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European Agency Approves Ventavis for Primary Pulmonary Hypertension

BERLIN, Sept. 22 /PRNewswire-FirstCall/ -- Schering AG, Germany (NYSE: SHR; FSE: SCH) announced today that the European Commission in a Centralized Procedure approved Schering's new drug Ventavis(R) for marketing in all EU countries. Ventavis(R) is an inhalation treatment for patients with primary pulmonary hypertension. It is the only prostacyclin product that targets the pulmonary vessels more directly by inhalation.

"Ventavis(R) improves the therapy for patients affected by severe symptoms and heart failure. It is a new, convenient treatment option for patients suffering from a life threatening disease," said Dr. Hubertus Erlen, CEO and Chairman of the Executive Board of Schering AG. "We will offer Ventavis(R) as soon as possible to doctors and patients in the EU countries."

Schering plans to start marketing Ventavis(R) in the first EU countries in 2003 and to roll-out the product in Europe fully by 2004. Ventavis(R) was designated as an orphan medicinal product in December 2000 and will fall under orphan drug protection until 2013.

Additional information
In May 2003, Schering received the positive opinion from the Committee of Proprietary Medicinal Products (CPMP). The CPMP is the scientific committee for human medicinal products of the European Agency for the Evaluation of Medicinal Products (EMEA) and its positive opinion a prerequisite of the EU decision.

The active substance of Ventavis(R) is iloprost, a synthetic prostacyclin analogue. The pharmacological effects after inhalation of Ventavis(R) are direct vasodilatation of the pulmonary arterial bed with consecutive significant improvement of pulmonary artery pressure, pulmonary vascular resistance and cardiac output as well as mixed venous oxygen saturation.

The benefits of Ventavis(R) include improvements in exercise capacity and symptoms. A randomized, double-blind, multi-center, placebo-controlled phase III trial has been conducted in 203 adult patients with stable pulmonary hypertension. Inhaled iloprost (or placebo) was added to patients' current therapy, which could include a combination of anticoagulants, vasodilators (e.g. calcium channel blockers), diuretics, oxygen, and digitalis, but not prostacyclin or its analogues.

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