

Barcelona,  
2<sup>nd</sup> October 2018

# FDA approves Seysara™, a New Chemical Entity for moderate to severe acne

- **Seysara™ (sarecycline) is part of Allergan's medical dermatology portfolio in the US, recently acquired by Almirall**
- **Seysara™ (sarecycline) is an innovative first in class oral antibiotic and the first in 40 years that has been specifically designed for dermatology**
- **It has been approved for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older<sup>i</sup>**
- **Seysara™ (sarecycline) is expected to contribute to the overall revenue of Almirall with peak sales from \$150MM to \$200MM**

[Almirall, S.A.](#) announced today that the Food and Drug Administration (FDA) has approved Seysara™ (sarecycline), a new, innovative first in class tetracycline-derived oral antibiotic for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. Seysara™ was part of Allergan's Medical Dermatology portfolio, recently acquired by Almirall for the United States. It is expected to be launched in January 2019.

Seysara™ is an oral tablet that is taken once daily with or without food. It has proven significant reduction of inflammatory lesions as early as three weeks after start of the treatment and is generally safe and well tolerated. Seysara™ represents an innovative treatment for patients with moderate to severe acne.

**Peter Guenter, Chief Executive Officer, Almirall**, commented *"We are proud to have obtained the FDA's approval for Seysara™, which will bring a new option for the many patients with unmet medical needs. It brings a major launch opportunity for Almirall in the US of an innovative first-in-class treatment for moderate to severe acne. This constitutes an important milestone for our medical dermatology portfolio in the US market, the biggest dermatology market in the world. We expect Seysara to reach peak sales of \$150 MM to \$200 MM."*

**Dr Leon Kircik**, a leading US dermatologist from Louisville, Kentucky and a sarecycline clinical trialist, added *"As dermatologists we are always seeking ways to improve the management of our patients' disease. The results of the studies are encouraging, with statistically significant efficacy vs placebo as early as 3 weeks. I'm looking forward to having this as an option for my patients when it becomes available in 2019."*

Acne vulgaris is a common chronic skin disease involving blockage and/or inflammation of pilosebaceous units (hair follicles and their accompanying sebaceous gland). Acne can present as non-inflammatory lesions, inflammatory lesions, or a mixture of both, affecting mostly the face but also the back and chest. According to the Global Burden of Disease (GBD) study, acne vulgaris affects 85% of young adults aged 12–25 years globally. It affects 80% of Americans at some time during their lives. Of these percentages of affected Americans, 20% have severe acne, which can result in permanent physical and mental scarring.<sup>ii, iii</sup>

With the approval of Seysara™ and its upcoming launch, Almirall will consolidate and reinforce its presence in the US, offering top dermatological products in the world's biggest market. This is an excellent fit with Almirall US's selling capabilities. There are several ex-Allergan senior executives in the R&D and US management team

with deep knowledge of the US oral acne market and the acquired portfolio. The oral antibiotic market generated 18 million TRx in 2017.

## 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 2002 subjects 9 years of age and older.

## Important Safety Information

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. SEYSARA is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines. The use of SEYSARA during tooth development may cause permanent discoloration of the teeth. If Clostridium difficile associated diarrhea (antibiotic associated colitis) or intracranial hypertension occurs, discontinue SEYSARA. Central nervous system side effects, including light-headedness, dizziness or vertigo, have been reported with tetracycline use. Most common adverse reaction (incidence  $\geq$  1%) is nausea.

## 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 continuous improvement, 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 provide them with solutions for real life. Total revenue in 2017 was 755.8 million euros and more than 1,830 employees are devoted to Science.

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

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## References

<sup>i</sup> U.S. Food and Drug Administration. October 1<sup>st</sup>, 2018. <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm592464.htm>

<sup>ii</sup> Acne Vulgaris Updated: Dec 15, 2017. Author: Jaggi Rao, MD, FRCPC;

<sup>iii</sup> The epidemiology of acne vulgaris in late adolescence. Darren D Lynn, Tamara Umari, Cory A Dunnick, and Robert P Dellavalle