U.S. Food and Drug Administration (FDA) Accepts Mirati Therapeutics' New Drug Application for Adagrasib as Treatment of Previously Treated KRASG12C-Mutated Non-Small Cell Lung Cancer

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SAN DIEGO, Feb. 15, 2022 /PRNewswire/ -- Mirati Therapeutics, Inc. (Nasdaq: MRTX), a clinical-stage targeted oncology company today announced that the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for *adagrasib* for the treatment of patients with non-small cell lung cancer (NSCLC) harboring the KRAS^{G12C} mutation who have received at least one prior systemic therapy. The Prescription Drug User Fee Action (PDUFA) date for *adagrasib* is December 14, 2022.

The *adagrasib* NDA is being reviewed by the FDA for Accelerated Approval (Subpart H), which allows for the approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. In addition, the application is being reviewed under the FDA Real-Time Oncology Review (RTOR) pilot program, which aims to explore a more efficient review process that ensures safe and effective treatments are made available to patients as early as possible. *Adagrasib* has also achieved Breakthrough Therapy Designation in the U.S. as a potential treatment for patients with NSCLC harboring the KRAS^{G12C} mutation who have received at least one prior systemic therapy.

Pasi A. Jänne, M.D., Ph.D., an investigator participating in the KRYSTAL-1 study, and director of the Lowe Center for Thoracic Oncology at Dana-Farber Cancer Institute, commented, "KRAS mutations have been notoriously hard to target and historically have had limited therapeutic options. The KRAS^{G12C} biomarker in particular is associated with poor survival outcomes. The FDA's review of the *adagrasib* NDA marks important progress toward potentially providing a new, targeted option for those living with KRAS^{G12C}-mutated non-small cell lung cancer."

"The acceptance of our NDA for *adagrasib* is a significant step forward in Mirati's ongoing efforts to advance innovative, differentiated treatment options for patients with KRAS^{G12C} cancers," said Charles Baum, M.D., Ph.D., president, founder and head of research and development, Mirati Therapeutics, Inc. "We look forward to working with the FDA during their review of our application and potentially provide a novel option for patients with non-small cell lung cancer."

The NDA is based on the Phase 2 registration-enabling cohort of the KRYSTAL-1 study, evaluating *adagrasib* 600mg BID in patients with advanced NSCLC harboring the KRAS^{G12C} mutation following prior treatment with immunotherapy and chemotherapy, either together or sequentially. The Company reported positive topline data from this cohort in September 2021, and plans to present detailed results at a medical conference during the first half of 2022.

The Company has an ongoing confirmatory Phase 3 trial, KRYSTAL-12, evaluating *adagrasib* versus docetaxel in patients with second-line KRAS^{G12C}-mutated NSCLC.

Mirati Therapeutics thanks the patients and investigators who participated in this clinical study.

About *Adagrasib* (MRTX849)

Adagrasib is an investigational, highly selective, and potent oral small-molecule inhibitor of KRAS^{G12C} that is optimized to sustain target inhibition, an attribute that could be important to treat *KRAS*^{G12C}-mutated cancers, as the KRAS^{G12C} protein regenerates every 24-48 hours. *Adagrasib* is a being evaluated as monotherapy and in combination with other anti-cancer therapies in patients with advanced *KRAS*^{G12C}-mutated solid tumors, including non-small cell lung cancer (NSCLC), colorectal cancer and pancreatic cancer. For more information visit Mirati.com/science.

Mirati has an Expanded Access Program (EAP) for investigational *adagrasib* for the treatment of eligible patients with KRAS^{G12C}-mutated cancers, regardless of tumor type, in the U.S. Learn more about the EAP at Mirati.com/expanded-access-policy.

About Mirati Therapeutics, Inc.

Mirati Therapeutics, Inc. is a clinical-stage biotechnology company whose mission is to discover, design and deliver breakthrough therapies to transform the lives of patients with cancer and their loved ones. The company is relentlessly focused on bringing forward therapies that address areas of high unmet need, including lung cancer, and advancing a pipeline of novel therapeutics targeting the genetic and immunological drivers of cancer. Mirati is using its scientific expertise to develop novel solutions in two registration-enabling programs: *adagrasib* (MRTX849), an investigational small molecule, potent and selective KRAS^{G12C} inhibitor, as monotherapy and in combination with other agents, and *sitravatinib*, an investigational spectrum-selective inhibitor of receptor tyrosine kinases in combination with checkpoint inhibitor therapies. Mirati is also advancing its differentiated preclinical portfolio, including MRTX1133, an investigational KRAS^{G12D} inhibitor, MRTX1719, an investigational PRMT5 inhibitor, and other oncology discovery programs. Unified for patients, Mirati's vision is to unlock the science behind the promise of a life beyond cancer.

For more information about Mirati Therapeutics Inc., visit us at Mirati.com or follow us on Twitter, LinkedIn and Facebook.

Forward Looking Statements

This press release contains forward-looking statements regarding the business of Mirati Therapeutics, Inc. ("Mirati"). Any statement describing Mirati's

goals, expectations, financial or other projections, intentions or beliefs, development plans and the commercial potential of Mirati's drug development pipeline, including without limitation *adagrasib* (MRTX849), *sitravatinib*, MRTX1719 and MRTX1133, is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to risks and uncertainties, particularly those challenges inherent in the process of discovering, developing and commercialization of new drug products that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs.

Mirati's forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Mirati's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Mirati. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Mirati's programs are described in additional detail in Mirati's quarterly reports on Form 10-Q and annual reports on Form 10-K, which are on file with the U.S. Securities and Exchange Commission (the "SEC") available at the SEC's Internet site (www.sec.gov). These forward-looking statements are made as of the date of this press release, and Mirati assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

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