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MGCD265 DEMONSTRATES CLINICAL EFFICACY WITH CONFIRMED RESPONSES IN NSCLC PATIENTS WITH MET AND AXL GENE AMPLIFICATION

- First Ever Confirmed Response in NSCLC Patient, with Axl Gene Amplification, Treated with an Orally Administered Small Molecule Inhibitor of MET and Axl to be Presented at IASLC 16th World Conference on Lung Cancer
- Company Announces a Confirmed Response in a NSCLC Patient with MET Gene Amplification and Provides Interim Update on Ongoing MGCD265 Phase 1b Expansion Cohort

DENVER, Sept. 9, 2015 /PRNewswire/ -- Mirati Therapeutics, Inc. ("Mirati") (NASDAQ: MRTX), an oncology company focusing on genetic and epigenetic drivers of cancer, today announced it will present data at the International Association of Lung Cancer (IASLC) 16th World Conference on Lung Cancer on the first non-small cell lung cancer (NSCLC) patient with *AXL* gene amplification enrolled in the MGCD265 Phase 1b expansion cohort. Data will be presented showing the patient had a confirmed Partial Response (PR) based on RECIST criteria. Additionally, the Company announced a confirmed PR in a NSCLC patient with MET gene amplification who was enrolled in the MGCD265 expansion cohort.

"Out of four non-small cell lung cancer patients whom have had at least one scan in the ongoing MGCD265 expansion cohort, two patients have RECIST-confirmed PRs. Those PRs, together with tumor regressions seen in all four of these patients, demonstrate the potentially significant clinical benefit of MGCD265 in patients with lung cancer," said Charles M. Baum, M.D., Ph.D., President and CEO, Mirati. "The study is progressing well due to the enthusiasm of the clinical investigators, and this has resulted in increased screening and enrollment at the clinical trial sites. Currently, nine patients with *MET* or *AXL* genetic alterations have been enrolled in the study. In light of the dramatic response being presented in the patient with *AXL* gene amplification at today's World Conference on Lung Cancer, we felt it was appropriate to provide an interim update on the program. As previously indicated, we will provide a more in-depth update when we have additional data."

NSCLC Patient with Axl Gene Amplification

The male patient was diagnosed with metastatic adenocarcinoma of the lung, with multiple tumors in both lungs which had spread to the lung cavity and lymph nodes. Prior to treatment with MGCD265, he had received multiple chemotherapies, as well as an experimental agent combined with chemotherapy, with the best response being disease progression. After 2 cycles of treatment with MGCD265, tumor imaging showed a PR with a tumor reduction of 42.3% compared to baseline. After 4 cycles of treatment, the PR was confirmed with a tumor reduction of 48.8% based on RECIST criteria. The patient, who remains on study in Cycle 7, also showed improvement in clinical symptoms. Prior to starting treatment with MGCD265, the patient was oxygen dependent. Shortly after treatment with MGCD265, he was off oxygen and able to ride his bike up to seven miles per day.

"To our knowledge, this is the first reported case of an objective response in a patient with a tumor harboring *AXL* gene amplification," said Geoffrey Shapiro, Principal Investigator and Director of the Early Drug Development Center, Department of Medical Oncology, Dana-Farber Cancer Institute. "This response, coupled with the patient's significant symptomatic improvement, provides clinical validation that *AXL* genomic alterations can result in oncogene addiction in patients with non-small cell lung cancer. We will continue to explore MGCD265, a potent kinase inhibitor, in patients with *MET* or *AXL* genomic alterations, in an effort to improve cancer treatment by targeting genetic drivers of cancer."

Data from the study will be presented on September 9, 2015 in an oral presentation titled, "Evaluation of the MET/Axl Receptor Tyrosine Kinase (RTK) Inhibitor MGCD265 in a Patient with Metastatic Non-Small Cell Lung Cancer (NSCLC) Harboring *AXL* Amplification" by Lynette Sholl, M.D, Assistant Professor, Translational Research Group, Brigham and Women's Hospital. The presentation is part of the New Kinase Targets session, Treatment of Advance Diseases - NSCLC track (abstract # 3611) from 6:30 - 8:00 PM MT/5:30 - 7:00 PM PT in Colorado Convention Center, Four Seasons Ballroom F3+F4.

Interim Update on the Ongoing MGCD265 Phase 1b Expansion Cohort

MGCD265 is an inhibitor of the MET and Axl receptor tyrosine kinases which, when mutated or amplified, can be drivers of tumor growth. Preclinical data have shown that MGCD265 can potently inhibit tumor cell growth in vitro, and demonstrate marked tumor regression in tumor xenograft models exhibiting *MET* gene amplification and *MET* exon 14 deletions.

This multi-national, multi-site, open label, single agent study is designed to evaluate the safety, pharmacokinetics/pharmacodynamics and clinical activity of twice-daily MGCD265 in patients who have failed at least one prior

therapy. The study continues to enroll patients with *MET* or *AXL* gene alterations. MGCD265 has been well tolerated at the recommended Phase 2 dose, which has demonstrated full inhibition of both MET and Axl tyrosine kinases, and is the only kinase inhibitor that we know of in clinical development that has demonstrated potent and selective inhibition of both MET and Axl.

As of September 1, 2015, 9 patients with genetic alterations in *MET* or *AXL* have been enrolled in the expansion cohort, including 7 with NSCLC and 2 with other solid tumors. The Company disclosed that 2 of the 4 NSCLC patients, who are currently evaluable (having had at least 1 on-treatment scan), have confirmed PRs based upon RECIST criteria, including the patient with *AXL* amplification highlighted above and a patient with MET gene amplification. Both patients remain on study. All 4 of the evaluable NSCLC patients showed clinically significant tumor regressions. Of the 9 patients enrolled, 7 remain on study for up to 8+ months.

About MET and Axl in NSCLC
MET is highly expressed in NSCLC tumors. Extensive preclinical and emerging clinical data indicate that MET is a driver of tumor growth when it is genetically altered by point mutations, exon 14 deletion mutations, and/or gene amplification in a significant fraction (6-7%) of NSCLC patients. *MET* gene amplification and *MET* mutations, including exon 14 deletion mutations, each exhibit the key characteristics of driver oncogenes in NSCLC.

Axl is over-expressed in patients with advanced NSCLC and has been associated with poor prognosis. Amplification and rearrangements of the *AXL* tyrosine kinase gene also appear to be a driver of tumor growth and occur in up to 2% of patients with NSCLC. Preclinical data has shown that dysregulation of Axl is implicated in tumor progression and resistance to standard and targeted cancer therapies. Extensive preclinical and clinical data also indicate that both MET and Axl are important factors in resistance to EGFR inhibitors, as well as the third-generation EGFR inhibitors.

About MGCD265
MGCD265 is a tyrosine kinase inhibitor that potently and selectively targets tumors in patients with driver alterations in *MET* (gene amplification and mutations) and *AXL* (gene amplification and rearrangements) that occur in approximately 8% of patients with non-small cell lung cancer (NSCLC). MGCD265 is in the expansion phase of a Phase 1/1b dose escalation study for NSCLC patients with *MET* or *AXL* genetic alterations. Genetic alterations in these targets have been implicated as drivers of tumor growth and disease progression in NSCLC, gastroesophageal cancer and other solid tumors. Mirati retains worldwide rights to MGCD265.

About Mirati Therapeutics
Mirati Therapeutics develops molecularly targeted cancer treatments that are intended to inhibit tumor growth. Mirati's approach combines the three most important factors in oncology drug development, 1) researching and developing drug candidates that target genetic and epigenetic drivers of cancer, 2) designing creative and agile clinical development strategies that select for patients whose tumors are dependent on specific driver alterations, and 3) leveraging a highly accomplished targeted oncology leadership team. The Mirati team uses a blueprint - proven by their prior work - for developing potential breakthrough cancer therapies, with accelerated development paths, in order to improve outcomes for patients. Mirati is 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, contain "forward-looking" statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve significant risks and uncertainties. For more detailed disclosures and discussions regarding such forward looking statements, please refer to Mirati's filings with the U.S. Securities and Exchange Commission ("SEC"), including without limitation Mirati's filings on Forms 10-K, 10-Q, and 8-K. Forward looking statements are based on the current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it. Such statements can usually be identified by the use of words such as "may," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," and other similar terminology, or by statements that certain actions, events or results "may" or "would" be taken, occur or be achieved. Such statements include, but are not limited to, statements regarding Mirati's development plans and timelines, potential regulatory actions, the timing and results of clinical trials, and the potential benefits of and markets for Mirati's product candidates. Forward looking statements involve significant risks and uncertainties and are neither a prediction nor a guarantee that future events or circumstances will occur. Such risks include, but are not limited to, potential delays in development timelines or negative clinical trial results, reliance on third parties for development efforts, changes in the competitive landscape, changes in the standard of care, as well as other risks described in Mirati's filings with the SEC. We are including this cautionary note to make applicable, and to take advantage of, the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The information in this news release is given as of the date above and Mirati expressly disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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