Mirati Therapeutics Announces Positive Phase 2 Topline Results for Investigational Adagrasib in Patients with KRAS G12C-Mutated Advanced Non-Small Cell Lung Cancer

September 20, 2021

Company to host Virtual Investor Event on September 20, 2021 at 8:30 a.m. ET / 5:30 a.m. PT

SAN DIEGO, Sept. 20, 2021 /PRNewswire/ -- Mirati Therapeutics, Inc. (NASDAQ: MRTX), a clinical-stage targeted oncology company, today announced positive topline results from the potentially registration-enabling cohort of the Phase 2 KRYSTAL-1 study, evaluating *adagrasib* in patients with advanced non-small cell lung cancer (NSCLC) harboring the *KRAS*^{G12C} mutation following prior systemic therapy.

The analysis was completed in the intent-to-treat population, which showed a*dagrasib* 600mg BID demonstrated an objective response rate (ORR) of 43% and a disease control rate of 80%, based on central independent review as of June 15, 2021. The median follow-up was 9 months. Importantly, 98.3% of patients received *adagrasib* following treatment with immunotherapy and chemotherapy. The safety and tolerability profile was consistent with previously reported findings for *adagrasib* in patients with advanced NSCLC.

The Company plans to submit detailed results from the ongoing Phase 2 registration-enabling cohort of the KRYSTAL-1 study in previously-treated patients with *KRAS*^{G12C}-mutated NSCLC for presentation at a medical congress in early 2022.

"The *KRAS* mutation has historically been challenging to target, leaving patients with limited treatment options," said Charles M. Baum, M.D., Ph.D., president and chief executive officer, Mirati Therapeutics, Inc. "These positive topline data further strengthen our belief in *adagrasib* as a potentially differentiated therapy for patients with non-small cell lung cancer harboring the *KRAS*^{G12C} mutation. We look forward to submitting our New Drug Application to the U.S. Food and Drug Administration in the fourth quarter of 2021 and advancing our expanding *adagrasib* development program, which includes numerous monotherapy and combination studies in *KRAS*^{G12C}-mutated solid tumors."

Updated Findings from Phase 1/1b NSCLC Cohort of KRYSTAL-1 Study

In addition to these topline Phase 2 results, the Company reported updated findings from the Phase 1/1b KRYSTAL-1 study evaluating *adagrasib* 600mg BID in all 19 patients enrolled with *KRAS*^{G12C}-mutated advanced NSCLC as of the June 15, 2021 data cutoff.

Results showed that the investigator assessed ORR was 58%. Two of the 11 responses occurred in patients after being on treatment for more than 10 months. The median follow-up was 17.3 months. The median duration of treatment and median duration of response were 9.5 months and 12.6 months, respectively. In addition, 64% of responders were still on treatment, and continuing to respond. The median progression free survival was 8.3 months and median overall survival was not reached. Grade 3/4 treatment related adverse events were observed in 26% of patients, with one Grade 5 event.

Virtual Investor Event

Mirati Therapeutics will host a virtual Investor Event on Monday, September 20, 2021 at 8:30 a.m. ET / 5:30 a.m. PT.

Company executives will discuss:

- A top-line update from the Phase 2 registrational cohort of the KRYSTAL-1 study evaluating *adagrasib* in previously-treated patients with *KRAS*^{G12C}-mutated NSCLC
- Findings from the colorectal cancer (CRC) cohort of the Phase 1/2 KRYSTAL-1 study evaluating *adagrasib* as monotherapy and in combination with cetuximab in patients with heavily pretreated CRC harboring the *KRAS*^{G12C} mutation, as presented at the 2021 European Society of Medical Oncology (ESMO) Congress
- Results from the Phase 2 MRTX-500 study evaluating *sitravatinib* combined with nivolumab in patients with non-squamous NSCLC who progressed on or after prior checkpoint inhibitor therapy, to be presented at the 2021 ESMO Congress

Investors and the general public are invited to register and listen to a live webcast of the event through the "Investors and Media" section on Mirati.com. A replay of the event will be available shortly after the conclusion of the event.

About the KRYSTAL-1 Study

KRYSTAL-1 is an open-label Phase 1/2 multiple expansion cohort trial evaluating *adagrasib* as monotherapy and in combination with other anticancer therapies in patients with advanced solid tumors harboring the *KRAS*^{G12C} mutation.

About KRAS^{G12C} in Non-Small Cell Lung Cancer

Lung cancer is one of the most common cancers worldwide, accounting for 2.21 million new cases and 1.8 million deaths worldwide in 2020. Lung cancer consists of non-small cell lung cancer (NSCLC) in approximately 85 percent of cases and small cell lung cancer (SCLC) in approximately 15

percent of cases. KRAS^{G12C} is the most common KRAS mutation in NSCLC, present in approximately 14 percent of patients with lung adenocarcinoma, and is a biomarker mutation of poor prognosis.

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.

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 and LinkedIn.

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.

Mirati Contacts

Investor Relations: Temre Johnson | 858-332-3562 | ir@mirati.com

Media Relations: Priyanka Shah | 908-447-6134 | media@mirati.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/mirati-therapeutics-announces-positive-phase-2-topline-results-for-investigational-adagrasib-in-patients-with-kras-g12c-mutated-advanced-non-small-cell-lung-cancer-301380159.html

SOURCE Mirati Therapeutics, Inc.