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CHUGAI
Roche Group

Translation

Launch of an Orphan Drug, "Pulmozyme®," a Recombinant Human Deoxyribonuclease I (rhDNase)

June 7, 2012 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it will launch on June 8, 2012, Pulmozyme® Inhalation Solution 2.5mg (hereafter, "Pulmozyme®")[recombinant human deoxyribonuclease I (rhDNase), generic name: dornase alfa] for "improvement of pulmonary function in patients with cystic fibrosis." Pulmozyme® received a manufacturing and marketing approval on March 30, 2012 and was listed on the National Health Insurance (NHI) reimbursement price list on May 29, 2012. Pulmozyme® is designated as an orphan drug for this indication by the Ministry of Health, Labour and Welfare (MHLW).

As a result of the evaluation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs*" held on April 18, 2011, it was concluded that it is reasonable that dornase alfa be filed for approval in this indication based on available data, and on July 15, 2011, the filing was made using overseas data. In overseas clinical studies, administration of dornase alfa by inhalation is confirmed to be effective for the improvement of pulmonary function and reduction of the risk of serious infection of the respiratory tract in cystic fibrosis patients, compared to placebo.

In Japan, the incidence of cystic fibrosis is only about one in 1.87 million, and according to MHLW-supported research done in 2009, "Investigational study on refractory pancreatic disease," there were 15 patients estimated in Japan in 2009. Cystic fibrosis is caused by genetic mutation of CFTR, a chloride ion-channel. There is no curative treatment for this disease, and typically, expectorants and bronchodilators are administered for respiratory tract disturbances, and antibiotics by inhalation or systemic treatment are used to treat infection.

Pulmozyme® cleaves extracellular DNA in the mucus of cystic fibrosis patients, reducing the adhesiveness and viscoelasticity of the mucus. Overseas, it is approved in approximately 70 countries including the U.S. and Europe, and is administered to around 50 thousand patients per year, as one of the standard treatments for cystic fibrosis.

Chugai is committed to contribute to the treatment of this very rare and difficult to treat disease in Japan, by providing "Pulmozyme®," a new treatment option that will enable better control of respiratory symptoms in cystic fibrosis.

* The "Review Committee on Unapproved Drugs and Indications with High Medical Needs" was established for the purpose of "enhancing development by pharmaceutical companies of drugs and indications that have been approved for use in the Western countries but not yet approved in Japan. Its activities include evaluating medical needs, confirming the appropriateness of an application based on evidence in the public domain and investigating the need for studies that should be additionally conducted."

[Reference information]

Brand name: Pulmozyme® Inhalation Solution 2.5mg

Japan accepted name (JAN): dornase alfa

Indications: improvement of pulmonary function in patients with cystic fibrosis

Dosage and administration:
The usual dosage is 2.5 mg dornase alfa (recombinant) inhaled once daily using a nebuliser. Based on the patient's condition, a 2.5-mg dose can be inhaled up to two times daily.

Date of approval: March 30, 2012

Date of listing in the NHI reimbursement price: May 29, 2012

Date of launch: June 8, 2012

Shelf life: 2 years

NHI price: Pulmozyme® Inhalation Solution 2.5mg / 6664.80 yen