

Regulators confirm Actikerall® for the treatment of actinic keratoses, including grade I and II, is approvable

- **Actikerall® receives positive recommendation and process enters national approval phase in seven European countries**
- **First launches are expected in Germany and UK in mid 2011**

Barcelona, Spain May 9th, 2011.- Almirall, S.A. (ALM:MC) today announced that the regulatory authorities in Germany, UK, Austria, Luxemburg, Poland, Czech Republic and Slovakia have granted a positive recommendation for the regulatory approval of Actikerall® (5 mg/g fluorouracil and 100 mg/g salicylic acid) for the treatment of palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in adult patients..

The regulatory process will now enter its national phase to finalise product packaging and related documents. Once this phase has been completed, national marketing approvals can be granted in each of the respective countries.

Actikerall® is a topical solution for lesion-directed treatment against hyperkeratotic actinic keratoses and has shown good clinical efficacy data confirmed by histological clearance of lesions in 72.0 % of patients after treatment and sustained clinical benefit of 85.8 % lesion clearance after 12 months post treatment. The tolerability profile was good and, as expected, only site application events of mild to moderate intensity were reported.

First launches are expected in the Germany and UK in mid 2011.

Actinic keratoses

Actinic keratosis (also known as solar keratosis) is a condition of thick, scaly, or crusty patches of skin. It is more common in fair-skinned people. It is associated with those who are frequently exposed to the sun, as it is usually accompanied by solar damage. Since some of these pre-cancers progress to squamous cell carcinoma, they should be treated. Untreated lesions have up to 20% risk of progression to squamous cell carcinoma.

Actinic keratoses may be divided into the following types: hyperkeratotic actinic keratosis, pigmented actinic keratosis, lichenoid actinic keratosis and atrophic actinic keratosis. It is very common, affecting half of the global population. Prevalence can vary with geographical location and age. People who take immunosuppressive drugs, such as organ transplant patients, are 250 times more likely to develop actinic keratoses which may lead to skin cancer.

About Almirall

Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing. Almirall focuses its research resources on therapeutic areas related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), gastrointestinal disorders, psoriasis and other dermatological conditions. Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 12 affiliates. For further information please visit: www.almirall.com.

Almirall media contact:

Fiona Gildea - Emanate PR
fiona.gildea@emanatepr.com
+44 (0)20 7611 3881