July 16, 2004

New Treatment Guidelines Cite ReoPro Favorably for PCI in Acute Heart Attack Patients

July 16, 2004

New guidelines issued by the American College of Cardiology and the American Heart Association are in favor of using ReoPro® (abciximab) in acute heart attack patients (ST-Elevation Myocardial Infarction or STEMI) who are having a balloon or stenting procedure (PCI). ReoPro, a glycoprotein IIb/IIIa inhibitor, is indicated for adjunctive use with PCI for the prevention of cardiac ischemic complications in patients undergoing this procedure.

"ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction - Executive Summary" was published July 13 in *Circulation*. In addition, the guidelines will be featured in the July 21 issue of the *Journal of the American College of Cardiology*. The last revision of the guidelines related to the treatment of patients with acute heart attacks was in 1999. Cardiologists use these guidelines to help manage more severe heart attack patients.

ReoPro received the "Class IIa, level of evidence B" recommendation in the new guidelines, meaning that the treatment is useful/effective but may have some conflicting evidence from a clinical trial. The guidelines are in favor of starting treatment with ReoPro as early as possible before primary PCI (with or without stenting) in patients with STEMI. Dosing and administration instructions for ReoPro indicate that ReoPro should be administered 10 to 60 minutes before the start of PCI.

"We are very pleased to get this recommendation. We believe ReoPro in conjunction with PCI is an excellent choice to help manage acute heart attack patients as well as many other patients who are having a balloon or stenting procedure," said Dr. Mark Effron, medical director, U.S. Acute Care, Eli Lilly and Company. "ReoPro has been studied extensively, including more than five randomized clinical trials in ST-elevation MI, as well as many other trials in a variety of patient types."

Nationwide, an estimated 500,000 people have an acute heart attack annually, according to the ACC. Aggressive recognition and treatment of acute heart attacks, as outlined in these guidelines, including the use of ReoPro with PCI, may contribute to a reduction in death and complications from this disease.

About ReoPro

ReoPro is a member of a class of drugs known as glycoprotein (GP) IIb/IIIa inhibitors that target the platelet component of blood clots and reduce the complications associated with blood flow restrictions during coronary intervention, including angioplasty and stenting. In these settings, ReoPro prevents complications associated with thrombi (blood clots), and has shown this in clinical trials by reducing the incidence of a composite of mortality, repeat heart attacks, or repeat PCI. ReoPro has the potential to increase the risk of bleeding, particularly in the presence of anti-coagulation agents, e.g., from heparin or other anticoagulants. The risk of a major bleed due to ReoPro therapy is increased in patients receiving thrombolytics and should be weighed against the anticipated benefits.

Because ReoPro may increase the risk of bleeding, its use is contraindicated in the following clinical situations: active internal bleeding, recent (within six weeks) gastrointestinal (GI) or genitourinary (GU) bleeding of clinical significance, history of cerebrovascular accident (CVA) within two years, or CVA with a significant residual neurological deficit, bleeding diathesis, administration of oral anticoagulants within seven days unless prothrombin time $\leq$1.2 times control, thrombocytopenia (<100,000 cells/µL), recent (within six weeks) major surgery or trauma, intracranial neoplasm, arteriovenous malformation, or aneurysm, severe uncontrolled hypertension, presumed or documented history of vasculitis, use of intravenous dextran before percutaneous coronary intervention, or intent to use it during intervention, known hypersensitivity to any component of this product or to murine proteins.

In clinical trials, patients treated with ReoPro were more likely than patients who received placebo to experience decreases in platelet counts, including severe thrombocytopenia.

Administration of ReoPro may result in the formation of human anti chimeric antibodies (HACA) that could potentially cause allergic or hypersensitivity reactions (including anaphylaxis), thrombocytopenia, or diminished benefit upon readministration. ReoPro readministration may be associated with an increased incidence and severity of thrombocytopenia. This increased risk was associated with a history of thrombocytopenia on prior ReoPro exposure, a positive HACA assay at baseline, and

readministration within 30 days.

Full prescribing information for ReoPro is available by calling 1-800-545-5979.

ReoPro was developed by Centocor of Malvern, Pa., USA, and is manufactured by Centocor, B.V., in Leiden, the Netherlands. Eli Lilly and Company markets and distributes the product worldwide except in Japan.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

About Centocor

Centocor is a leading biopharmaceutical company that creates, acquires and markets cost-effective therapies that yield long-term benefits for patients and the health care community. Its products, developed primarily through monoclonal antibody technology, help physicians deliver innovative treatments to improve human health and restore patients' quality of life. Centocor is a wholly owned subsidiary of Johnson & Johnson, a worldwide leader of health care products.

ReoPro® (abciximab, Centocor), Lilly