Aadi Bioscience Presents New Subgroup Analysis of Patients with Advanced Malignant PEComa of Gynecologic Origin Treated with nab-Sirolimus at Society of Gynecologic Oncology (SGO)

March 17, 2024

Subgroup experienced efficacy and safety consistent with overall study population

Advanced malignant PEComa tumors of gynecologic origin accounted for more than half of the evaluable patients enrolled in AMPECT

Additional data presented highlight nab-sirolimus as potential approach for mTOR-driven gynecologic cancers

LOS ANGELES, March 17, 2024 /PRNewswire/ -- Aadi Bioscience, Inc. (NASDAQ: AADI), a commercial-stage precision oncology company focused on developing and commercializing therapies for cancers with alterations in the mTOR pathway, today announced patients in the AMPECT trial whose malignant perivascular epithelioid cell tumor (PEComa) had gynecologic origins experienced efficacy and safety consistent with the overall study population. The AMPECT trial formed the basis for the FDA approval of the company's *nab*-sirolimus, FYARRO®, for advanced malignant PEComa regardless of mutational status. This new subgroup analysis will be presented during an oral plenary at the Society of Gynecologic Oncology (SGO) Annual Meeting in San Diego, CA on March 17, 2024.

"In AMPECT, advanced malignant PEComa tumors originating from uterine, ovarian, pelvic or retroperitoneal sites had a response to *nab*-sirolimus consistent with that of the full study population, including overall response rate, onset and duration of tumor response," said Thomas J. Herzog, MD, Deputy Director, University of Cincinnati Cancer Center. "Malignant PEComa tumors of gynecologic or retroperitoneal origin accounted for more than half of the evaluable patients enrolled, offering important insights into this population and reinforcing the need for awareness and understanding of this rare but aggressive cancer among the gynecologic oncologist community."

Oral plenary presentation details and study highlights include:

Title: *"Response to Treatment with nab-Sirolimus in Patients with Perivascular Epithelioid Cell Sarcoma (PEComa) of Gynecologic or Retroperitoneal Origin: Subgroup Analysis from AMPECT"*
Presenting Author: Thomas J. Herzog, MD
Session Title: Focused Plenary V: Rare Care: Updates in Uncommon Cancers
Location: Ballroom 20CD
Date/Time: Sunday, March 17, 2024 – 1:45 PM to 2:45 PM

- Of the 31 patients enrolled in AMPECT, 16 had malignant PEComas originating from uterine, ovarian, pelvic or retroperitoneal sites
- Overall response rate to *nab*-sirolimus for the subgroup was 37.5% (6/16), consistent with the overall AMPECT population
- Subgroup responses were rapid and durable, with 1.4 months median time to response and 36.2 months median duration of response
- Safety profile of the subgroup was manageable and consistent with the overall AMPECT population

Additional data presented at SGO further highlight *nab*-sirolimus as a potential approach for mTOR-driven gynecologic cancers. These presentations include a real-world study characterizing *TSC1* and *TSC2* inactivating alterations in patients with advanced gynecologic cancers; trial-in-progress updates for the ongoing, tumor agnostic, registration-intended PRECISION1 trial; and a Phase 2 study of *nab*-sirolimus in combination with letrozole for advanced or recurrent endometrioid-type endometrial cancer (EEC).

"Overactivation of the mTOR pathway has been implicated in gynecological cancers," said Loretta Itri, MD, Chief Medical Officer at Aadi. "*nab*-Sirolimus is a nanoparticle albumin-bound (nab) mTOR inhibitor under investigation in *TSC1*- and *TSC2*-mutated tumors as well as other mTOR-driven tumors. We are diligently continuing to explore the potential of *nab*-sirolimus for this patient community in need of new therapies."

Poster presentation details and highlights include:

Title: *"Analysis of inactivating TSC1 and TSC2 alterations in a real-world patient population with advanced gynecological cancers in the Foundation Medicine genomic database"*
Presenting Author: Lauren E. Dockery, MD, MS
Session Title: Poster Session 1
Location: Exhibit Hall (Hall GH)
Poster Number: 1176
Date/Time: Sunday, March 17, 2024 – 1:15 PM to 2:45 PM

- Registration-directed PRECISION1 study is enrolling patients with solid tumors harboring *TSC1* and/or *TSC2* inactivating alterations
- In a large real-world database of patients with advanced cancer, 1,342 (2.4%) of the 54,911 patients with gynecological cancers harbored at least one inactivating alteration in *TSC1* or *TSC2*

- *TSC1* and/or *TSC2* inactivating alterations were present in 3.6% of endometrial cancers, 2.0% of ovarian cancers and 1.5% of cervical cancers

Title: *"nab-Sirolimus Plus Letrozole in Advanced or Recurrent Endometrioid Endometrial Cancer: A Phase 2, Open-Label, Single-Arm, Prospective, Multi-Center Study"*
Presenting Author: Lauren E. Dockery, MD, MS
Session Title: Poster Session 2
Location: Exhibit Hall (Hall GH)
Poster Number: 2127
Date/Time: Monday, March 18, 2024 – 11:45 AM to 12:45 PM

- This ongoing phase 2, open-label, single-arm, multicenter study is evaluating *nab*-sirolimus in combination with letrozole for the treatment of patients with advanced or recurrent EEC
- Prior clinical studies with mTOR inhibitors and endocrine therapy have yielded promising results in EEC

Title: *"nab-Sirolimus for Malignant Solid Tumors Harboring Pathogenic Inactivating Alterations in TSC1 and TSC2 in a Phase 2, Multicenter, Open-Label Tumor-Agnostic Trial: PRECISION 1"*
Presenting Author: Debra L. Richardson, MD
Session Title: Poster Session 2
Location: Exhibit Hall (Hall GH)
Poster Number: 2126
Date/Time: Monday, March 18, 2024 – 11:45 AM to 12:45 PM

- *TSC1* and/or *TSC2* inactivating alterations have been observed in patients with gynecological cancers with a frequency of up to 5.0% in endometrial cancer, 2.2% in ovarian cancer and 1.5% in cervical cancer

About Aadi Bioscience
Aadi is a commercial-stage precision oncology company focused on the development and commercialization of therapies for cancers with alterations in the mTOR pathway, a key regulator of cell growth and cancer progression. To unlock the full potential of mTOR inhibition, Aadi uniquely combines nanoparticle albumin-bound (*nab*) technology with the potent mTOR inhibitor, sirolimus. Aadi received FDA approval and commercializes FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Aadi is exploring *nab*-sirolimus in PRECISION1, a Phase 2 tumor-agnostic registration-intended trial in mTOR inhibitor-naïve malignant solid tumors harboring *TSC1* or *TSC2* inactivating alterations. Aadi is also exploring *nab*-sirolimus in two single-indication Phase 2 trials for difficult-to-treat mTOR-driven cancers: neuroendocrine tumors (NETs), and advanced or recurrent endometrioid-type endometrial cancer (EEC) in combination with letrozole. 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: expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; expectations regarding the clinical responses and safety profile, regulatory approval and commercialization, 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 uncertainties associated with the clinical development and regulatory approval of FYARRO in additional indications; the risk that interim or subgroup analysis results of clinical trials may not be reproduced and do not necessarily predict final results; the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and as more patient data become available; 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, 2023, including under the caption "Item 1A. Risk Factors," 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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