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Press Release

Exton, PA
JUNE 18, 2020

ALMIRALL ANNOUNCES FDA APPROVAL OF UPDATED LABEL FOR SEYSARA® (SARECYCLINE) TABLETS

- *Seysara® is a novel oral antibiotic developed specifically for the treatment of 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® label update states that Propionibacterium acnes (P acnes) strains displayed a low propensity for development of resistance to sarecycline*

EXTON, PA, June 18, 2020 — Almirall LLC today announced that the FDA approved an important update to the Seysara® label stating that *P. acnes* strains displayed a low propensity for the development of resistance to sarecycline. This information is included in the Microbiology Section (12.4) of the prescribing information. Seysara® is a novel tetracycline-derived oral antibiotic developed specifically for the treatment of acne, and was approved by the FDA in October 2018. Since its launch in January 2019, Seysara® has been prescribed for close to 100,000 patients.

"The data demonstrated that *P. acnes* strains display low propensity for the development of resistance to sarecycline, with spontaneous mutation frequencies being 10^{-10} (or 1 in 10 billion) at 4 to 8 times the minimum inhibitory concentration (MIC). What this means in practice is that the main bacterium associated with acne *(P acnes)* has shown very low potential of developing resistance to sarecycline" stated Ayman Grada, MD, Head of R&D and Medical Affairs for Almirall US.

According to the most recent American Academy of Dermatology (AAD) guidelines on the management of acne[2], oral antibiotics are a first-line treatment for moderate to severe acne, however Seysara® is the only one specifically designed and studied for this indication.

Due to concerns regarding antimicrobial resistance, the Centers for Disease Control and Prevention (CDC) has stressed antibiotic stewardship. This is an initiative to promote the appropriate use of antibiotics where patients receive the right dose of the right antibiotic at the right time for the right duration[2].

Dr Grada added "We support antibiotic stewardship and the appropriate use of antibiotics in general, including when used to treat dermatologic conditions."

"When considering the importance of antibiotic stewardship, this new data for sarecycline provides another reason to consider it as a viable treatment option for inflammatory lesions of non-nodular moderate to severe acne" commented Dr. Lawrence Eichenfield, Professor of Dermatology and Pediatrics at the University of California, San Diego and Rady Children's Hospital, San Diego.

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 delighted that the FDA recognized the importance of this data and approved the update to our label. This highlights Seysara® as a distinct option for the treatment of the appropriate acne patient".

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. Guidelines of care for the management of acne vulgaris, https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext