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# Press Release

Exton, PA
December 6, 2019

**ALMIRALL LLC ANNOUNCES THE PUBLICATION OF LONG-TERM SAFETY DATA FOR THE USE OF SEYSARA® (SARECYCLINE) TABLETS IN PATIENTS 9 YEARS OF AGE AND OLDER**

- *Seysara® is a novel oral antibiotic developed specifically for acne*
- *It is FDA approved for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients nine years of age and older*[1]
- *Seysara® has now been prescribed for more than 60,000 patients*[2]

EXTON, PA, December 6, 2019 — Almirall LLC today announced the publication of long-term safety data from a 40 week, Phase 3 open-label extension study of Seysara® in patients 9 years of age and older. Seysara® is a novel tetracycline-derived oral antibiotic developed specifically for the treatment of acne and was approved by the FDA in October of 2018. Since its launch in January of this year, Seysara® has been prescribed for more than 60,000 patients[2].

This long term study included 483 subjects who had previously completed 12 weeks of Seysara® treatment in one of two pivotal, randomized, double-blind, placebo-controlled, phase 3 trials. The extension phase involved additional treatment of up to 40 weeks with Seysara®.

"This extension study in patients 9 years and older showed safety and tolerability results that were consistent with the 12 week pivotal Phase 3 studies, including low rates of vestibular, phototoxic and gastrointestinal adverse events. Of the subjects that were enrolled, almost three quarters of them completed the 40 week trial[3]" said David M. Pariser, MD, FACP, FAAD of the Virginia Clinical Research Center in Norfolk, Virginia and principal investigator for the study.

In this open-label study, the treatment emergent adverse events seen in more than 2% of patients were nasopharyngitis (3.7%), upper respiratory tract infection (3.3%), headache (2.9%), and nausea (2.1%). One patient in the study reported sunburn and one hyperpigmentation, neither of which were judged to be related to Seysara®. Of the treatment emergent serious adverse events, 1 (headache) was considered possibly related to Seysara®. There were no additional safety findings[3].

"Seysara® was specifically studied and approved for the treatment of acne and not for infections. We support antibiotic stewardship, as highlighted in the most recent American Association of Dermatology (AAD) acne management guidelines where it recommends not only the appropriate use of antibiotics but also limiting antibiotic use to the shortest possible duration[4]" states Ayman Grada, MD, Director of R&D and Medical Affairs at Almirall, LLC.

Also included in the publication were the findings of a phase 1, single-dose, placebo-controlled, randomized crossover study investigating the potential for sarecycline to cause phototoxicity. This single-dose crossover study examined dermal response to UV exposure with 240 mg sarecycline or placebo in 18 healthy adult male subjects. There was a minimum of 9 days between each of the two treatment cycles. Mean and maximum numerical UV-induced dermal response scores were low for both sarecycline and placebo (0.3 and 0.7 for sarecycline and 0.1 and 0.3 for placebo, respectively). There was no evidence of edema at any time point in any subject.

Seysara® is one of thirteen branded products marketed in the US by Almirall, a global family-owned company focused on medical dermatology and skin health. Ron Menezes, President and General Manager at Almirall, LLC, underscores "We are pleased that Seysara® is now the most frequently prescribed branded oral treatment for acne[2], and this data further positions it as an option for patients suffering from this condition".

To learn more about Seysara®, please visit Seysara.com

To learn more about Almirall LLC, please visit almirall.us.

**About Seysara®**
Seysara® (sarecycline) is a once-daily, oral tetracycline-class antibiotic for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. Seysara® has demonstrated to be a safe and effective treatment in two adequate and 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**
• SEYSARA, like other tetracyclines, can cause fetal harm when administered to a pregnant woman. If SEYSARA is used during pregnancy or if the patient becomes pregnant while taking SEYSARA, the patient should be informed of the potential hazard to the fetus and treatment should be stopped immediately.
• 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 click here for full prescribing information.

**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 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 Science 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.

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## References

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2. Almirall LLC data on file.
3. Safety and Tolerability Profile of Sarecycline for the Treatment of Acne Vulgaris: Results From a Phase 3, Multicenter, Open-Label Study and a Phase 1 Phototoxicity Study http://jcadonline.com/sarecycline-acne/
4. Guidelines of care for the management of acne vulgaris, https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext