Barcelona, October 28th 2019

SIGNIFICANT EVENT

ALMIRALL ANNOUNCES PIPELINE UPDATE

Almirall, S.A. ("ALM"), in accordance with the Spanish Securities Markets Law, notifies the following:

Almirall announced today the following update to the late stage pipeline:

Lebrikizumab - atopic dermatitis

On the 9th of October the Phase 3 program for Lebrikizumab was initiated. The program includes two identical, randomized, double-blind, placebo-controlled, parallel-group Phase 3 studies designed to confirm the safety and efficacy of lebrikizumab as monotherapy in patients with moderate-to-severe atopic dermatitis. The studies are expected to enrol a total of approximately 800 adult and adolescent patients ages 12 years and older with moderate-to-severe atopic dermatitis at approximately 200 sites in the United States, Europe and Asia.

Key patient inclusion criteria for the monotherapy studies include:

- The presence of chronic atopic dermatitis for at least one year, an Investigator's Global Assessment (IGA) score of 3 or 4 (on a 5-point scale ranging from 0 to 4);
- An Eczema Area Severity Index (EASI) score of 16 or greater and body surface area (BSA) involvement of at least 10 percent at screening and baseline.

The studies will evaluate a 250 mg dose of lebrikizumab administered by subcutaneous injection every two weeks, following a loading dose of 500 mg administered at baseline (day 0) and week 2, compared to placebo for 16 weeks (the induction period). Following the end of the 16-week induction period, study patients who respond during the induction period (as evidenced by achievement of an IGA 0/1 response, representing a reduction of 2 or more points in IGA score from baseline to a final score of 0 (clear) or 1 (almost clear), or an EASI-75 response, representing an improvement in EASI score of at least 75 percent from baseline) will be re-randomized to one of the following treatment groups for an additional 36-week maintenance period:

- Group A: Lebrikizumab 250 mg given every two weeks;
- Group B: Lebrikizumab 250 mg given every four weeks; or
- Group C: Placebo given every two weeks.

Patients who do not achieve an IGA of 0/1 response or an EASI-75 response at week 16 and patients who do not maintain an EASI-50 response during the maintenance period will be assigned to receive lebrikizumab 250 mg as open-label treatment every two weeks through week 52.

The primary efficacy endpoint of the studies is the percentage of patients with an IGA 0/ 1 response from baseline to week 16.

Key secondary efficacy endpoints that will be evaluated during the 16-week induction period include: the percentage of patients achieving EASI-75; the percentage of patients achieving EASI-90; the percentage of patients with a pruritus (itch) numerical rating (NRS) score of at least 4 at baseline who achieve a reduction of at least 4 points; percentage changes in pruritus and sleep-loss scores; and change in BSA.

The company expects to report topline findings from the 16-week induction period in the first half of 2021. In addition to the two monotherapy studies, the company plans to include a study in the Phase 3 program that evaluates lebrikizumab when used in combination with topical corticosteroids. The impact of lebrikizumab treatment on quality of life will also be assessed across a number of additional measures.

ALM14789 - actinic keratosis

As announced in the 2019 American Academy of Dermatology Annual Meeting in Washington, DC (on March 2, 2019), both Phase III studies, KX01-AK-003 and KX01-AK-004, achieved their primary endpoint, which was defined as 100% clearance of the AK lesions at Day 57 within the face or scalp treatment areas: Complete Clearance was observed in 44% and 54% of the patients for tirbanibulin respectively while it was 5% and 13% for vehicle treated groups.

Only patients showing complete clearance at the primary evaluation endpoint on day 57 were followed quarterly in the extension period until recurrence was observed in the treatment area. Recurrence rates were defined as proportion of patients in whom at least one treated or new actinic keratosis lesion was identified in the treated area throughout one year follow up.

The recurrence rates in patients treated with tirbanibulin 1% ointment were 74% and 72% in the pivotal trials KX01-AK-003 and KX01-AK-004, respectively. Overall, at the recurrence follow up study visit when actinic keratosis (up to eight initial number of lesions) in the treated area was first observed, 86% had only one or two lesions and 48% reported at least one lesion that was not identified at the time of the initial treatment i.e. newly occurring lesions that were considered as recurrences.

These results represent the last piece of information to submit the New Drug Application (NDA) in the US and the Marketing Authorization Application (MAA) in Europe that are expected to be launched in Q1 2021 and Q2 2021 respectively.

Finasteride (ALM12845) - androgenetic alopecia

On the 26th of September the Marketing Authorization Application (MAA) was submitted for Finasteride.

The product is a cutaneous spray, solution has been demonstrated to be safe and effective in the topical treatment of adult men with male pattern hair loss (androgenetic alopecia, AGA).

The product is subject to medical prescription. First national phase approval is estimated in 2020 or early 2021 in Europe.

Terbinafine (ALM12834) - onychomycosis

On the 31st of July, the Marketing Authorization Application (MAA) was submitted.

The product is a medicated nail lacquer and it´s indicated for the topical treatment of mild to moderate fungal infections of the nails caused by dermatophytes and/or other terbinafine-sensitive yeasts and moulds, without nail matrix/lunula involvement.

First national phase approval is estimated during in 2020 or early 2021 in Europe.

Yours sincerely,

Pablo Divasson del Fraile
Investor Relations Department
investors@almirall.com