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## **Pulmozyme early intervention shows sustained maintenance of lung function in Cystic Fibrosis** Pulmozyme Reduces Risk of Respiratory Tract Infections by 34 percent

Roche announced today that the results of a clinical trial of Pulmozyme (dornase alfa), a currently approved treatment for cystic fibrosis (CF), demonstrated a significant benefit in pulmonary function when Pulmozyme was administered to early-stage CF patients for two years. The new data, presented at the North American Cystic Fibrosis Conference (NACFC) in Baltimore, also showed that Pulmozyme reduced patient risk for respiratory tract infections by 34 percent when compared to placebo.

"This study is especially important since two critical factors in managing cystic fibrosis are minimizing respiratory tract infections, and improving overall pulmonary function," said one of the lead investigators Dr Harm Tiddens, Department of Pediatrics-Lung Diseases, Sophia Children's Hospital, The Netherlands. "We are especially encouraged that Pulmozyme, already shown to be a safe and effective option in treating mild-to-moderate cystic fibrosis, also provides a significant benefit to patients with early-stage disease."

### **About Cystic Fibrosis**

Cystic fibrosis is an inherited disorder that affects approximately 60,000 people world-wide. A defective gene in CF patients leads to the production of thick viscous secretions, which can cause persistent bacterial infections and congestion. As white blood cells attempt to destroy bacteria, they release DNA, which further thickens the secretions. These thick secretions encourage and prolong respiratory tract infections, which damage lung tissue and ultimately lead to death. The median survival age for CF patients is about 32 years.

### **Pulmozyme Early Intervention Trial Summary**

The Pulmozyme Early Intervention Trial (PEIT) was designed to determine whether Pulmozyme, when initiated at an early stage of CF, maintains pulmonary function and reduces the risk of respiratory tract infections requiring intravenous antibiotics. A total of 474 early-stage CF patients (from 6 to 10 years of age) were enrolled at 49 centres in 12 countries for the two-year trial (96 weeks).

Patients received Pulmozyme (2.5 mg) or placebo daily, via a nebulizer. Measurements for FEV<sub>1</sub>, FEF<sub>25-75</sub>, V<sub>E50</sub> and FVC<sup>1</sup> were taken regularly throughout the trial - at the beginning of the study, week 4, week 12 and every 12 weeks thereafter.

239 patients treated with Pulmozyme performed significantly better than those receiving placebo (n=235) in the key pulmonary function tests: FEV<sub>1</sub> (3 percent better than placebo) and FEF<sub>25-75</sub> and V<sub>E50</sub> (both 8 percent better than placebo). Additionally, the risk of respiratory tract infections was reduced in the Pulmozyme group by 34 percent, compared to placebo.

### **About Pulmozyme**

Pulmozyme Solution for Inhalation, a recombinant human deoxyribonuclease 1, is a bioengineered copy of a naturally occurring enzyme in the body. Pulmozyme is approved for the management of CF patients over 5 years of age and with forced vital capacity (FVC) over 40% of predicted, to improve pulmonary function.

Pulmozyme acts like molecular scissors, "cutting up" the excess DNA in the thick secretions that line CF patients' airways, to thin out the secretions and aid in their clearance from the lungs. When used every day, Pulmozyme helps make breathing easier and reduces the number of serious lung infections that require antibiotic treatment. Pulmozyme is marketed by Roche and, in the US, by Genentech Inc.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life. Roche has approximately 62,000 employees and sells its products in over 170 countries. The Roche Group posted sales of 20.3 billion Swiss francs in the first nine months of 2000. In the first half of 2000 the company's net income amounted to 3 billion Swiss francs. It invested 1.9 billion Swiss francs in research and development.

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<sup>1</sup>The FEV<sub>1</sub> (forced expiratory volume) test measures the volume of air exhaled in the first second, and is used to gauge the severity of CF. The FEF<sub>25-75</sub> (forced expiratory flow) and V<sub>E50</sub> (mid-expiratory flow) tests measure the flow of exhaled air at different stages of a breath, and are sensitive indicators of pulmonary function in the small airways, where CF begins. FVC (forced vital capacity) is a test to measure the overall volume of exhaled air.

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