MolecularMD to Develop Highly Sensitive Companion Diagnostic Test to Support CML Treatment Free Remission Clinical Trials

Portland, OR, February 19, 2014 -- MolecularMD Corp. today announced that it has entered into a collaboration with Novartis Pharmaceuticals Corporation to develop a companion diagnostic test to aid in the identification of Ph+ chronic myelogenous leukemia (CML) patients who have achieved durable minimal residual disease (MRD) with nilotinib (Tasigna®), and to provide molecular monitoring for patients during treatment-free remission.

MolecularMD will validate an *in vitro* companion diagnostic test (IVD) designed specifically to monitor CML patients during treatment-free remission. Clinical studies are currently ongoing to evaluate whether patients can maintain MRD after stopping nilotinib therapy, also called treatment-free remission.

The test design is based on highly sensitive quantitative real-time PCR (RT-qPCR) detection of BCR-ABL mRNA transcripts and the endogenous ABL mRNA transcript control in peripheral blood specimens from patients previously diagnosed with CML[1].

Novartis is conducting a global clinical trial program to investigate whether nilotinib treatment can be safely suspended, called the treatment-free remission phase, with no recurrence of CML in selected patients who obtained MR4.5 (BCR-ABL ≤ 0.0032% IS) on nilotinib therapy. Once treatment is stopped, molecular monitoring is used to identify if a patient's level of disease remains in deep molecular response or if the reintroduction of treatment is needed. The program includes a single-arm, multicenter clinical trial to evaluate patients with Ph+ CML in chronic phase who have achieved durable MRD status. Molecular determination of MRD status may be made by sensitive detection of BCR-ABL mRNA transcript levels. MolecularMD is performing the clinical trial assay (CTA) quantifying BCR-ABL mRNA transcript levels for this trial.

Stopping treatment is not a clinical recommendation and should only be attempted in the context of a well conducted clinical study.

Dr. Glenn Miller, EVP and Chief Technology Officer of MolecularMD commented, "We have a long and productive history working with Novartis, providing molecular testing to support clinical development and regulatory approvals. We look forward to working with Novartis to identify CML patients with minimal residual disease and provide sensitive surveillance to ensure effective monitoring of patients who achieve treatment-free remission."

About MolecularMD

MolecularMD Corporation develops and commercializes specialty molecular diagnostics for oncology applications. Its tests are designed to allow appropriate selection, monitoring and management of patients treated with molecularly-targeted cancer therapies. MolecularMD integrates gold-standard and innovative platform technologies with custom clinical assay design and validation to accelerate all phases of clinical development, including FDA approval and commercialization of *in vitro* companion diagnostic tests for novel anticancer agents. A private company based in Portland, Oregon, MolecularMD was founded by Dr. Brian Druker, director of the Knight Cancer Institute at Oregon Health & Science University, and Sheridan G. Snyder, entrepreneur and founder of Genzyme Corporation.

[1]Toplin et al., 2013. Blood (ASH Annual Meeting Abstracts) 122 (21): Abstract 2617

MolecularMD
1341 SW Custer Dr.
Portland, OR 97219

T: 1-877-459-4979
bd@molecularmd.com
www.molecularmd.com