



Aadi Bioscience Presents PRECISION 1 Trial in Progress Poster and AMPECT Trial Final Analysis at the Connective Tissue Oncology Society (CTOS) 2022 Annual Meeting

November 17, 2022

Trial-in-progress poster showcases clinical trial design for PRECISION 1 and two additional posters demonstrate favorable durability of response and long-term safety of nab-sirolimus in the completed AMPECT study

LOS ANGELES, Nov. 17, 2022 /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 presented three posters on completed and ongoing clinical trials for *nab-sirolimus* at the Connective Tissue Oncology Society (CTOS) 2022 Annual Meeting, taking place November 16-19, 2022 in Vancouver, Canada. *nab-sirolimus* (FYARRO®) is a novel mTOR inhibitor that leverages albumin-bound nanoparticle technology and is approved for the treatment of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

"We are thrilled to share more information from our AMPECT and PRECISION 1 trials with the leading sarcoma specialists from around the globe at CTOS 2022," said Loretta Itri, M.D., Chief Medical Officer of Aadi Bioscience. "The trial-in-progress poster presents the design of our PRECISION 1 trial, while our two additional posters provide long-term analysis from our AMPECT trial that demonstrates *nab-sirolimus*' durability of response and long-term safety. We want to thank the CTOS organizers for the opportunity to showcase Aadi's clinical success and the patients who participated in these studies."

Details of the poster presentations are below:

Title: "Phase 2, Multicenter, Open-Label Basket Trial of nab-Sirolimus for Patients with Malignant Solid Tumors Harboring Pathogenic Inactivating Alterations in TSC1 or TSC2 Genes (PRECISION 1)"

Date/Time: Thursday, November 17, 2022

Aadi and its collaborators present a trial-in-progress poster for PRECISION 1, a registrational-directed trial now recruiting for patients with solid tumors driven by *TSC1/TSC2* alterations, an underserved patient population with no targeted therapeutic options.

Title: "Study-end Analysis from AMPECT, an Open-Label, Phase 2 Registration Trial of Patients with Advanced Malignant PEComa Treated with nab-Sirolimus, Showing Durability of Responses and Long-Term Safety"

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Aadi and its collaborators present final 3-year follow up data from the AMPECT Phase 2 study. The AMPECT study met its primary endpoint, showing a median Duration of Response (DoR) of over 3 years. In addition, median Overall Survival (OS) was updated to 53.1 months. Overall Response Rate (ORR), Disease Control Rate (DCR), and Progression Free Survival (PFS) were consistent with prior analysis of *nab-sirolimus* in AMPECT.

Title: "Management of Adverse Events in the AMPECT Trial of nab-Sirolimus for the Treatment of Advanced Malignant Perivascular Epithelioid Cell Neoplasm (PEComa)"

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Aadi and its collaborators present data on the adverse event (AE) management in the AMPECT trial over three years after the primary analysis was presented. *nab-Sirolimus* was generally well-tolerated, and the majority of the AEs due to *nab-sirolimus* treatment in the AMPECT trial were manageable. Importantly, dose reductions for AE management did not appear to compromise efficacy in patients who responded to therapy.

More information can be found on the CTOS meeting website at [2022 CTOS Annual Meeting \(eventscribe.net\)](https://www.ctosmeeting.com/2022-CTOS-Annual-Meeting-(eventscribe.net)).

About Aadi Bioscience

Aadi is a commercial-stage biopharmaceutical company focused on precision therapies for genetically defined cancers. Aadi's primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations 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. In November 2021, Aadi received FDA approval for FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa), and in February 2022, Aadi announced the commercial launch of FYARRO in this indication.

Based on exploratory data from AMPECT, a registrational study supporting approval in advanced malignant PEComa, and following a pre-IND meeting with the FDA, Aadi has 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 is available on the Aadi Bioscience website at www.aadibio.com.

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; the Company's anticipated growth; plans and potential for success relating to commercializing FYARRO; expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; expectations regarding management's performance; plans related to further development and manufacturing of FYARRO; pricing and reimbursement of FYARRO; the rate and degree of

market acceptance of FYARRO; anticipated reception of FYARRO in the physician community; the clinical results and timing of additional clinical trials, including the registration-directed trial in patients harboring *TSC1* or *TSC2* inactivating alterations; the timing and likelihood of regulatory filings and approvals of FYARRO, including in potential additional indications and potential filings in additional jurisdictions; plans regarding clinical trials, in collaboration with Mirati Therapeutics, for the combination of adagrasib and nab-sirolimus in patients with KRASG12C-mutant tumors and related timing and expectations regarding the efficacy of the combination; and the sufficiency of our existing capital resources and the expected timeframe to fund our 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, those associated with the ability to successfully commercialize FYARRO; risks related to reimbursement and pricing of FYARRO; 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; 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 pandemic 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 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, including under the caption "Item 1A. Risk Factors," and in Aadi's subsequent Quarterly Reports on Form 10-Q filed on May 12, 2022, August 10, 2022 and November 9, 2022, 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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