

Actikerall[®] launched in the UK for the treatment of actinic keratosis, including grade I and II severity

- **Actikerall[®] receives marketing approval from the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK**
- **Launch in Germany is also expected this year**

Barcelona, Spain, June 6th, 2011.- Almirall, S.A. (ALM:MC) today announced that the MHRA in the UK have granted a marketing authorisation for Actikerall[®] (5 mg/g fluorouracil and 100 mg/g salicylic acid) cutaneous solution for the treatment of palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in adult patients. Actinic keratosis is a common disorder of the skin and is seen predominantly on sun exposed areas such as the face. The changes in the skin are precancerous in nature.

Commonly, treatment of actinic keratosis (AK) lesions involves local procedures such as cryotherapy, laser, and surgical excision. Large area treatment, or field treatment, options include topical therapies or photodynamic therapy.

Actikerall[®] is a new easy to use topical solution for lesion-directed treatment against palpable and/or moderately thick hyperkeratotic AKs. Actikerall's efficacy was demonstrated in a 12 weeks Phase III trial, which enrolled 470 patients with 4-10 AK lesions. The complete clearance of a representative lesion was confirmed, by histology, in 72% of patients after a 12 weeks treatment. This benefit was sustained, as 85.8% of lesion clinically assessed as cleared after initial treatment were still clear after 12 months post treatment. Actikerall[®] was well tolerated during the study with less than 4% of patients withdrawing from the study due to adverse reactions reported on application sites.

Actikerall[®] is supplied in a 25ml bottle which is sufficient for the treatment duration. The solution is applied by an integral brush that allows for more precise application and may reduce the risk of affecting normal skin.

European guidelines¹ currently recommend Solaraze[®] from Almirall, the market leading treatment for AK, for field treatment. Almirall will now be able to offer a range of therapeutic options to dermatologists and patients with actinic keratoses, including Actikerall[®] which offers an effective easy to use, local treatment even in hyperkeratotic (grade II) lesions.

Notes to Editors

Actinic keratosis

Actinic keratosis is the presence of thick, scaly, or crusty patches on the skin. They are caused by prolonged exposure to ultraviolet (UV) from sunlight and are most commonly seen in fair-skinned people. These UV-light induced lesions are the most common lesions with malignant potential to arise on the skin and can potentially progress to invasive squamous cell carcinoma (SCC). The risk of untreated lesions progressing to a malignant lesion is quite high, although recognition and timely treatment can help to prevent progression. It is estimated that there are around 1 in 10 adults in Europe who suffer from Actinic keratosis with up to 1 in 4 adults in the United Kingdom currently suffering from at least one Actinic keratosis lesion.^{2,3}

Actinic keratosis is divided into the following subtypes: 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 keratosis 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.

The company started its activity in the United Kingdom and Ireland at the beginning of 2008, with the aim of strengthening its European presence.

Almirall's UK affiliate, Almirall Ltd., is currently focused on the marketing of dermatology products and was formed after the acquisition of Hermal, a company specialising in dermatology, and the purchase of a mostly dermatology product portfolio from Shire.

For further information please visit: www.almirall.com.

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References

¹ Stockfleth E Development of a treatment algorithm for actinic keratoses: a European Consensus Eur J Dermatol 2008; 18 (6): 651-9

²Harvey I, Frankel S, Marks R *et al.* Non-melanoma skin cancer and solar keratoses. Methods and descriptive results of the South Wales skin cancer study. *Br J Cancer* 1996; 74:1302–7.

³ Memon AA, Tomenson JA, Bothwell J, Friedmann PS. Prevalence of solar damage and actinic keratosis in a Merseyside population. *Br J Dermatol* 2000; 142:1154–9.