Press Release

Malvern, PA
October 21, 2022

Almirall PROSES study demonstrates appropriate acne treatment decreases the burden of impact on acne sufferers' social and emotional wellbeing.

The Patient Reported Outcomes for Sarecycline Effectiveness and Safety (PROSES) study results show significant improvement in certain health-related quality of life measures for acne patients during 12-week treatment

[MALVERN, PA]: Almirall, LLC, a global biopharmaceutical company focused on skin health, is excited to announce the release of its privately funded PROSES study at this year's Fall Clinical Dermatology Conference® in Las Vegas, Nevada, October 20-23, 2022. Over the course of the 12-week study, patients with moderate to severe non-nodular acne vulgaris showed a significant improvement in certain health-related quality of life measures during treatment with sarecycline.

"This important real-world study demonstrated not only the impact that acne has on a patient's mental health, but also that successful treatment can improve both a patient's acne and related quality of life outcomes." says Emmy Graber, MD, co-principal investigator of PROSES.

The study evaluated patient-reported outcomes (PROs), using two separate questionnaires (ASIS and EPQ*), investigator global assessment (IGA), and safety of sarecycline use among patients with moderate to severe non-nodular acne vulgaris.

Baseline results from PROs clearly reflect an impact of substantial burden on certain aspects of a patient's quality of life across four distinct domains within the ASIS tool. When asked about the impact of acne on measures specific to social or emotional attributes over the past seven days, patient's baseline response was recorded as all/most/some of the time in the following categories: 78.77% felt sad, 71.15% felt embarrassed, 76.68% felt self-conscious, and 35.57% chose not to be around others.[1]

"With the PROSES initiative, we are able to witness the emotional and physical suffering of individual acne patients and – for the first time – how treatment is able to make a difference for these patients." says Hilary Baldwin, MD, co-principal investigator of PROSES. *"We're very excited to present PROSES results and look forward to publishing our findings in a peer-reviewed journal by the end of this year."*

Overall, the change from baseline measures across all domains of the ASIS questionnaire reflected a significant improvement. Additionally, PROSES study results showed an overwhelming majority of physicians (88.1%) were satisfied/very satisfied with patient sarecycline treatment.[1]

Over the 12-week study period, EPQ responses displayed a significant increase in patients reporting no/least acne burden.[2]

"Almirall US is proud to have spearheaded this innovative real-world evidence study and we are looking forward to seeing the outcomes realized in how the dermatology community recognizes the importance of evaluating the patient beyond their skin." says Pablo Alvarez, PhD, President & General Manager, Almirall, LLC.

General understanding of acne impact on patients and burden of the disease beyond the skin is still evolving. Assessing the impact of sarecycline treatment on patient-reported outcomes in real-world community practice settings highlights the improvement of certain health-related quality of life measures.

This study reinforces Almirall's vision for improving patient lives. *"I know from personal experience the profound impact acne can have on a young adult's life. This is also compounded by social media and lack of understanding of these societal pressures. To this end, I am confident that the PROSES study will make a significant contribution to a deeper understanding of the true burden of acne and the potential impact novel therapies such as sarecycline can bring to patients."* says Volker Koscielny, MD, Almirall's Chief Medical Officer.

*ASIS = Acne Symptom and Impact Scale
EPQ = Expert Panel Questionnaire

About Acne: Acne vulgaris affects up to 50 million Americans and is the most common skin condition in the United States (U.S).[3] Acne has been shown to negatively affect quality of life, resulting in low self-esteem and increased social and emotional anxiety.[4,5] Moderate to severe acne is classified by papules, pustules, nodules, or cysts on the face, shoulders, chest or back.

About PROSES

Study Design: PROSES was a 12-week, single-arm, prospective observational study conducted in 300 moderate to severe non-nodular acne patients ≥9 years who were prescribed sarecycline in 30 real-world community practices in the US. Two hundred fifty-three (253) patients had full data and were included in the analyses.

Study Limitations: This study may be subject to the typical limitations associated with real-world studies and single-arm, open-label studies including recall bias, reporting bias, and selection bias. In addition, concomitant acne medications were allowed in this study, as per usual care.

Study Endpoints: The Acne Symptom and Impact Scale (ASIS) questionnaire collected responses at baseline and at week 12 from subjects (≥12 years) and caregivers (for subjects 9-11 years). ASIS is a 17-item validated instrument that asks patients about symptoms and impacts associated with acne vulgaris.[6]

The Expert Panel Questionnaire (EPQ) is an exploratory tool created by a selected steering committee of medical experts. EPQ was developed using a three-step modified Delphi method, and established consensus on how acne impacts the patients' emotional and social functioning, activities of daily living, as well as the perspectives and concerns of parents and caregivers.[7]

Secondary outcome measures included both safety and clinical effectiveness by way of investigator global assessment (IGA), which was collected on a five-point adjectival response scale (score 0 [clear] - 4 [severe]). IGA success was assessed as ≥2-grade improvement in IGA and a score 0 [clear] or 1 [almost clear] at week-12.

About SEYSARA®:

INDICATIONS AND USAGE

SEYSARA (sarecycline) tablet is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.[8]

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

- Like other tetracyclines, SEYSARA 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 see full Prescribing Information.

About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life." We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenues in 2021 were 836.5 million euros.

For more information, please visit https://www.almirall.us/.

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References:

1. Graber E, Baldwin H, Harper J, et al. Patient reported outcomes and investigator global assessment of acne vulgaris among patients with moderate to severe non-nodular acne vulgaris administered sarecycline in real-world community practices across the U.S. *SKIN The Journal of Cutaneous Medicine*. Forthcoming, 2022
2. Fried R, Rieder, E, Alexis, A, et al. Impact of acne on social functioning, emotional functioning, and activities of daily living with moderate to severe non-nodular acne vulgaris administered sarecycline in real-world community practices across the U.S. *SKIN The Journal of Cutaneous Medicine*. Forthcoming, 2022
3. Bickers DR, Lim HW, Margolis D, et al. J Am Acad Dermatol. 2006; 55:490-500
4. Timms RM. Psychol Health Med. 2013; 18(3):310–320
5. Revol O, Milliez N, Gerard D. Br J Dermatol. 2015; 172(Suppl 1):52–58
6. Hudgens S, Harper JC, Daniels SR, et al. J Drugs Dermatol. 2015; 14(6):552-9
7. Baldwin H, Graber E, Fried R, et al. An expert panel questionnaire for assessing patient-reported and caregiver-reported outcomes in acne vulgaris. *SKIN The Journal of Cutaneous Medicine*. Forthcoming, 2022
8. SEYSARA [package insert]. Malvern, PA: Almirall, LLC, 2021