Aadi Bioscience Announces Poster Presentations at 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

October 12, 2023

Two new real-world next-generation sequencing studies reinforce prevalence of TSC1/2 mutations in up to 2% of all tumors, a significant addressable cancer population

PRECISION1 tumor-agnostic trial testing nab-sirolimus for patients with TSC 1/2 mutations on track for interim analysis on 40 patients before the end of 2023

Evaluation of nab-sirolimus in preclinical combination with PI3K and AKT inhibitors indicate enhanced antitumor effects in PIK3CA-mutated breast cancer

LOS ANGELES, Oct. 12, 2023 /PRNewswire/ -- Aadi Bioscience, Inc. (NASDAQ: AADI), a biopharmaceutical company focused on developing and commercializing precision therapies for patients with mTOR pathway alterations, today announced details of four poster presentations at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place October 11-15, 2023, in Boston, MA.

Abstracts and poster presentation details are below:

Title: "*Inactivating TSC1 and TSC2 alterations, co-mutations, and genomic instability in advanced cancers: Analysis of a real-world (RW) patient population using the Foundation Medicine genomic database"*
Poster Number: C019
Session Title: Poster Session C
Date/Time: Saturday, October 14, 2023, 12:30 pm-4:00 pm EDT
Authors: David J. Kwiatkowski, MD, PhD; Norma A. Palma, PhD; Willis H. Navarro, MD; Gopa Iyer, MD

Abstract highlights:

- To appreciate the potential for *TSC1* and *TSC2* as therapeutic biomarkers, *TSC1* and *TSC2* mutational data from an RW genomic database were analyzed.
- Next-generation sequencing data from Foundation Medicine's genomic database of patients primarily with advanced cancer were analyzed using the FoundationInsights™ web-based platform.
- In a large RW database of patients with advanced cancer, inactivating *TSC1* and *TSC2* variants occurred in 1.9% of patients. These occurred across common tumor types at rates as high as 8.6% (urinary bladder tumors).
- These observations suggest cancers with *TSC1* and/or *TSC*2 alterations may be candidates for targeted therapy.

Title: "*Real-world (RW) characterization and frequency of TSC1 and/or TSC2 alterations collected from tumor tissue and liquid biopsies from the Tempus genomic database in patients with advanced cancer"* Poster Number: B003
Session Title: Poster Session B
Date/Time: Friday, October 13, 2023, 12:30 pm-4:00 pm EDT
Authors: David J. Kwiatkowski, MD, PhD; Norma A. Palma, PhD; Willis H. Navarro, MD; Gopa Iyer, MD

Abstract highlights:

- PRECISION1 will assess the clinical benefit of *nab*-sirolimus in patients with cancer with inactivating *TSC1* or *TSC2* alterations.
- To appreciate the potential for *TSC1* and/or *TSC2* targeted therapy, *TSC1* and *TSC2* alterations across a large RW patient population with advanced cancer using data from tissue and liquid biopsies were analyzed.
- In a large (N=154,965) NGS database of patients with cancer, inactivating *TSC1* and/or *TSC2* variants occurred in about 1.7% of patients overall and were frequently identified in commonly occurring cancers.
- The frequency of *TSC1* and/or *TSC2* alterations and tumor types were generally consistent between tumor tissue samples and liquid biopsies.
- Consistency between primary vs metastatic samples suggests *TSC1* and *TSC2* alterations may not be acquired, although samples were not longitudinal.

Title: *"Evaluation of nab-sirolimus in combination with PI3K pathway inhibitors to overcome PI3K/mTOR resistance in PI3K-mutant breast cancer cell lines"* Poster Number: A117
Session Title: Poster Session A
Date/Time: Thursday, October 12, 2023, 12:30 pm-4:00 pm EDT
Authors: Sean Wallace, PhD; Khine Nyein Myint, PhD; Shihe Hou, PhD; Maria Zalath, BA; Andrew Kwon, PhD; Brian McMorran, PhD; Igor Vivanco,

PhD

Abstract highlights:

- The PI3K-AKT-mTOR pathway is frequently activated in many cancer types and plays a central role in tumorigenesis. However, clinical use of therapies targeting this pathway is limited by compensatory vertical and horizontal feedback activation loops, which limit antitumor efficacy and lead to drug resistance.
- Combination therapy strategies employing simultaneous inhibition of multiple PI3K-AKT-mTOR pathway elements may overcome these resistance mechanisms and improve antitumor activity. In these studies, we analyzed the effects of *nab*-sirolimus combinations in PI3K-mutant breast cancer (BrCa) cells.
- The antitumor effects of PI3K and AKT inhibitors were enhanced by the addition of the novel mTOR inhibitor *nab*-sirolimus. The improved effectiveness of the PI3K and mTOR inhibitor combination was due to the reciprocal overcoming of resistance mechanisms induced by single agent treatment.
- These data potentially support a vertical PI3K pathway inhibition strategy using *nab*-sirolimus and PI3K/AKT inhibitors in PIK3CA-mutated BrCa, regardless of hormone receptor status.

An encore presentation titled, "*Phase 2, Multicenter, Open-label Basket Trial of nab-Sirolimus for Malignant Solid Tumors Harboring Pathogenic Inactivating Alterations in TSC1 and TSC2 (PRECISION1)*" will also be presented during the late breaking session on Friday, October 13, 2023.

More information can be found on the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics meeting website.

About Aadi Bioscience, Inc.

Aadi is a commercial-stage biopharmaceutical company focused on precision therapies for genetically defined cancers to bring transformational therapies to cancer patients with mTOR pathway driver alterations. Aadi received FDA approval and has commercialized FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Aadi has also initiated PRECISION1, a Phase 2 tumor-agnostic registration-intended trial in mTOR inhibitor-naïve malignant solid tumors harboring *TSC1* or *TSC2* inactivating alterations. More information on the Company's development pipeline is available on the Aadi website at www.aadibio.com and connect with us on Twitter and LinkedIn.

Forward-Looking Statements
This press release contains certain forward-looking statements regarding the business of Aadi Bioscience that are not a description of historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based on the Company's current beliefs and expectations and may include, but are not limited to, statements regarding: the Company's anticipated growth and continued advancements, including in potential additional indications; expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; expectations regarding the size of the potential targeted markets for FYARRO, including the market for patients harboring *TSC1*/*TSC2* inactivating alterations; and the clinical results and timing of additional clinical trials, including the registration-directed PRECISION1 trial in patients harboring *TSC1*/*TSC2* inactivating alterations and the release of data with respect thereto. 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, 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; and risks related to the Company's estimates regarding future expenses, capital requirements and need for additional financing.

Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, including under the caption "Item 1A. Risk Factors," and in Aadi's subsequent Quarterly Reports on Form 10-Q, 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 cautionary statement is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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