Aadi Bioscience Reports First Quarter 2022 Financial Results and Provides a Corporate Update

May 12, 2022

- *FYARRO net product sales of $2.3 million in partial first quarter*
- *Dosing of patients initiated in PRECISION 1, a Phase 2 tumor-agnostic registration-directed trial evaluating nab-sirolimus in TSC1 or TSC2 altered solid tumors*

LOS ANGELES, May 12, 2022 (GLOBE NEWSWIRE) -- 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 2022 and provided a corporate update.

"We are very pleased and encouraged by the strong demand for FYARRO since its February 22nd launch despite the ultra-rare nature of advanced malignant PEComa," commented Neil Desai, Ph.D., Founder, President and Chief Executive Officer of Aadi. "A number of factors are believed to have contributed to the sales in Q1 including pent up demand since FYARRO's approval on November 22, 2021, transition of expanded access and clinical trial patients to the commercial drug, significant physician awareness and favorable reimbursement," he added.

Dr. Desai continued, "Our clinical team has been focused on advancing *nab*-sirolimus and the first patient was dosed in our PRECISION 1 tumor-agnostic registration-directed trial in March. Based on data recently presented at AACR, *TSC1* and *TSC2* genetic alterations within tumors represent one of the larger opportunities within targeted oncology. We have also partnered with large community oncology center networks and next generation sequencing (NGS) providers to identify these patient candidates for our trial, which we believe will augment the pace of enrollment in the PRECISION 1 trial. We anticipate initial clinical data to be available in the first half of next year."

Recent and First Quarter 2022 Corporate Highlights

- In May, Aadi was granted a product-specific permanent J-code (J9331) for FYARRO that will become effective on July 1, 2022. This code is expected to further facilitate reimbursement for the drug.
- Also in May, Aadi announced a partnership with NGS providers and leaders in genomic testing and profiling, including Foundation Medicine, Tempus and others, to assist with identifying patients for its PRECISION 1 trial. Aadi plans to leverage these partnerships and others to expedite patient recruitment and increase physician familiarity with FYARRO.
- Aadi announced a poster presentation at the Annual Meeting of the American Association for Cancer Research (AACR), held April 8-13, 2022 in New Orleans, LA. The project determined the incidence of advanced cancer patients on an annual basis carrying *TSC1* or *TSC2* alterations and characterized approximately 12,000 patients who may carry "definite impact" mutations (frameshift, nonsense, splice-site mutations and deep deletions). These data confirmed Aadi's initial projections on the size of the patient population that could be addressed by a potential *nab*-sirolimus tumor-agnostic therapy. The study also found that *TSC1* alterations were most frequent in bladder, kidney, and lung squamous cell cancers, while *TSC2* alterations were most frequent in hepatobiliary, ovarian cancers, and soft tissue sarcomas.
- In April, Aadi opened an additional office location in Morristown, New Jersey.
- In March, Aadi dosed its first patient in its Phase 2 tumor-agnostic registration-directed trial, PRECISION 1, to evaluate *nab*-sirolimus in adult and adolescent patients 12 years and older with solid tumors harboring pathogenic inactivating alterations in *TSC1* or *TSC2* genes. The trial consists of two separate arms of 60 patients each for *TSC1* or *TSC2* alterations. Initial clinical data from PRECISION 1 are expected in the first half of 2023.
- In February, Aadi announced the launch and commercial availability of FYARRO (sirolimus protein-bound particles for injectable suspension) (albumin-bound) for intravenous use for the treatment of adult patients with locally advanced unresectable or metastatic malignant PEComa.
- Also in February, FYARRO was added to the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN® Guidelines) as the only preferred treatment regimen for malignant PEComa.

First Quarter 2022 Financial Highlights

As of March 31, 2022, cash and cash equivalents totaled $129.8 million, compared to $149.0 million as of December 31, 2021. Based on our current plans, we expect cash and cash equivalents to fund operations into 2024.

For the three months ended March 31, 2022, net product sales were $2.3 million resulting from the launch of FYARRO in February. This compares to $0.1 million of grant revenue during the three months ended March 31, 2021. No grant revenue was recognized during the three months ended March 31, 2022.

Operating expenses for the three months ended March 31, 2022 were $16.1 million compared to $4.2 million for the same period last year.

Selling, general and administrative expenses for the three months ended March 31, 2022 were $9.1 million, an $8.5 million increase over the same period last year. This increase was primarily the result of increased personnel expenses related to the buildout of our commercial operations and infrastructure, as well as increased marketing expenses related to the commercial launch of FYARRO in February 2022.

Research and development expenses for the three months ended March 31, 2022 were $6.8 million, a $3.2 million increase over the same period last year. This increase was primarily the result of increased clinical trial expenses and costs related to the buildout of the organization.

Net loss for the three months ended March 31, 2022 was $13.9 million compared to $5.5 million for the three months ended March 31, 2021.

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).

Important Safety Information

Contraindication

FYARRO is contraindicated in patients with a history of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin.

Warnings and Precautions

Stomatitis

Stomatitis, including mouth ulcers and oral mucositis, occurred in 79% of patients treated with FYARRO, including 18% Grade 3. Stomatitis was most often first reported within 8 weeks of treatment. Based on the severity of the adverse reaction, withhold, resume at reduced dose, or permanently discontinue FYARRO.

Myelosuppression

FYARRO can cause myelosuppression including anemia, thrombocytopenia and neutropenia. Anemia occurred in 68% of patients; 6% were Grade 3. Thrombocytopenia and neutropenia occurred in 35% of patients each. Obtain blood counts at baseline and every 2 months for the first year of treatment and every 3 months thereafter, or more frequently if clinically indicated. Based on the severity of the adverse reaction, withhold, resume at reduced dose, or permanently discontinue FYARRO.

Infections

FYARRO can cause infections. Infections such as urinary tract infections (UTI), upper respiratory tract infections and sinusitis occurred in 59% of patients. Grade 3 infections occurred in 12% of patients, including a single case each of a UTI, pneumonia, skin, and abdominal infections. Monitor patients for infections, including opportunistic infections. Based on the severity of the adverse reaction, withhold, resume at reduced dose, or permanently discontinue FYARRO.

Hypokalemia

FYARRO can cause hypokalemia. Hypokalemia occurred in 44% of patients including 12% Grade 3 events. Monitor potassium levels prior to starting FYARRO and implement potassium supplementation as medically indicated. Based on the severity of the adverse reaction, withhold, resume at reduced dose, or permanently discontinue FYARRO.

Hyperglycemia

FYARRO can cause hyperglycemia. Hyperglycemia occurred in 12% of patients treated with FYARRO, all of which were Grade 3 events. Monitor fasting serum glucose prior to starting FYARRO. During treatment, monitor serum glucose every 3 months in non-diabetic patients, or as clinically indicated. Monitor serum glucose more frequently in diabetic patients. Based on the severity of the adverse reaction, withhold, resume at reduced dose, or permanently discontinue FYARRO.

Interstitial Lung Disease / Non-Infectious Pneumonitis

FYARRO can cause interstitial lung disease (ILD) / non-infectious pneumonitis. ILD / non-infectious pneumonitis occurred in 18% of patients treated with FYARRO, of which all were Grades 1 and 2. Based on the severity of the adverse reaction, withhold, reduce the dose, or permanently discontinue FYARRO.

Hemorrhage

FYARRO can cause serious and sometimes fatal hemorrhage. Hemorrhage occurred in 24% of patients treated with FYARRO, including Grade 3 and Grade 5 events in 2.9% of patients each. Monitor patients for signs and symptoms of hemorrhage. Based on the severity of adverse reaction, withhold, resume at reduced dose, or permanently discontinue FYARRO.

Hypersensitivity Reactions

FYARRO can cause hypersensitivity reactions. Hypersensitivity reactions, including anaphylaxis, angioedema, exfoliative dermatitis, and hypersensitivity vasculitis have been observed with administration of the oral formulation of sirolimus. Hypersensitivity reactions including anaphylaxis have been observed with human albumin administration. Monitor patients closely for signs and symptoms of infusion reactions during and following each FYARRO infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Monitor patients for at least 2 hours after the first infusion and as clinically needed for each subsequent infusion. Reduce the rate, interrupt infusion, or permanently discontinue FYARRO based on severity and institute appropriate medical management as needed.

Embryo-Fetal Toxicity

Based on animal studies and the mechanism of action, FYARRO can cause fetal harm when administered to a pregnant woman. In animal studies, mTOR inhibitors caused embryo-fetal toxicity when administered during the period of organogenesis at maternal exposures that were equal to or less than human exposures at the recommended lowest starting dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to avoid becoming pregnant and to use effective contraception while using FYARRO and for 12 weeks after the last dose.

Male Infertility

Azoospermia or oligospermia may be observed in patients treated with FYARRO. FYARRO is an anti-proliferative drug and affects rapidly dividing cells such as germ cells.

Immunizations and Risks Associated with Live Vaccines

No studies in conjunction with immunization have been conducted with FYARRO. Immunization during FYARRO treatment may be ineffective. Update immunizations according to immunization guidelines prior to initiating FYARRO, if possible. Immunization with live vaccines is not recommended during treatment and avoid close contact with those who have received live vaccines while on FYARRO. The interval between live vaccinations and initiation of FYARRO should be in accordance with current vaccination guidelines for patients on immunosuppressive therapies.

Risk of Transmission of Infectious Agents with Human Albumin

FYARRO contains human albumin, a derivative of human blood. Human albumin carries only a remote risk of transmission of viral diseases because of effective donor screening and product manufacturing processes. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been associated with albumin.

Adverse Reactions

Adverse Reactions in PEComa

The most common adverse reactions (≥30%) were stomatitis in 27 (79%) patients; fatigue and rash in 23 (68%) patients each; infection in 20 (59%) patients; nausea and edema in 17 (50%) patients each; diarrhea, musculoskeletal pain and decreased weight in 16 (47%) patients each; decreased appetite in 15 (44%) patients; cough in 12 (35%) patients; and vomiting and dysgeusia in 11 (32%) patients each.

Laboratory Abnormalities in PEComa

The most common Grade 3 to 4 laboratory abnormalities (≥6%) were decreased lymphocytes in 7 (21%) patients; increased glucose and decreased potassium in 4 (12%) patients each; decreased phosphate in 3 (9%) patients; and decreased hemoglobin and increased lipase in 2 (6%) patients each.

Dosage interruptions

Dose interruptions of FYARRO due to an adverse reaction occurred in 22 (65%) patients. Adverse reactions which required dosage interruption in >5% of patients included stomatitis in 6 (18%) patients, pneumonitis in 5 (15%) patients, anemia in 3 (9%) patients, and dehydration, dermatitis acneiform, and thrombocytopenia in 2 (6%) patients each.

Dose reduction

Dose reductions of FYARRO due to an adverse reaction occurred in 12 (35%) patients. Adverse reactions which required dose reductions in > 5% of patients included stomatitis and pneumonitis in 3 (9%) patients each.

Drug Interactions

Reduce the dosage of FYARRO to 56 mg/m^2 when used concomitantly with a moderate or weak cytochrome P-450 3A4 (CYP3A4) inhibitor. Avoid concomitant use with drugs that are strong CYP3A4 and/or P-glycoprotein (P-gp) inhibitors and inducers and with grapefruit and grapefruit juice.

Use in Specific Populations

Pregnancy

Based on the mechanism of action and findings in animals, FYARRO can cause fetal harm when administered to a pregnant woman. Advise females of the potential risk to a fetus and to avoid becoming pregnant while receiving FYARRO.

Lactation

Sirolimus is present in the milk of lactating rats. There is potential for serious adverse effects from sirolimus in breastfed infants based on mechanism of action. Because of the potential for serious adverse reactions in breastfed infants from FYARRO, advise women not to breastfeed during treatment with FYARRO and for 2 weeks after the last dose.

Females and Males of Reproductive Potential

FYARRO can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to

starting treatment with FYARRO. Advise females of reproductive potential to use effective contraception and avoid becoming pregnant during treatment with and for at least twelve weeks after the last dose of FYARRO. Advise males with female partners of reproductive potential to use effective contraception and avoid fathering a child during treatment with FYARRO and for at least twelve weeks after the last dose of FYARRO. Although there are no data on the impact of FYARRO on fertility, based on available clinical findings with oral formulation of sirolimus and findings in animals, male and female fertility may be compromised by the treatment with FYARRO.

Pediatric

The safety and effectiveness of FYARRO in pediatric patients have not been established.

Geriatric Use

Of the 34 patients treated with FYARRO, 44% were 65 years of age and older, and 6% were 75 years of age and older. Clinical studies of FYARRO did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

Hepatic Impairment

FYARRO is not recommended for use in patients with severe hepatic impairment. Reduce FYARRO dosage in patients with mild or moderate hepatic impairment.

Full prescribing information can be found here.

About Malignant PEComa

Advanced malignant PEComa, defined by the World Health Organization as 'mesenchymal tumors composed of distinctive cells that show a focal association with blood-vessel walls and usually express both melanocytic and smooth muscle markers,' are a rare subset of soft-tissue sarcomas, with an undefined cell of origin. While there is no formal epidemiology for malignant PEComa, it is estimated that there are about 100-300 new patients per year in the United States. Malignant PEComas may arise in almost any body site (typically the uterus, retroperitoneum, lung, kidney, liver, genitourinary, and gastrointestinal tract with a female predominance) and can have an aggressive clinical course including distant metastases and ultimately death. The estimated prognosis based on retrospective reports is 12-16 months. Cytotoxic chemotherapies typically used for sarcoma show minimal benefit. Malignant PEComas have been shown to frequently harbor mutations in the *TSC1* and/or *TSC2* genes that result in the activation of mTOR pathway making it a rational therapeutic target for this disease.

About the PRECISION 1 Trial

The PRECISION 1 trial is a multi-center, open-label, tumor-agnostic pivotal study, of *nab*-sirolimus designed as a basket trial that will evaluate approximately 120 adult and adolescent patients with solid tumors harboring pathogenic inactivating alterations in *TSC1* or *TSC2* genes. The trial will have two independent arms of 60 patients each to separately evaluate patients with either *TSC1* or *TSC2* inactivating alterations. Aadi has received Fast Track designation to evaluate *nab*-sirolimus in this indication from the FDA. The first patient in the PRECISION 1 trial was dosed in March 2022.

About the National Comprehensive Cancer Network® (NCCN)
The NCCN is a not-for-profit alliance of 27 leading U.S. cancer centers devoted to patient care, research and education, is dedicated to improving the quality, effectiveness and efficiency of cancer care. The intent of the NCCN Guidelines is to assist in the decision-making process of individuals involved in cancer care – including physicians, nurses, pharmacists, payers, patients and their families – with the ultimate goal of improving patient care and outcomes. For more information about the National Comprehensive Cancer Network go to: https://www.nccn.org/home/about.

About Aadi Bioscience

Aadi is a 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 data from Aadi's Phase 2 registrational study (the Advanced Malignant PEComa Trial or "AMPECT") with FYARRO, and, following discussions with the FDA about other emerging data with FYARRO, Aadi has initiated PRECISION 1, a Phase 2 tumor-agnostic registration-directed trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations. More information on Aadi's development pipeline is available on the Aadi website at **www.aadibio.com**.

Forward-Looking Statements

Aadi cautions you that certain statements included in this press release that are not a description of historical facts are forward-looking statements. These statements are based on Aadi's current beliefs and expectations. Forward-looking statements include statements regarding: our plans and potential for success relating to commercializing FYARRO; the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; our plans related to further development and manufacturing of FYARRO; the pricing and reimbursement of FYARRO; the rate and degree of market acceptance of FYARRO; anticipated reception of FYARRO in the physician community; the timing of additional clinical trials, including the registration-directed trial in patients harboring *TSC1* or *TSC2* inactivating alterations, the timing of likelihood of regulatory filings and approvals of FYARRO, including in potential additional indications and potential filings in additional jurisdictions; 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: risks related to Aadi's 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 under the caption "Risk Factors" in Aadi's Form 10-Q filed on May 12, 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 caution 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, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 129,849	$ 148,989
Accounts receivable	2,708	-
Inventory	202	-
Prepaid expenses and other current assets	2,861	2,283
Total current assets	135,620	151,272
Property and equipment, net	101	57
Operating lease right-of-use asset	518	557
Intangible asset, net	3,743	3,811
Other assets	2,337	2,213
Total assets	$ 142,319	$ 157,910
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 4,010	$ 6,439
Accrued liabilities	7,337	8,703
Operating lease liabilities, current portion	163	131
Total current liabilities	11,510	15,273
Operating lease liabilities, net of current portion	424	474
Due to licensor	5,757	5,757
Total liabilities	17,691	21,504
Stockholders' equity:		
Preferred stock	-	-
Common stock	2	2
Additional paid-in capital	281,168	279,089
Accumulated deficit	(156,542)	(142,685)
Total stockholders' equity	124,628	136,406
Total liabilities and stockholders' equity	$ 142,319	$ 157,910

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

	Three months ended March 31,	
	2022	**2021**
Revenue		
Product sales, net	$ 2,307	$ -
Grant revenue	-	120
Total Revenue	2,307	120
Operating expenses		
Selling, general and administrative	9,148	563
Research and development	6,794	3,644
Cost of goods sold	179	-
Total operating expenses	16,121	4,207
Loss from operations	(13,814)	(4,087)
Other income (expense)		
Change in fair value of convertible promissory note	-	(1,165)
Interest income	15	-
Interest expense	(58)	(224)
Total other expense, net	(43)	(1,389)
Loss before income taxes	(13,857)	(5,476)
Income tax expense	-	-
Net loss	$ (13,857)	$ (5,476)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (2.15)
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	20,914,842	2,542,358

Source: Aadi Bioscience