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# Press Release

Exton, PA
January 17, 2019

## NOVEL ORAL ANTIBIOTIC TREATMENT SEYSARA™ (SARECYCLINE) NOW AVAILABLE

- *Seysara is a novel oral antibiotic developed specifically for 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 older*[1]
- *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*

EXTON, PA, January 17, 2019 — Almirall LLC announces the launch of Seysara™ (sarecycline), a novel tetracycline-derived oral antibiotic 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.

“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® (dapsone), 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 U.S.

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.”

To access the Seysara patient copay card visit Almirall Copay. 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 identical 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.

**Limitations of Use**
Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established.
SEYSARA has not been evaluated in the treatment of infections.
To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SEYSARA should be used only as indicated.

**IMPORTANT SAFETY INFORMATION**
**CONTRAINDICATIONS**
SEYSARA is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
**WARNINGS AND PRECAUTIONS**

- The use of SEYSARA during **tooth development** (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown).
- ***Clostridium difficile* associated diarrhea (CDAD)** has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If Clostridium difficile Associated Diarrhea (antibiotic associated colitis) occurs, discontinue SEYSARA.
- **Central nervous system side effects,** including light-headedness, dizziness or vertigo, have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued.
- **Intracranial hypertension** in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension.
- **Photosensitivity** manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using SEYSARA.
- **Bacterial resistance** to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.

- As with other antibiotic preparations, use of SEYSARA may result in overgrowth of non-susceptible organisms, including fungi. If **superinfection** occurs, SEYSARA should be discontinued and appropriate therapy instituted.

**ADVERSE REACTIONS**
Most common adverse reaction (incidence ≥ 1%) is nausea.
**Please see full Prescribing Information at www.almirall.us.**

**About Almirall**
Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying sScience 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 their quest to find continuous improvement to treatments, by bringing our innovative solutions where they are needed. The company, founded in 1943 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 with its major shareholders and its decision to help others, to understand their challenges and to use sScience to help provide them with solutions for real life health challenges. Total revenue in 2017 was 755.8 million euros and more than 1,830 employees are devoted to Science

**Investors & Corporate Communications contact:**
Almirall
Pablo Divasson del Fraile
pablo.divasson@almirall.com
Tel.: (+34) 93 291 30 87



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