

# Almirall announces an international agreement with Basilea to commercialize Toctino<sup>®</sup> (alitretinoin) for severe chronic hand

- Toctino<sup>®</sup> is the only therapy approved for adults with severe chronic hand eczema (CHE) unresponsive to potent topical corticosteroids
- The international agreement includes selected European markets and Mexico
- With this collaboration Almirall strengthens its growing international dermatological portfolio, entering in a debilitating skin condition that imposes a significant economic burden on society

**Barcelona – June 15, 2010.-** Almirall, S.A. today announced an international exclusive distribution agreement to commercialize Basilea's Toctino<sup>®</sup>, a once-daily oral treatment for adults with severe chronic hand eczema (CHE) unresponsive to potent topical corticosteroids, in Austria, Belgium, Czech Republic, Italy, Luxembourg, Mexico, the Netherlands, Poland, Portugal, Slovakia and Spain.

Toctino<sup>®</sup> is already approved in all the countries under the scope of this agreement except in Czech Republic and Mexico. The product has been granted pricing and reimbursement in Italy and Austria where, launch preparations are being initiated. A sequential roll-out to European countries is foreseen during the second half of 2010 and 2011.

Under the terms of the agreement, Almirall will make an upfront and milestone payments related to the launch of Toctino<sup>®</sup> in two key markets of the territory of up to € 16 million, and will pay future milestones related to pre-specified sales achievements.

"We are very pleased to have entered into this collaboration with Basilea. With the addition of Toctino®, Almirall has broadened its growing international dermatological portfolio with an exciting and unique treatment in an area of high unmet need" said Dr. Jorge Gallardo, Chairman and Chief Executive Officer of Almirall. "Through this agreement Almirall will reinforce its international presence in a therapeutic area that is a strategic priority. We will leverage our international regulatory and commercial capabilities to bring Toctino® to new patients in 2010.", he added.

"We are excited to further expand the commercial availability of Toctino® through this partnership with Almirall, a leading dermatology company in Europe. Almirall has a well-established and significant sales force with a successful track record in markets where Basilea has not established a full commercial sales presence, including in Almirall's home market Spain," said Dr. Anthony Man, CEO Basilea Pharmaceutica Ltd. "Through this partnership Toctino® will be available sooner and to more patients than otherwise possible in these selected markets".

## **About Toctino®**

Toctino<sup>®</sup> (alitretinoin), the only therapy approved for severe chronic hand eczema unresponsive to potent topical treatments

Toctino<sup>®</sup> was developed by Basilea Pharmaceutical International Ltd. To date, Toctino<sup>®</sup> is launched in Denmark, France, Germany, Switzerland and the United Kingdom for the treatment of severe chronic hand eczema. The drug is approved in 15 additional European

countries as well as in Canada and has been recommended for approval in seven further European countries.

In the largest ever phase III clinical trial program in CHE, Toctino<sup>®</sup> was the first treatment to show effective clearing of severe CHE, with clear or almost clear hands achieved in nearly 50 percent of patients treated with 30 mg Toctino<sup>®</sup>. The once-daily oral therapy is given for 12 to 24 weeks, depending on patient response, and six-month post-treatment observations in patients who responded to Toctino<sup>®</sup> indicate that treatment can provide long periods free from relapse and improve patient satisfaction.

Toctino<sup>®</sup> is a known teratogen (a substance that can cause birth defects when women are exposed during pregnancy). Strict pregnancy prevention one month before, during, and one month after cessation of treatment as well as monthly pregnancy testing are required for women of childbearing age. A comprehensive pregnancy prevention program for Toctino<sup>®</sup> has been developed and implemented. In clinical trials, Toctino<sup>®</sup> was well tolerated and demonstrated a safety profile overall consistent with the retinoid class. Overall, the most frequently reported adverse events in the phase III clinical trials were headache and increased levels of blood lipids. Side effects were dose dependent and reversible.

# About Chronic hand eczema (CHE) (1)

### Chronic hand eczema, a debilitating skin disease

Hand eczema is a common inflammatory skin disease and is often chronic and relapsing. Hand eczema is reported to affect up to ten percent of the general population. The more severe, chronic form of the condition is thought to affect five to seven percent of these patients, causing impaired use of their hands and a considerable impact on their ability to perform everyday activities.

#### **About Almirall**

Almirall, an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, 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 11 affiliates.

For further information please visit the website at: www.almirall.com

#### **About Basilea**

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX:BSLN). Its integrated research and development operations are currently focused on antibiotics and antifungals, as well as on the development of dermatology and oncology drugs, targeting the medical challenge of resistance and non-response to current treatment options in the hospital and specialty care setting.

Basilea is currently marketing Toctino® (alitretinoin), for the treatment of severe chronic hand eczema, in Denmark, France, Germany, Switzerland and the United Kingdom. The company has entered into a global partnership with Astellas Pharma Inc. for its phase III compound isavuconazole for the treatment of life-threatening invasive fungal infections. Full rights to a

third late-stage product, ceftobiprole for the treatment of potentially life-threatening resistant bacterial infections, will be transferred back to Basilea.

(1) Source: Diepgen TL, et al., Contact Dermatitis 2007; 57: 203-210

### More information:

Ketchum Pleon Sonia San Segundo/Victorino Ballesteros sonia.sansegundo@ketchumpleon.com

Tel.: 00 34 91 788 32 00