

# **Press Release**

Barcelona, Spain 20th February 2023

# Almirall's Full-Year 2022 Results

# Almirall closes 2022 with a Core Net Sales growth of 6.6%, driven by its European Dermatology Business

- Almirall consolidates its position in Europe. The Dermatology business in this continent grew 18.4% year-on-year, boosted by new launches
- Almirall achieved its guidance for 2022, delivering its mid-single-digit Core Net Sales target and hitting
  the mid-range of the EBITDA level: Core Net Sales\* reached €863.2 MM (+6.6% year-on-year) and Total
  EBITDA €198.3 MM (-15.8% year-on-year) due mainly to a higher investment in R&D and SG&A. Growth
  drivers contributed to robust operational performance: Ilumetri® -52.1% year-on-year sales increase-;
  Klisyri® -Net Sales of c.€15 MM-; and Wynzora® -Net Sales of c. €7 MM-
- In October 2022, lebrikizumab (atopic dermatitis) was submitted for EU regulatory approval, which is
  expected in late 2023. Almirall's focused strategy on Medical Dermatology and the biologics market
  space positions the company well for continued growth acceleration over the mid-term
- Pipeline continues to progress: Phase I for anti-IL-1RAP monoclonal antibody is initiated. Almirall
  entered in 2022 into a licensing agreement for IL-2muFc fusion protein with Simcere; more recently, the
  company signed a research collaboration with Isolex to explore novel approaches for IgE-mediated
  diseases
- Guidance for 2023: Core Net Sales growth of low to mid-single-digit and Total EBITDA of €165-€180 MM
- In light of the very positive evolution, performance and momentum of the Company towards its key priorities over the last few months, the Board of Directors of Almirall has asked Carlos Gallardo to remain as CEO and has suspended the search for a new CEO for the time being. He will also continue in the role of Chairman of the Board of directors
- The company will submit a dividend to its shareholders of €0.19 per share at the next Annual General Meeting on May 5<sup>th</sup>, in line with previous years' dividend

# Financial highlights (€ rounded million)

	2022	2021	Variation
Total Revenues	878.5	836.5	5.0%
<ul> <li>Net Sales</li> </ul>	863.2	827.2	4.4%
Other Income	15.3	9.3	64.5%
<b>Gross Profit</b>	572.9	571.3	0.3%
• % of sales	66.4%	69.1%	
EBITDA	198.3	235.6	(15.8%)
Normalized Net Income	33.5	81.4	(58.8%)

<sup>1\*</sup> Core results excludes AstraZeneca/Covis 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 and Covis.

"We are pleased to see that Almirall achieved strong financial results in 2022, delivering our guidance thanks to the excellent evolution of our core dermatology business, which continues to perform well and is driven by our recently launched products and strength in the European business. In the meantime, we have also made good progress with our pipeline.

We started 2023 on a high note. We are confident that Almirall's growth drivers will continue their positive trajectory during 2023 while we keep preparing for Lebrikizumab's launch.

We are very well-positioned for mid and long-term growth. Our strong balance sheet and flexible capital structure will allow us to continue to explore inorganic growth options that align with our corporate strategy."

Carlos Gallardo, Chairman and CEO.

Almirall, S.A. (ALM) a global biopharmaceutical company based in Barcelona, has announced its full-year 2022 financial results today.

# **Summary of results**

- Net Sales\* at €863.2 MM represent a 6.6% year-on-year growth, driven by strong EU Dermatology portfolio performance.
- Total EBITDA\* reached €198.3 MM, a 15.8% year-on-year decrease, and was impacted by due to higher R&D, SG&A investment related to new and coming launches, US sales decrease.
- Almirall closed 2022 with a healthy balance sheet and solid liquidity position at 0.8x Net Debt to EBITDA.
- **Core Gross Margin** of 66.4%, as expected, was impacted by higher energy costs and inflation affecting purchase costs of certain materials.
- Research & Development investment of €103.2 MM, increasing as expected reaching 12% of Core Net Sales, driven by investment in studies for lebrikizumab and Klisyri® (tirbanibulin), as well as the acquisition of earlier stage assets, such as the anti IL1-Rap and the IL-2 mu-Fc.
- Selling, General & Administrative expenses were €409.7 MM, up 4.3%, due to supporting recent launches of Wynzora<sup>®</sup>, Klisyri<sup>®</sup> in Europe and Ilumetri<sup>®</sup> rollout in new countries.
- Divestment of Motilex<sup>®</sup> in Italy, with a positive impact of €18.5 MM in Q4 2022, broadly in line with the positive divestment impact of €16m in 2021.

#### **Growth Drivers Performance**

#### **Psoriasis**

**Ilumetri**<sup>®</sup>, an anti-IL-23 high-affinity humanized monoclonal antibody indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis, had a strong performance in 2022 reaching Net Sales of over €124.6 MM and achieving a 52.1% sales increase year-on-year. Growth was boosted by the positive contribution from



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new country launches, and sales in Germany, where the new patient market is clearly driven by the anti-IL23 class, with over 40% market share of new patients within biologics.

This growth trend is expected to continue during 2023, with added contribution of new country launches.

Almirall strengthened its psoriasis franchise with the successful rollout of **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. The launch of this product also reinforces Almirall's position as the only company with an entire portfolio of psoriasis products covering the treatment paradigm.

Wynzora® keeps increasing its market share in key countries, achieving Net Sales of c. €7 MM in 2022, driven by the strong performance in Germany and Spain where the product reached double digit market share. The product also had a successful rollout campaign during 2022 in the UK, Denmark, Netherlands, and Austria and Almirall is confident that Wynzora® will have a good uptake in these markets as well as in additional EU countries in the upcoming quarters.

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

# **Actinic Keratosis (AK)**

Klisyri®\* (tirbanibulin), a microtubule inhibitor for the topical treatment of actinic keratosis (AK) of the face or scalp, delivered a solid performance and positive uptake in Europe thanks to the positive feedback among users and physicians due to its convenience and safety profile. The product reached Net Sales of c.€9 MM in 2022 in Europe with strong performance in Germany, where Klisyri® was awarded "Most Innovative Product 2022" at the Pharma Trend Image & Innovation Awards. It is also gaining strong traction in countries like the Netherlands, Austria, Switzerland, Spain, and Italy.

In the US, where AK is the second most common diagnosis made by dermatologists, **Klisyri**® received a recommendation in the AAD guidelines. The product continues to gain penetration in the AK topical market with around 70,000 prescriptions since its launch in February 2021, a result that highlights the product's good performance despite being a new product launched in a market with numerous generic alternatives. Since its launch, Klisyri® has been prescribed by over 5,000 healthcare professionals, who have reported positive feedback and successful patient engagement. The product now has a greater than 70% commercial coverage.

#### Acne

**Seysara**<sup>®</sup>, an oral antibiotic derived from tetracycline and specifically designed to treat acne, has registered continued volume recovery during 2022. With over 250,000 TRx, the product achieved 22% growth year-on-year in prescriptions.

The product continues to make good progress on market access with 75% commercial payer coverage. Furthermore, Seysara® achieved a 6% market share in the oral antibiotic market and Almirall continues to focus its efforts on driving demand and improving the commercial profile and productivity (TRx/HCP) which will be key for continued growth.



# Progressing promising late-stage pipeline, while building early stage

# **Atopic Dermatitis (AD)**

In October 2022, Almirall submitted a Marketing Authorisation Application (MAA) to the EMA for **Lebrikizumab**, an anti-IL13 monoclonal antibody for the treatment of moderate-to-severe atopic dermatitis (AD). AD is an underserved, large and growing market, estimated to have more than 5 million moderate-to-severe patients in Europe by 2026. <sup>1</sup>. The application of lebrikizumab is currently under review, and the approval is expected in Q4 2023.

Lebrikizumab showed a consistent safety profile across a clinical development program with more than 2000 patients. Consistent across geographies, whether in monotherapy or in combination with topical corticosteroids, in adults as well as in adolescents and across ethnicities.

In terms of clinical updates, the Advantage Phase 3b study is fully recruited. This study is a randomised, double-blind, placebo-controlled Phase 3 clinical trial to assess the efficacy and safety of Lebrikizumab in combination with Topical Corticosteroids in Adult and Adolescent Patients with Moderate-To-Severe Atopic Dermatitis that are not adequately controlled with cyclosporine or for whom cyclosporine is not medically advisable. The results for the Week 16 readout are expected in H1 2023. In addition, a paediatric study was initiated by Almirall's partner

The data presented to date demonstrate the potential benefit that lebrikizumab could bring to HCPs and patients and confirm the potential of lebrikizumab to be a first-line advanced biologic treatment for moderate-to-severe atopic dermatitis.

# **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 under the European decentralised procedure. The German regulatory authority is acting as the Reference Member State. The outcome of the filing is expected in 2023.

With the potential launch of this antifungal expected in 2023, Almirall will reinforce its onychomycosis franchise by complementing Ciclopoli<sup>®</sup>, Almirall's OTC product indicated to treat this condition.

#### **Acne**

The Phase III clinical trial conducted in China for the oral antibiotic Seysara® (sarecycline) met primary and key secondary endpoints and Almirall plans to file the application to the Chinese National Medical Products Administration later this year.

#### Autoimmune dermatological diseases

Almirall is working on building its early-stage pipeline with some promising recent in-licensing. 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. The start of the Phase I clinical trial is expected in the second half of 2023.

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).

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



In September 2022, Almirall announced the initiation of the phase I study evaluating the safety, pharmacokinetics, pharmacodynamics and clinical activity of ALM27134\*, a 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 commercialise ALM27134. The company is confident that this monoclonal antibody could bring the opportunity to address the unmet needs in several autoimmune dermatology indications.

\*Previously referred to as ISB 880

# Agreement with Isolex to develop novel approaches for IgE-mediated diseases

Recently, Almirall has entered a collaboration and option to license agreement with the biotechnology company Isolex with the aim of identifying and developing a novel class of medicines that modulates Immunoglobulin E (IgE). The signed Option and Licensing Agreement will allow the teams to develop a biotherapeutic treatment that utilises a novel mechanism of action to target IgE.

The research project brings together Almirall's strong knowledge in Medical Dermatology with the expertise of Isolex team, leveraging the technology developed between Combikine Biotechnology Ltd and King's College London.

# **Board of Directors of Almirall**

The Board of Directors of Almirall views very positively the evolution, performance, and momentum of the Company towards its key priorities over the last few months. Therefore, it has asked Carlos Gallardo to remain as CEO and has suspended the search for a new CEO for the time being. Carlos Gallardo has accepted, and he will also continue in the role of Chairman of the Board of directors. Additionally, the Board will set up a new Governance Committee to check and balance the position of the Chairman-CEO.

#### **Conclusions**

Almirall achieved its 2022 guidance, delivering a good operational performance driven by the excellent momentum of its Medical Dermatology business in Europe.

Almirall's focused strategy on the Medical Dermatology space positions the company well for the mid and long term. Its growth drivers are expected to continue their trajectory during 2023 ewhile keeping the focus on important near-term launches such as the biologic lebrikizumab. Ilumetri® should continue to show strong performance thanks to growing contribution from new country launches. The rollouts of Klisyri® and Wynzora® in Europe are also expected to continue driving positive trends during the year.

The company will also remain focused on unlocking the value of its late-stage pipeline, while strengthening the early-stage with exciting new assets, ensuring sustained growth in the medium and long term.

Almirall is fully committed to creating long-term shareholder value with growth expected to accelerate in the coming years with recent and future launches. The company has a good credit rating, reflecting its healthy balance sheet, and which gives management the flexibility in the current environment to actively pursue bolt-on acquisitions and in-licensing opportunities that align with its corporate strategy.

# **Board proposals to the Annual General Meeting: Dividend**

The AGM will be proposed a dividend of €0.19 per share for approval May 5<sup>th</sup> 2023.



## 2023 Full Year Guidance

Core Net Sales: low to mid-single-digit growth vs. previous year (€863 MM)

Total EBITDA: between €165 MM and €180 MM

# **Investor Calendar 2023**

- Q1 2023 Financial Results 8th May 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 revenues in 2022 were €878.5MM.

#### For more information, please visit almirall.com

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<sup>&</sup>lt;sup>1</sup> Atopic Dermatitis/Atopic Eczema –Disease Landscape & Forecast, DRG Dec 2017.