

Almirall receives FDA approval to produce Seysara[®] (sarecycline) at the Sant Andreu de la Barca (Barcelona) plant

- The production of this drug in Sant Andreu de la Barca (Barcelona) provides the company with a dual supply source and ensures the continuity of the business of this strategic product
- Seysara[®] is an innovative first-in-class tetracycline-derived oral antibiotic commercialised in the United States for the treatment of inflammatory lesions of moderate to severe non-nodular acne vulgaris
- This approval opens the door to possible authorisation to produce other drugs not currently in production at Almirall's plants in Spain for sale in the United States
- Almirall has reached a key milestone, as the rigorous validation and approval process of the US agency once again proves its quality standards and confirms its position as a leading company in Medical Dermatology

BARCELONA, Spain. June 1st, 2021 – Almirall S.A. (BME: ALM), a global biopharmaceutical company focused on skin health, has received **US Food and Drug Administration (FDA)** approval to produce Seysara[®], a first-in-class tetracycline-derived oral antibiotic for the treatment of inflammatory lesions of moderate to severe non-nodular acne vulgaris, in 100 mg tablet form at its production site in Sant Andreu de la Barca (Barcelona, Spain) for its commercialisation in the United States. This is an important milestone as it will provide Almirall with a double source of supply and ensure the continuity of production of this strategic product.

The Sant Andreu de la Barca plant currently supplies the active ingredients needed for toxicology, pre-clinical, and clinical studies, and produces 56 million units of finished products per year. This approval opens the door to other possible FDA authorisations to produce other drugs which are not currently manufactured at this industrial plant. The FDA approval highlights the rigorous quality and safety system that the Almirall's plants have in place to ensure high standards of production.

The internalisation project for Seysara[®] 100 mg tablets began in January 2019 and US authority approval was granted in April 2021. During this intense two-year period, all industrial activities needed for the regulatory submission were completed, including the procurement of raw materials, purchase of machinery, validations, manufacturing, stabilities, and serialisation, all with great precision and to the very highest internal quality standards. The first units manufactured at the Sant Andreu de la Barca plant are due to be placed in the market at the end of the year and enter into regular supply in the United States in 2022.

“FDA approval to produce a drug for the United States marks a key milestone for Almirall as it allows us to have a double source of supply for this product and it shows the company's commitment to ensuring the continuity of a strategic product for the business,” stated **Marc Pérez**, Almirall's **Global Pharma Operations Director**.

Almirall received the FDA approval for the sale of Seysara® in the United States in 2018, and since its launch in early 2019 it has continued to gain ground in the branded and non-branded segment of the market. Besides its presence in the US market, Almirall's strategy for the product includes future expansion to China. The company has received approval for the Clinical Trial Application in this country and expects to commence a phase 3 clinical trial in 2021 to prove the efficacy and safety of the drug for submission to the Chinese National Medical Products Administration (NMPA) in 2023.

About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life". We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange and is a member of the IBEX35 (ticker: ALM). Throughout its 77-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, through 13 subsidiaries, with about 1,800 employees. Total revenues in 2020 were 814.5 million euros.

For more information, please visit [almirall.com](https://www.almirall.com)

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