

Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

FDA Approves FRAGMIN[®], an Injectable Anti-Clotting Agent, for Extended Treatment to Reduce the Recurrence of Blood Clots in Patients with Cancer

Eisai Co., Ltd. announced today that on May 1, 2007 (the U.S. Eastern time) the U.S. Food and Drug Administration (FDA) 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. With this approval, 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.

The FDA approval is based on data from the CLOT^{*} study, which evaluated the safety and efficacy of FRAGMIN[®] compared to warfarin sodium (an oral anticoagulant that has been used for many years as the standard drug in the long-term treatment of VTE). The six-month study involved 672 patients with DVT, PE or both. The study demonstrated that FRAGMIN[®] significantly reduced the risk of recurrent DVT/PE in patients with cancer compared to warfarin.

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.

Eisai is positioning oncology as one of its areas of focus. Aided in part through its acquisition of four oncology products from Ligand Pharmaceuticals Inc. (Headquarters: California, Chairman and interim CEO: Henry F. Blissenbach) in October 2006 and the acquisition in April 2007 of a U.S. biopharmaceutical company that discovers and develops monoclonal antibodies, Morphotek Inc. (Headquarters: Pennsylvania, President & CEO: Dr. Nicholas Nicolaides), Eisai is currently expanding its global oncology research as well as commercial infrastructure to prepare for marketing new oncology products.

With this approval, Eisai hopes to strengthen its oncology-related product portfolio, through which the company aims to make further contributions to increasing the benefits to cancer patients and their families.

[Please see the following notes for the CLOT Study data of FRAGMIN[®] submitted to FDA and glossary]

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^{*} 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).

<Notes to Editor>

About the CLOT study data submitted to FDA

The FDA approval is based on data from the CLOT study, which evaluated the safety and efficacy of FRAGMIN[®] compared to warfarin sodium, an oral anticoagulant that has been used for many years as the standard drug in the long-term treatment of VTE.

Patients diagnosed with acute DVT, PE or both were randomized into two groups of 336 patients each. One group received warfarin sodium, while the other group received FRAGMIN[®], for six months.

The study demonstrated that a once-daily administration of FRAGMIN[®] during a six-month period significantly reduced (P=0.002) the risk of recurrent DVT/PE by 52 percent in patients with cancer compared to warfarin sodium. Results from the CLOT study were published in the July 10, 2003 issue of the *New England Journal of Medicine*.

Glossary

1. Venous Thromboembolism (VTE)

A proximal (rather than peripheral) deep vein thrombosis (DVT) – that is, the formation of a blood clot near the center or trunk of the body that can travel from a leg vein to the lung – and /or a pulmonary embolism (PE) – a blood clot in the lung.

2. Deep Vein Thrombosis (DVT)

DVT is caused by blood clots in the veins, which can break away, travel to the lungs and cause pulmonary embolisms. Symptoms of DVT commonly occur in just one leg and include pain or tenderness and swelling or redness. However, half of all DVT patients show no symptoms.

3. Pulmonary Embolism (PE)

PE is a condition where blood clots formed elsewhere in the body migrate to the lungs and obstruct the pulmonary artery or a branch of it, impairing the arterial circulation in the lungs. Common symptoms of PE involve shortness of breath and chest pain when breathing. Approximately 30% of all DVT cases are said to develop PE.

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