



## Media Release

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10 August 2009

### **Ventavis (Iloprost) in pulmonary arterial hypertension receives US approval for increased 20 mcg/ml strength formulation**

**ALLSCHWIL, SWITZERLAND – 10 August 2009 – Actelion Ltd (SIX: ATLN)** announced today that the US Food and Drug Administration (FDA) has approved a new 20 microgram per milliliter (mcg/ml) formulation of Ventavis® as a therapy for New York Heart Association Class III and IV pulmonary arterial hypertension (PAH). This new increased 20 mcg/ml strength formulation will deliver the same dose in half the volume which is expected to reduce inhalation time and further support patient compliance.

The approval was based on the submission of technical data showing that the new formulation did not alter the functional characteristics of the delivery system or the emitted dose to the patient.

Jean-Paul Clozel, M.D. and Chief Executive Officer of Actelion commented: "This is another major improvement for Ventavis® in the US and for the patients who use this important inhaled therapy for PAH. The only inhaled prostacyclin therapy to show significant patient improvement measured by both exercise capacity and improvement in NYHA Functional Class. [1] In 2008, Actelion successfully implemented an improved cleaning protocol for the device which significantly reduced the time each patient spent on maintenance."

Jean-Paul added: "We have now been successful with this new strengthened formulation offering additional convenience for US patients using Ventavis®. We will continue our commitment to Ventavis® as well as our portfolio of PAH programs in order to achieve further improvements for the PAH community."

Dr. Harold Palevsky, Professor of Medicine at the University of Pennsylvania School of Medicine, Chief of the Pulmonary, Allergy and Critical Care Division, and Director of the Pulmonary Vascular Disease Program at Penn Presbyterian Medical Center in Philadelphia commented: "Ventavis is an important treatment option for many patients with PAH. Decreasing the time required per inhalation will allow these patients more time to focus on activities that are important in their lives. In addition, the new formulation should help maintain patient compliance, an important part of any PAH therapy"

### **About Ventavis®**

Ventavis® is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) in patients with NYHA Class III or IV symptoms.

In January 2007, Actelion announced the successful completion of its cash tender offer for shares of CoTherix, Inc., thereby strengthening its PAH franchise by adding Ventavis® to its product offerings in the United States. Bayer Schering Pharma - the inventor of Ventavis® - markets the drug as the first inhaled prostacyclin in Europe and other countries outside the US.

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### **Notes to Editor:**

#### **About Pulmonary Arterial Hypertension (PAH)**

Pulmonary arterial hypertension (PAH) is a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs of an affected individual. The function of the heart and lungs is severely compromised, manifested by a limited exercise capacity, and, ultimately, a reduced life expectancy. Approximately 100,000 people in Europe and the United States are afflicted with either primary or secondary forms of the disease related to conditions or tissue disorders that affect the lungs, such as scleroderma, lupus, HIV/AIDS or congenital heart disease.

PAH is associated with structural changes in both the pulmonary vasculature and the right ventricle. Recent advances [2] in the understanding of the pathogenic factors leading to the pulmonary vascular disease have led to the development of new therapies targeting specific pathways (the prostacyclin pathway; the endothelin pathway; and the nitric oxide pathway) [3]. The available therapies have positive effects in PAH, but they do not provide a cure, and in many patients the disease will progress. PAH remains a serious life-threatening condition [3,4]. Early recognition and an understanding of the selection and timing of therapeutic options remain critical elements in the optimal management of patients with this disorder.

#### **About Ventavis®**

Ventavis® (iloprost) is an inhaled synthetic analog of prostacyclin (PGI<sub>2</sub>) that produces potent pulmonary vasodilation and inhibits platelet aggregation, among other benefits. Prostacyclin functions as a hormone, binding to receptors on smooth muscle cells, thereby affecting their function. Prostacyclin has multiple physiological effects, including vasodilation, inhibition of platelet aggregation, antiproliferation, anti-inflammation, and enhanced cardiac contractility. Ventavis® is an inhaled synthetic prostacyclin which has been shown to:

- Significantly increase (p = 0.0033) patient improvement after 12 weeks of treatment compared to baseline on a composite endpoint of improved exercise capacity 30 minutes after dosing, improvement of at least one NYHA class and no clinical deterioration.
- Significantly improve 6-minute walk distance at week 12 with a 10% or greater increase in individual walk distance (p < 0.01).
- Significantly improve patients' functional class at week 12 (p = 0.03).

For patients with PAH (WHO Group 1) with NYHA Class III or IV symptoms [1]

## References

1. Ventavis® Prescribing Information
2. Farber HW; Loscalzo J. Mechanisms of disease: pulmonary arterial hypertension. N. Eng. J. Med. 2004; 351:1655-65.
3. Humbert M; Sitbon O; Simonneau G. Treatment of pulmonary arterial hypertension. N. Eng. J. Med. 2004;351:1425-36.
4. Humbert M; Morrell NW; Archer SL; et al. Cellular and molecular pathobiology of pulmonary arterial hypertension. J. Am. Coll. Cardiol. 2004; 43: Suppl. 12: 13S-24S.

## Actelion Ltd

Actelion Ltd is a biopharmaceutical company with its corporate headquarters in Allschwil/Basel, Switzerland. Actelion's first drug Tracleer®, an orally available dual endothelin receptor antagonist, has been approved as a therapy for pulmonary arterial hypertension. Actelion markets Tracleer® through its own subsidiaries in key markets worldwide, including the United States (based in South San Francisco), the European Union, Japan, Canada, Australia and Switzerland. Actelion, founded in late 1997, is a leading player in innovative science related to the endothelium - the single layer of cells separating every blood vessel from the blood stream. Actelion's over 2000 employees focus on the discovery, development and marketing of innovative drugs for significant unmet medical needs. Actelion shares are traded on the SIX Swiss Exchange (ticker symbol: ATLN) as part of the Swiss blue-chip index SMI (Swiss Market Index SMI®).

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