**Indication & Important Safety Information**

**Indication**

Pulmozyme (dornase alfa) is indicated for daily administration in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with an FVC ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

**Important Safety Information**

Pulmozyme is contraindicated in patients with known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product.

The most common adverse reactions associated with the use of Pulmozyme include: voice alteration, pharyngitis, rash, laryngitis, chest pain, conjunctivitis, rhinitis, decrease in FVC of ≥ 10%, fever, dyspepsia, and dyspnea. There have been no reports of anaphylaxis attributed to the administration of Pulmozyme. Mild to moderate urticaria and mild skin rash have been observed and have been transient.

For further information, please see the Pulmozyme full Prescribing Information.
Important Safety Information (cont)

PEDiatric USE

The safety and effectiveness of Pulmozyme have been established in pediatric patients 5 years of age and older. The safety of Pulmozyme, 2.5 mg by inhalation, was studied with 2 weeks of daily administration in 65 patients with cystic fibrosis aged 3 months to < 5 years. While clinical trial data are limited in pediatric patients younger than 5 years of age, the use of Pulmozyme should be considered for pediatric CF patients who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.

The safety of Pulmozyme, 2.5 mg by inhalation, was studied with 2 weeks of daily administration in 98 pediatric patients with cystic fibrosis 3 months to 10 years of age (65 aged 3 months to < 5 years, 33 aged 5 to ≤ 10 years). The PARI BABY™ reusable nebulizer (which uses a facemask instead of a mouthpiece) was utilized in patients unable to demonstrate the ability to inhale or exhale orally throughout the entire treatment period (54/65, 83% of the younger; and 2/33, 6% of the older patients). Overall, the nature of adverse reactions was similar to that seen in the placebo-controlled trials in older patients. The number of patients reporting cough was higher in the younger age group as compared to the older age group (29/65, 45%; compared to 10/33, 30%) as was the number reporting moderate to severe cough (24/65, 37%; compared to 6/33, 18%). The number of patients reporting rhinitis was higher in the younger age group as compared to the older age group (23/65, 35%; compared to 9/33, 27%) as was the number reporting rash (4/65, 6% as compared to 0/33, 0%).

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

For further information, please see the Pulmozyme full Prescribing Information.