



Mirati Therapeutics Presents Positive Clinical Data with Investigational Adagrasib as Monotherapy and in Combination with Cetuximab in Patients with KRAS G12C-Mutated Colorectal Cancer

September 19, 2021

SAN DIEGO, Sept. 19, 2021 /PRNewswire/ -- [Mirati Therapeutics, Inc.](#) (NASDAQ: [MRTX](#)), a clinical-stage targeted oncology company, today announced results from a cohort of the Phase 1/2 KRYSTAL-1 study evaluating *adagrasib* at the 600mg BID dose as both monotherapy and in combination with cetuximab in patients with heavily pretreated colorectal cancer harboring a *KRAS*^{G12C} mutation. Results showed that *adagrasib* alone and with cetuximab demonstrated significant clinical activity and broad disease control in these patients. The findings (Abstract # LBA6) will be presented today at 9:47 a.m. ET as a late-breaking oral presentation during the Presidential Symposium II session at the European Society for Medical Oncology Congress (ESMO) 2021.

"Patients living with *KRAS*-mutated colorectal cancer face a significant medical need for new treatment options," said Dr. Jared Weiss M.D., lead study investigator and associate professor of medicine, division of oncology at University of North Carolina-Chapel Hill. "The positive results presented today show that *adagrasib* alone or in combination with cetuximab may improve clinical outcomes in patients with colorectal cancer harboring a *KRAS*^{G12C} mutation."

Summary of Clinical Results

- As of May 25, 2021, 80% of patients enrolled in the *adagrasib* monotherapy arm (n=46) received at least two prior lines of systemic anticancer therapies, and had a median follow up of 8.9 months. Of the evaluable patients (n=45), results showed an investigator assessed response rate (RR) of 22%, including one unconfirmed partial response (PR), and a disease control rate (DCR) of 87%; the median duration of response (DOR) was 4.2 months. In all enrolled patients, the median progression free survival (PFS) was 5.6 months (95% Confidence Interval, CI: 4.1,8.3).
- As of July 9, 2021, 90% patients enrolled in the *adagrasib* plus cetuximab arm (n=32) received at least two prior lines of systemic anticancer therapies, and had a median follow up of 7 months. Of the evaluable patients (n=28), results showed an investigator assessed RR of 43%, including two unconfirmed PRs and a DCR rate of 100%. After the data cutoff date, of the two unconfirmed PRs, follow up scans showed one patient had a confirmed PR, and the second patient progressed. At the time of the analysis, 63% (20/32) of enrolled patients remained on treatment.
- *Adagrasib* monotherapy and in combination with cetuximab was well-tolerated in this study, with a manageable safety profile. Grade 3/4 treatment related adverse events (TRAEs) were observed in 30% of patients treated with *adagrasib* alone, and in 16% of patients treated with the combination. Treatment related adverse events led to treatment discontinuation in 6% of patients who received combination therapy and in none (0%) of those who received *adagrasib* monotherapy. No Grade 5 TRAEs were observed in either treatment arm.

"*Adagrasib* represents Mirati's scientific commitment to the discovery and development of novel targets that may lead to new treatment options for people with cancer," said [Charles M. Baum, M.D., Ph.D.](#), president and chief executive officer, Mirati Therapeutics, Inc. "The results presented at ESMO support further study of *adagrasib* in *KRAS*-mutated colon cancer, including with our ongoing, global registrational Phase 3 trial, KRYSTAL-10, comparing *adagrasib* plus cetuximab to standard of care chemotherapy in second-line *KRAS*^{G12C}-mutated colorectal cancer."

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 non-small cell lung cancer (NSCLC)
- Findings from the 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 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 a *KRAS*^{G12C} mutation.

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 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](https://www.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, visit us at [Mirati.com](https://www.mirati.com) or follow us on [Twitter](https://twitter.com/mirati) and [LinkedIn](https://www.linkedin.com/company/mirati).

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

SOURCE Mirati Therapeutics, Inc.