Mirati Therapeutics Presents Interim Clinical Data From Ongoing MGCD516 Phase 1 Dose Escalation Study In Patients With Advanced Solid Tumors

Data Presented at the 2015 European Cancer Congress Demonstrates MGCD516 is Well Tolerated with Favorable PK Profile

SAN DIEGO, Sept. 28, 2015 /PRNewswire/ -- Mirati Therapeutics, Inc. ("Mirati") (NASDAQ: MRTX), an oncology company focusing on genetic and epigenetic drivers of cancer, today announced it presented data from the study titled, "A First-in-Human Phase 1/1b Study of Receptor Tyrosine Kinase (RTK) Inhibitor, MGCD516, in Patients with Advanced Solid Tumors" at the 2015 European Cancer Congress (ECC) in Vienna, Austria.

"The data we presented this weekend provide initial clinical evidence of MGCD516's safety and tolerability," said Charles M. Baum, president and CEO, Mirati. "MGCD516 is a potent, orally bioavailable inhibitor of certain RTKs reported to be key drivers of tumor growth. The favorable pharmacokinetics and tolerability of MGCD516 is encouraging and we look forward to starting the expansion cohort of the study in selected patients this year."

MGCD516 is a potent RTK inhibitor that targets the RET, DDR and Trk tyrosine kinase signaling pathways, which are reported oncogenic drivers, as well as other signaling pathways that may play a role in tumor growth. This ongoing Phase 1, open label, single agent study is designed to evaluate the safety, pharmacokinetics/pharmacodynamics (PK/PD) and clinical activity of MGCD516 in unselected patients with advanced solid tumors, with an initial focus on non-small cell lung cancer (NSCLC).

The objective of the dose escalation phase of the study, in unselected patients, is to characterize the safety of MGCD516, determine a Phase 2 dose and establish the maximum tolerated dose. MGCD516 is orally administered to unselected patients with advanced solid tumors once daily (QD) on a 21-day cycle. The study is exploring escalating doses of 10 mg, 20 mg, 40 mg, 80 mg, 110 mg, 150 mg and 200 mg, with twenty-eight patients enrolled to date. The 200 mg dose level is currently being evaluated.

MGCD516 was well tolerated, with the most frequently reported adverse events (all grades, > 25%) being fatigue, diarrhea, cough, hypertension, nausea and vomiting. The only dose limiting toxicity (DLT) seen to date was grade 3 Palmar-Plantar Erythrodysesthesia (Hand-Foot Syndrome) in one patient at the 80 mg dose. No DLTs were observed at the 110 mg and 150 mg doses. PK/PD data indicate MGCD516 is achieving serum levels associated with tumor inhibition seen in preclinical models.

Next Steps
The Company expects to initiate the Phase 1b dose expansion cohort of the MGCD516 trial in the fourth quarter of 2015. The dose expansion cohort will select for patients with genetic alterations in RET, DDR and Trk, and will also explore other mechanisms that may play a role in regulating tumor growth, including selecting for patients with CBL mutations and chromosome 4 amplicon alterations.

The MGCD516 Phase 1 study poster presented at the ECC can be found on the Company's website at www.mirati.com. Additional information about this clinical trial of MGCD516 is available at www.clinicaltrials.gov using identifier: NCT02219711.

About MGCD516
MGCD516 is a tyrosine kinase inhibitor that has demonstrated potent inhibition of a closely related spectrum of tyrosine kinases, including RET, DDR and Trk, which are key regulators of signaling pathways that lead to cell growth, survival and tumor progression. MGCD516 also targets 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. MGCD516 is in a Phase 1 dose escalation study in unselected patients who have advanced solid tumors, with an initial focus on NSCLC. Mirati retains worldwide rights to MGCD516.

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](http://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.


**SOURCE** Mirati Therapeutics, Inc.

News Provided by Acquire Media