

April 22, 2011

Press Release

Abbott Japan Co., Ltd.
Eisai Co., Ltd.

Abbott Japan and Eisai Receive Approval to Market the Pancreatic Digestive Enzyme Replacement Drug Lipacreon® (pancrelipase) in Japan

Abbott Japan Co., Ltd. (Pharma Products Group Headquarters: Tokyo, President: Gary M. Winer) and Eisai Co., Ltd. (Headquarters: Tokyo, President: Haruo Naito) announced today that they have received approval to market the pancreatic enzyme replacement drug Lipacreon® (pancrelipase) in Japan as a pancreatic digestive enzyme replacement in patients with pancreatic exocrine insufficiency (PEI). While Abbott Japan is the marketing authorization holder of Lipacreon®, Eisai intends to sell the drug once it is listed on the National Health Insurance (NHI) price list.

Lipacreon® is the first pancreatic digestive enzyme replacement drug to be approved in Japan for the treatment of PEI due to chronic pancreatitis, pancreatectomy, cystic fibrosis and other conditions. The drug contains high-titer pancreatic enzymes such as amylase, lipase and protease, which have been extracted and purified from porcine pancreas.

In Europe and North America, enzyme-replacement therapy using high-titer pancreatin is recognized as a fundamental treatment for PEI and Lipacreon® is already sold in over 80 countries around the world including Germany, the United Kingdom and the United States under the brand names Creon® and Kreon®.

The results of a placebo-controlled double-blind trial carried out in Japan in patients with PEI due to chronic pancreatitis or pancreatectomy showed a significant improvement compared with placebo in fat absorption before and after the administration of Lipacreon® as calculated from the volume of fat intake and the volume of fat in the patients' stools. In addition, a long-term trial found a significant improvement in nutritional endpoints. Further, a clinical trial in patients with PEI due to cystic fibrosis also demonstrated significant improvements in fat absorption. While the most commonly reported adverse effects of Lipacreon® include constipation, diarrhea, fever, abdominal distension and hyperglycemia, it has been confirmed to have a favorable tolerability profile.

In comparison with Japanese Pharmacopoeia-listed pancreatin, the titer per unit weight of Lipacreon® is approximately 8 times that of lipase, approximately 7 times that of protease and approximately 6 times that of amylase. The product also has an enteric coating to prevent gastric juices from causing inactivity. Further, because the product has been designed with an optimal granule diameter to ensure that it passes into the duodenum, it is expected to effectively encourage digestion and absorption in PEI patients, thereby improving their nutritional health.

Both Abbott Japan and Eisai will make contributions to improving the quality of life of PEI patients by providing Lipacreon® as a new treatment for PEI.

[Please refer to the following notes for a product outline, glossary of terms and further information about Abbott]

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Notes to editors

1. Lipacreon® Product Outline

1) Product Name

Lipacreon® Granules 300mg Sachets

Lipacreon® Capsules 150mg

2) Generic name

Pancrelipase

3) Indications and Usage

Pancreatic digestive enzyme replacement for the treatment of pancreatic exocrine insufficiency

4) Dosage and Administration

Pancrelipase should be administered orally immediately after meals at a dose of 600mg three times a day. The dose can be adjusted as appropriate for each patient.

2. Glossary of Terms

1) Pancreatic Exocrine Insufficiency (PEI)

Pancreatic exocrine insufficiency (PEI) is a collective term that refers to the inability to digest and absorb fats, proteins and carbohydrates due to a lack of pancreatic enzymes that would ordinarily be secreted by the pancreas into the duodenum, as a result of reduced pancreatic exocrine function. PEI can cause conditions such as fatty stools, diarrhea, fat-soluble vitamin deficiency and fatty acid deficiency, which in turn results in a weight loss and malnutrition. These symptoms not only decrease the quality of life of patients, they also increase the risk of contracting infectious diseases and developing other complications.

2) Chronic Pancreatitis

Chronic pancreatitis refers to the ongoing and repeated inflammation of the pancreas, an irreversible condition that results in the gradual fibrosis of the entire pancreas as pancreatic cells are gradually destroyed. The causes of chronic pancreatitis are not yet entirely known, however, approximately 60% of patients are said to develop the condition as a result of excessive alcohol intake. According to a nationwide study carried out by the Japanese Ministry of Health, Labour and Welfare's Research Committee for Intractable Diseases of the Pancreas as part of the Ministry's research into measures against intractable diseases, approximately 47,100 chronic pancreatitis patients sought treatment at medical institutions in 2007. Prevalence within the population is estimated at 36.9 people per 100,000.

3) Cystic fibrosis

Cystic Fibrosis (CF) is a disease which affects not only the pancreas but also exocrine glands throughout the entire body that secrete digestive fluids and mucus, including the airways and the intestine. The disease occurs due to genetic mutation and is more common in Caucasians while being extremely rare among Japanese people. CF is designated in Japan as a specified rare and intractable disease. CF is almost always diagnosed shortly after birth or during early infancy. Currently, approximately 30 people in Japan are thought to have the condition.

3. About Abbott

Headquartered in Chicago, Illinois, Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 83,000 people and markets its products in more than 130 countries.

In Japan, approximately 2,800 Abbott employees are devoted to the manufacture, development, distribution, and marketing of pharmaceuticals and medical products, including nutritionals, devices, diagnostics, and products for vision care. Abbott's main offices in Japan are located in Tokyo, Fukui, and Chiba. News releases issued by Abbott Japan and Abbott Headquarters are available at www.abbott.co.jp and www.abbott.com, respectively.