Aadi Bioscience to Present Multiple Posters on nab-Sirolimus at the 2023 American Association for Cancer Research (AACR) Annual Meeting

April 14, 2023

LOS ANGELES, April 14, 2023 /PRNewswire/ -- Aadi Bioscience, Inc. (NASDAQ: AADI), a commercial-stage biopharmaceutical company focused on developing and commercializing precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced the presentation of three posters at the 2023 American Association for Cancer Research Annual Meeting (AACR), taking place April 14-19, 2023, in Orlando, FL.

The presentations at AACR 2023 include: a trials-in-progress (TIP) poster for the ongoing PRECISION 1 trial, a registrational directed tumor agnostic study for patients with solid tumors driven by *TSC1* or *TSC2* alterations; results on the anti-tumor activity of *nab*-sirolimus in combination with KRAS-G12C inhibitors in xenograft models; and results of a biomarker analysis from the AMPECT trial correlating response to *nab*-sirolimus with *TSC1* and *TSC2* inactivating alterations, which includes previously reported response data from AMPECT.

Abstracts and poster presentation details are below:

Title: "*Phase 2, multicenter, open-label basket trial of nab-sirolimus for patients with inactivating alterations in TSC1 or TSC2 (PRECISION I)*"
Date and Time: Monday, April 17, 2023, 9:00 AM - 12:30 PM
Session Title: Phase II and Phase III Clinical Trials in Progress
Presentation Number: CT057

Abstract highlights:

- *nab*-Sirolimus is a novel albumin-bound mTOR inhibitor (mTORi) approved in the US for adult patients with advanced malignant PEComa.
- Eligible patients are ≥12 years old and mTORi-naïve, possess malignant solid tumors with *TSC1* or *TSC2* inactivating alterations (confirmed by central review of sequencing reports), and have received appropriate standard treatments, as determined by the investigator.
- Available data from the AMPECT exploratory analysis and an expanded access program suggest acceptable efficacy and safety of nab-sirolimus, an mTORi with enhanced antitumor activity, in patients with solid tumors harboring inactivating alterations in *TSC1* and/or *TSC2*.
- *nab*-Sirolimus 100 mg/m2 will be given weekly intravenously over 30 minutes on Days 1 and 8 of each 21-day cycle. The primary endpoint is overall response rate per independent radiographic review (IRR) using RECIST v1.1. Other endpoints include duration of response, time to response, progression-free survival by IRR, overall survival, patient-reported quality of life, and safety.
- Enrollment began in March 2022. Collaboration with leading next-generation sequencing vendors will expedite the identification of patients with qualifying *TSC1* or *TSC2* mutations; study access will be facilitated through a "just-in-time" approach to trial location activation.
- Based on the prevalence of *TSC1* or *TSC2* inactivating alterations, the most frequent tumor types expected are bladder, hepatobiliary, endometrial, soft tissue sarcoma, ovarian, and esophagogastric.

Title: "*Synergistic anti-tumor activity of nab-sirolimus in combination with KRAS inhibitors (KRASis) sotorasib and adagrasib in KRAS G12C NSCLC and bladder cancer xenografts*"
Date and Time: Tuesday, April 18, 2023, 1:30 - 5:00 PM
Session Category: Clinical Research Excluding Trials
Session Title: Combination Therapies for Cancer
Presentation Number: 5484

Abstract highlights:

- *KRAS* is frequently mutated in non-small cell lung cancer (NSCLC) and other tumor types, with *KRAS G12C* mutation representing ~12% of patients with NSCLC. Sotorasib and adagrasib are approved for the treatment of *KRAS G12C* NSCLC. Mutations in *KRAS* may lead to mTORC1 activation, and mTOR may contribute to adaptive resistance to KRASis.
- This study investigated the antitumor activity of *nab*-sirolimus in combination with KRASis in *KRAS G12C* NSCLC and bladder xenograft models.
- *nab*-sirolimus in combination with either sotorasib or adagrasib showed greater tumor growth inhibition, a higher meaningful tumor regression rate and synergistic antitumor activity vs single agent therapy.
- A multicenter, single-arm, open-label Phase 1/2 clinical study is planned to determine the recommended Phase 2 dose,

safety, tolerability, and efficacy for the combination of adagrasib and *nab*-sirolimus in patients with *KRAS G12C* tumors.

Title: *"Biomarker analysis from AMPECT correlating response to nab-sirolimus with TSC1 and TSC2 inactivating alterations"*
Date and Time: Wednesday, April 19, 2023, 9:00 AM - 12:30 PM
Session Category: Clinical Research Excluding Trials
Session Title: Late-Breaking Research: Clinical Research 3
Presentation Number: LB288

Abstract Highlights:

- An exploratory biomarker analysis was performed on samples from patients enrolled in the AMPECT study, a Phase 2, multicenter, open-label trial in advanced malignant PEComa (NCT02494570).
- A variety of pathogenic inactivating alterations were observed in *TSC1* and *TSC2* genes, though *TSC2* mutations were most commonly frameshift mutations; no recurring mutations were observed.
- A tumor-agnostic study (PRECISION 1: NCT05103358) is now recruiting patients with pathogenic inactivating *TSC1* or *TSC2* alterations to further examine these biomarker findings.

Full session and meeting details are available through the AACR Annual Meeting planner: AACR Annual Meeting 2023 | Meetings | AACR. Each poster will be made available following the date of presentation at AACR, on the investor relations page of the Aadi website at **www.aadibio.com**

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 PRECISION 1, 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**.

Cautionary Note Regarding Forward-Looking Statements

This press release contains certain forward-looking statements regarding the business of Aadi Biosciences that are not a description of historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the Company's current beliefs and expectations; anticipated future growth; the potential commercialization of FYARRO in the tumor agnostic oncology market; expectations regarding management performance following the leadership transition; and the Company's potential as a commercial precision oncology company. 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, those associated with 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; and risks related to collaborations with third-parties.

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," anticipated to be filed on or about the date hereof, 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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