Barcelona, 18th December 2018

SIGNIFICANT EVENT

Pipeline update

Almirall, S.A. ("Almirall"), pursuant to article 17 of Regulation (EU) No. 596/2014 on market abuse and article 228 of the restated text of the Securities Market Act approved by the Royal Legislative Decree 4/2015, of 23 October and related provisions, hereby announces that:

The pivotal study for P-3058 (10% terbinafine nail solution) has met the primary endpoint of complete cure rate and key secondary endpoints in the treatment of mild to moderate onychomycosis. P-3058 was statistically significantly superior to P-3058 nail solution vehicle at Week 60, following a treatment for 48 weeks.

The study included an open label arm of amorolfine 5% nail lacquer. Complete cure rate was numerically in favour of P-3058 nail solution.

Almirall continues to have a strong commitment to R&D, which will ensure the success of future programs in skin health.

Please find below the Press Release to be sent to media.

Yours sincerely,

Pablo Divasson del Fraile
Investor Relations & Corporate Comms. Department
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Press Release

Barcelona,
18th December 2018

Almirall announces that the Phase III trial of P-3058 for onychomycosis achieved primary endpoint

Almirall, S.A (ALM) has announced today that the pivotal study for P-3058 (10% terbinafine nail solution) has met the primary endpoint of complete cure rate and key secondary endpoints in the treatment of mild to moderate onychomycosis. P-3058 was statistically significantly superior to P-3058 nail solution vehicle at Week 60, following a treatment for 48 weeks.

The study included an open label arm of amorolfine 5% nail lacquer. Complete cure rate was numerically in favour of P-3058 nail solution.

Study description

This phase III study was a multicentre, randomized, double-blind, vehicle controlled, parallel-group study to evaluate the efficacy and safety of P-3058 10% terbinafine nail solution versus its Vehicle (double blind) and versus an active comparator (open label).

A total of 953 patients with mild-to-moderate distal lateral subungual onychomycosis (DLSO) caused by dermatophytes involving ≥ 20% to ≤ 50% of the target big toenail area without lunula/matrix involvement were randomised to P-3058, its vehicle, or amorolfine 5% nail lacquer. Patients applied P-3058 nail solution or its vehicle once daily for 4 weeks then once weekly for the remaining 44 weeks of treatment. Amorolfine 5% nail lacquer was applied once weekly for 48 weeks.

Primary Endpoint:

Rate of complete cure at the end of follow up (12 weeks after the 48-week treatment course) defined as composite of negative KOH microscopy and negative culture for dermatophytes and no residual clinical involvement (nail totally clear) of the target nail.

Key Secondary Endpoints:

- Responder rate defined as negative KOH microscopy and negative culture for dermatophytes and ≤ 10% residual involvement of the target toenail at the end of follow up.
- Mycological cure rate defined as negative KOH microscopy and negative culture for dermatophytes of the target toenail at the end of follow up.

Disease

Onychomycosis is a fungal infection of the nail. It is difficult to treat, requiring long-term treatment and good compliance to achieve eradication of the fungus and acceptable clinical out-come.

P-3058 10% terbinafine nail solution is an antifungal product for treatment of dermatophyte-induced onychomycosis formulated for drug application to nails. The technology is based on a water soluble semi-synthetic derivative of chitosan which acts as a film-forming agent, does not require nail filing and is easily removed with water.

P-3058 is the first terbinafine nail lacquer solution for onychomycosis treatment. The product has a convenient posology: applied once-daily for 1 month, and then once-weekly for 48 weeks.

Terbinafine is an antimycotic agent that inhibits the biosynthesis of the principal sterol in fungi, ergosterol, at the level of squalene epoxidase. Squalene epoxidase inhibition results in ergosterol depleted fungal cell membranes (fungi static effect) and the toxic accumulation of intracellular squalene (fungicidal effect).

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed. The company, founded in 1943 and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenue in 2017 was 755.8 million euros and more than 1,830 employees are devoted to Science.

For more information, please visit almirall.com linkedin.com/company/almirall

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