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FDA Approves FRAGMIN[®] as First Low-Molecular-Weight Heparin for Extended Treatment to Reduce the Recurrence of Blood Clots in Patients with Cancer

WOODCLIFF LAKE, NJ and NEW YORK, NY – MAY 2, 2007 —The U.S. Food and Drug Administration (FDA) has approved a new indication for FRAGMIN[®] (dalteparin sodium injection), for the extended treatment of symptomatic venous thromboembolism (VTE) [proximal deep vein thrombosis (DVT) and/or pulmonary embolism (PE)] to reduce the recurrence of VTE in patients with cancer.

VTE is the formation of a blood clot that can travel from a leg vein to the lung, with potentially fatal results. FRAGMIN is the first low-molecular-weight heparin (LMWH) approved in the U.S. for the extended treatment of recurrent VTE in patients with cancer.

“Cancer treatments and the disease itself put this patient population at significantly higher risk than non-cancer patients for developing DVT or PE, the two conditions described as VTE,” said Frederick Rickles, MD, FACP, clinical professor of medicine at George Washington University Medical Center.

VTE is a frequent medical complication for patients with cancer. Patients with cancer have an increased risk of VTE compared to those without cancer. Additionally, patients with cancer may be immobilized, which predisposes the patient to this condition.

Today’s FDA approval is based on data from the CLOT^{*} study, which evaluated the safety and efficacy of FRAGMIN in reducing the recurrence of DVT/PE in patients with cancer, compared to an oral anticoagulant. Patients diagnosed with acute DVT, PE or both were randomized into two groups of 338 patients each. One group received FRAGMIN for six months. The other group received FRAGMIN for five to seven days, followed by warfarin for six months. Warfarin is an oral anticoagulant that has been used for many years as the standard drug in the long-term treatment of VTE.

The CLOT study showed that, during a six-month period, nearly twice as many patients (53) treated with warfarin experienced at least one episode of DVT or PE compared to those treated

* CLOT refers to the Randomized Comparison of Low-Molecular-Weight Heparin versus Oral Anticoagulant Therapy for the Prevention of Recurrent Venous Thromboembolism in Patients with Cancer (CLOT).

with a once-daily administration of FRAGMIN (27). Most of the difference occurred during the first month of treatment. The benefit was maintained over the six-month study period. Mortality rates were similar between the study groups at the end of the study. The safety findings were numerically higher for the FRAGMIN group versus the warfarin group for major bleeding, thrombocytopenia (drop in platelet count) and liver enzyme elevations. Results from the CLOT study were published in the July 10, 2003 issue of the *New England Journal of Medicine*.

“The CLOT study provides clinical evidence that FRAGMIN is more effective than traditional oral anticoagulant therapy in reducing risk of recurrent VTE in patients with cancer,” said Dr. Rickles. “Physicians now have an FDA-approved low-molecular-weight heparin specifically for extended treatment to reduce the recurrence of blood clots in patients with cancer.”

Eisai licensed exclusive U.S. rights to promote FRAGMIN from Pfizer Inc in September 2005, and has assumed responsibility for product distribution. This agreement for FRAGMIN is aimed at strengthening Eisai’s position in oncology and critical care in the United States. Eisai and Pfizer currently have three product alliances.

Additional Indications

In the United States, FRAGMIN is also indicated for prevention of DVT, which may lead to PE, in patients undergoing hip replacement surgery, in at-risk patients undergoing abdominal surgery and in at-risk acutely ill patients whose mobility is severely restricted. FRAGMIN is also approved for prophylaxis of ischemic complications resulting from unstable angina and non-Q-wave myocardial infarction (heart attack), when used with aspirin.

Important Safety Information

SPINAL/EPIDURAL HEMATOMAS

When neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is employed, patients anticoagulated or scheduled to be anticoagulated with low molecular weight heparins or heparinoids for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events is increased by the use of indwelling epidural catheters for administration of analgesia or by the concomitant use of drugs affecting hemostasis such as non steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants. The risk also appears to be increased by traumatic or repeated epidural or spinal puncture.

Patients should be frequently monitored for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

The physician should consider the potential benefit versus risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis (also see WARNINGS, Hemorrhage and PRECAUTIONS, Drug Interactions).

FRAGMIN is contraindicated in patients with active major bleeding or with known hypersensitivity to the drug, heparin, or pork products, or with thrombocytopenia associated with a positive anti-platelet antibody test. It should be used with extreme caution in patients with a history of heparin-induced thrombocytopenia.

Patients undergoing regional anesthesia should not receive FRAGMIN for unstable angina or non-Q-wave myocardial infarction, and patients with cancer undergoing regional anesthesia should not receive FRAGMIN for extended treatment of symptomatic VTE, due to an increased risk of bleeding associated with the dosage of FRAGMIN recommended for these indications.

FRAGMIN cannot be used interchangeably (unit for unit) with unfractionated heparin or other low-molecular-weight heparins.

FRAGMIN, like other anticoagulants, should be used with extreme caution in patients who have an increased risk of hemorrhage; bleeding can occur at any site during therapy. An unexpected drop in hematocrit or blood pressure should lead to a search for a bleeding site.

The most commonly reported side effect is hematoma at the injection site.

Please see www.FRAGMIN.com for full prescribing information.

FRAGMIN is a registered trademark of Pfizer Health AB and is licensed to Eisai Inc.

About Eisai Inc.

Eisai Inc. is a U.S. pharmaceutical subsidiary of Eisai Co., Ltd., a research-based human health care (hhc) company that discovers, develops and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: neurology, gastrointestinal disorders and oncology/critical care. Established in 1995, Eisai Inc. began marketing its first product in the United States in 1997 and has rapidly grown to become an integrated pharmaceutical business with sales of approximately \$2.2 billion in fiscal year 2005 (year ended March 31, 2006).

About Pfizer Inc

Founded in 1849, Pfizer is the world's largest research-based pharmaceutical company taking new approaches to better health. We discover and develop innovative medicines to treat and help prevent disease for both people and animals. Through consistent, high-quality manufacturing and distribution operations, our medicines reach patients in 180 nations. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality healthcare and health system support. At Pfizer, our colleagues work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

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