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Mirati Therapeutics Receives Orphan Designation from U.S. Food & Drug Administration for Mocetinostat in Diffuse Large B-Cell Lymphoma

SAN DIEGO, Aug. 11, 2014 /PRNewswire/ -- Mirati Therapeutics, Inc. (NASDAQ: MRTX) today announced that the U.S. FDA has granted Orphan Drug Designation to mocetinostat, a spectrum selective HDAC inhibitor, for diffuse large B-cell lymphoma (DLBCL). In June, mocetinostat was granted Orphan Drug Designation as a treatment for myelodysplastic syndrome (MDS). Orphan drug designation is also being sought for bladder cancer patients with specific genetic alterations.

Mocetinostat is being developed as a single agent treatment in patients with diffuse large B-cell lymphoma (DLBCL) and bladder cancer with specific genetic mutations in Histone Acetyl Transferases (HATs) that we believe to be critically involved in the pathogenesis and progression of these tumor types. Mocetinostat reverses aberrant acetylation resulting from HAT mutations and is predicted to halt tumor progression and reduce tumor burden in patients. Mocetinostat is also in Phase 2 clinical studies in combination with Vidaza as a treatment for intermediate and high-risk MDS.

"We have identified genetic alterations in histone acetylation pathways (CREBBP and EP300) in approximately one third of DLBCL and bladder tumors. Nonclinical tumor models exhibiting these mutations are particularly responsive to mocetinostat," said Dr. Charles Baum, M.D. PhD, president and CEO of Mirati. "Among other benefits, orphan designation provides seven years of market exclusivity to target these genetically defined patients with unmet medical need in the event we achieve regulatory approval."

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for underserved patient populations or rare disorders that affect fewer than 200,000 people in the United States. Orphan drug designation provides certain benefits, including market exclusivity upon regulatory approval if received, exemption of FDA application fees and tax credits for qualified clinical trials.

About Mocetinostat

Mocetinostat is an orally-bioavailable, spectrum-selective HDAC inhibitor. Mocetinostat is enrolling patients in a Phase 2 dose confirmation study in combination with Vidaza as treatment for intermediate and high-risk MDS. Mirati also plans to initiate Phase 2 studies of mocetinostat as a single agent in patients with mutations in histone acetyl transferases in bladder cancer and DLBCL. Initial data from the Phase 2 studies is expected by the end of 2014. In addition to the ongoing Phase 2 clinical trials, mocetinostat has completed 13 clinical trials in more than 400 patients with a variety of hematologic malignancies and solid tumors.

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 mocetinostat for patients with bladder cancer or DLBCL, the success around selecting patients whose

cancers may be sensitive to mocetinostat, and the timing of data readouts.

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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