



Aadi Bioscience to Present New Preclinical Data on nab-Sirolimus (ABI-009) at AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics

October 6, 2021

- Poster Presentation to go Live on October 7, 2021 at 9 a.m. ET and on Demand at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics -

LOS ANGELES, Oct. 06, 2021 (GLOBE NEWSWIRE) -- Aadi Bioscience, Inc. ("Aadi") (Nasdaq: AADI), a clinical-stage biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced it will present a poster at the [Virtual International Conference on Molecular Targets and Cancer Therapeutics](#) to be held this year from October 7th -10th.

The Company will present preclinical data evaluating nab-sirolimus (ABI-009) in *PTEN*-deleted and *TSC2*-deleted cancer models in comparison with other mTOR inhibitors sirolimus and everolimus and evaluating their effects on important downstream targets S6 and 4EBP1.

Learn more about Aadi's development of therapies that target the genetic drivers of cancers of the mTOR pathway at www.aadibio.com.

Aadi's presentation at the 2021 AACR-NCI-EORTC International Conference:

All times noted are U.S. Eastern Time (ET).

Presentation Title: nab-Sirolimus improves mTOR pathway suppression and antitumor activity versus oral mTOR inhibitors in *PTEN* null bladder cancer (UMUC3) and *TSC2* null liver cancer (SNU398) xenografts

Author: Shihe Hou, Ph.D., Aadi Bioscience, Inc.

Session: mTOR/PI3-kinase, P138

Session Date/Time: Thursday, October 7, 9:00 a.m. and on-demand throughout conference

The poster will be posted to the Events and Presentations section of Aadi Bioscience's [website](#) after 9 am ET on October 7th.

About Aadi Bioscience and FYARRO™

Aadi is a clinical-stage biopharmaceutical company developing precision therapies for genetically-defined cancers. Aadi's primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations such as alterations in *TSC1* or *TSC2* genes, 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 lead product candidate is FYARRO™ (sirolimus albumin-bound nanoparticles for injectable suspension; nab-sirolimus; ABI-009), 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 models².

Aadi's registration trial of FYARRO in advanced malignant PEComa (the "AMPECT trial") demonstrated meaningful clinical efficacy in malignant PEComa¹, a type of cancer with the highest known alteration rate of *TSC1* or *TSC2* genes. FYARRO has received Breakthrough Therapy, Fast-Track and Orphan Designations from the U.S. Food and Drug Administration (FDA). A rolling New Drug Application (NDA) submission was completed in May 2021 for this indication and the FDA accepted the NDA in July 2021 and granted Aadi Priority Review status with a Prescription Drug User Fee Act ("PDUFA") target action date of November 26, 2021.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* inactivating alterations³, and following discussions with the FDA, Aadi plans to initiate a tumor-agnostic registrational trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations by the end of 2021. Aadi also has ongoing studies to evaluate dosing of FYARRO in combination regimens. FYARRO is an investigational drug that has not been approved by the FDA for commercial distribution in the United States. More information is available on the Aadi website at www.aadibio.com.

Forward-Looking Statements

Aadi Bioscience, Inc. ("Aadi", "The Company") 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, regulatory approval and commercialization, and the timing of the initiation of additional clinical trials. 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, or the timeline to obtain, regulatory approval from the FDA and other regulatory authorities for FYARRO in advanced malignant PEComa; risks related to Aadi's ability to successfully commercialize, including the timing of a commercial launch of FYARRO in advanced malignant PEComa; 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 may not be reproduced and do not necessarily predict final results; the risk 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; 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 outbreak 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" 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.

References:

¹ ASCO 2020 Abstract: https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.11516?af=R

² AACR 2019 Abstract: https://cancerres.aacrjournals.org/content/79/13_Supplement/348

³ ASCO 2021 Abstract: <https://meetings.asco.org/abstracts-presentations/197602>

Contacts

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Source: Aadi Bioscience