



Mirati Therapeutics' Adagrasib Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Patients with Advanced Non-Small Cell Lung Cancer Harboring the KRAS G12C Mutation

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SAN DIEGO, June 24, 2021 /PRNewswire/ -- [Mirati Therapeutics, Inc.](https://www.mirati.com) (NASDAQ: MRTX), a clinical-stage targeted oncology company, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to *adagrasib* for the potential treatment of patients with non-small cell lung cancer (NSCLC) who harbor the KRAS^{G12C} mutation following prior systemic therapy.

Breakthrough Therapy Designation is an FDA program designed to expedite the development and regulatory review of drugs that have demonstrated preliminary clinical evidence of a substantial improvement over available therapy in the treatment of patients with serious diseases on at least one clinically significant endpoint.

The designation for *adagrasib* is supported by preliminary results from the registrational Phase 1/2 KRYSTAL-01 trial in patients with advanced NSCLC, whose cancer had progressed following prior treatment with immunotherapy and/or chemotherapy.

"We are pleased to receive this breakthrough therapy designation for *adagrasib*, which emphasizes the significant need for new treatment options for patients with lung cancer who harbor the KRAS^{G12C} mutation," said [Charles M. Baum, M.D., Ph.D.](#), president and chief executive officer, Mirati Therapeutics, Inc. "We look forward to submitting a New Drug Application for *adagrasib* in the second half of this year and further advancing *adagrasib* across a broad development plan with the goal of improving clinical outcomes in patients with KRAS^{G12C} mutated cancers."

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. Studies of *adagrasib* have shown that the drug has a long half-life, extensive tissue distribution and is well tolerated. *Adagrasib* has also shown single-agent responses in non-small cell lung cancer (NSCLC), colorectal cancer, pancreatic cancer, and other solid tumors with KRAS^{G12C} mutations. *Adagrasib* is being evaluated in several clinical trials in combination with other anti-cancer therapies with strong scientific rationale in patients with advanced solid tumors. Registration-enabling studies are ongoing in NSCLC and colorectal 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, 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](https://www.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* 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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