Barcelona, May 21st 2021

OTHER RELEVANT INFORMATION

Almirall receives positive CHMP opinion 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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for the regulatory approval of Klisyri® (tirbanibulin), indicated for the topical treatment of actinic keratosis (AK) on the face or scalp.

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

The CHMP opinion is based on two phase III studies (KX01-AK-003 and KX01-AK-004) positive results. These two double-blind, vehicle-controlled, randomized, parallel-group, multi-centre phase III clinical trials, which included 702 patients from 62 clinical sites across the US, showed that application of tirbanibulin ointment 1% (10 mg/g) in adults with AK on the face or scalp is effective and well tolerated.

The European Commission (EC) generally follows the recommendations of the CHMP (EMA) and delivers its final decision thereafter. The approval of Klisyri® (tirbanibulin) is expected in approximately 60 days and its launch in Europe could take place in late 2021. Concerning other territories, Almirall submitted for a marketing authorisation in Switzerland in Q4 2020 and the dossier is currently under review by Swissmedic. The company will also submit in Great Britain via the European Commission Decision Reliance Procedure.

Yours sincerely,

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