

Barcelona, Spain  
July, 25<sup>th</sup> 2022

## Almirall's H1 2022 Results

# Almirall achieves Core Net Sales growth of 5.1% to 436.6 MM Euros in H1

- Strong operational performance during the first half of the year. The business continues to perform well boosted by the growth in Core Net Sales (+5.1% year-on-year) from key products of the Medical Dermatology portfolio
- The EU Dermatology portfolio continues to lead the growth of Almirall's business. Ilumetri® maintained an excellent sales momentum driven by new country launches, and Klisyri® and Wynzora® are gaining good traction in Europe
- Total EBITDA reached €107.6MM year-to-date (-21.2%), though the comparison to 2021 is impacted by product divestments in the previous year and the finalization of deferred income from AstraZeneca
- SG&A reached €210.1MM (+9.0%) driven by the support of recent launches and R&D was at €44.9MM, increasing as expected and reaching 10.3% of Core Net Sales
- Almirall and its partner Eli Lilly announced positive data from Phase III 52-week topline results of lebrikizumab (atopic dermatitis). These encouraging results reinforce Almirall's confidence that the product has the potential to be a first-line biologic and may support less frequent dosing
- Based on the solid performance of the business in H1, Almirall is reiterating its 2022 guidance

Almirall, S.A. (ALM), the global biopharmaceutical company based in Barcelona, today announced its H1 2022 financial results.

**Financial highlights (€ rounded million)**

	H1 2022	H1 2021	Variation
<b>Core Net Sales*</b>	<b>436.6</b>	<b>415.5</b>	<b>5.1%</b>
<b>Core EBITDA*</b>	<b>98.3</b>	<b>125.6</b>	<b>(21.7%)</b>
<b>Total EBITDA</b>	<b>107.6</b>	<b>136.6</b>	<b>(21.2%)</b>
<b>Net Income</b>	<b>27.3</b>	<b>(42.8)</b>	<b>n.m.</b>
<b>Normalized Net Income</b>	<b>27.6</b>	<b>57.8</b>	<b>(52.2%)</b>

## Summary of results

- **Core Net Sales\*** reached €436.6 MM, a +5.1% year-on-year increase, and Core **EBITDA\*** reached €98.3 MM, a -21.7% year-on-year decrease, tracking in line with guidance due to a strong EU Dermatology performance and positive contribution from growth drivers.
- **Core Gross Margin\*** of 67.7% in line with expectations for the year.
- **Total EBITDA** was at €107.6 MM, a -21.2% year-on-year decrease, though the comparison to 2021 is impacted by product divestments in the previous year and the finalization of historical deferred income.
- **R&D** expenses of €44.9 MM increased as expected reaching 10.3% of Core Net Sales. R&D investment will continue to rise in line with Almirall's expectations due to the Phase IIIb studies for lebrikizumab, the Klisyri® large field studies, as well as increased spending on earlier stage assets such as the anti IL1-RAP.
- **SG&A (Selling, General and Administrative)** expenses were €210.1 MM, 9% higher than last year as Almirall continued to add investment towards the successful execution of recent product launches such as Wyzora®, Klisyri® in the US and EU, and Ilumetri® rollout in key countries.
- Almirall finished the first semester with a very healthy balance sheet with a leverage of 0.9 x Net Debt to EBITDA and an optimal **cash position**, generating €56 MM of operating cash flow during H1, which gives the company flexibility to continue to explore inorganic growth opportunities.

\* Core results excludes AstraZeneca contribution: Deferred Income and Other Income. From 2022 onwards, there is no difference between Core Net Sales and Net Sales as no additional Deferred Income from AstraZeneca is registered, the difference related to Core EBITDA and EBITDA is explained by the other income related to AstraZeneca.

*"We closed the first semester delivering a strong operational performance as the business continues to perform well and in line with our expectations. The strong growth of our Medical Dermatology portfolio puts us on target to achieve our 2022 guidance. In addition to the excellent progress of our growth drivers, this semester we have also announced positive Phase III 52-week topline data from lebrikizumab to treat atopic dermatitis. These results encourage us to continue working towards a targeted late 2023 EU approval of one of our most promising assets that has the potential to become a game-changing growth driver for the company".*

**Gianfranco Nazzi, CEO**

### Psoriasis

**Ilumetri® (tildrakizumab)**, an anti-IL-23 biologic for moderate-to-severe plaque psoriasis, continues to show excellent sales momentum. During H1, Net Sales achieved an overall of €57.6 MM, representing a solid continuation of sequential quarterly sales growth and 58% growth year-on-year supported by new country launches. The product continues its growth path in Europe. In the German market, for example, the anti-IL23 class holds a leading position of new patient market.

Almirall continues to strengthen its psoriasis franchise in Europe with **Wynzora®\***, a once-daily aqueous cream with a fixed combination of calcipotriene and betamethasone dipropionate (CAL/BDP) indicated for the topical treatment of mild to moderate psoriasis vulgaris in adults. During H1, this product showed excellent traction with a 7% and 6% market share achieved in Germany and Spain respectively. Since its launch, a total of 49,000 units have been sold, reaching over 17,000 patients. The rollout campaign continues with launches in Austria, Sweden and Italy expected in the coming quarters.

*\*Wynzora® is authorized with this name in France, UK, Spain, Czech Republic, Denmark, Norway, Sweden, Finland, Germany, Portugal, Italy, Ireland and The Netherlands. In Austria it is authorized with a different tradename: Winxory®.*

### Actinic Keratosis (AK)

**Klisyri®** (tirbanibulin), a novel microtubule inhibitor for the topical treatment of actinic keratosis (AK) of the face or scalp, is gaining strong traction in the countries where it has been launched. The rollout in Europe is progressing well, having achieved a very good uptake, particularly in the German market with more than 10% unit market share just only 9 months since its launch. The product has been launched in the Netherlands, Switzerland, and Austria, with further markets planned for this year and 2023.

Focusing on the progress of this treatment in the US market, it continues to make steady gains in total prescriptions and improve market share, while the Almirall team continues working on driving demand and gaining market access. Klisyri® has increased penetration in the AK topical market with over 41,000 prescriptions having been generated since launch, a good result for a new product launched in a highly generic market. In the US, where AK is the second most common diagnosis made by dermatologists, 4,000 healthcare professionals have prescribed the product since its launch, receiving positive feedback and good patient engagement. Additionally, the large field expansion study has started with launch expected in the second half of 2024.

### Acne

**Seysara®** (sarecycline), an innovative oral antibiotic, showed an acceleration in Net Sales in the second quarter in the US, following a good improvement in year-over-year volume growth in a more normalised environment after the high deductible season in the first quarter. The product continued the progress made on payer coverage, with effective current coverage increased during the quarter.

## Late-stage pipeline with promising potential

### Atopic Dermatitis (AD)

Almirall announced during Q2 Phase III data 52 weeks topline results of clinical trials **ADvocate 1 and 2** for **lebrikizumab**, an anti-IL13 monoclonal antibody for the treatment of moderate-to-severe atopic dermatitis (AD) and considered Almirall's most promising pipeline asset. The reported top-line Phase III results showed that 8 out of 10 patients who achieved clinical response from EASI-75 at 16 weeks maintained skin clearance at one year of treatment. The data supported both once every two week and once every four week maintenance dosing, with consistent and durable responses.

ADvocate 1 and 2 results add to the growing body of evidence from the Phase III clinical trial programme and demonstrate that lebrikizumab may provide much-needed relief for those seeking new treatment options. In addition, according to the data presented, the product has the potential to be a first-line biologic and may support less frequent dosing.

Almirall and its partner Eli Lilly plan to present the full data from ADvocate 1&2 52-week studies at an upcoming congress in H2 2022. Furthermore, also in H2, the company is expected to submit for regulatory approval a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for this asset based on data from the Phase III clinical trial program.

Almirall and Eli Lilly continue to collaborate on advancing their clinical programme and, if all processes run on schedule, it is expected that lebrikizumab could be approved in 2023 and launched in the EU in Q4 of 2023.

### Onychomycosis

**Efinaconazole** is a triazole antifungal compound indicated for the treatment of mild-to-moderate fungal infection of the nail in adults and children (aged 6 years and older). Almirall has submitted regulatory filings in Germany and Italy under the European decentralized procedure. The German regulatory authority is acting as the Reference Member State and the outcome of the filing is expected to be known in 2023.

With launch of this antifungal, assuming regulatory approval, Almirall will reinforce its onychomycosis franchise by complementing Ciclopoli®, Almirall's OTC product indicated to treat this condition.

This product is commercialised in other countries by other pharmaceutical companies.

### Acne

A phase III clinical trial is ongoing in China for the oral antibiotic Seysara® (sarecycline). Almirall started treating the first patients at the end of last year and is working towards an expected submission in 2023.

### Autoimmune dermatological diseases

Almirall is also building its early pipeline with its anti-IL-1-RAP monoclonal antibody. Almirall in-licensed exclusive global rights from Ichnos Science to develop and commercialise ALM27134\*, a first-in-class fully human, high-affinity monoclonal antibody that targets human IL-1RAP and has the potential to treat underserved patients with a variety of autoimmune dermatological diseases. The company is initiating the Phase I clinical study for this antibody.

\*Previously referred to as ISB 880

## Latest R&D advances

Almirall continues to work on expanding its R&D pipeline to make a real difference for patients and healthcare professionals.

During the first semester of 2022, Almirall announced a multi-target alliance in Medical Dermatology with **Evotec**, a globally operating life science company. With this alliance the companies aim to discover and develop novel therapeutics for severe skin diseases, including immune-mediated inflammatory conditions such as atopic dermatitis and non-melanoma skin cancer such as basal cell carcinoma.

In May 2022, Almirall also signed with **Inserm Transfert**, the private subsidiary of the **French National Institute of Health and Medical Research (Inserm)**, a licensing agreement and research collaboration to advance treatment options for vitiligo. The partnership, signed by Inserm Transfert, on behalf of Inserm, Centre Hospitalier Universitaire of Nice and University of Nice Côte d'Azur, will focus on identifying and developing a novel class of medicines that modulate the Wnt pathway, a key target involved in skin repigmentation.

## 2022 Full Year Guidance

Guidance maintained: Core Net Sales: mid-single-digit growth, Total EBITDA between €190 - €210 MM.

## Investor Calendar 2022

- 9M 2022 Financial Results – 10<sup>th</sup> November 2022

## 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 [almirall.com](https://almirall.com)

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