Aadi Bioscience Announces Preliminary Data for FYARRO™ in Patients with Solid Tumors Harboring TSC1 and TSC2 Alterations from a Multi-Institution Expanded Access Study to be Presented at ASCO 2021 Virtual Meeting

May 19, 2021

LOS ANGELES, May 19, 2021 (GLOBE NEWSWIRE) — Aadi Bioscience ("Aadi"), a privately-held biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, announces the release of an abstract selected for poster presentation at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting being held virtually on June 4-8, 2021. The poster presentation will highlight antitumor activity in a subset of patients with *TSC1* or *TSC2* alterations and neoplasms other than advanced malignant PEComa who were treated with single-agent nab-sirolimus (FYARRO™) in an expanded access program (NCT03817515). Details on the abstract are summarized below.

- **Abstract Title:** Institutional experience with *nab*-sirolimus in patients with malignancies harboring *TSC1* or *TSC2* mutations
- **Abstract Number:** 3111
- **Session Title:** Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
- **Session Date and Time:** June 4, 2021 at 9 AM CT

About Aadi Bioscience

Aadi is a clinical stage biopharmaceutical company developing precision therapies for genetically-defined cancers. Aadi's primary goal is to bring transformational outcomes 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. Aadi's product FYARRO™ (sirolimus albumin-bound nanoparticles for injectable suspension; *nab*-sirolimus; ABI-009) is an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, mTOR target suppression, and superior efficacy over other mTOR inhibitors in preclinical models.[1] Aadi's initial focus is on treating patients with alterations in *TSC1* or *TSC2* genes, tumor suppressors that when inactivated, may be drivers in many different cancer types. Aadi's registration trial in advanced malignant PEComa (the AMPECT trial) of FYARRO demonstrated meaningful clinical efficacy in malignant PEComa[2, 3], a type of cancer with the highest known mutation rate of *TSC1* or *TSC2* genes. Based on the AMPECT trial, emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* alterations, and following discussions with the FDA, Aadi plans to initiate a tumor-agnostic registrational trial in cancers harboring *TSC1* or *TSC2* inactivating alterations by the end of 2021.

Aadi also has ongoing studies to evaluate dosing of FYARRO in combination regimens. More information is available on the Aadi website at https://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 FYARRO, including expectations regarding the clinical responses and safety profile. 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 obtain sufficient additional capital to continue to advance FYARRO; uncertainties associated with the clinical development and regulatory approval of FYARRO, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of clinical trials do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of 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; and risks related to the impact of the COVID-19 outbreak on Aadi's operations, the biotechnology industry and the economy generally. 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.

References:

[1] AACR 2019 Abstract: https://cancerres.aacrjournals.org/content/79/13_Supplement/348

[2] ASCO 2020 Abstract: https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.11516?af=R

[3] The data have not been reviewed by the FDA

Contacts

Investors & Media:
Investors:
Irina Koffler
ikoffler@lifesciadvisors.com

Aadi Bioscience, Inc.

Nancy Jorgesen
njorgesen@aadibio.com