



FIRST DIRECT THROMBIN INHIBITOR FOR DVT PREVENTION NOW AVAILABLE FROM CANYON PHARMACEUTICALS

Iprivask[®] (desirudin for injection) Is First Alternative to Heparin Introduced in Nearly a Decade

PARSIPPANY, NJ, March 1, 2010 – Canyon Pharmaceuticals™ (www.canyonpharma.com) today announced the availability of Iprivask (desirudin for injection), the first direct thrombin inhibitor (DTI) approved in the United States by the Food and Drug Administration (FDA) for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism in patients undergoing elective hip replacement surgery.

In head-to-head clinical trials, Iprivask was found to be superior to both heparin and low-molecular weight heparin (LMWH) enoxaparin for the prevention of proximal DVT and for major venous thromboembolic events (VTE) after elective hip replacement surgery. VTE, one of the most common complications in surgical patients, is associated with increased hospital costs, length of stay, morbidity, and mortality.^{1,2}

Vic Tapson, MD, Professor of Medicine at Duke University, said: "Desirudin is an important advance and promises to be a valuable alternative to heparin-based DVT prophylaxis agents."

Few alternatives exist to heparin-based anticoagulation for DVT prophylaxis in the hospitalized patient. VTE prophylaxis therapy with heparin-based anticoagulation can be complicated by a variety of untoward events including thrombocytopenia, which has been shown to increase short-term mortality.³ The development of thrombocytopenia often results in suspension of VTE prophylaxis with heparin leaving patients unprotected for a period of time due to the lack of alternatives.⁴

"Significant need exists in the US for alternatives to heparin-based anticoagulants that are more effective and easier to use than currently available DTIs. Desirudin becoming available is a step forward in that direction," said Craig Kessler, MD, Georgetown University Professor of Medicine and Pathology and Section Chief of Hematology.

Kessler pointed out that because Iprivask is administered as a fixed subcutaneous dose, "it is easier to use than intravenous DTIs and provides a safer alternative for DVT prophylaxis."

"Iprivask is a promising advance because it is superior to the current standard of care in preventing proximal DVT and major VTE, with no difference in bleeding," said Dawn Bell, PharmD, Senior Vice President and General Manager of Canyon Pharmaceuticals. "It does not have a risk for thrombocytopenia or heparin-induced thrombocytopenia, is relatively short-acting, and is easy to monitor."

"We are excited to be launching the first new DVT prophylaxis agent in nearly 10 years," said Seng Chin Mah, CEO, Canyon Pharmaceuticals. "Iprivask is an important addition to the DVT prophylaxis armamentarium because options for DVT prophylaxis are limited, especially in the peri-operative setting."

March is DVT Awareness Month

The Coalition to Prevent DVT (www.preventdvt.org) has declared March DVT Awareness Month to raise awareness of this serious medical condition among consumers, healthcare professionals, and government and public health leaders. According to the American Heart Association (www.americanheart.org), up to two million Americans are affected annually by DVT. Of those who develop pulmonary embolism (PE), up to 200,000 will die each year. More Americans die annually from DVT/PE than from breast cancer and AIDS combined (ClotCare).⁵

The Office of the Surgeon General and the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health recently issued a “Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism.”⁶ The report acknowledged that substantial gaps exist in our knowledge of how to best provide adequate VTE prophylaxis in certain patient subgroups.

About Iprivask

Iprivask is modeled after hirudin, a naturally occurring anticoagulant found in the saliva of medicinal leeches. It acts by directly inhibiting thrombin, an essential protein in blood clotting.

Iprivask is provided as a unique unit-dose package that facilitates easy bedside reconstitution and administration. Iprivask is much less expensive than other DTIs – the cost is \$150/vial compared with other non-heparin options which require monitoring and intravenous administration and cost \$600 to \$1000 per day. Iprivask was the first DTI approved for DVT prophylaxis in Europe, where it has been on the market for more than 10 years under the trade name Revasc[®].

Iprivask is contraindicated in patients with known hypersensitivity to natural or recombinant hirudins, and in patients with active bleeding and/or irreversible coagulation disorders. Iprivask must be used with caution in patients with renal impairment, particularly in those with moderate and severe renal impairment. Based on use during the clinical trials in 2159 patients undergoing elective hip replacement surgery, a comparable incidence of hemorrhagic events was seen in patients using Iprivask, heparin, and enoxaparin.

According to the labeling, nonhemorrhagic adverse events occurring at greater than a 2% incidence in patients treated with Iprivask 15 mg during elective hip replacement surgery *and* considered to be remotely, possibly, or probably related to the drug were: injection site mass, wound secretion, anemia, deep thrombophlebitis, and nausea. Adverse events with a frequency of less than 2% and greater than 0.2% were, in decreasing order of frequency: thrombosis, hypotension, leg edema, fever, decreased hemoglobin, hematuria, dizziness, epistaxis, vomiting, impaired healing, cerebrovascular disorder, leg pain, and hematemesis.

According to the labeling, because neuraxial hematoma formation is possible with the use of Iprivask in patients undergoing spinal/epidural anesthesia, frequent monitoring is required. The physician should consider placement of the catheter prior to initiating desirudin and removal of the catheter when the anticoagulant effect of desirudin is low.

About Canyon Pharmaceuticals™

Canyon Pharmaceuticals™ is a privately held specialty biopharmaceuticals company focused on delivering innovative therapeutic solutions that target important cellular pathways in thrombosis and tumor growth. Canyon holds exclusive world-wide rights to desirudin, a subcutaneous (SC) recombinant direct thrombin inhibitor (DTI), and to pegmusirudin, a pegylated recombinant DTI with a longer duration of action than desirudin.

This press release contains forward-looking statements, which involve risks and uncertainties within the meaning of the Private Securities Litigation Reform Act of 1995. There can be no assurance that actual results will not differ materially from the forward-looking statements discussed in this press release.

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