Mirati Therapeutics To Present Abstracts On Pipeline Programs At 2016 American Society Of Clinical Oncology (ASCO) Annual Meeting

SAN DIEGO, May 19, 2016 /PRNewswire/ -- Mirati Therapeutics, Inc. (NASDAQ: MRTX) today announced that abstracts on its investigational tyrosine kinase inhibitor candidates, glesatinib (MGCD265) and sitravatinib (MGCD516), will be presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting to be held in Chicago, IL from June 3-7, 2016.

"We are excited to highlight several of the recent advancements from our maturing clinical pipeline during these presentations at the 2016 ASCO Annual Meeting," said Charles Baum, M.D., Ph.D., CEO of Mirati. "We also plan to provide an update on our three ongoing clinical programs during ASCO, including progress made in the Phase 1b and Phase 2 trials in glesatinib, the Phase 1b trial in sitravatinib, and the Phase 2 trial in mocetinostat. We look forward to delivering further updates and additional data for each of our targeted oncology candidates in late 2016."

Ongoing clinical work from both programs will be highlighted during the following poster and publication sessions:

- **Abstract No. TPS9099:** "Amethyst NSCLC trial: Phase 2, parallel-arm study of receptor tyrosine kinase (RTK) inhibitor, MGCD265, in patients (pts) with advanced or metastatic non-small cell lung cancer (NSCLC) with activating genetic alterations in mesenchymal-epithelial transition factor (MET)"
  - **Presenting Author:** Igor Rybkin
  - **Session:** Lung Cancer - Non-Small Cell Metastatic
  - **Time/Location:** Saturday, June 4, 2016 from 8:00 - 11:30 AM CT in Hall A
  - **Summary:** The abstract provides an overview of the protocol for this ongoing Phase 2 study. NSCLC patients with driver alterations in MET are enrolled in one of four study arms, based on the type of MET dysregulation and where it is detected, and are then treated with MGCD265 in 21-day cycles until RECIST-defined progression or unacceptable toxicity. The primary endpoint is Objective Response Rate (ORR), with secondary objectives including safety and tolerability; secondary efficacy endpoints; correlations between tissue and blood testing; and pharmacokinetics (PK) and pharmacodynamics (PD).

- **Abstract No. 2575:** "A first in human phase 1 study of receptor tyrosine kinase (RTK) inhibitor MGCD516 in patients with advanced solid tumors"
  - **Presenting Author:** Todd Michael Bauer
  - **Session:** Developmental Therapeutics - Clinical Pharmacology and Experimental Therapeutics
  - **Time/Location:** Sunday, June 5, 2016 from 8:00 - 11:30 AM CT in Hall A
  - **Summary:** The abstract highlights a Phase 1 study in which 32 patients with advanced solid tumors received either 10, 20, 40, 80, 110, 150 or 200mg of MGCD516, first to establish an initial PK profile and then for continuous daily dosing (QD) in 21-day cycles. The primary objectives include evaluation for safety, PK/PD, the maximum tolerated dose and clinical activity of MGCD516 in patients with advanced solid tumors. The Phase 1b dose for MGCD516 was established at 150mg QD, and MGCD516 shows favorable PK characteristics, on-target PD effects and is associated primarily with constitutional or GI-related AEs. A Phase 1b portion of the study is currently being enrolled in patients with NSCLC or other solid tumors with specific genetic alterations in MGCD516 target RTK genes.

- **Abstract No. e14087:** "Evaluation of a spray-dried dispersion (SDD) formulation of MGCD265, a receptor tyrosine kinase (RTK) inhibitor, in a phase 1 study of patients (pts) with advanced solid tumors."
  - **Lead Author:** Sunil Sharma
  - **Session:** Publication only
  - **Summary:** The abstract highlights the evaluation of an SDD formulation of MGCD265 within an ongoing Phase 1 trial of MGCD265 in patients with solid advanced tumors. Eighteen patients were treated with MGCD265 using either softgel capsules (12 patients) or SDD tablets (six patients) in 21-day cycles to evaluate the maximum tolerated dose/recommended Phase 2 dose. The SDD tablet formulation of MGCD265 showed similar PK characteristics to the softgel capsule formulation, but with greater bioavailability - thus reducing the pill burden - and a more favorable safety profile to date.

**About Glesatinib (MGCD265)**

Glesatinib (MGCD265) is a tyrosine kinase inhibitor that is expected to potently and selectively target tumors in patients with driver alterations in MET (mutations and gene amplification) and Axl (rearrangements) that occur in approximately 8% of patients with non-small cell lung cancer (NSCLC). Glesatinib is being evaluated in a Phase 1b study in patients with solid tumors that have genetic alterations in MET or AXL genes. The Phase 2 trial in NSCLC patients with MET genetic alterations is underway to confirm and extend the data that supports the clinical benefit of glesatinib in patients with driver mutations in...
MET. Genetic alterations in these targets have been implicated as drivers of tumor growth and disease progression in NSCLC, gastroesophageal cancer 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. Therefore, Mirati believes that the combination of glesatinib with an EGFR inhibitor could potentially treat patients who have become resistant to agents targeting EGFR. Mirati retains worldwide rights to glesatinib.

About Sitravatinib (MGCD516)
Sitravatinib (MGCD516) is being evaluated in a Phase 1b dose expansion cohort in selected patients with specific genetic alterations that are drivers of tumor growth. The initial focus for MGCD516 is on NSCLC. MGCD516 is a tyrosine kinase inhibitor that has demonstrated potent inhibition of a closely related spectrum of tyrosine kinases, including RET, CBL, CH4q12, DDR and Trk, which are key regulators of signaling pathways that lead to cell growth, survival and tumor progression. MGCD516 is also expected to target other signaling pathways that may play a role in tumor growth. These key regulatory pathways are genetically altered in multiple cancer indications and act as oncogenic drivers that promote cancer development and progression in solid tumors, including NSCLC. Mirati retains worldwide rights to sitravatinib.

About Mirati Therapeutics
Mirati Therapeutics develops molecularly targeted therapies intended to treat cancer by combining the three most important factors in oncology drug development: 1) researching and developing drug candidates that target genetic and epigenetic drivers of cancer as single agents and in combination, including combination with immune therapy, 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 oncology precision medicine leadership team. The Mirati team uses a blueprint proven by their prior work for developing potential breakthrough cancer therapies with accelerated development paths 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, expected use of cash resources, 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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