Aadi Bioscience Announces Data Presentation on incidence of TSC1 and TSC2 Alterations in Advanced Cancers at the Annual Meeting of the American Association for Cancer Research (AACR)

April 8, 2022

- First rigorous analysis estimates TSC1 and TSC2 definite impact alteration incidence in U.S. as approximately 12,000 advanced cancer patients in 2030

- Findings also identify highest frequency of TSC1 alterations in bladder, kidney, and lung squamous cell cancers, while TSC2 alterations have the highest frequency in hepatobiliary, ovarian, and soft tissue sarcomas

LOS ANGELES, April 08, 2022 (GLOBE NEWSWIRE) -- Aadi Bioscience, Inc. (“Aadi”) (Nasdaq: AADI), a biopharmaceutical company focused on developing and commercializing precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced the presentation of a poster (#5799) at the Annual Meeting of the American Association for Cancer Research (AACR), being held April 8-13, 2022 in New Orleans, LA. The research that was presented quantifies the type and number of advanced cancer patients with malignant tumors carrying *TSC1* or *TSC2* alterations.

The study, presented by Gunsagar S. Gulati, M.D., Ph.D., Resident Physician at Brigham and Women’s Hospital (BWH) in Boston evaluated the landscape of *TSC1* or *TSC2* alterations across 31 solid tumors from The Cancer Genome Atlas (TCGA; *n* ~10,000 patients), AACR GENIE database (Memorial Sloan Kettering (MSK): *n* ~ 15,000 patients, and Dana Farber Cancer Institute (DFCI): *n* ~ 5,500 patients) and subsequently estimated the annual incidence of patients with these alterations using the Surveillance, Epidemiology, and End Results Program (SEER) database.

The study, which was conducted by additional researchers at BWH, The University of Texas MD Anderson Cancer Center, and Tessellon in Missouri, found that the incidence of advanced cancer patients with *TSC1* or *TSC2* alterations in 2030 in the U.S. is projected to be approximately 32,000, of which approximately 12,000 patients carry “definite” mutations (frameshift, nonsense, splice-site mutations and deep deletions). *TSC1* alterations were most frequent in bladder, kidney, and lung squamous cell cancers, while *TSC2* alterations were most frequent in hepatobiliary, ovarian, and soft tissue sarcomas.

Neil Desai, Ph.D., Founder, Chief Executive Officer, and President of Aadi, stated, “Consistent with our expectations, the incidence of patients with *TSC1* or *TSC2* definite impact alterations is significant, and only exceeded by the incidence of actionable mutations in *EGFR, KRAS, HER2, PIK3CA*, or *BRAF*. We are actively enrolling patients into our ongoing pivotal PRECISION 1 trial to evaluate *nab*-sirolimus in patients harboring *TSC1* or *TSC2* mutations and look forward to reporting preliminary data in the first half of next year.”

About Aadi Bioscience

Aadi is a biopharmaceutical company focused on precision therapies for genetically-defined cancers. Aadi’s primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. In November 2021, Aadi received FDA approval for FYARRO™ for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa), and in February 2022 Aadi announced the commercial launch of FYARRO in this indication. FYARRO is an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, greater mTOR target suppression, and increased tumor growth inhibition over other mTOR inhibitors in preclinical models.

Based on data from the AMPECT trial with FYARRO and following discussions with the FDA about other emerging data with FYARRO, Aadi has initiated PRECISION 1, a tumor-agnostic registrational trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations. Aadi also has ongoing studies to evaluate dosing of FYARRO in combination regimens. More information on Aadi’s development pipeline is available on the Aadi website at www.aadibio.com.

Forward-Looking Statements

Aadi cautions you that certain statements included in this press release that are not a description of historical facts are forward-looking statements. These statements are based on Aadi’s current beliefs and expectations. Forward-looking statements include statements regarding: our plans and potential for success relating to commercializing FYARRO; the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; our plans related to further development and manufacturing of FYARRO; the timing of additional clinical trials, including the registrational trial in patients harboring *TSC1* and *TSC2* inactivating alterations; the timing or likelihood of regulatory filings and approvals of FYARRO, including in potential additional indications and potential filings in additional jurisdictions; anticipated reception of FYARRO in the physician community; and the sufficiency of our existing capital resources and the expected timeframe to fund our future operating expenses and capital expenditure requirements. Actual results could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to Aadi’s ability to successfully commercialize FYARRO; uncertainties associated with the clinical development and regulatory approval of FYARRO in additional indications, including potential delays in the commencement, enrollment and

completion of clinical trials for additional indications; the risk that unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; risks associated with the failure to realize any value from FYARRO in light of inherent risks and difficulties involved in successfully bringing product candidates to market; risks related to Aadi's estimates regarding future expenses, capital requirements and need for additional financing; and risks related to the impact of the COVID-19 pandemic on Aadi's operations, the biotechnology industry and the economy generally.

Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" in Aadi's Form 10-K filed on March 17, 2022, and elsewhere in Aadi's reports and other documents that Aadi has filed, or will file, with the SEC from time to time and available at www.sec.gov.

All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Aadi undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

FYARRO™ is a trademark of Aadi Bioscience, Inc.

For more information about FYARRO, visit: https://fyarro.com/

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Source: Aadi Bioscience