Aadi Bioscience Announces Financial Results and Operational Update for the First Quarter 2023 and Provides Update on PRECISION 1 Tumor Agnostic Trial

May 10, 2023

Total 1Q 2023 revenue on FYARRO® sales of $5.9 million

PRECISION 1 tumor agnostic trial enrolling equally in TSC1 and TSC2 arms with more than 15 discreet tumor types represented

Interim analysis on 40 patients with appropriate follow-up in PRECISION 1 trial expected by end of 2023

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

LOS ANGELES, May 10, 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 first quarter of 2023 and provided an initial update on the tumor-agnostic PRECISION 1 trial, a registration-directed Phase 2 study of *nab*-sirolimus in patients with solid tumors with pathogenic inactivating alterations in *TSC1* or *TSC2* genes.

"We are excited about the uptake of FYARRO and its continued sales growth after our first year on the market and believe we are operating from a position of strength with solid cash balances into 2025," said Scott Giacobello, Interim CEO and President and CFO of Aadi. "We are also encouraged by initial PRECISION 1 enrollment data, indicating more than 15 different tumor types on study, shaping the foundation for a truly tumor agnostic trial. We believe in the potential of this study and given the importance of maintaining its integrity, we will provide the results of an efficacy analysis later in the year when response data is unblinded in conjunction with a pre-planned interim analysis on 40 patients with appropriate follow-up."

First Quarter 2023 Updates and Recent Operational Highlights

- **Based on initial information from the PRECISION 1 trial**, enrollment is well-balanced, and the trial is accruing evenly between the *TSC1* and *TSC2* arms. More than 15 discreet tumor types have been enrolled with no more than three of any type, supporting the thesis that *TSC1* and *TSC2* alterations occur broadly across different solid tumors. A pre-planned interim analysis on 40 patients with appropriate follow-up is expected by the end of 2023.
- **FYARRO net product sales were $5.9 million** in the first quarter, continued double-digit growth of 12% quarter-over-quarter.
- **The appointment of Mohammad Hirmand, M.D., to Board of Directors.** Dr. Hirmand, previously Chief Medical Officer of Turning Point Therapeutics prior to its acquisition by BMS, is the co-founder of Avenzo Therapeutics, Inc., and serves as executive vice president and chief medical officer of this privately held biotechnology company focused on oncology therapeutics.
- **Multiple presentations at AACR Annual Meeting 2023.** Aadi presented an encore trials-in-progress (TIP) poster for the ongoing PRECISION 1 trial; results on the anti-tumor activity of *nab*-sirolimus in combination with $KRAS^{G12C}$ inhibitors in xenograft models; and results of a biomarker analysis from AMPECT correlating response to *nab*-sirolimus with *TSC1* and *TSC2* inactivating alterations. The AACR posters can be found here on the Aadi website.
- **Multiple presentations at SGO Annual Meeting 2023.** Aadi presented a TIP poster for the ongoing PRECISION 1 trial and additional data with *nab*-sirolimus from its AMPECT trial at SGO 2023. The SGO posters can be found here on the Aadi website.
- **Upcoming presentations at ASCO Annual Meeting 2023**. Aadi will present a company-sponsored TIP update from the PRECISION 1 Phase 2 study and combination data of *nab*-sirolimus and pazopanib (PAZO) from an ongoing Investigator Initiated Trial at ASCO 2023, taking place June 2-6, 2023, in Chicago. Following Aadi's presentation at ASCO, the posters will be made available on the investor relations page of the Aadi website at www.aadibio.com.
- **Initiation of Phase 1/2 trial in $KRAS^{G12C}$** is expected to begin with first patient dosing in the second quarter of 2023. The study will evaluate the combination of adagrasib with *nab*-sirolimus in collaboration with Mirati Therapeutics. The open-label Phase 1/2 trial is intended to determine the optimal dose and recommended Phase 2 dose in patients with $KRAS^{G12C}$ mutant solid tumors.

First Quarter 2023 Financial Results

- Total revenue resulting from sales of FYARRO for the quarter ended March 31, 2023 was $5.9 million. This compares to the prior year period of $2.3 million and $5.2 million in the fourth quarter 2022.
- Cash, cash equivalents and short-term investments as of March 31, 2023 were $151.2 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 March 31, 2023 was $15.2 million as compared to $13.9 million for the three months ended March 31, 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 first 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 PRECISION 1 Trial

The PRECISION 1 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 2022, 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 in November of 2021 and in February of 2022 commercialized FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Aadi is conducting the PRECISION 1 trial, a Phase 2 tumor-agnostic registration-directed study in patients with 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 include statements regarding the Company's current beliefs and expectations; the Company's anticipated growth and continued advancements, including the progression and timing of the Company's first collaboration; 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, and the release of data with respect thereto; 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 $KRAS^{G12C}$-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; 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," anticipated to be filed on or about the date hereof, 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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AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2022	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 34,046	$ 39,019
Short-term investments	117,128	133,541
Accounts receivable, net	5,565	1,862
Inventory	3,803	1,861
Prepaid expenses and other current assets	4,388	3,746
Total current assets	164,930	180,029
Property and equipment, net	2,225	508
Operating lease right-of-use assets	1,437	1,522
Other assets	2,062	2,178
Total assets	$ 170,654	$ 184,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,510	$ 3,519
Accrued liabilities	10,833	14,922
Operating lease liabilities, current portion	404	394
Total current liabilities	17,747	18,835
Operating lease liabilities, net of current portion	1,164	1,267
Due to licensor	5,757	5,757
Total liabilities	24,668	25,859
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	364,437	361,689
Accumulated other comprehensive loss	(32)	(115)
Accumulated deficit	(218,421)	(203,198)
Total stockholders' equity	145,986	158,378
Total liabilities and stockholders' equity	$ 170,654	$ 184,237

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

	Three months ended March 31,	
	2023	2022
Revenue		
Product sales, net	$ 5,867	$ 2,307
Total Revenue	5,867	2,307
Operating expenses		
Selling, general and administrative	11,207	9,148
Research and development	10,956	6,794
Cost of goods sold	529	179
Total operating expenses	22,692	16,121
Loss from operations	(16,825)	(13,814)

Other income (expense)		
Interest income	1,660	15
Interest expense	(58)	(58)
Total other income (expense), net	1,602	(43)
Net loss	$ (15,223)	$ (13,857)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.66)
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	26,862,646	20,914,812

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