Aadi Bioscience Reports Financial Results for the Third Quarter 2023 and Provides Corporate Update

November 8, 2023

PRECISION1 trial of nab-sirolimus in solid tumors with TSC1 or TSC2 inactivating alterations on track for presentation of early interim analysis by mid-December 2023; multiple 2024 catalysts expected

Latest real-world, next generation sequencing (NGS) analysis reinforces large unmet need in TSC1 and TSC2 mutated cancers

FYARRO® sales of $6.0 million in the third quarter, an increase of 40% year-over-year

Conference call to be held today at 8:30 am EST

LOS ANGELES, Nov. 8, 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 announced financial results for the quarter ended September 30, 2023, and highlighted recent corporate progress.

"The third quarter was marked by strong execution by our Aadi Bio team. Our PRECISION1 tumor-agnostic trial continued rapid enrollment, and we look forward to sharing an early interim analysis on the first third of patients by mid-December," said Dave Lennon, President and CEO of Aadi Bioscience. "FYARRO continued to demonstrate the importance of a tumor-targeting mTOR inhibitor for PEComa patients, and we are progressing in our previously announced development strategy with the initiation of new Phase 2 studies for endometrial cancer and in neuroendocrine tumors."

Key Operational Highlights

- **PRECISION 1 interim analysis on track for mid-December 2023.** Presentation of an interim analysis on the first third of trial participants (n=40) with a minimum of 4.5 months of follow-up is planned for mid-December 2023. The presentation is expected to include safety and investigator-assessed response in approximately 20 patients in each of the TSC1 and TSC2 arms.

- **PRECISION1 catalysts expected in 2024.** The trial is expected to reach full enrollment (n=120) with approximately 60 patients per arm in the spring of 2024 with trial completion expected by the end of 2024. Presentation of an additional interim analysis is planned when two-thirds of trial patients reach six months of follow-up, currently anticipated in the third quarter of 2024.

- **Presentations at 2023 EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics highlight real-world impact of TSC1 and TSC2 inactivating alterations in cancer.** Real-world NGS analysis of nearly 440,000 patients with advanced cancer showed that TSC1 or TSC2 known or likely pathogenic alterations occurred in approximately 2% of all advanced cancers. TSC1 or TSC2 inactivating alterations most commonly occurred in lung, gastrointestinal, genitourinary, breast and gynecological tumors. Posters with this and other related data are available on the Aadi Bio website under "Publications and Abstracts."

- **Dave Lennon, Ph.D., appointed President and CEO**. In early October, Aadi announced the appointment of Dave Lennon, Ph.D. as President and Chief Executive Officer. Dr. Lennon brings more than twenty years of experience leading global biotechnology and pharmaceutical teams, with significant expertise in development and commercialization in mTOR-driven diseases.

- **Initiation of Phase 2 combination trial in endometrial cancer.** The Phase 2 trial investigating the combination of *nab*-sirolimus with letrozole for the treatment of advanced or recurrent endometrioid-type endometrial cancer (EEC) has been initiated and is currently enrolling patients. The Company presented a trials-in-progress poster on the EEC Phase 2 study at the International Gynecologic Cancer Society (IGCS) 2023 Annual Global Meeting earlier in November.

- **Initiation of Phase 2 study in neuroendocrine tumors (NETs).** The Phase 2 study in neuroendocrine tumors (NETs) has been initiated and is currently enrolling patients. This multicenter, open-label, single-arm trial is evaluating *nab*-sirolimus in adult patients with functional or non-functional, well-differentiated, locally advanced unresectable or metastatic NETs of the GI tract, lung, or pancreas who have received no more than two prior lines of therapy.

Third Quarter 2023 Financial Results

- Total revenue resulting from sales of FYARRO for the quarter ended September 30, 2023, was $6.0 million. This compares

to the prior year period of $4.2 million.

- Cash, cash equivalents and short-term investments as of September 30, 2023, were $119.3 million as compared to $172.6 million as of December 31, 2022, which is expected to fund operations into 2025 based on current plans.

- Net loss for the three months ended September 30, 2023, was $16.3 million as compared to $14.5 million for the three months ended September 30, 2022.

Conference Call Information

The Aadi management team is hosting a conference call and webcast today at 8:30 am ET (5:30 am PT) to provide a corporate update and discuss results for the third quarter 2023.

Participants may access a live webcast of the call on 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 FYARRO®

FYARRO is an mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

About the PRECISION1 Trial

The PRECISION1 trial is a multi-center, open-label, tumor-agnostic registrational 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 November 2021, the FDA granted Fast Track designation to evaluate *nab*-sirolimus for this patient population.

nab-Sirolimus 100 mg/m2 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: potential 2024 catalysts based on PRECISION1 data and expected enrollment; the Company's anticipated growth and continued advancements, including in potential additional indications; expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; expectations regarding the size of the potential targeted markets for FYARRO, including the market for patients harboring *TSC1* and *TSC2* inactivating alterations; and the timing and clinical results of the registration-directed PRECISION1 trial in patients harboring *TSC1* and *TSC2* inactivating alterations and the additional clinical trials in NETs and EEC, including the enrollment timing and the release of data with respect thereto. 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, 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; risks related to the release of interim, topline and preliminary data from 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 any value from FYARRO in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and risks related to the Company's estimates regarding future expenses, capital requirements and need for additional financing.

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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AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 68,803	$ 39,019
Short-term investments	50,532	133,541
Accounts receivable, net	5,717	1,862
Inventory	3,615	1,861
Prepaid expenses and other current assets	4,217	3,746
Total current assets	132,884	180,029
Property and equipment, net	3,601	508
Operating lease right-of-use assets	1,260	1,522
Other assets	1,914	2,178
Total assets	$ 139,659	$ 184,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,605	$ 3,519
Accrued liabilities	11,732	14,922
Operating lease liabilities, current portion	423	394
Due to licensor payable	5,757	-
Total current liabilities	20,517	18,835
Operating lease liabilities, net of current portion	946	1,267
Due to licensor	-	5,757
Total liabilities	21,463	25,859
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	370,904	361,689
Accumulated other comprehensive loss	(16)	(115)
Accumulated deficit	(252,694)	(203,198)
Total stockholders' equity	118,196	158,378
Total liabilities and stockholders' equity	$ 139,659	$ 184,237

AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share data and earnings per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue				
Product sales, net	$ 5,959	$ 4,245	$ 18,028	$ 9,989
Total Revenue	5,959	4,245	18,028	9,989
Operating expenses				
Selling, general and administrative	11,221	9,915	34,204	29,069
Research and development	11,890	8,773	36,161	23,292
Cost of goods sold	697	593	1,882	1,113
Impairment of acquired contract intangible asset	-	-	-	3,724
Total operating expenses	23,808	19,281	72,247	57,198
Loss from operations	(17,849)	(15,036)	(54,219)	(47,209)
Other income (expense)				
Foreign exchange loss	-	-	(3)	-
Interest income	1,605	620	4,900	791
Interest expense	(58)	(58)	(174)	(173)
Total other income (expense), net	1,547	562	4,723	618
Loss before income tax expense	(16,302)	(14,474)	(49,496)	(46,591)

Income tax expense	-	-	-	(9)
Net loss	$ (16,302)	$ (14,474)	$ (49,496)	$ (46,600)
Net loss per share, basic and diluted	$ (0.60)	$ (0.68)	$ (1.84)	$ (2.21)
Weighted average number of common shares outstanding, basic and diluted	26,946,683	21,269,163	26,901,810	21,052,786

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