital market.

Xellia's lead specialty product VANCO READY[®] Vancomycin Injection, USP, showed great progress in 2021 with 131% revenue growth compared to 2020. Approximately 190,000 patients in the US were treated with Xellia's VANCO READY[®] product in 2021, and the number of new healthcare providers using the product continues to expand into 2022. VANCO READY[®] provides a unique offering to small and large US healthcare systems by supplying all relevant dosage strengths of vancomycin in a RTU and room-temperature-stable presentation.

Throughout 2021, the Group sustained its planned investments in the expansion of its US injectable business. The experienced team from Xellia's R&D Center of Excellence in Zagreb, Croatia, along with other key stakeholders across the Group, successfully expanded the pipeline of RTU premix bag products throughout the year. Moving into 2022, the pipeline comprises of approximately 10 new products, most of which Xellia will manufacture at its Cleveland manufacturing facility, and make available to healthcare systems throughout the US, through Xellia's US commercial organization headquartered in Chicago, Illinois.

The Cleveland manufacturing site is a central pillar of Xellia's future growth. As an integral part of the Group's US injectable business, Xellia has invested substantially over recent years to establish a state-of-the-art manufacturing facility for aseptic parenteral products. In 2021, the site entered commercial operations with the release of the first anti-infective lyophilized vials to be distributed for use by US hospitals. The site also successfully completed the installation of the first aseptic fill premix bag line to provide local manufacturing for VANCO READY[®], as well as for the Group's pipeline products. Through the duration of 2021, Xellia continued to work with its strategic partners to provide and plan for contract manufacturing services at the Cleveland site.

2021 trading and 2022 business outlook

As forecasted, the financial performance of the Group was impacted negatively in 2021 due to several external factors, particularly price pressure on generic injectables in the US and the effects of COVID-19 on the market, as well as the continued investment in the Cleveland site. As a result, Xellia's revenue declined from MUS\$ 318.1 in 2020 to MUS\$ 302.3 in 2021, and Adjusted EBITDA declined from MUS\$ 75.2 to MUS\$ 44.9.

The ongoing COVID-19 pandemic affected all businesses globally but came at a time when the Group continued to invest significantly in its facilities, specifically at its Cleveland site, and during a period of building and seeking new partnerships. Despite this, Xellia continued the development of its pipeline, commenced manufacturing at the Cleveland facility, and continued to grow sales of VANCO READY® through Xellia's specialized US hospital sales organization. The start-up costs in Cleveland, exceeded MUS\$ 46 for the year.

Although there has been pressure on the Group's results the last two years, the management team believes these continued investments are essential for the long-term strategy of the business. The Group will continue to invest in the US injectable business in 2022, and it is expected that 2022 will remain unprofitable due to the Group's committed investments, which will continue to create the foundation for the future.

Conclusion

2021 was an eventful year for Xellia and looking forward, the Group continues to see a strong demand for its portfolio across all geographic markets. Xellia is running a very strong business, as a global leader in the anti-infective market and as a fast-growing US focused specialty injectable franchise. Xellia remains committed to its purpose to save lives by leading the fight against infections, through maintaining a robust and reliable supply of critical-care anti-infectives to reach patients in need.

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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 115 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, the Middle East, and North America. 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. Connect with us on [LinkedIn](#).