Clinipace Worldwide Selected to Manage Prometheus Laboratories Oncology Program

The Associated Press

MORRISVILLE, N.C.--(BUSINESS WIRE)--Jul 17, 2012--Clinipace Worldwide, a global digital research organization (dCRO), today announced Prometheus Laboratories Inc., a specialty pharmaceutical and diagnostic company, has awarded the company an Oncology Program. Immediate plans are commencing for two metastatic melanoma studies.

Initially, Clinipace Worldwide will manage a study of Proleukin® (aldesleukin) and Vemurafenib therapy in patients with metastatic melanoma (mM). This particular study is expected to have up to 30 sites in the U.S. with a sample size of 135 patients in the naïve patient arm. The study is expected to enroll patients over an 18-month period, with additional follow-up of two years required. Proleukin remains the only therapy to deliver durable remissions in metastatic renal cell carcinoma and metastatic melanoma.

A second study will compare the sequence of high dose Proleukin (aldesleukin) and 3mg/kg Ipilimumab immunotherapy in patients with metastatic melanoma. The study will enroll up to 120 patients at approximately 15 study sites around the U.S.

“Patient enrollment is one of the biggest challenges we face when starting an oncology trial; thus, it was critically important for us to team with a CRO we felt could provide oncology expertise along with a robust electronic data management platform,” commented Todd Butler, Director Clinical Operations, Prometheus Laboratories Inc. “We will be able to monitor our studies to ensure they are on track right from the start, specifically, the number of patients enrolled at each of our sites, as well as factors that impact enrollment and protocol compliance. With the ability to monitor these critical areas in real-time, the study teams will have the ability to adjust patient enrollment strategies with improved data quality.” “Embracing technology can be on one of the most powerful and cost-effective ways to enhance the success of a clinical trial,” said Jeff Williams, CEO, Clinipace Worldwide. “By partnering with a digital clinical research organization (CRO), you can be assured of safer trials, and higher quality data delivered more efficiently and cost-effectively.” About Proleukin Proleukin (aldesleukin) for injection is a recombinant human interleukin-2 for treatment in adults with metastatic melanoma and metastatic kidney cancer (mRCC). Proleukin therapy is a form of immunotherapy that enhances the body's natural immune system to help fight these types of cancer. Proleukin has been used for over 10 years in the treatment of metastatic melanoma and over 15 years in the treatment of metastatic kidney cancer (renal cell carcinoma). Complete plus partial response rates were 15% in mRCC patients and 16% in mM patients.

Important Safety Information Therapy with Proleukin (aldesleukin) should be

restricted to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing. Extreme caution should be used in patients with a normal thallium stress test and a normal pulmonary function test who have a history of cardiac or pulmonary disease.

Proleukin should be administered in a hospital setting under the supervision of a qualified physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

Proleukin administration has been associated with capillary leak syndrome (CLS) which is characterized by a loss of vascular tone and extravasation of plasma proteins and fluid into the extravascular space. CLS results in hypotension and reduced organ perfusion which may be severe and can result in death. CLS may be associated with cardiac arrhythmias (supraventricular and ventricular), angina, myocardial infarction, respiratory insufficiency requiring intubation, gastrointestinal bleeding or infarction, renal insufficiency, edema, and mental status changes.

Proleukin treatment is associated with impaired neutrophil function (reduced chemotaxis) and with an increased risk of disseminated infection, including sepsis and bacterial endocarditis. Consequently, preexisting bacterial infections should be adequately treated prior to initiation of Proleukin therapy. Patients with indwelling central lines are particularly at risk for infection with gram positive microorganisms. Antibiotic prophylaxis with oxacillin, nafcillin, ciprofloxacin, or vancomycin has been associated with a reduced incidence of staphylococcal infections. Proleukin administration should be withheld in patients developing moderate to severe lethargy or somnolence; continued administration may result in coma.

About Interleukin-2 Interleukin-2 (IL-2) is a protein that occurs naturally in the body and plays an important role in activating the immune system. The immune system protects the body from foreign substances, cells, and tissues by responding to and resisting diseases. Proleukin therapy is a genetically engineered or recombinant version of IL-2. Proleukin therapy possesses the same properties as naturally occurring IL-2 and helps activate the immune system to recognize and eliminate certain kinds of cancer cells.

Please see full Prescribing Information for Proleukin. About Prometheus Prometheus Laboratories Inc. is committed to improving lives through the development and commercialization of novel pharmaceutical and diagnostic products that enable physicians to provide greater individualized patient care. Prometheus is a leader in applying the principles of personalized medicine to the diagnosis and treatment of gastrointestinal diseases and is applying these principles to oncology. Its strategy includes the marketing and delivery of pharmaceutical products complemented by proprietary diagnostic testing services. By integrating therapeutics and diagnostics, Prometheus believes it can provide physicians with more targeted solutions to optimize care for their patients. Prometheus became part of Nestlé Health Science in July 2011. Prometheus’ corporate offices are located in San Diego, California. For more information about Prometheus, please visit www.prometheuslabs.com.

About Clinipace Worldwide As a global full-service digital contract research organization (dCRO), we have pioneered an innovative technology-amplified research model to serve the unique needs of emerging and mid-tier biopharmaceutical and medical device firms. Powered by TEMPO™, our proprietary eClinical platform, our team of experts brings extensive therapeutic knowledge and insight into assisting life science firms in developing and executing regulatory strategies, clinical development, and post-approval research to ensure a successful drug and medical device development program. We have managed over 600 global contract research and regulatory projects. Clinipace Worldwide is headquartered in Research Triangle Park, North Carolina with offices in Boulder, Overland Park, Zurich, Munich, Tel-Aviv, Sao Paulo, Buenos Aires, Lima, and New Delhi. For more information, visit our website at www.clinipace.com.

Proleukin is a registered trademark of Novartis.

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