Aadi Bioscience Reports Interim Results from PRECISION1 Trial of nab-Sirolimus Demonstrating Anti-Tumor Activity in Solid Tumors with TSC1 or TSC2 Inactivating Alterations

December 14, 2023

Interim results from investigator-assessed responses in first 40 patients from TSC1 and TSC2 arms demonstrate sustained tumor reductions in heavily pre-treated population

80 patients now enrolled in PRECISION1 supporting two-thirds interim analysis expected in 3Q 2024

Study on track for completion by end 2024; final data readout expected in early 2025

Company to host conference call today at 5:00 pm EST

LOS ANGELES, Dec. 14, 2023 /PRNewswire/ -- Aadi Bioscience, Inc. (NASDAQ: AADI), a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes, today reported results from a planned interim analysis on the first third of participants in the ongoing tumor-agnostic PRECISION1 trial evaluating *nab*-sirolimus in patients with *TSC1* or *TSC2* inactivating alterations.

"Our tumor agnostic PRECISION1 trial is designed to elucidate the impact of *nab*-sirolimus on cancers expressing inactivating alterations of *TSC1* or *TSC2*, regardless of tumor type. We are encouraged by the preliminary data from this pre-planned analysis and by the responses and clinical benefit demonstrated in advanced cancer patients who have failed an average of three prior lines of therapy," said Loretta Itri, MD, CMO of Aadi Bioscience. "Full enrollment in the trial is expected by the spring of 2024 and we believe we are on track to generate compelling clinical evidence for advancing *nab*-sirolimus toward potential expansion of the current registration, bringing this innovative therapeutic agent to more cancer patients."

The interim analysis includes data from the first third of trial participants (n=40) with a minimum of 4.5 months of follow-up, including investigator-assessed response and safety analyzed separately in each of the *TSC1* and *TSC2* arms. Nine different tumor types were enrolled in the *TSC1* arm and 13 tumor types were enrolled in the *TSC2* arm.

Efficacy of *nab*-sirolimus in patients with tumors harboring pathogenic inactivating alteration in *TSC1*

Of the 22 patients enrolled, 19 patients received ≥ 1 post baseline scan and were evaluable for efficacy. Observations included:

- A 26% Overall Response Rate (ORR) including 5 partial responses (PR) with 4 confirmed responses and 1 unconfirmed response (uPR)
- All responses were ongoing at the time of data cutoff. The patient with uPR remains on treatment and is awaiting a confirmatory scan
- 9 patients had stable disease (SD), 3 of which were greater than or equal to six months in duration, resulting in a clinical benefit rate of 42% (5 PR + 3 SD ≥ 6 mos)
- Patients were heavily pre-treated with median of 3 prior lines of therapy
- Median time to response was 1.4 months
- Responses were seen across four different epithelial carcinomas
- 60% of responders experienced > 50% tumor reduction

Efficacy of *nab*-sirolimus in patients with tumors harboring pathogenic inactivating alteration in *TSC2*

Of the 18 patients enrolled, all 18 patients received ≥ 1 post baseline scan and were evaluable for efficacy. Observations included:

- An 11% ORR including 2 PRs with 1 confirmed and 1 uPR
- 12 patients had SD, 3 of which were greater than or equal to six months resulting in a clinical benefit rate of 28% (2 PR + 3 SD ≥ 6 mos)
- Patients were heavily pre-treated with median of 3.5 prior lines of therapy; 50% had ≥ 5 prior lines of therapy
- Responses were seen in one epithelial carcinoma and one sarcoma

No new safety signals were observed, and no grade four treatment-related events or deaths occurred. One patient discontinued the study due to grade two pneumonitis that completely resolved after discontinuation of therapy. Across both arms, the safety profile was consistent with the *nab*-sirolimus label and the mTOR inhibitor drug class.

80 patients are currently enrolled in the PRECISION1 trial, supporting the two-thirds interim analysis expected in the third quarter of 2024. The ORR analysis in this cohort will be based on independent radiological review with a minimum of six months of follow-up for all patients. The trial is expected to be completed by the end of 2024 with results anticipated in early 2025.

Conference Call Information

The Aadi management team is hosting a conference call and webcast today at 5:00 pm ET (2:00 pm PT) to discuss the interim results from the PRECISION1 trial.

Participants may access a live webcast of the call and the associated slide presentation on these data through the "Investors & News" page of the Aadi Bioscience website at aadibio.com. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the Company's website for at least 30 days.

About PRECISION1

The PRECISION1 trial is a multi-center, open-label, tumor-agnostic prospective registration intended clinical trial of *nab*-sirolimus. This tumor agnostic study will evaluate approximately 60 mTOR inhibitor naïve patients in each of two independent study arms, or approximately 120 in total, comprised of patients with solid tumors harboring pathogenic inactivating alterations in either TSC1 or TSC2 genes. In September 2021, the FDA designated the investigation of *nab*-sirolimus for the treatment of adults and adolescents with solid tumors that have a pathogenic inactivating alteration of the TSC1 or TSC2 gene as a Fast Track development program.

Nab-Sirolimus 100 mg/m^2 is 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.

About Aadi Bioscience

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 relating to: the anticipated timing of commencement, enrollment, data releases and completion of the Company's clinical trials, including the expected full enrollment of the PRECISION 1 trial by spring of 2024, the expected PRECISION 1 two-thirds interim analysis in 3Q 2024, the anticipated completion of the PRECISION 1 study by the end of 2024, and the final PRECISION 1 data readout anticipated in early 2025; management's belief that the Company is on track to generate additional clinical evidence in the PRECISION 1 study and for advancing *nab*-sirolimus toward registration; the timing and likelihood of regulatory filings and approvals of FYARRO for new indications; the anticipated timing for potential catalysts based on data for the Company's clinical trials; and the sufficiency of the Company's existing capital resources and the expected timeframe to fund the Company's 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 the release of interim, topline and preliminary data from clinical trials; 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 unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; risks associated with the failure to realize further value from FYARRO in light of inherent risks and difficulties involved in successfully bringing FYARRO to market in additional indications, including in patients harboring *TSC1* and *TSC2* inactivating alterations; 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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