Annual Report 2007

In Detail

ACTELION

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01 Marketed Products

Summary of achievements

Actelion continued its strong performance in 2007 and further built its leadership position in pulmonary arterial hypertension (PAH) with Tracleer® (bosentan) sales of CHF 1,18 billion, a growth of 31% compared to the previous year (+32% in local currencies). This strong performance was seen in all regions worldwide, including the United States, Europe, and Japan in particular. It was also the first full year of marketing Ventavis® (iloprost) after the acquisition of CoTherix in the United States. In an increasingly competitive PAH market, Ventavis® was able to contribute CHF 78.2 million to our PAH franchise revenues.

These excellent results are particularly remarkable considering that new competition entered the market in 2007 within the class of endothelin receptor antagonists (sitaxentan in the European Union and ambrisentan in the United States). Actelion's in-depth knowledge of the PAH market, together with our highly professional and determined worldwide marketing and sales force, continued medical education activities, and further geographical expansion, were the basis for maintaining leadership and further growth.

Actelion further strengthened the profile of its flagship brand, Tracleer®. In 2007, we submitted an application in the US and Europe to expand the indication of Tracleer® for patients with PAH in WHO Functional Class II* (FC II), based on the conclusive results of the EARLY study – the only study investigating the effects of a PAH therapy specifically in a FC II patient group. With EARLY, Tracleer® has shown a significant effect on delaying time to clinical worsening, a measure of disease progression, in three separate randomized controlled trials.

The positive results of the double-blind, placebo-controlled, multi-national BENEFIT trial – which investigated the effects of Tracleer® in a patient population outside of WHO group I*, namely patients with chronic thromboembolic pulmonary hypertension (CTEPH) – further proved to the value of Tracleer® for patients. In June 2007, the EMEA granted approval in the European Union for an expansion of the indication of Tracleer® for reducing the number of new digital ulcers in patients suffering from systemic sclerosis and ongoing digital ulcer disease. Digital ulcers are a serious and very debilitating consequence of this disease.

Actelion's strong commitment to expand Tracleer® into new indications is demonstrated by the comprehensive clinical trial program, including the COMPASS trials (combination therapy), BUILD 3 (idiopathic pulmonary fibrosis) and FUTURE (pediatric indication).

Several marketing and life cycle activities were initiated for Ventavis® in 2007 to enhance its profile and set it up for continued success in 2008.

Zavesca® (miglustat), Actelion's second global brand, generated sales of CHF 35.3 million, a growth of 39% compared to the previous year. Increased awareness and acceptance of the value of Zavesca® for patients suffering from Type 1 Gaucher disease are the basis for future market share growth. New data published in 2007 confirmed the positive effects of Zavesca® on Gaucher disease related bone manifestations, and bone pain in particular, strengthening the competitive profile of the brand.

The submission for an expansion of the indication to patients suffering from Niemann-Pick Type C disease is still under review by the European regulatory authorities.

Actelion currently markets the following products:

Product	Indication(s)	Status	Commercialization rights
Tracleer®	Pulmonary arterial hypertension	marketed	Actelion
	Prevention of digital ulcers in patients with systemic sclerosis	registered(1)	Actelion
	Prevention of digital ulcers in patients with systemic sclerosis	in registration(2)	Actelion
Ventavis®	Pulmonary arterial hypertension	marketed	Actelion(3)
Zavesca®	Type 1 Gaucher disease	marketed	Actelion(4)

(1) Only in the EU
(2) A product is said to be "in registration" when it has completed Phase III clinical trials and its developer is in discussion with the relevant regulatory authorities relating to the filing of a new drug application for the product.
(3) Only in the USA.
(4) Except Israel, the West Bank and Gaza Strip.

* WHO clinical classification of pulmonary hypertension group diseases sharing similarities. PAH is WHO group 1. Group 1 comprises the following classifications:

I. Patients with pulmonary hypertension in whom there is no limitation of usual physical activity
II. Patients with pulmonary hypertension who have mild limitation of physical activity
III. Patients with pulmonary hypertension who have a marked limitation of physical activity
IV. Patients with pulmonary hypertension who are unable to perform any physical activity at rest and who may have signs of right ventricular failure.

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