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Mirati Therapeutics Doses First Patient in Expansion Cohorts of Phase 1b Trial of MGCD265 in Genetically Selected Patients

Study Seeks to Confirm a High Response Rate among Cancer Patients with MET and Axl Genetic Alterations

SAN DIEGO, Dec. 23, 2014 /PRNewswire/ -- Mirati Therapeutics, Inc. (NASDAQ: MRTX) today announced that the first patient with Non-Small Cell Lung Cancer (NSCLC) has been dosed in a Phase 1b clinical trial of MGCD265 in selected patients exhibiting genetic alterations of MET or Axl. In this segment of the study, one of the expansion cohorts will enroll patients with NSCLC and another will enroll patients with other solid tumors. Both cohorts will enroll only those patients that have specific MET driver mutations including MET gene point mutations, gene amplification, and MET or Axl gene rearrangements.

"In the dose escalation phase of this trial, we identified an optimal dose that achieved serum levels that we believe will result in greater than 90% inhibition of MET and Axl," said Charles M. Baum, M.D., Ph.D., president and CEO of Mirati. "We are focused on patients whose tumors harbor the specific MET and Axl genetic alterations that MGCD265 is designed to treat. By selecting and treating only those patients who carry the targeted mutations, there is strong rationale that we'll see proof of concept based on a high overall response rate in early 2015 that supports accelerated drug development."

MGCD265 is an orally bioavailable tyrosine kinase inhibitor that selectively targets MET and Axl. Genetic alterations in these targets have been implicated as drivers of tumor growth and disease progression in NSCLC, and other solid tumors. MET and Axl are also implicated as drivers of tumor progression in patients whose tumors have become resistant to EGFR inhibitors such as Tarceva, Iressa and Erbitux. Therefore, the combination of MGCD265 with EGFR inhibitors may also address acquired resistance to agents targeting EGFR.

The open-label Phase 1b study of MGCD265 is expected to enroll up to 60 patients with one cohort focused on NSCLC and another that will enroll patients with advanced solid tumors that carry genetic alterations in MET or Axl. The purpose of this trial is to evaluate the safety and efficacy of MGCD265 administered to selected patients with specific activating MET driver mutations, MET gene amplification, and MET or Axl gene rearrangements. Additional information about this clinical trial of MGCD265 is available at www.clinicaltrials.gov using identifier: NCT00697632.

About NSCLC
Despite available treatment options, the overall five year survival rate for patients with NSCLC is only 16.8% and NSCLC results in the greatest number of cancer deaths in the United States. Moreover, the five year over survival rate for Stage 4 metastatic disease is a mere 4.0% (SEER Lung and Bronchus Cancer-2011). Over recent years, new therapies have been approved that target gene pathways implicated in progression of NSCLC, including EGFR kinase inhibitors, EML4-ALK inhibitors, and VEGF monoclonal antibodies. However, these targets represent only a fraction of the growing list of cancer genes that play a role in NSCLC. Given these factors, there remains a significant unmet medical need to develop new therapies that inhibit multiple targets, particularly those that also inhibit novel targets for which no therapy exists.

About MET and Axl
MET and Axl are receptor tyrosine kinases (RTK) that play key roles in the pathogenesis of several human cancers and are critical mediators of tumor cell survival and metastatic progression, as well as the inappropriate formation of blood vessels (angiogenesis) that nourish the tumors.

The MET RTK is expressed in a wide variety of epithelial cells and signaling activity is normally tightly controlled in healthy tissues. However, MET has been shown to be dysregulated by mutation, gene amplification, and/or overexpression in NSCLC and other cancers. Dysregulation of the MET pathway is implicated in increased tumor cell proliferation, invasive growth, tumor angiogenesis, and metastatic progression of these cancers. In addition, MET has been implicated in evasive resistance to both chemotherapeutics and targeted therapies including VEGF pathway inhibitors, EGF receptor inhibitors, and Raf inhibitors.

Axl is an oncogenic RTK that is also normally involved in the regulation of cell growth and survival but is dysregulated in multiple human cancers. Studies in recent years have shown that Axl expression is correlated with clinical stage and lymph node status in NSCLC, and involved in the mechanism of resistance to EGFR inhibitors such as Tarceva®. Axl is expressed in other tumor types and may be important in Renal Cell Carcinoma, Hepatocellular Carcinoma, Head and Neck, and other cancers.

About Mirati Therapeutics
Mirati Therapeutics is a targeted oncology company developing a pipeline of oncology therapeutics for precisely defined patient populations. Mirati's approach combines the three most important factors in oncology drug development - drug candidates targeting genetic and epigenetic drivers of cancer, creative and agile clinical development that selects for patients whose tumors are dependent on those driver alterations, and a highly accomplished precision medicine leadership team. The Mirati team is using a blueprint proven by their prior work for developing potential breakthrough therapies with accelerated development paths. Mirati is currently advancing three drug candidates through clinical development for multiple oncology indications. More information is available at www.mirati.com.

Forward Looking Statements
Certain statements contained in this news release, other than statements of fact that are independently verifiable at the date hereof, may constitute forward-looking information and forward-looking statements (collectively "forward-looking statements" within the meaning of applicable securities laws). Such statements, based as they are on the current expectations of management of Mirati and upon what management believes to be reasonable assumptions based on information currently available to it, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond Mirati's control. Such statements can usually be identified by the use of words such as "may", "would", "believe", "intend", "plan", "anticipate", "estimate" and other similar terminology, or state that certain actions, events or results "may" or "would" be taken, occur or be achieved. Forward-looking statements in this release include, but are not limited to, statements regarding the ability to achieve complete inhibition of targets and that the inhibition of targets will result in high response rates or accelerated drug development.

Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks, assumptions and uncertainties, many of which are beyond our control, and the effects of which can be difficult to predict. These risks include those inherent in drug development, whether Mirati will be able to obtain financing when needed or on favorable terms, and other risks described in Mirati's filings with the Securities and Exchange Commission. In evaluating any forward-looking statements in this release, Mirati cautions readers not to place undue reliance on any forward-looking statements. Unless otherwise required by applicable securities laws, Mirati does not intend, nor does it undertake any obligation, to update or revise any forward-looking statements contained in this news release to reflect subsequent information, events, results or circumstances or otherwise.

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