

Spain
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Novel oral antibiotic treatment Seysara™ (sarecycline) now available in the U.S.

- **Seysara™ is the first oral antibiotic that has been specifically developed for use in acne.**
- **It is approved for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients nine years of age and older¹**
- **Two pivotal studies confirmed efficacy of Seysara™ at 12 weeks, with reduction of inflammatory acne lesions seen as early as three weeks.**
- **Seysara™ has a demonstrated safety profile and is taken once-daily, with or without food.**

Almirall, LLC, Almirall's affiliate in the U.S., announces the launch of Seysara™ (sarecycline), a novel tetracycline-derived oral antibiotic and the first to be developed specifically for the treatment of acne. Seysara™ was approved in October 2018 by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe non-nodular inflammatory acne vulgaris in patients 9 years of age and older, and is now commercially available in US.

“Seysara™ was the first new chemical entity for the treatment of acne to be approved by the FDA in a decade, and the acquisition of the product in September 2018 represented a significant investment by our company in the future of medical dermatology” said **Peter Guenter, CEO of Almirall**. *“This launch further demonstrates our commitment to our healthcare partners and patients in the U.S.”*

Seysara™ is one of five former Allergan products acquired by Almirall, comprising a balanced portfolio of mature and growth brands including Aczone® (dapsons), Tazorac® (tazarotene), Azelex® (azelaic acid) and Cordran® Tape (flurandrenolide).

In the two identical Phase 3 clinical trials (SC1401 and SC1402), a significant number of patients receiving once-daily Seysara™ experienced improvement of their acne severity at 12 weeks versus placebo based on the Investigator's Global Assessment (IGA) (21.9% vs 10.1% SC1401; 22.6% vs 15.3% SC1402). Seysara™ also led to a reduction in the number of inflammatory acne lesions at 12 weeks (51.8% vs 35.1% SC1401; 49.9% vs 35.4% SC1402), with significant results seen as early as week 3 (29.6% vs 22.4% SC1401; 28% vs 18.6% S1402).^{2,3,4}

“Unlike most other pivotal acne studies, the Seysara™ trials analysed the impact of the study drug on chest and back acne where it was also shown to be effective” stated **Angela Moore, MD a coordinating investigator and Clinical Assistant Professor in Dermatology at the University of Texas Southwestern (UTSW)** *“In addition, this will be one of very few acne treatments that are FDA approved for patients 9 years of age”*.

In clinical trials, treatment with Seysara™ was found to be generally safe and well-tolerated, with low rates of treatment-emergent adverse events (TEAEs) reported in the Seysara™ safety study which followed subjects up to 52 weeks. Patients receiving Seysara™ reported no cases of vertigo or tinnitus and fewer cases of dizziness than seen in the placebo group. Less than one percent of patients experienced photosensitivity or sunburn, and rates of GI issues were relatively low. The most common adverse reaction (incidence ≥ 1%) was nausea.^{2,3,4}

“Acne is affecting an increasing number of patients, and we are always looking for ways to improve our treatment management. Seysara showed a statistically significant reduction in inflammatory acne lesion counts with an early onset, and a favorable tolerability profile. I believe that Seysara™ can play a major role in our future treatment decisions”, said **Linda Stein Gold, MD, coordinating investigator and Director of Dermatology Clinical Research at Henry Ford Health System in Detroit, Michigan**.

Acne vulgaris is a common skin condition involving blockage and/or inflammation of hair follicles and their glands, which can present as non-inflammatory lesions, inflammatory lesions, or a mixture of both, affecting the face, back and chest. According to the Global Burden of Disease study, acne vulgaris affects 85 percent of young adults aged 12–25 years around the world. In the United States, 80 percent of people will experience acne vulgaris at some time during their lives, one in five of whom have severe acne.⁵

“Seysara™ is an exciting new product in the acne space, where unmet needs still exist for patients ranging from pre-teens through adulthood,” said **Ron Menezes, President and General Manager of Almirall, LLC**. He went on to state *“We have a passionate, committed team, and we are looking forward to partnering with the dermatology community to deliver innovative therapies like Seysara™ to those who may benefit from them, building on our shared goal of improving skin health outcomes for patients.”*

For more information on the Almirall product portfolio please visit [Almirall US](#)

About Seysara™

Seysara™ (sarecycline) is a once-daily, oral tetracycline-derived antibiotic with anti-inflammatory properties for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. Seysara™ has proven to be a safe and effective treatment in two 12-week multicenter, randomized, double-blind, placebo-controlled studies (Study 1 [NCT02320149] and Study 2 [NCT02322866]). Efficacy was assessed in a total of 2,002 subjects 9 years of age and older.

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed.

The company, founded 75 years ago and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment to major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenues in 2017 were 755.8 million euros. More than 1,830 employees are devoted to Science.

For more information, please visit [almirall.com](#) [linkedin.com/company/almirall](#)

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