UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 14, 2023

AADI BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38560**	**61-1547850**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

17383 Sunset Boulevard, Suite A250
Pacific Palisades, California **90272**
(Address of principal executive offices) **(Zip code)**

Registrant's telephone number, including area code: (424) 744-8055

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AADI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Information.

On December 14, 2023, Aadi Bioscience, Inc. (the "Company") issued a press release ("Press Release") announcing results from an interim analysis on the first third of participants in the ongoing tumor-agnostic PRECISION1 trial evaluating *nab*-sirolimus in patients with *TSC1*/*TSC2* inactivating alterations. As part of the Press Release, the Company announced that it would be hosting a conference call and webcast at 5:00 p.m. ET on December 14, 2023 ("Webcast") to discuss the interim results from the PRECISION1 trial.

The Press Release and the corporate presentation to be used in connection with the Webcast are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated December 14, 2023
99.2	Corporate Presentation, dated December 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 14, 2023

/s/ Scott Giacobello
Scott Giacobello
Chief Financial Officer

PRESS RELEASE

Aadi Bioscience Reports Interim Results from PRECISION1 Trial of *nab*-Sirolimus Demonstrating Anti-Tumor Activity in Solid Tumors with *TSC1* or *TSC2* Inactivating Alterations

Interim results from investigator-assessed responses in first 40 patients from TSC1 and TSC2 arms demonstrate sustained tumor reductions in heavily pre-treated population

80 patients now enrolled in PRECISION1 supporting two-thirds interim analysis expected in 3Q 2024

Study on track for completion by end 2024; final data readout expected in early 2025

Company to host conference call today at 5:00 pm EST

LOS ANGELES, CA, December 14, 2023 – 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 reported results from a planned interim analysis on the first third of participants in the ongoing tumor-agnostic PRECISION1 trial evaluating *nab*-sirolimus in patients with *TSC1* or *TSC2* inactivating alterations.

"Our tumor agnostic PRECISION1 trial is designed to elucidate the impact of *nab*-sirolimus on cancers expressing inactivating alterations of *TSC1* or *TSC2*, regardless of tumor type. We are encouraged by the preliminary data from this pre-planned analysis and by the responses and clinical benefit demonstrated in advanced cancer patients who have failed an average of three prior lines of therapy," said Loretta Itri, MD, CMO of Aadi Bioscience. "Full enrollment in the trial is expected by the spring of 2024 and we believe we are on track to generate compelling clinical evidence for advancing *nab*-sirolimus toward potential expansion of the current registration, bringing this innovative therapeutic agent to more cancer patients."

The interim analysis includes data from the first third of trial participants (n=40) with a minimum of 4.5 months of follow-up, including investigator-assessed response and safety analyzed separately in each of the *TSC1* and *TSC2* arms. Nine different tumor types were enrolled in the *TSC1* arm and 13 tumor types were enrolled in the *TSC2* arm.

Efficacy of *nab*-sirolimus in patients with tumors harboring pathogenic inactivating alteration in *TSC1*

Of the 22 patients enrolled, 19 patients received ≥ 1 post baseline scan and were evaluable for efficacy. Observations included:

- A 26% Overall Response Rate (ORR) including 5 partial responses (PR) with 4 confirmed responses and 1 unconfirmed response (uPR). The patient with uPR remains on treatment and is awaiting a confirmatory scan
- 9 patients had stable disease (SD), 3 of which were greater than or equal to six months in duration, resulting in a clinical benefit rate of 42% (5 PR + 3 SD ≥ 6 mos)
- Patients were heavily pre-treated with median of 3 prior lines of therapy

- Median time to response was 1.4 months and all responses were ongoing at time of data cutoff
- Responses were seen across four different epithelial carcinomas
- 60% of responders experienced > 50% tumor reduction

Efficacy of *nab*-sirolimus in patients with tumors harboring pathogenic inactivating alteration in *TSC2*

Of the 18 patients enrolled, all 18 patients received ≥ 1 post baseline scan and were evaluable for efficacy. Observations included:

- An 11% ORR including 2 PRs with 1 confirmed and 1 uPR
- 12 patients had SD, 3 of which were greater than or equal to six months resulting in a clinical benefit rate of 28% (2 PR + 3 SD ≥ 6 mos)
- Patients were heavily pre-treated with median of 3.5 prior lines of therapy; 50% had ≥ 5 prior lines of therapy
- Responses were seen in one epithelial carcinoma and one sarcoma

No new safety signals were observed, and no grade four treatment-related events or deaths occurred. One patient discontinued the study due to grade two pneumonitis that completely resolved after discontinuation of therapy. Across both arms, the safety profile was consistent with the *nab*-sirolimus label and the mTOR inhibitor drug class.

80 patients are currently enrolled in the PRECISION1 trial, supporting the two-thirds interim analysis expected in the third quarter of 2024. The ORR analysis in this cohort will be based on independent radiological review with a minimum of six months of follow-up for all patients. The trial is expected to be completed by the end of 2024 with results anticipated in early 2025.

Conference Call Information

The Aadi management team is hosting a conference call and webcast today at 5:00 pm ET (2:00 pm PT) to discuss the interim results from the PRECISION1 trial.

Participants may access a live webcast of the call and the associated slide presentation on these data through 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 PRECISION1

The PRECISION1 trial is a multi-center, open-label, tumor-agnostic prospective registration intended 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 September 2021, the FDA designated the investigation of *nab*-sirolimus for the treatment of adults and adolescents with solid tumors that have a pathogenic inactivating alteration of the TSC1 or TSC2 gene as a Fast Track development program.

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: the anticipated timing of commencement, enrollment, data releases and completion of the Company's clinical trials, including the expected full enrollment of the PRECISION 1 trial by spring of 2024, the expected PRECISION 1 two-thirds interim analysis in 3Q 2024, the anticipated completion of the PRECISION 1 study by the end of 2024, and the final PRECISION 1 data readout anticipated in early 2025; management's belief that the Company is on track to generate additional clinical evidence in the PRECISION 1 study and for advancing *nab*-sirolimus toward registration; the timing and likelihood of regulatory filings and approvals of FYARRO for new indications; the anticipated timing for potential catalysts based on data for the Company's clinical trials; 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, risks related to the release of interim, topline and preliminary data from clinical trials; uncertainties associated with the clinical development and regulatory approval of FYARRO, including potential delays in the commencement, enrollment and completion of 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 further value from FYARRO in light of inherent risks and difficulties involved in successfully bringing FYARRO to market in additional indications, including in patients harboring *TSC1* and *TSC2* inactivating alterations; and risks related to the Company's estimates regarding future expenses, capital requirements and need for additional financing.

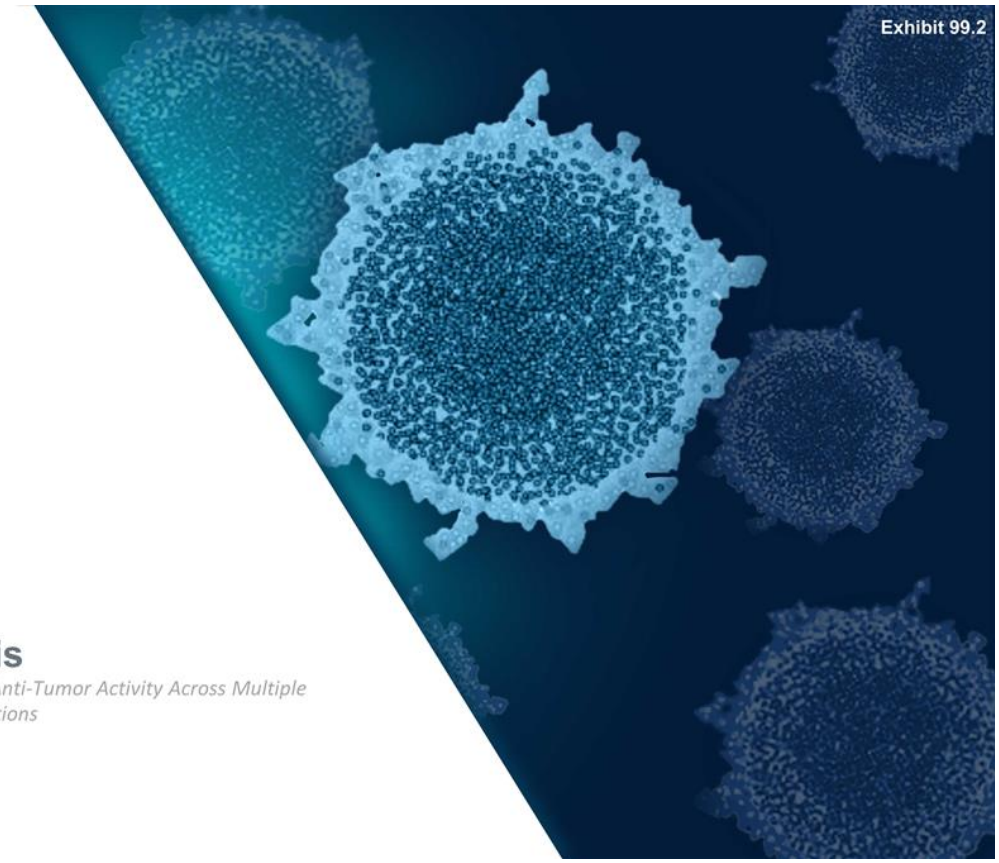
Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, including under the caption "Item 1A. Risk 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.

Contact:

Marcy Graham
IR@aadibio.com

Exhibit 99.2



PRECISION1
One-Third Interim Analysis

PRECISION1 Trial of nab-Sirolimus Demonstrating Anti-Tumor Activity Across Multiple Solid Tumors with TSC1 or TSC2 Inactivating Alterations

December 2023

Forward-Looking Statements

Certain statements contained in this presentation regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Act of 1995, known as the PSLRA. These include statements regarding management's intention, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. Forward-looking statements may include, without limitation, statements regarding: the anticipated timing of commencement, enrollment, data releases and completion of clinical trials of Aadi Bioscience, Inc. ("Aadi"), including the expected full enrollment of the PRECISION 1 trial by spring of 2024, the expected PRECISION 1 two-thirds interim analysis in 3Q 2024, the anticipated completion of the PRECISION1 study by the end of 2024, and the final PRECISION1 data readout anticipated in early 2025; management's belief that the Company is on track to generate additional clinical evidence in the PRECISION 1 study and for advancing nab-sirolimus toward registration; the timing and likelihood of regulatory filings and approvals of FYARRO for new indications; the anticipated timing for potential catalysts based on data for Aadi's clinical trials; Aadi's anticipated cash runway; Aadi's potential to become a leading precision oncology company; and projected annual incidence of cancers with *TSC1* & *TSC2* alterations and related market opportunities. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Aadi uses words such as "anticipates," "believes," "plans," "expects," "projects," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA.

Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, uncertainties associated with the clinical development and regulatory approval of FYARRO, including potential delays in the commencement, enrollment and completion of clinical trials; risks related to the release of interim, topline and preliminary data from clinical trials; Aadi's plans to develop and commercialize FYARRO® (*nab*-sirolimus, ABI-009); Aadi's commercialization, marketing and manufacturing capabilities and strategy; the clinical utility, potential benefits and market acceptance of FYARRO; risks related to the sufficiency Aadi's cash balance to fund operations; Aadi's plans to research, develop and commercialize its current and future product candidates; Aadi's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to market size, Aadi's competitors and its industry; the impact of government laws and regulations; Aadi's ability to protect its intellectual property position; and Aadi's estimates regarding future revenue, expenses, capital requirements and need for additional financing.

These risks are described in detail under the caption "Risk Factors" in Aadi's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the Securities and Exchange Commission (the "SEC") on November 8, 2023, and other documents filed from time to time with the SEC. Forward-looking statements included in this presentation are based on information available to Aadi as of the date of this presentation. Except as required by law, Aadi undertakes no obligation to revise or update any forward-looking statement, whether as a result of new information, future events or otherwise.

Aadi Bioscience Advanced Oncology Development Pipeline

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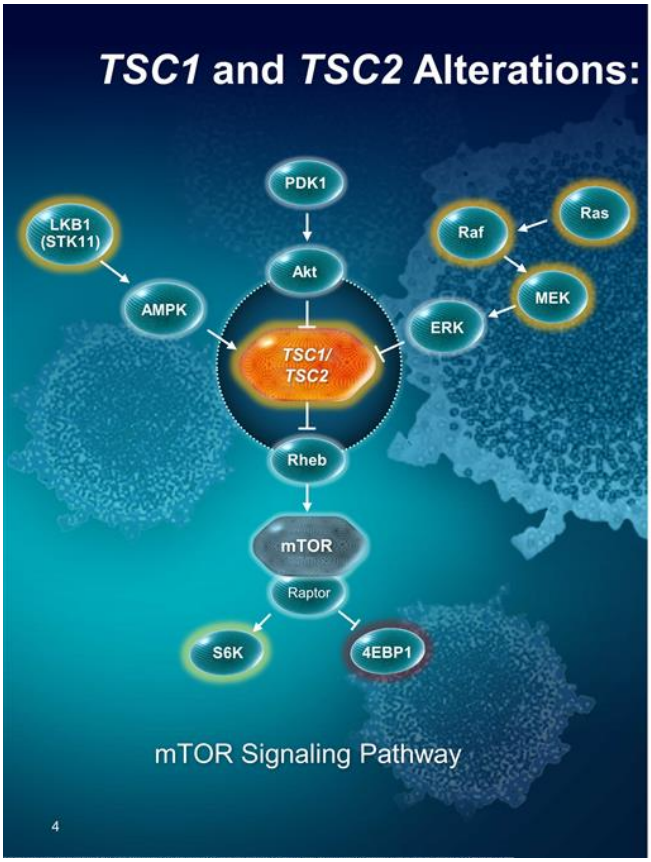
TSC1 and *TSC2* Alterations: Key Oncogenic Drivers in the mTOR Pathway



mTOR Signaling Pathway

Inactivating mutations in *TSC1* and *TSC2* drive mTOR pathway activation and tumor growth

- *TSC1* and *TSC2* are upstream regulators of mTOR activity within the PI3K/Akt/mTOR pathway
- *TSC1* and *TSC2* mutations occur at a rate of ~2% across cancers or ~16,000 new cases each year
- No approved therapies for *TSC1* and *TSC2* mutant patients but numerous case reports with durable responses to mTOR inhibition
- Standard CLIA-certified NGS panels already capture *TSC1* and *TSC2* mutations

Frequently mutated in cancer and/or validated target

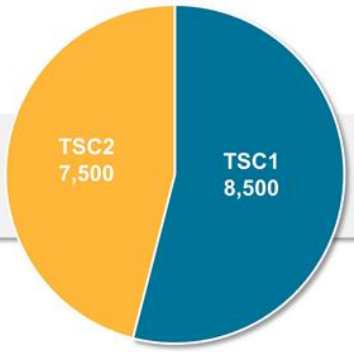
TSC1 and *TSC2* Inactivating Alterations Represent Significant Opportunity Across Common Cancer Types

Real-World Analysis of TSC1 and TSC2 Patient Population[1]

- **Next generation sequencing (NGS) of nearly 440,000 cancer patients** from the Foundation Medicine database
- **2% of patients have known or likely inactivating alterations in TSC1 or TSC2**
- Based on extrapolation from SEER database, **~16,000 new cancer cases each year would have actionable TSC1 or TSC2 alterations**

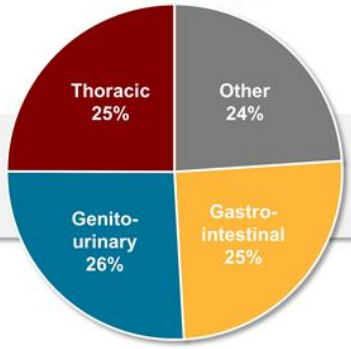
Alteration Split

Patients (n=16,000)



Tumor Clusters

% Patients (n=16,000)



Approximately 16,000 patients with TSC1 or TSC2 inactivating alterations across varying tumor types represent a potential multi billion-dollar total addressable market in *each* alteration

[1] *Kwiatkowski, MD. Inactivating TSC1 and TSC2 alterations, co-mutations, and genomic instability in advanced cancers: Analysis of a real-world (RW) patient population using the Foundation Medicine genomic database. Poster presented at: EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium (ENA). Boston, MA; October 11-15, 2023*

Note: Methodology to determine TAM consists of applying FMI RW data (TSC1/2 mutation frequency) presented at AACR-NCI-EORTC and incident cancer volume for solid tumors in the SEER database (2023)

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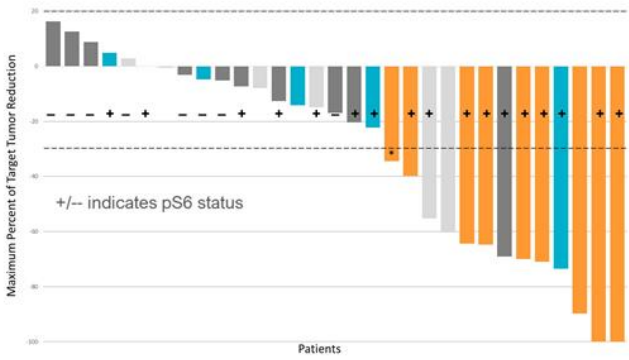
Data from AMPECT in *TSC1* or *TSC2* Inactivating Alterations Supports Further Investigation Across Different Tumor Types



Best Overall Responses Patients with NGS* (N=25)	*TSC1/TSC2* n = 14	Non *TSC1/TSC2* n = 11
Complete or Partial Response	**9/14 (64%)**	**1/11 (9%)**
Stable Disease	**4/14 (29%)**	**8/11 (73%)**
Stable Disease ≥12 weeks	3/14 (21%)	5/11 (45%)
Progressive Disease	**1/14 (7%)**	**2/11 (18%)**

- 25 patients had available NGS reports
- Confirmed Responders: 9/14 (64%) pts with *TSC1/TSC2* vs 1/11 (9%) with no *TSC1/TSC2* alterations
- *TSC1/TSC2*: 12/14 (86%) patients had Disease Control (CR or PR or SD ≥12 weeks)

TSC2 mutation *TSC1* mutation No *TSC1* or *TSC2* mutation UNK mutational status

*Note: *1 patient with TSC2 mutation had an unconfirmed PR and thus best response is an SD as per RECIST 1.1; Source: AJ Wagner et al., JCO. 2021*

PRECISION1: Registration Directed Tumor-Agnostic Trial of *nab*-sirolimus in *TSC1* or *TSC2* Inactivating Alterations

PRECISION1 Trial

- Two independently evaluable arms, one each for *TSC1* and *TSC2*
- Primary endpoint: ORR by blinded, independent radiologic review
- Patient accrual based on local NGS results
- First patient dosed March 2022 with expected 24-month enrollment period

Key Eligibility Criteria

- Metastatic or locally advanced disease ineligible for surgery
- Naïve to mTOR inhibitor treatment
- Pathogenic *TSC1* or *TSC2* inactivating alterations identified through NGS
- Must have received standard therapy for the disease or in investigator opinion unlikely to benefit

PRECISION1: Demographics, Efficacy Evaluable Population

	TSC1 n=19[1]	*TSC2* n=18
Age median (range)	64 (37-72)	62 (28-82)
M/F	5 / 14	7 / 11
PRIOR Rx median (range)	3 (0-7)	3.5 (1-7)
≥ 3rd Line (%)	15 (79)	15 (83)
≥ 5th Line (%)	5 (26)	9 (50)
ECOG		
0	7	8
1	12	10
Different tumor types	9	13

[1] *Three patients without post-baseline assessment not included; all three patients received two or fewer doses and none withdrew due to treatment-related adverse events*

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PRECISION1: Tumor Types Enrolled in Arms A (*TSC1*) and B (*TSC2*)

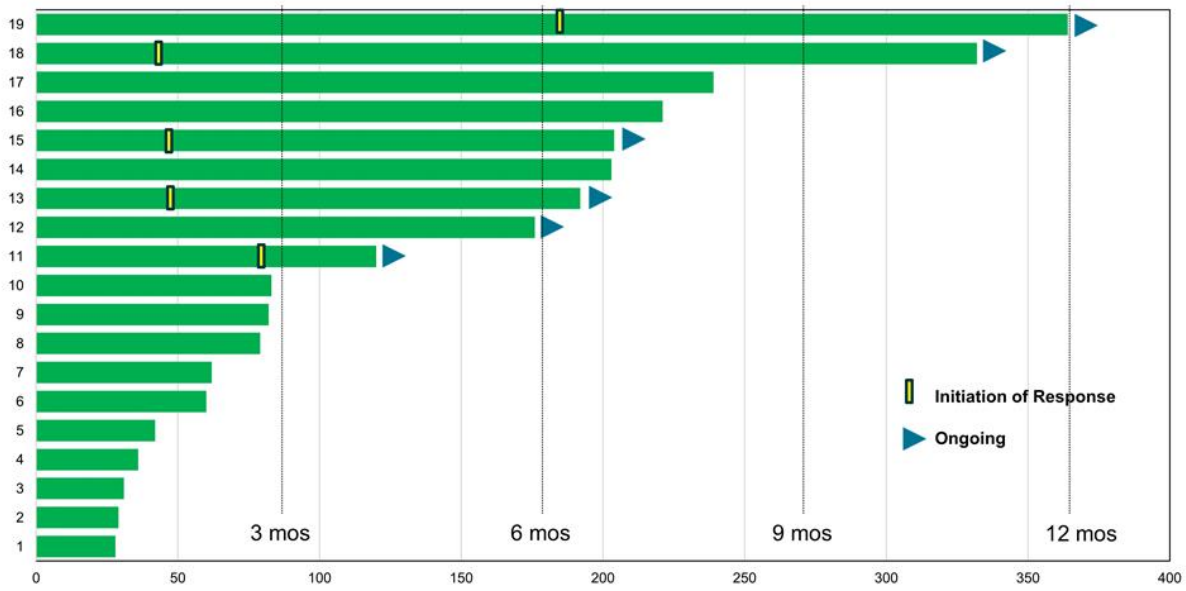
Tumor	TSC 1 n=19	TSC 2 n=18
Bladder	4	0
Ovary	3	2
Endometrial	3	0
Colon	3	1
Leiomyosarcoma	2	2
Breast	1	3
Cervix	1	1
Adrenocortical	1	0
Hepatocellular	1	1
Soft Tissue Sarcomas	0	2
GIST	0	1
PNET	0	1
Vaginal	0	1
Osteosarcoma	0	1
Mesothelioma	0	1
Head & Neck	0	1

TSC1 Inactivating Alterations: Efficacy

	Efficacy Evaluable[1] (N=19)[2]
Response	
Partial Response[3] (n, %)	5 (26)
Stable Disease (SD) (n, %) SD SD ≥ 6 mos	 9 (47) 3 (16)
Progressive Disease (PD) (n,%)	5 (26)
Clinical Benefit Rate (n,%) (PR+SD ≥ 6 mos)	8 (42)
Duration of Response (median)	NE
Time to Response Median – mos	1.4

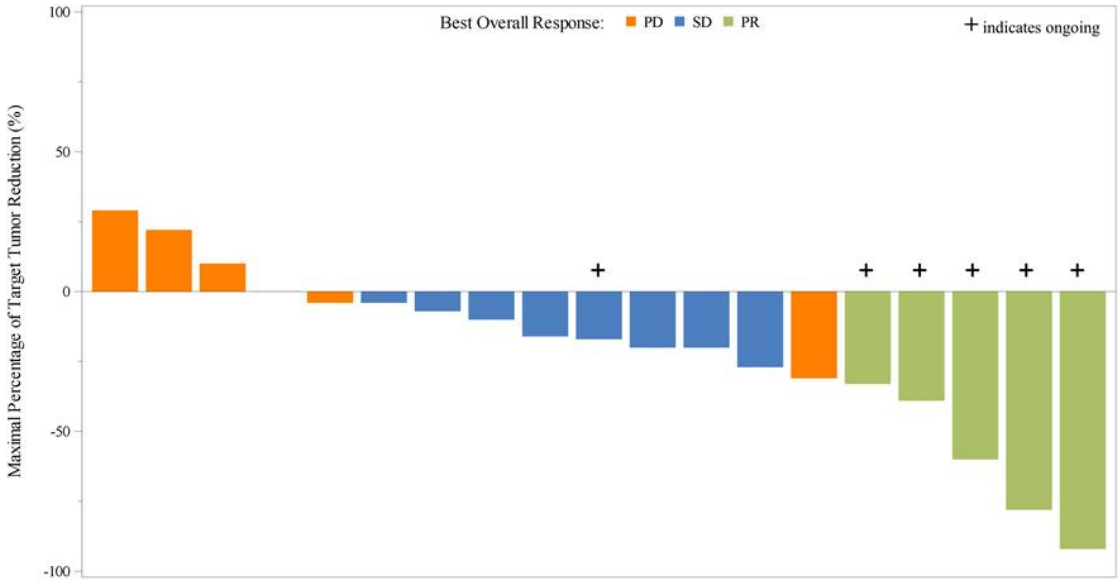
[1] *By Investigator Assessment*
[2] *Three patients without post-baseline assessment not included*
[3] *One unconfirmed PR, patient on treatment and awaiting confirmatory scan*

TSC1 Inactivating Alterations: Patient Time on Treatment



TSC1 Inactivating Alterations: Best Overall Response

Tumor reduction observed in 79% of patients



TSC1 Inactivating Alterations: Investigator-Assessed Efficacy Observations

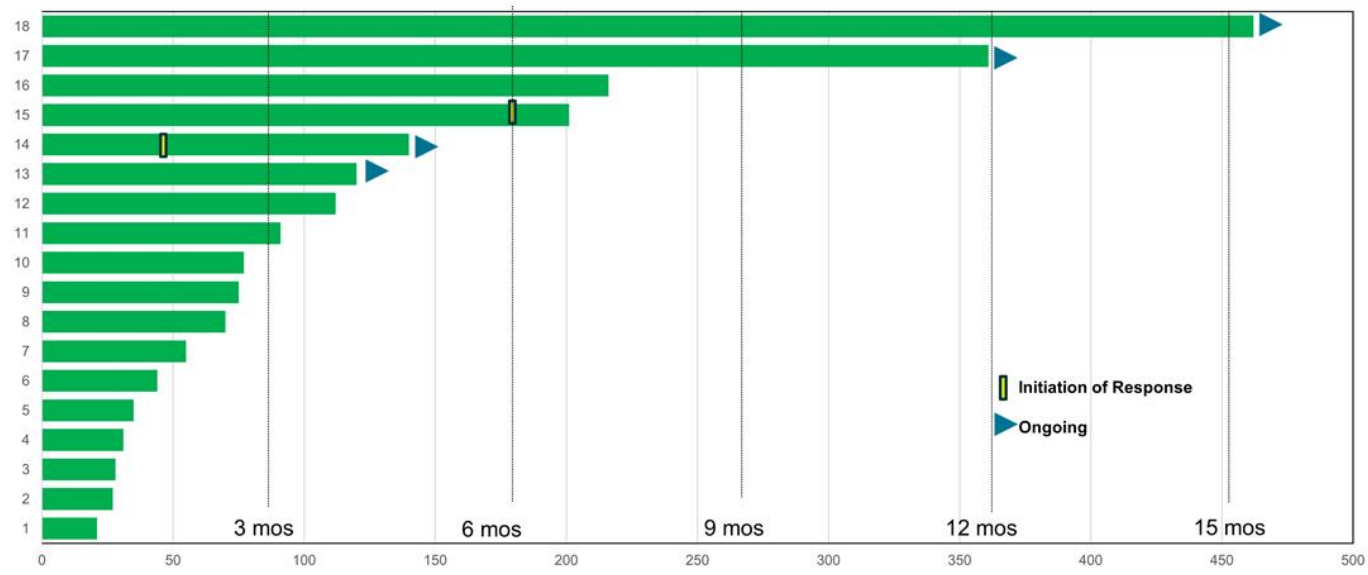
- ORR of 26% encouraging
  - 5 Responses seen in 4 different epithelial carcinoma types
  - Heavily pre-treated population
    - Median of 3 prior lines of therapy
  - Responses appear to be early, deep and durable
    - All are ongoing; more than half have >50% reduction

TSC2 Inactivating Alterations: Efficacy

	Efficacy Evaluable[1] (N=18)
Response	
Partial Response[2] (n, %)	2 (11)
Stable Disease (n, %) SD SD ≥ 6 mos	 12 (67) 3 (17)
Progressive Disease	4 (22)
Clinical Benefit Rate (PR+SD ≥ 6 mos)	5 (28)
Duration of Response (median)	NE
Time to Response (mo)	3.6

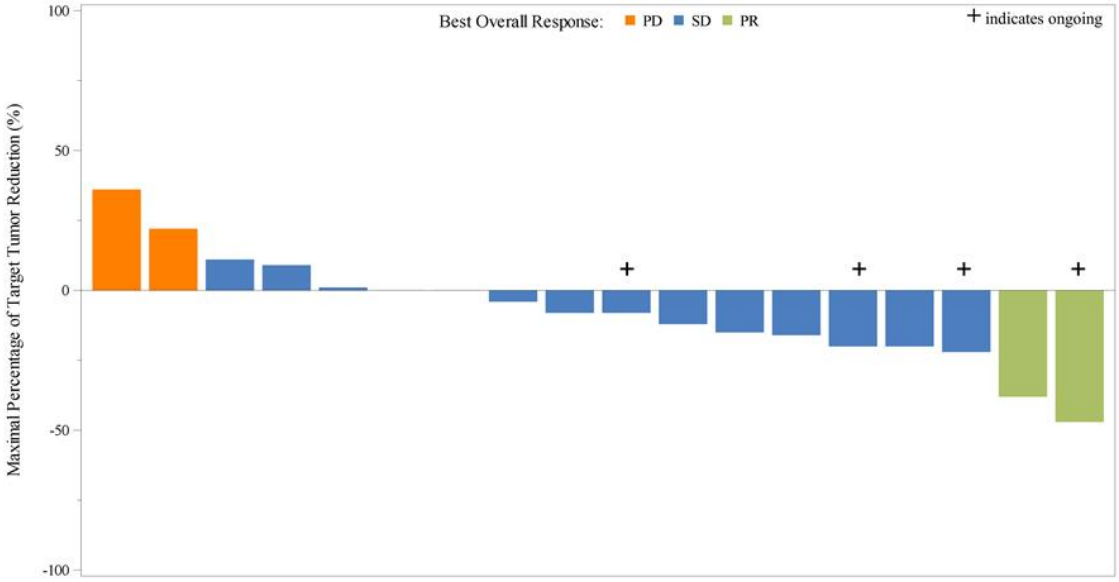
[1] *By Investigator Assessment*
[2] *One unconfirmed PR with a single PR assessment*

TSC2 Inactivating Alterations: Patient Time on Treatment



TSC2 Inactivating Alterations: Best Overall Response

Tumor reduction observed in 61% of patients



TSC2 Inactivating Alterations: Investigator-Assessed Efficacy Observations

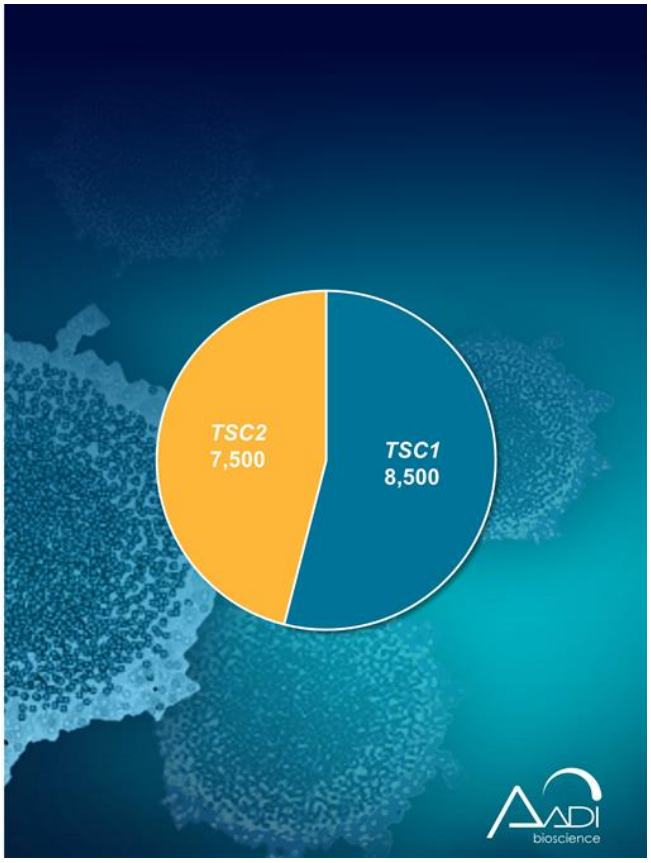
- ORR 11% (2/18)
- Responses seen in epithelial carcinoma and sarcoma
- CBR 28% (2 PR + 3 SD >6 mos)
- Population was heavily pre-treated
  - 9/18 are ≥ 5th line

PRECISION1: Safety Conclusions

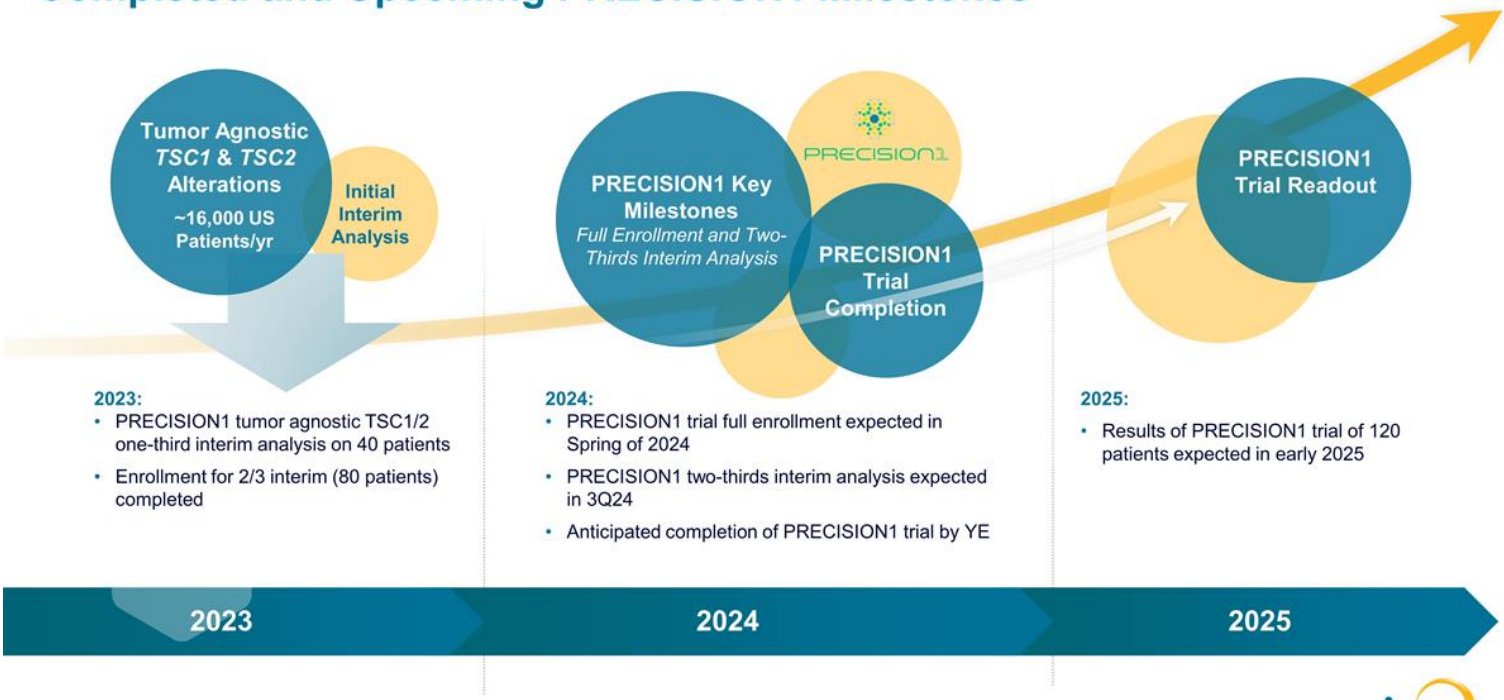
- No new safety signals
- Pattern of AEs consistent with *nab*-sirolimus label and mTORi class
- No grade 4 TRAEs or deaths due to study drug
- 1 patient discontinued study due to grade 2 recurrent pneumonitis

PRECISION1 Interim Analysis Summary

- ***TSC1* arm results encouraging**
  - Response rate in range of our expectations
  - Responses appear to be deep and durable in a heavily pre-treated population
  - Responses in different tumor types supportive of a tumor agnostic indication
- ***TSC2* arm ORR interpretation is complicated by small sample size and heavy pre-treatment**
  - 50% patients received 5 or more prior therapies
- **Two-third interim enrollment of 80 patients completed**



Completed and Upcoming PRECISION1 Milestones



2023:
- PRECISION1 tumor agnostic TSC1/2 one-third interim analysis on 40 patients
- Enrollment for 2/3 interim (80 patients) completed

2024:
- PRECISION1 trial full enrollment expected in Spring of 2024
- PRECISION1 two-thirds interim analysis expected in 3Q24
- Anticipated completion of PRECISION1 trial by YE

2025:
- Results of PRECISION1 trial of 120 patients expected in early 2025

2023 2024 2025

Thank You

NASDAQ: AADI
www.aadibio.com