

Labceutics to Conduct Pan European Quality Assurance Study on Standardization of BCR-ABL1 Testing to Improve Patient Management in CML

(Belfast, UK, March 12, 2013) – Labceutics Inc. announced today that it has partnered with Asuragen Inc., a leading molecular diagnostics company, to conduct an international multi-center quality assurance study on the standardization of BCR-ABL1 quantitative measurements on the International Scale (IS). The study will assess the inter-laboratory variability of molecular monitoring results in chronic myeloid leukaemia (CML) patients treated with imatinib or second-generation tyrosine kinase inhibitors (TKIs). Labceutics will perform, analyze and report the study and Asuragen will provide analytical reference materials that are calibrated to the primary international reference standards of the World Health Organization, the BCR-ABL1 ARQ™ IS Calibrator Panels.

Molecular testing for the BCR-ABL1 fusion gene by real time quantitative polymerase chain reaction (RT-qPCR) is the most sensitive routine approach for monitoring the response to therapy of patients with CML. In the context of TKI therapies, the technique is most appropriate for patients who have achieved cytogenetic response and can be used to further define specific molecular response levels associated with therapeutic milestones. Harmonization of the various laboratory procedures and reporting methods utilized worldwide is essential to standardize optimal treatment response criteria and facilitate comparison across laboratories and patients.

The study will be a quality assurance scheme modeled on existing External Quality Assessment (EQA) programs to evaluate the inter-laboratory variability of BCR-ABL1 RT-qPCR results using different standardization modalities. Participating laboratories engaged in the continual improvement of their BCR-ABL1 testing performance via IS standardization have been recruited in 5 countries in Europe. “The aim is more reliable and accurate test results that ultimately will improve the management of patients with CML,” said Dr. Labourier, Director of Clinical Development at Asuragen. “The use of stable and commutable ARQ™ IS Calibrator Panels, based on our well-characterized and clinically validated Armored RNA® technology, will give laboratories the ability to directly generate IS compatible results without the lengthy and complex process of sample exchange.”

“One of the main reasons Labceutics was created is to help ensure that Pharmaceutical and Diagnostic companies have access to well organized quality assurance laboratory testing services across Europe, where the Laboratory market is very fragmented,” said Maria Fe Paz, Managing Director of Labceutics. “Demand for companion diagnostic testing is increasing rapidly across Europe and greater involvement of the Laboratory community is essential if we are to ensure physicians have the right test at the right time. This study is an example of laboratory collaboration on a pan European scale.”

About Asuragen

Asuragen is a molecular diagnostics company with a pioneering position in miRNA using genomics to drive better patient management through best-in-class clinical testing solutions. The Company uses a breadth of technologies and talent to discover, develop and commercialize diagnostic products and clinical testing services with efficiency and flexibility both internally and for our companion diagnostic partners. Today, Asuragen's products, services and technologies drive countless patient management decisions across oncology, genetic disease and other molecular testing modalities. In the future, we envision the Company's development of miRNA-based clinical diagnostics will help transform medicine by improving clinical outcomes and health economics. For more information, visit www.asuragen.com.

About Labceutics

Labceutics partners with leading laboratories in the EU and Asia to provide pharmaceutical and diagnostic companies with the only "one-stop" personalized medicine laboratory partner. Currently Labceutics enables seamless introduction of companion diagnostic testing to over 160 leading institutions and laboratories and ensures a focus on delivering high quality laboratory services to physicians. Learn more at www.labceutics.com.

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