

Barcelona, Spain May, 8th 2023

Almirall's First Quarter 2023 Results:

Almirall's Net Sales reach € 232MM and increase by 6%, boosted by a solid European dermatology business

- The European dermatology business achieved excellent performance, with Net Sales increasing by 11.4% year-on-year, driven by solid business momentum from key products and positive trajectories of recently launched products
- Total EBITDA of €51.8 MM, reflecting a lower contribution from Other Income compared to Q1 2022
- Growth drivers show steady increases. Ilumetri® maintains its positive momentum across geographies, with good performances in Germany and Spain, while Wynzora® and Klisyri® continue to gain market share in Europe following a successful rollout in key countries
- The company is preparing the launch of lebrikizumab, a promising biologic for atopic dermatitis. Positive Week 16 results from the Almirall phase IIIb study ADvantage. The marketing authorisation by the European Commission is expected in late 2023
- Progress in the pipeline: Advancing in the extension label for Klisyri® (tirbanibulin) to treat a larger field. Almirall presented topline evidence that this product is well tolerated when applied on a surface up to 100 cm2
- Regarding the early-stage, the phase I study of anti-IL1RAP is ongoing and the company aims to launch the phase I for IL-2-mu-Fc during the year
- Based on the good performance of the business in Q1, Almirall is reiterating its 2023 guidance

Almirall, S.A. (ALM), the global biopharmaceutical company based in Barcelona, has announced its Q1 2023 financial results.

Financial highlights (€ rounded million)

	Q1 2023	Q1 2022	Variation
Net Sales	232.0	218.8	6.0%
Total EBITDA	51.8	59.6	(13.1%)
Net Income	7.7	20.4	(62.3%)
Normalized Net Income	7.7	20.5	(62.4%)

Summary of results

- **Net Sales** reached €232.0 MM, a +6% year-on-year increase underpinned by the strong sales growth of the dermatology portfolio in Europe.
- Total EBITDA was at €51.8 MM, reflecting the lower contribution from Other Income due to Astra Zeneca / Covis milestones compared to Q1 2022.
- SG&A (Selling, General and Administrative) investment was €106.7 MM. 3.7% higher than last year, as expected, to support the upcoming and recent launches of Wynzora® and Klisyri® in the US and in the EU, and Ilumetri® rollout in key countries; as well as some internal launch readiness for lebrikizumab.
- **Gross Margin** of 65.4% was in line with expectations and reflects the impact of higher energy costs and the inflation affecting some material purchases.
- **R&D** investment was €23.9 MM, reaching 10.3% of Net Sales, increasing 13.3% year-on-year as expected.
- Almirall finished Q1 with a very healthy balance sheet with Net Debt of €216.0MM, an increase compared to Q4 2022 mainly explained by the high amount of investment we had in the first quarter, including Efficib®/Tesavel® extension deal, Physiorelax® acquisition, Ilumetri® and Klisyri® milestones and the Isolex upfront payment. 1.1 x Net Debt to EBITDA remains comfortable.

"Q1 2023 marks a solid start for Almirall. We delivered an excellent operational performance that sets us on track to meet our 2023 guidance. Our European business is continuing its positive trend, driven by the consistent growth of key products such as Ilumetri®, Klisyri®, and Wynzora®.

Our innovative late-stage pipeline and robust balance sheet pave the way for sustainable long-term growth. We remain focused on preparing the business for the expected approval of lebrikizumab in late 2023, a product with the potential to transform our company.

We are building a strong position across key dermatology indications, and the significant progress of our early and late-stage pipeline demonstrates that we are on the right path to strengthen our leadership position in medical dermatology".

Carlos Gallardo Piqué, Chairman and CEO

Growth Drivers Perfomance

Psoriasis

Ilumetri® (tildrakizumab), an anti-IL-23p19 biologic for moderate-to-severe plaque psoriasis, has continued to show resilient growth and maintain strong momentum, achieving an overall Net Sales of €38 MM, a 41% increase compared to Q1 2022. Almirall is confident that its European business will continue to flourish throughout 2023 with the contribution of new countries where Ilumetri® has been recently launched.

Despite the entrance of some biosimilars in the market, the anti-IL23 class continues to lead the market share of new patients in the German biologics market, around 40% market share of new patients within biologics.

Almirall has been the first to assess wellbeing in a dermatology clinical study, in a real-world setting. The protocol of the study, which evaluated patients receiving tildrakizumab, has been recently published in the British Medical Journal (BMJ).



Additionally, **Wynzora**® cream, a once-daily aqueous cream with a fixed combination of calcipotriene and betamethasone diproprionate (CAL/BDP) indicated for the topical treatment of mild to moderate psoriasis vulgaris in adults, achieved sales of over €3.5 MM in Q1 2023, following the good progress since its launch in May 2022. Almirall expects that traction in the first countries launched will continue, improving double-digit market share in Germany and Spain, reaching c.19% and 14% respectively.

The company is confident that it has potential for significant growth in markets where the product has been already launched, such as Germany, Spain, the UK, Denmark, the Netherlands, and Austria; as well as in additional EU countries in the upcoming quarters.

Wynzora® is commercialized in Austria under a different tradename: Winxory.

Actinic keratosis (AK)

Klisyri® (tirbanibulin) ointment for actinic keratosis (AK) of the face or scalp achieved Net Sales of c.€4.7 MM in the first quarter vs. €3.0MM registered in the same period of the last year in Europe and the US. In Europe, the product is increasing market share across countries launched, such as Netherlands, Austria, Germany, the UK, Switzerland, Spain, and Italy, and the company expects to launch the product in further EU countries throughout the year.

In the US, Klisyri® received a strong recommendation in the American Academy of Dermatology (AAD) guidelines. Net Sales grew by 57% in the US and EU compared to the same period last year, an excellent result for a product launched in a market with numerous generic alternatives.

Around 5,700 healthcare professionals have prescribed Klisyri® since its launch and continues to receive positive feedback with good patient engagement. While Almirall continues to focus on driving demand by differentiating Klisyri® from what is already available on the market based on efficacy, tolerability and convenience, the company is also working on the large field (surface up to 100 cm2) label expansion over the mid-term. Large field indication launch is anticipated in 2024 in the US and 2026 in Europe.

Acne

Seysara® (sarecycline), an innovative oral antibiotic, showed continued volume growth throughout Q1 2023 along with a sales increment of 12% vs Q1 2022, achieving Net Sales of €4.8 MM and a TRx volume of 64,000 as Almirall continues to focus on gaining market access via commercial payer coverage expansion during Q1 2023.

During Q1 2023, Seysara® achieved a 5.8% market share in the oral antibiotic market. The company remains focused on driving demand and boosting profile and productivity (TRx/HCP), which is key to continued growth.

Late-stage pipeline with promising potential

Atopic dermatitis (AD)

Almirall submitted a marketing authorization application to the EMA for lebrikizumab, an anti-IL13 monoclonal antibody for the treatment of moderate-to-severe atopic dermatitis (AD). This application is currently under review, and approval is expected in Q4 2023.

In the first quarter of 2023, Almirall announced several positive clinical updates on lebrikizumab. The ADvantage phase IIIb study met the primary endpoint at the Week 16 analysis. The randomized, double-blind, placebo-controlled phase IIIb study evaluated the efficacy and safety of lebrikizumab in combination with topical corticosteroids in adult and adolescent patients with moderate-to-severe atopic dermatitis not adequately controlled with cyclosporine or for whom cyclosporine is not medically advisable. Safety was consistent with the known profile of lebrikizumab.



Atopic dermatitis is a chronic condition that requires long-term treatment. Almirall believes that the potential shown in the ADvocate trials to effectively control the disease with dosing of lebrikizumab every four weeks during the maintenance phase is suitable in achieving this, and we are in the advanced planning stages of an extension study to investigate lebrikizumab's benefits over a period up to 5 years.

The totality of the data and the profile for lebrikizumab lead Almirall to believe that this treatment has the potential to be a first-line treatment option for people living with atopic dermatitis and their healthcare professionals. Lebrikizumab showed a consistent profile across a clinical development program, whether in monotherapy or in combination with topical corticosteroids, and in both adult and adolescent populations. In maintaining patients who responded to treatment at week 16, the Q4W dosing shows strong results similar to the Q2W dosing. The evidence has been published in several peer-reviewed scientific journals, such as the New England Journal of Medicine (NEJM), the British Journal of Dermatology (BJD), and JAMA Dermatology.

Other indications

Almirall has submitted regulatory filings under the European decentralized procedure in 2022 for **efinaconazole**, for the treatment of mild-to-moderate fungal infection of the nail in adults and children (aged 6 years and older). This product would reinforce Almirall's onychomycosis franchise by complementing Ciclopoli®.

As for the oral antibiotic **Seysara**® (sarecycline), Almirall plans to file an application to the Chinese National Medical Products Administration later this year, after presenting positive results of a phase III clinical trial conducted in this country.

Autoimmune dermatological diseases

Almirall is also building an exciting early pipeline with promising recent in-licensing assets. The company is carrying on a phase I study for the anti-IL-1RAP monoclonal antibody, which has potential utility across different autoimmune skin diseases. In September 2022, Almirall announced the initiation of the phase I study evaluating the safety, pharmacokinetics, pharmacodynamics, and clinical activity of ALM27134*, a potential first-in-class fully human, high-affinity monoclonal antibody that targets IL-1RAP (interleukin-1 receptor accessory protein) for the treatment of autoimmune dermatological diseases. Almirall in-licensed in 2021 exclusive global rights from Ichnos Science to develop and commercialize ALM27134.

*Previously referred to as ISB 880

2023 Full Year Guidance

Guidance reiterated: Net Sales growth of low to mid single-digit and Total EBITDA between €165 MM - €180 MM

Dividend and Investor Calendar 2023

On May 5, in the General Shareholders' Meeting, the distribution of a dividend charged to unrestricted reserves for the amount of €34.5 million (equivalent to €0.19 per share) was approved. For the purposes of this dividend distribution, it was approved to use the scrip dividend shareholder remuneration system, which has already been applied in previous years.

Investor calendar 2023

- H1 2023 Financial Results 24th July 2023
- 9M 2023 Financial Results 13th November 2023

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 revenue in 2022 was €878.5MM.

For more information, please visit almirall.com

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