Barcelona, July 19th 2021

OTHER RELEVANT INFORMATION

Almirall receives European Commission approval for Klisyri® (tirbanibulin), an innovative topical treatment for actinic keratosis

In accordance with Securities Markets Law approved Almirall, S.A. ("Almirall") announce the following:

The European Commission (EC) has approved Klisyri® (tirbanibulin) for the topical treatment of actinic keratosis (AK) on the face or scalp in adults.

Tirbanibulin is a novel, topical first-in-class microtubule inhibitor with a selective antiproliferative mechanism of action that represents a significant step forward in the treatment of AK due to its short treatment protocol one application daily for 5 days, proven efficacy, and safety profile with very acceptable local tolerability.

This approval is based on two pivotal phase III studies' (KX01-AK-003 and KX01-AK-004) positive results, published in the New England Journal of Medicine (NEJM). These two double-blind, vehicle-controlled, randomised, parallel-group, multi-centre phase III clinical trials, included 702 patients from 62 clinical sites across the US, and demonstrated that once-daily application of tirbanibulin ointment 1% (10 mg/g) during 5 consecutive days in adults with AK on the face or scalp is effective and well tolerated.

In December 2020, Klisyri® (tirbanibulin) received approval from the U.S. Food and Drug Administration (FDA) for the commercialisation in the United States for the topical treatment of actinic AK of the face or scalp.

In addition, Almirall has submitted Klisyri® for a marketing authorisation in Switzerland in Q4 2020 and the dossier is currently under review by Swissmedic. The company has already submitted in Great Britain via the European Commission Decision Reliance Procedure.

Yours sincerely,

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