Aadi Bioscience Announces Publication of Long-Term Efficacy and Safety Data Further Supporting FYARRO® for the Treatment of Malignant PEComa

March 1, 2024

After 3 years of follow-up in AMPECT trial, confirmed clinically meaningful overall response rate, including multiple patients with complete responses

Demonstrated 40 months median duration of response and median survival >53 months

Historically, median survival has ranged from 16 to 29 months in the setting of metastatic/unresectable malignant PEComa[1,2]

LOS ANGELES, March 1, 2024 /PRNewswire/ -- Aadi Bioscience, Inc. (NASDAQ: AADI), a biopharmaceutical company focused on developing and commercializing precision therapies for patients with mTOR-driven cancers, announced today that long-term efficacy and safety results from its completed Phase 2 registrational AMPECT study of *nab*-sirolimus in malignant PEComa were published in the *Journal of Clinical Oncology (JCO)*. The manuscript, "A Phase 2 Trial of *nab*-Sirolimus in Patients with Advanced Malignant Perivascular Epithelioid Cell Tumors (AMPECT): Long-term Efficacy and Safety Update," authored by Andrew J. Wagner, MD, PhD and colleagues can be accessed online ahead of print here.

"We are excited to report the final outcomes of this registrational trial after an additional 3 years of follow-up. Responses to *nab*-sirolimus in patients with advanced PEComa lasted a median of 39.7 months," commented Dr. Wagner, Senior Physician at the Dana-Farber Cancer Institute and Associate Professor of Medicine at Harvard Medical School. "The median survival outcomes were consistent with the primary analysis, and the confirmed overall response rate remained at 38.7% and included an additional patient with a complete response. The long-term, durable responses to *nab*-sirolimus with tolerable safety are great news for patients with this rare disease."

"The data published in *JCO* highlight the potential for *nab*-sirolimus to be an effective and highly differentiated treatment that may help patients suffering from this aggressive cancer achieve longer duration of responses and survival rates," said Loretta Itri, MD, Chief Medical Officer of Aadi. "We want to thank the principal investigators, study coordinators, and the patients who participated in AMPECT. We believe these results provide a significant contribution to sarcoma research and we look forward to continuing to advance *nab*-sirolimus."

The AMPECT trial (NCT02494570) evaluated the efficacy and safety of *nab*-sirolimus in patients with advanced malignant PEComa and was the first prospective registrational study in this setting. Data from this Phase 2, open-label, single-arm, multi-center study served as the basis for the FDA approval of FYARRO® in advanced malignant PEComa regardless of mutational status.

Key updates reported:

- **Efficacy:** At study completion, the confirmed ORR on the basis of independent radiographic review using RECIST v1.1 remained at 38.7% (95% CI, 21.8%-57.8%), with an additional converted confirmed complete response (CR) since the previously published analysis. The disease control rate (DCR) remained at 71% (95% CI, 52.0%–85.8%).

- **Durability:** At the time of the primary analysis, the median duration of response (mDOR) had not been reached. At study completion, the mDOR was reached at 39.7 months (95% CI, 6.5 months to NR), median PFS remained the same at 10.6 months (95% CI, 5.5-41.2 months), and median OS was 53.1 months (95% CI, 22.2 months to NR).

- **Safety:** The most common TRAEs were stomatitis (82.4%) and fatigue and rash (each 61.8%). No new or unexpected adverse events occurred, and no grade 4 or 5 TRAEs were reported.

1. Bleeker JS, et al. *Sarcoma*. 2012;541626.
2. Benson C, et al. *Anticancer Res*. 2014;34(7):3663-3668.

About Aadi Bioscience, Inc.

Aadi is a commercial-stage biopharmaceutical company focused on precision therapies for cancers to bring transformational therapies to cancer patients with alterations in the mTOR pathway, a key regulator of cell growth and cancer progression. 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 clinical trials of *nab*-sirolimus as a single agent or in combination for the treatment of other mTOR-driven cancers. PRECISION 1 (NCT05103358), a Phase 2 tumor-agnostic registration-intended trial in mTOR inhibitor-naïve malignant solid tumors harboring *TSC1* or *TSC2* inactivating alterations is currently enrolling in the US and globally. A multicenter, open-label, single-arm Phase 2 study of *nab*-sirolimus in combination with letrozole is currently enrolling patients with advanced or recurrent endometrioid endometrial cancer (NCT05997017); *nab*-sirolimus is also being investigated as a single agent in an open-label, single-arm, Phase 2 trial for the treatment of patients with neuroendocrine tumors of the GI tract, pancreas, or lung (NCT05997056). More information on the Company's development pipeline is available on the Aadi website at www.aadibio.com and connect with us on X (formerly 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 plans and potential for success relating to commercializing FYARRO; expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; plans related to further development and manufacturing of FYARRO; 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, those associated with the ability to successfully commercialize FYARRO; uncertainties associated with the clinical development and regulatory approval of FYARRO in 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 Aadi'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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