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Mirati Therapeutics Initiates Phase 1 Study of MGCD516 for Non-Small Cell Lung Cancer and Other Advanced Solid Tumors

SAN DIEGO, Sept. 4, 2014 /PRNewswire/ -- Mirati Therapeutics, Inc. (NASDAQ: MRTX) today announced that the first patient has been dosed in its Phase 1 clinical study of MGCD516 in the treatment of patients with advanced solid tumors, with an initial focus on non-small cell lung cancer (NSCLC). MGCD516 is a Receptor Tyrosine Kinase (RTK) inhibitor with molecular targets that act as critical genetic drivers of cancer progression.

"This study is designed to identify an optimal dose and move quickly into expansion cohorts in selected patients who have genetic alterations of certain kinases including the Trk, RET and DDR RTK pathways," said Charles M. Baum, M.D., Ph.D., president and CEO of Mirati. "By focusing on patients that harbor these genetic drivers of disease, we believe MGCD516 will be more likely to demonstrate a high response rate in defined patient subsets, with the potential to support an accelerated development path."

MGCD516 has demonstrated potent inhibition of a closely related spectrum of tyrosine kinases including the Trk, RET and DDR families, which are key regulators of signaling pathways that lead to cell growth, survival and tumor progression. These kinases and their key regulatory pathways are genetically altered in multiple cancer indications including lung and head and neck cancers, and act as oncogenic drivers that promote cancer development and progression. MGCD516 demonstrated tumor regression in multiple preclinical human xenograft tumor models.

In this study, MGCD516 is orally administered to patients with advanced solid tumor malignancies to evaluate its safety, pharmacokinetic, metabolism, pharmacodynamic and clinical activity profiles. During the Phase 1 segment, the dose and regimen of MGCD516 will be assessed. During the Phase 1b segment, the clinical activity of MGCD516 will be evaluated in selected NSCLC and other solid tumor patient populations whose tumors have genetic alterations in targets potently inhibited by MGCD516 including Trk, RET and DDR.

Additional information about this clinical trial of MGCD516 is available at www.clinicaltrials.gov using identifier: NCT02219711.

About Mirati Therapeutics

Mirati Therapeutics is a targeted oncology company developing an advanced pipeline of breakthrough medicines for precisely defined patient populations. Mirati's approach combines the three most important factors in oncology drug development - drug candidates with complementary and compelling targets, creative and agile clinical development, and a highly accomplished precision medicine leadership team. The Mirati team is using a proven blueprint for developing targeted oncology medicines to advance and maximize the value of its pipeline of drug candidates, including MGCD265 and MGCD516, which are orally bioavailable, multi-targeted kinase inhibitors with distinct target profiles, and mocetinostat, an orally bioavailable, spectrum-selective histone deacetylase inhibitor. 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 response rates to MGCD516, the ability to find an optimal dose and potential to move into expansion cohorts.

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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