

# **Press Release**

Barcelona, Spain 21<sup>st</sup> February 2022

# Almirall's Full-Year 2021 Results

# Almirall delivers high end of the 2021 upgraded guidance with solid performance from growth drivers

- Almirall delivered at the high end of its upgraded guidance: Core Net Sales\* reached €809.8 MM (+7% year-on-year) and Core EBITDA\* €211.3 MM (+17% year-on-year). The strong operational performance was driven by the positive contribution from growth drivers and strong performance of the EU dermatology portfolio
- Excellent sales momentum of the growth drivers: Ilumetri<sup>®</sup> contributed to overall growth achieving Net Sales of €82 MM in Europe, Seysara<sup>®</sup> saw a steady improvement in TRx and OAB market share in the US, and Klisyri<sup>®</sup> showed very positive initial uptake in the German and UK markets
- Solid operating cash flow generation of €233.8 MM resulted in a very healthy balance sheet as the company finished the year at 1.0 x Net Debt to EBITDA
- Encouraging progress made on R&D pipeline with positive topline phase 3 results from 3 pivotal clinical trials for lebrikizumab for atopic dermatitis. Almirall is well positioned for long-term growth by unlocking the value of the late-stage pipeline and expects R&D spend to be 11-12% of Net Sales in 2022
- Introducing Guidance for 2022: Core Net Sales growth of mid-single-digit and Total EBITDA of €190-€210 MM
- Dividend proposal of €0.19 per share will be submitted at the next Annual General Meeting on May 6<sup>th</sup>

#### Financial highlights (€ rounded million)

	2021	2020	Variation	Variation (CER¹)
Total Revenues	836.5	814.5	2.7%	3.2%
<ul> <li>Net Sales</li> </ul>	827.2	807.4	2.5%	2.9%
• Other Income	9.3	7.1	31.0%	33.8%
Gross Profit	571.3	560.1	2.0%	2.5%
• % of sales	69.1%	69.4%		
EBITDA	235.6	238.3	(1.1%)	(0.3%)
Normalized Net Income	81.4	95.1	(14.4%)	(15.4%)

<sup>&</sup>lt;sup>1</sup> CER (Constant Exchange Rates): Excluding the effects of exchange rate fluctuations

"2021 has been a strong year for Almirall both from a financial perspective and in terms of pipeline progress. We had strong business momentum driven by our growth drivers and we are pleased to have delivered on our upgraded financial guidance, achieving the upper range of the Core EBITDA. Our operational performance was robust as the core business continued to perform well driven by our recently launched products and European dermatology business. We are making good progress on the pipeline, which offers significant potential, and we continue to look at inorganic growth opportunities within our key markets to complement our portfolio. We begin 2022 with the certainty that we are moving in the right strategic direction. We are seeing excellent momentum of the business and are confident that Almirall's key products will continue their trajectory as we invest to support our recent launches."

Gianfranco Nazzi, CEO.

Almirall, S.A. (ALM) a global biopharmaceutical company based in Barcelona, has announced its full-year 2021 financial results today.

# **Summary of results**

- **Net Sales** of €827.2 MM represent a 2.5% year-on-year growth, driven by positive contribution from growth drivers and a strong EU dermatology performance.
- Core Net Sales\* reached €809.8 MM, a 7.2% year-on-year increase.
- Total Revenues reached €836.5 MM, a 2.7% year-on-year increase.
- Gross Profit of €571.3 MM reflected a growth of 2.0%.
- Operating Cash Flow reached €233.8 MM resulting in a very healthy balance sheet as the year finished at 1.0x Net Debt to EBITDA.
- Research & Development expenses were €73.6 MM, a -6.7% decrease, as expected, 9.1% of Core Net Sales.
- Selling, General & Administrative expenses were €392.8 MM, a 6.1% increase in spend.
- Core EBITDA\* was €211.3 MM, a growth of 16.7%, boosted by strong performance of the growth drivers
- Normalised Net Income was €81.4 MM.
- **Net Loss** of €40.9 MM was due to impairment charges of €103 MM associated with the carrying value of the intangible asset for Seysara<sup>®</sup> (€69 MM), the US Legacy Portfolio (€22 MM), and the Bioniz option payment which was not exercised (€12 MM) as announced at H1 results.

\*Core business excludes AstraZeneca contribution: Deferred income and other income



# **Growth drivers' performance**

#### **Psoriasis**

**Ilumetri**®, 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 with Net Sales of €82 MM representing growth of 87% year-on-year, which contributed to overall growth. The product is gaining traction in recent country launches including France, Spain and Italy. At present, the anti-IL23 class is capturing c.40% market share in new patients in Germany.

A few weeks ago, **Wynzora**® cream was launched in Germany, Spain, and the UK. Wynzora® is the first and only once-daily aqueous cream, with a fixed combination of calcipotriene and betamethasone diproprionate (CAL/BDP) powered by PAD Technology, a new method for mixing oil and water, which creates a stable, less greasy formulation¹ and offers a favourable safety profile²,³, as well as patient convenience².

Initial sales data has been positive, having achieved >5,400 prescriptions. The decentralised procedure is advancing successfully, and the EU rollout campaign will continue during the year following the attainment of other 11 country approvals.

Wynzora® has a clear strategic fit within Almirall's portfolio. With the addition of this treatment to its product portfolio, Almirall strengthens its position in the EU psoriasis market and becomes the only biopharmaceutical company in Europe to offer psoriasis patients multiple options covering the entire spectrum of disease ranging from topicals to oral systemics and biologics.

# **Actinic Keratosis (AK)**

Almirall is one of the main players in the actinic keratosis market, a dermatological disease that affects approximately 18%<sup>4</sup> of the EU population. The company strengthened its European AK franchise with the launch of **Klisyri**<sup>®</sup> (tirbanibulin), a novel microtubule inhibitor for the topical treatment of AK of the face or scalp.

Klisyri® showed very positive initial uptake in countries where it was launched. Since its launch in Germany and the UK, the product has achieved more than 28,500 prescriptions and received positive feedback from both dermatologists and patients, who highlighted its short 5-day application and good tolerability profile.

In the US, Klisyri® continues to make steady gains within commercial lives quarter-on-quarter with c.55% or >100 MM commercial lives covered. As dermatologists seek new options to treat their AK patients, Almirall's team is focused on gaining market access through the differentiation of Klisyri® based on specific patient types for efficacy, tolerability, and convenience.

#### Acne

**Seysara**®, an innovative oral antibiotic derived from tetracycline and specifically designed to treat acne, registered a steady rebound in TRx in 2021 which helped drive c.30% year-on-year growth in Net Sales and an increase in market share to 5% of the OAB market.

The company benefited from new commercial coverage which resulted in improved market access. Effective coverage increased to c.53% or c. 100 MM commercial lives. Almirall will focus on the message around the antimicrobial resistance.



# Innovative pipeline delivering key milestones in 2021

# **Atopic Dermatitis (AD)**

**Lebrikizumab**, an anti-IL13 monoclonal antibody for the treatment of moderate-to-severe atopic dermatitis (AD), significantly improved disease severity when combined with topical corticosteroids (TCS) in people with moderate-to-severe AD in a third pivotal phase 3 trial (ADhere). Primary and all key secondary endpoints including itch, interference of itch on sleep, and quality of life were met at Week 16 with a safety profile consistent with prior studies. As a part of the phase 3b clinical trials, Almirall has started one study against cyclosporine. The study will analyse the efficacy of lebrikizumab in combination with topical corticosteroids in adult and adolescent patients with moderate-to-severe AD that are not adequately controlled with cyclosporine.

The company expects to present the completion of the ongoing ADvocate 1 and ADvocate 2 52-week monotherapy trials in H1 2022. The development schedule remains on track with submission to the European Medicines Agency (EMA) expected in 2022 and launch estimated to be in 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). The launch of efinaconzole, a topical prescription product, will strengthen the onychomycosis franchise, complementing Ciclopoli<sup>®</sup>, Almirall's OTC product indicated to treat patients with mild-to-moderate onychomycosis.

The company is working towards EU regulatory submission in H1 2022, and assuming approval, expects to launch efinaconazole in Europe in 2023. This product has been commercialised in other countries by other pharmaceutical companies.

#### **Acne**

Phase 3 clinical trials are underway in China for the oral antibiotic Seysara<sup>®</sup>. Almirall started treating the first phase 3 patients in Q4 2021.

#### **Autoimmune dermatological diseases**

At the end of 2021, Almirall in-licensed exclusive global rights from Ichnos Science to develop and commercialise **ALM27134\*\***, a monoclonal antibody for use in autoimmune dermatological diseases. ALM27134 is a first-in-class fully human, high-affinity monoclonal antibody that targets human IL-1RAP.

ALM27134 is different because it blocks IL-1RAP and simultaneously abrogates multiple disease drivers among the IL-1 family of pro-inflammatory cytokine receptors, including IL-1R, IL-33R, and IL-36R. These cytokines have been implicated in numerous autoimmune conditions, opening opportunities for ALM27134 to be positioned across several disease indications. Almirall expects the IND process to be ready by H1 2022.

Given its novel mechanism of action, ALM27134 has great potential to treat underserved patients with a variety of autoimmune dermatological diseases. The company has the ambition to develop and commercialise it globally.

\*\*Previously referred to as ISB 880



# **Conclusions**

Almirall achieved solid operating results, delivering on the upgraded 2021 guidance, as the core business continued to perform well in line with expectations. The company started 2022 with excellent business momentum set to improve with recent launches and the innovative late-stage pipeline.

The company is focused on its core medical dermatology business, which should drive strong mid-term sales acceleration. Extensive rollout campaigns will continue this year following the European launches of Klisyri® and Wynzora®, as well as preparing the business for the European launch of its biologic for atopic dermatitis in 2023.

Almirall is well positioned for long-term growth. This growth will come from the increasing contribution of current and future growth drivers, as well as opportunistic inorganic growth from external opportunities, leveraging the strong balance sheet and flexible capital structure.

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

The AGM will be proposed a dividend of €0.19 per share for approval May 6<sup>th</sup> 2022.

## 2022 Full Year Guidance

Core Net Sales: mid single-digit growth vs. previous year (€809.8 MM)

Total EBITDA: between €190 MM and €210 MM

#### **Investor Calendar 2021**

- Q1 2022 Financial Results 9<sup>th</sup> May 2022
- H1 2022 Financial Results 25<sup>th</sup> July 2022
- 9M 2022 Financial Results 14<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 and is a member of the IBEX35 (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



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<sup>&</sup>lt;sup>1</sup> Præstegaard M, et al. Phase 3 trial demonstrates superior patient treatment convenience of MC2-01 calcipotriene plus betamethasone dipropionate cream compared to current topical suspension. J of Skin. 2020;4(5):s62

<sup>&</sup>lt;sup>2</sup> Stein Gold L, et al. A phase 3, randomized trial demonstrating the improved efficacy and patient acceptability of fixed dose calcipotriene and betamethasone dipropionate cream. J Drugs Dermatol. 2021;20(4): doi:10.36849/JDD.5653.

<sup>&</sup>lt;sup>3</sup> Pinter A, et al. A pooled analysis of randomized, controlled, phase 3 trials investigating the efficacy and safety of a novel, fixed dose calcipotriene and betamethasone dipropionate cream for the topical treatment of plaque psoriasis. JEADV. 2021; 10.1111/JDV.17734

<sup>&</sup>lt;sup>4</sup> Lucas R, McMichael T, Smith W, Armstrong B. Solar ultraviolet radiation: Global burden of disease from solar ultraviolet radiation: World Health Organization, 2006.