Press Release

Barcelona, Spain
November, 9th 2023

Almirall's Nine-month 2023 Results:

Almirall achieves Net Sales growth of 6.4%, driven by strong European dermatology performance

- **Almirall's European Dermatology business continued to be the driving force behind Almirall's strong performance in the first nine months of 2023, with a growth rate of 15.9% underpinned by the success of Ilumetri® and other recently launched products**
- **Good performance of Key products in Europe: strong year-on-year growth of Ilumetri® (psoriasis) across geographies; Wynzora® (psoriasis) sales gaining traction, reinforced by recent country launches; and Klisyri® (actinic keratosis) rollout driving its favourable uptake**
- **Lebrikizumab (EBGLYSS®) received positive CHMP opinion for marketing authorization in patients with moderate-to-severe atopic dermatitis; EU approval is usually expected within two months of the CHMP's positive opinion.**
- **Pipeline development: based on the large field study data of tirbanibulin, the company submitted a supplementary New Drug Application (sNDA) in August 2023 and expects approval and a subsequent launch in H2 2024**
- **The additional funds obtained from the capital increase executed in June allowed Almirall to take strategic steps to expand its capabilities. In the third quarter Almirall completed the acquisition of the rights of Prometax® in Spain, highly synergetic with Almirall's existing neurology business in Spain. In parallel, the company continues to explore other opportunities for early and mid-stage assets**
- **Almirall is on track to meet mid-single net sales digit growth (vs. initial low- to mid-single guidance) and continues to expect total EBITDA between €165 MM - €180 MM**

Almirall, S.A. (ALM), the global biopharmaceutical company based in Barcelona, has announced its 9M 2023.

Financial highlights (€ rounded million)

	9M 2023	9M 2022	Variation
Net Sales	**674.6**	**633.8**	*6.4%*
Core EBITDA	**137.1**	**134.0**	*2.3%*
Total EBITDA	**138.2**	**146.4**	*(5.6%)*
Net Income	**13.6**	**10.9**	*24.8%*
Normalized Net Income	**14.4**	**34.5**	*(58.3%)*

Summary of results

- **Net Sales** reached €674.6 MM, a +6.4% year-on-year increase driven by good performance of the dermatology portfolio in Europe.
- **Total EBITDA** was €138.2 MM, consistent with expectations and reflecting the lower contribution from Other Income due to Astra Zeneca / Covis milestones compared to 9M 2022.
- **SG&A (Selling, General and Administrative)** investment was €316.7 MM, 2.5% higher than last year, as expected. This increase reflects the company's ongoing investments in the premarketing ramp-up for lebrikizumab, as well as its investments in the recent launches of Wynzora® and Klisyri® in the US and EU, and the rollout of Ilumetri®.
- **Gross Margin** of 64.9% was in line with expectations and reflects the impact of high input costs and inflation affecting some material purchases.
- **R&D** investment was €78.4 MM, reaching 11.6% of Net Sales. R&D expenses are expected to normalize for the full year in the range of 12% of Net Sales.
- Almirall finished the first 9 months of 2023 with a favourable balance sheet and solid liquidity position at **0.2x Net Debt to EBITDA**.

"Almirall has delivered a consistently strong operational performance throughout the first nine months of 2023, and we are pleased to modestly upgrade our Net Sales guidance for the year. As we gear up for the lebrikizumab launch, we're embarking on a transformative journey for our company. The expected EMA approval, following the positive CHMP opinion, is just around the corner.

We maintain confidence in the positive trajectory of our growth drivers as we continue to support their success. Moreover, we have strategically utilized the additional capital from our recent capital increase to strengthen our portfolio, while we continue to explore other opportunities to enhance our R&D portfolio. This reflects our commitment to advancing innovation in dermatology and positions us favourably to realize our ambition of becoming a leading dermatology company, paving the way in medical dermatology by providing innovative solutions that profoundly impact patients' lives."

Carlos Gallardo Piqué, Chairman and CEO

Growth Drivers Performance

Psoriasis

Ilumetri® (tildrakizumab), an anti-IL-23 biologic for moderate-to-severe plaque psoriasis, has continued its strong performance in 9M 2023, posting 38% growth compared to 9M 2022 and achieving Net Sales of €42 MM in Q3 in Europe. Almirall expects Q4 to resume growth momentum and anticipates that the absolute growth for 2023 will be comparable to that of 2022.

Penetration of the European market continues to be on track. Furthermore, Germany accounted for almost half of the sales, while other European countries contributed more than half, demonstrating the good traction of the product in other key markets.

Almirall unveiled new data at the European Association of Dermatology and Venereology Congress 2023 demonstrating for the first time that tildrakizumab improved patients' wellbeing in moderate-to-severe psoriasis, achieving levels similar to the general population after 16 weeks and which was maintained up to week 28.[1] Additionally, tildrakizumab demonstrated its effectiveness, improving patients' health-related quality of life (HRQoL), with high rates of treatment satisfaction in patients with moderate-to-severe plaque psoriasis after 28 weeks in a real-world setting,[2] with no new safety signals and a reassuring safety profile[3] consistent with previous randomized clinical trials (RCT) and real-world studies.[4,5]

The new evidence on the TRIBUTE study demonstrated that tildrakizumab improved other important patient-reported outcomes (PROs) such as sleep quality, which is highly correlated with itch, pain, quality of life, and work productivity and not with PASI.[6,7] The results also revealed that tildrakizumab demonstrated similar efficacy and safety regardless of the baseline characteristics of the patients.[8,9]

Almirall also reported results from the TILOT study that demonstrated sustained efficacy and safety of tildrakizumab over 2 years in patients with moderate-to-severe plaque psoriasis in routine clinical practice including sensitive areas and improvements of itch.[10] This was reflected in significant improvements in all measured parameters, including treatment satisfaction and quality of life.[11]

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 €11.8 MM in 9M 2023 vs €4.5 MM in 9M 2022. The growth of the product was primarily driven by recent country launches and the continuous expansion in key countries.

The cream has maintained strong performance throughout the year. Notably, both healthcare professionals and patients have expressed positive feedback about the product, emphasizing its efficacy, quick absorption, and non-sticky feel texture.

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, Italy 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) on the face or scalp achieved net sales of €14.4 million in Europe and the United States during the first nine months of 2023, representing a 57% increase compared to the €9.2 MM recorded in the same period in 2022.

Klisyri® showed robust performance in key markets and its presence in the EU continues to grow. The product has experienced solid adoption in key countries where it has been launched. In the US, Almirall continues to focus on driving demand by differentiating Klisyri® from what is already available on the market based on efficacy, tolerability, and convenience. As a result, Klisyri® usage is associated with high overall patient satisfaction and a strong willingness to repeat treatment, as reported by dermatologists and patients.[12]

Prometax®

In September 2023, Almirall announced the acquisition of exclusive rights to **Prometax®** in Spain. The product is a transdermal patch with rivastigmine to treat Alzheimer's Disease, increasing the level of the neurotransmitter acetylcholine which helps reduce the symptoms of Alzheimer's. The product is highly synergetic with Almirall's existing neurology business in Spain. The transaction was agreed based on an upfront payment of €45 MM and potential milestones of up to €15 MM.

Late-stage pipeline with promising potential

Atopic dermatitis (AD)

In the third quarter of 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) **issued a positive opinion recommending the marketing authorization of lebrikizumab (EBGLYSS)** for the treatment of adult and adolescent patients (12 years and older with a body weight of at least 40 kg) with moderate-to-severe atopic dermatitis (AD), who are candidates for systemic therapy.

The positive CHMP opinion is now being reviewed by the European Commission (EC). **The approval in the European Union is expected in November and its launch in the first European country could take place soon after.** The company expects regulatory decisions for lebrikizumab in moderate-to-severe AD in additional European markets. Regarding the UK, approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) is expected by the end of the year, following the EC's Reliance Procedure. In Switzerland, Almirall submitted the MAA in June 2023 and approval is expected by the end of 2024.

In addition to the regulatory milestone, Almirall announced several positive clinical updates on lebrikizumab. At the European Academy of Dermatology and Venereology (EADV) Congress in October, lebrikizumab showed clinical improvements in combination with topical corticosteroids (TCS) in adult and adolescent patients with moderate-to-severe AD not adequately controlled with cyclosporine or for whom cyclosporine was not medically advisable, who were assessed over 16 weeks in the **Phase III ADvantage study.**[13] The study met the primary endpoint at Week 16. At Week 16, lebrikizumab 250mg Q2W plus TCS significantly improved signs and symptoms of AD measured by EASI75* in 68.4% of patients, while only 40.8% of patients on placebo plus TCS achieved EASI75. Consistent benefit was also seen in additional endpoints such as EASI90, IGA, or Pruritus NRS*.

Additional data presented at the EADV Congress showed **sustained depth of response** in patients that participated in the Phase III monotherapy ADvocate 1 & 2 studies treated with lebrikizumab over 52 weeks. Deep responses, defined as total skin clearance (Investigator's Global Assessment (IGA), Eczema Area and Severity Index (EASI 100) and itch relief (NRS 0,1), were achieved in 20% and 31% of patients by Week 16 respectively and were maintained or increased through Week 52.[14] These results suggest that lebrikizumab treatment can potentially allow patients and healthcare providers to elevate their expected treatment goals in AD beyond EASI75 and NRS 0/1 response.

New data on this biologic were also presented at the 43rd Annual Fall Clinical Dermatology Conference this quarter. The **long-term extension study ADjoin** showed patients with moderate-to-severe AD who continued treatment with lebrikizumab for up to two years experienced sustained skin clearance, itch relief and reduced disease severity with monthly maintenance dosing.[15] Nearly 80% of patients with moderate-to-severe AD maintained clear or almost-clear skin with lebrikizumab monthly maintenance dosing at two years.

The data set makes Almirall confident that **lebrikizumab has the potential to be a first-line biologic and may support less frequent dosing**. The company is working with partner Eli Lilly on further clinical studies to maximize the value of lebrikizumab, which it believes is the best antibody targeting IL-13, the key pathogenic driver of AD. Almirall looks forward to its expected approval and launch by the end of the year, while steadily intensifying its internal efforts to be ready for a successful commercial launch.

*EASI=Eczema Area and Severity Index; EASI 75=at least 75% improvement from baseline in EASI; EASI 90=at least 90% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; NRS=numeric rating scale; Q2W=every 2 weeks; Q4W=every 4 weeks (monthly)

Actinic keratosis (AK)

Almirall has completed the clinical study of tirbanibulin (Klisyri®) addressing the expansion to Large Field in the US. This phase III clinical study, multi-centre, open-label, single-arm study evaluated the safety and tolerability of tirbanibulin ointment 1% applied to a field of approximately 100 cm2 on the face or balding scalp in about 100 adult patients with actinic keratosis. The administration of Klisyri was well tolerated. Based on these data Almirall submitted a supplementary NDA in August 2023 and expects approval and subsequent launch in the US in H2 2024.

Autoimmune dermatological diseases

The company is also building an exciting early pipeline with promising recent in-licensed assets. The company is continuing its 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). Almirall in-licensed exclusive global rights from Ichnos Science in 2021 to develop and commercialize ALM27134.

In addition, Almirall expects to initiate a phase I clinical study for IL-2muFc autoimmune drug candidate around the end of 2023. In 2022, Almirall entered into a licensing agreement with Simcere Pharmaceutical Group for Simcere's IL-2 mutant fusion protein (IL-2muFc) autoimmune drug candidate, ALM223** (previously SIM0278). This molecule, developed utilising Simcere's protein engineering platform, activates regulatory T-cells. Preclinically, ALM223 exhibits an improved PK profile and the potential to restore immune balance. Under the agreement signed with Simcere Pharmaceutical Group, Almirall will be granted an exclusive right to develop and commercialise ALM223 for all indications outside the Greater China region (Mainland China, Hong Kong, Macau and Taiwan).

**Previously referred to as ISB 880*

*** ALM223 in licensed from Simcere. Formally referred to as SIM-0278, worldwide ex-Greater China.*

Bispecific antibodies

In October, Almirall and EpimAb Biotherapeutics announced a license agreement for the development of bispecific antibodies for up to three undisclosed target pairs. Under the terms of this agreement, Almirall will gain a license to utilize EpimAb's proprietary Fabs-In-Tandem Immunoglobulin (FITIg®) platform technology to generate, develop and commercialize bispecific antibodies, for which Almirall will have exclusive global rights. EpimAb Biotherapeutics shall retain all rights to the FITIg® Technology.

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®. The regulatory approval is expected in the second half of 2024.

As for the oral antibiotic **Seysara®** (sarecycline), the phase III clinical study conducted in China met primary and key secondary endpoints and Almirall has submitted a dossier with the Chinese National Medical Products Administration at the end of September 2023. The regulatory approval is expected in 2024.

2023 Full Year Guidance

Net sales guidance upgraded: mid-single digit net sales growth (vs. initial low- to mid-single guidance) and total EBITDA between €165 MM - €180 MM.

Investor Calendar 2024

- Full year 2023 Financial Results – February 19th, 2024
- Q1 2024 Financial Results – 13th May 2024
- H1 2024 Financial Results – 22nd July 2024
- 9M 2024 Financial Results – 11th November 2024

About Almirall

Almirall is a global biopharmaceutical company focused on medical dermatology. We collaborate with scientists and healthcare professionals to address patients' 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 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has focused intensely on patients' needs. Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenue in 2022 was €878.5 MM.

For more information, please visit almirall.com

Media contact Almirall
Tinkle
Laura Blázquez
lblazquez@tinkle.es
Phone: (+34) 600 430 581

Investors' Relations contact
Almirall
Pablo Divasson del Fraile
pablo.divasson@almirall.com
Phone: (+34) 93 291 3087

Corporate Communications contact
Almirall
Mar Ramírez
mar.ramírez@almirall.com
Phone: (+34) 659 614 173

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[7] Costanzo A, et al. Tildrakizumab improves sleep quality, quality of life and work productivity in patients with moderate-to-severe plaque psoriasis in conditions close to real clinical practice. Presented at the 32nd European Academy of Dermatology and Venereology (EADV) Congress, 11 – 14 October 2023, Berlin, Germany. Abstract 3123.

[8] Costanzo A, et al. Super responders to tildrakizumab treatment in moderate-to-severe chronic plaque psoriasis in conditions close to real clinical practice. Presented at the 32nd European Academy of Dermatology and Venereology (EADV) Congress, 11 – 14 October 2023, Berlin, Germany. Abstract 3121.

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[12] PROAK: Patient-reported Outcomes for Tirbanibulin Effectiveness and Safety in Actinic Keratosis. SKIN The Journal of Cutaneous Medicine 2023.

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[14] Simpson E, et al. Raising the bar of efficacy in atopic dermatitis: depth of response in patients treated with lebrikizumab over 52 weeks Presented at the 32nd European Academy of Dermatology and Venereology (EADV) Congress, 11 – 14 October 2023, Berlin, Germany. Abstract 3117.
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