Aadi Bioscience Provides PRECISION1 Trial and Corporate Updates

August 20, 2024

PRECISION1 tumor-agnostic trial unlikely to meet regulatory threshold to support an accelerated approval and will be halted

Aadi will focus on FYARRO® commercial business for its approved indication, PEComa, and conduct a comprehensive strategic review to maximize shareholder value

To further preserve cash position, Aadi will adjust ongoing Phase 2 trials and reduce R&D headcount by 80%, thereby extending cash runway into at least 2H 2026

LOS ANGELES, Aug. 20, 2024 /PRNewswire/ -- Aadi Bioscience, Inc. (NASDAQ: AADI) today announced it will halt the registration-intended PRECISION1 trial of *nab*-sirolimus in patients with solid tumors harboring *TSC1* or *TSC2* inactivating alterations. An analysis by the Independent Data Monitoring Committee demonstrated that the study was unlikely to exceed an efficacy threshold necessary to support an accelerated approval, the key goal of this Phase 2 study. The approximately 25 patients in PRECISION1 who are still benefiting from *nab*-sirolimus will be eligible for transition to a planned expanded access protocol, and a complete analysis of the PRECISION1 trial will be provided at a later date.

Aadi will now focus on preserving cash while maximizing its commercial business. Aadi's marketed product, FYARRO®, is the only preferred treatment for patients with advanced malignant PEComa, a rare and aggressive cancer. In the second quarter of this year, FYARRO delivered sales of $6.2M.

To further preserve cash runway, Aadi will pause new enrollment, but continue dosing previously enrolled patients, in two, ongoing Phase 2 trials of *nab*-sirolimus for advanced or recurrent endometrioid-type endometrial cancer (EEC) and neuroendocrine tumors (NETs). Both studies have enrolled sufficient patients (n=20 and n=10 for EEC and NETs, respectively) to assess initial efficacy signals later this year. Aligned to these pipeline adjustments, the Company is reducing its Research & Development workforce by 80%. Together these actions extend cash runway into at least 2H 2026.

"We are humbled by the effort of the investigators, support staff, and most importantly, the patients and their families who took part in PRECISION1. While *nab*-sirolimus showed monotherapy activity in the study population, the trial fell short of delivering what we believe would be required to support an accelerated approval in the broad *TSC1/TSC2* inactivating mutations indication. We look forward to providing the full trial analysis at a later date," said David Lennon, President and CEO of Aadi Bioscience. "I want to thank the dedicated Aadi employees who worked tirelessly on this trial and are negatively impacted by this outcome. Given the change in the development pipeline, we have taken the necessary steps to immediately preserve cash runway, and have hired an advisory firm to explore all options to maximize value for shareholders."

About Aadi Bioscience

Aadi is a precision oncology company focused on the commercialization of FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). More information on the Company 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 Company's cash runway extending into the second half of 2026; the Company's strategic review; the Company's workforce reduction; the anticipated timing of data releases of the Company's clinical trials, including the analysis of the PRECISION1 trial and initial efficacy signals of the EEC and NETS 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 associated with the ability to successfully commercialize FYARRO; the risk that unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; uncertainties associated with the clinical development and regulatory approval of FYARRO in additional indications; failure to demonstrate the efficacy of FYARRO in clinical trials for additional indications; 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, 2023, 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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