



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.

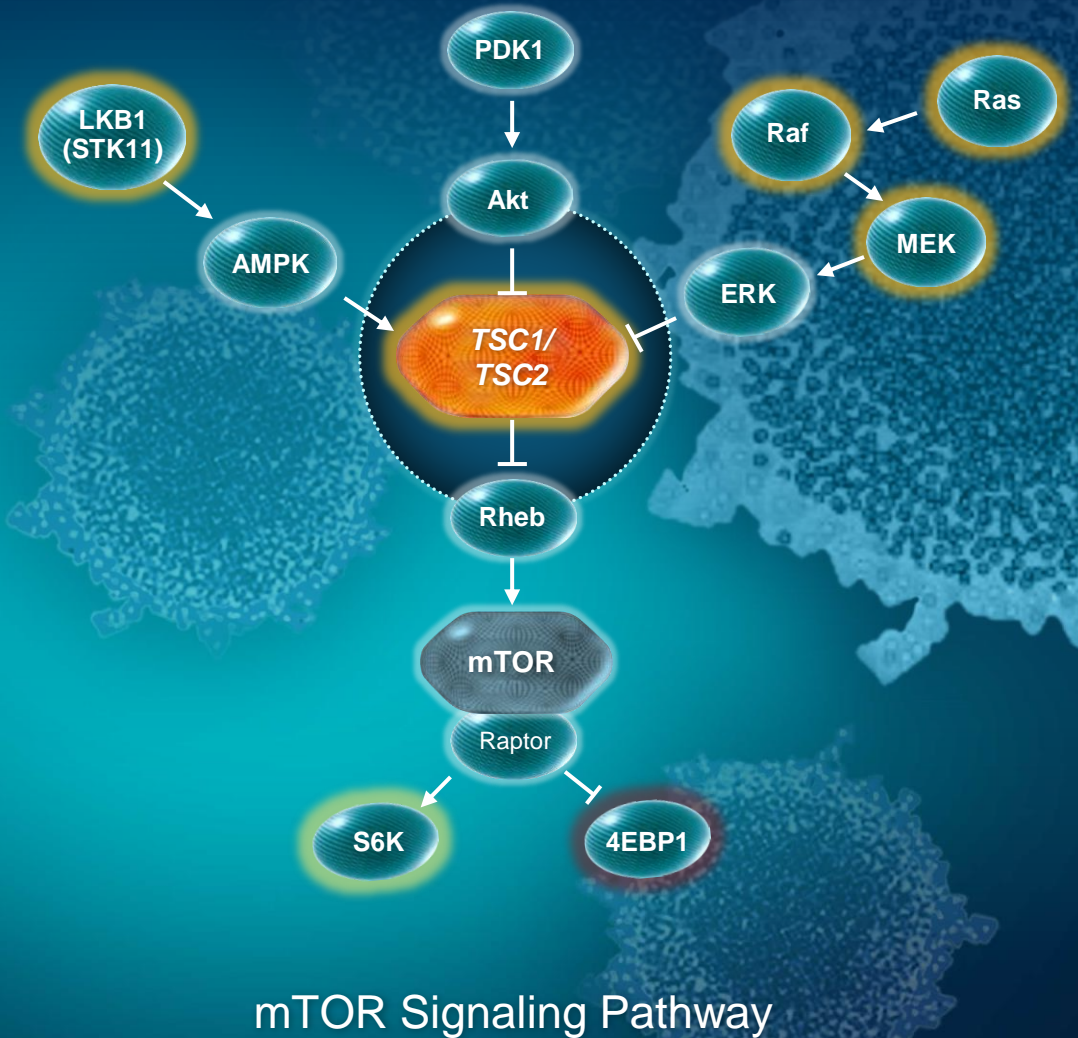
These risks are described in detail under the caption “Risk Factors” in Aadi’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the Securities and Exchange Commission (the “SEC”) on November 8, 2023, and other documents filed from time to time with the SEC. Forward-looking 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

Populations	Phase 1	Phase 2	Approved	Current Status
 Advanced Malignant PEComa, AMPECT Clinical Trial	Single Agent			First FDA approved therapy for advanced malignant PEComa
 Pan-Tumor <i>TSC1</i> / <i>TSC2</i> Inactivating Alterations	<i>TSC1</i> Arm, Single Agent			Registration directed tumor-agnostic pivotal study in <i>nab</i> -sirolimus with independent arms for <i>TSC1</i> or <i>TSC2</i> inactivating alterations; Open for enrollment
	<i>TSC2</i> Arm, Single Agent			
Advanced or recurrent endometrial cancer	<i>nab</i> -sirolimus + letrozole			Trial combining <i>nab</i> -sirolimus with letrozole for patients with endometrioid-type endometrial carcinoma; Open for enrollment
Neuroendocrine tumors (NETs)	Single Agent			Utilizing <i>nab</i> -sirolimus as a monotherapy in neuroendocrine tumors; Open for enrollment
Advanced solid tumors or NSCLC with <i>KRAS</i> ^{G12C} mutation	<i>nab</i> -sirolimus + adagrasib			Ongoing collaboration with  Open for enrollment

Evaluation of additional new single agent and combination trials ongoing

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



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

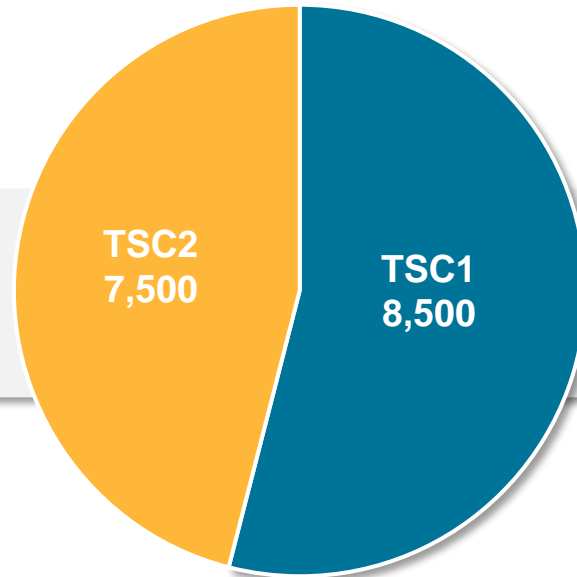
- *TSC1* and *TSC2* are upstream regulators of mTOR activity within the PI3K/Akt/mTOR pathway
- *TSC1* and *TSC2* mutations occur at a rate of ~2% across cancers or ~16,000 new cases each year
- No approved therapies for *TSC1* and *TSC2* mutant patients but numerous case reports with durable responses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

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

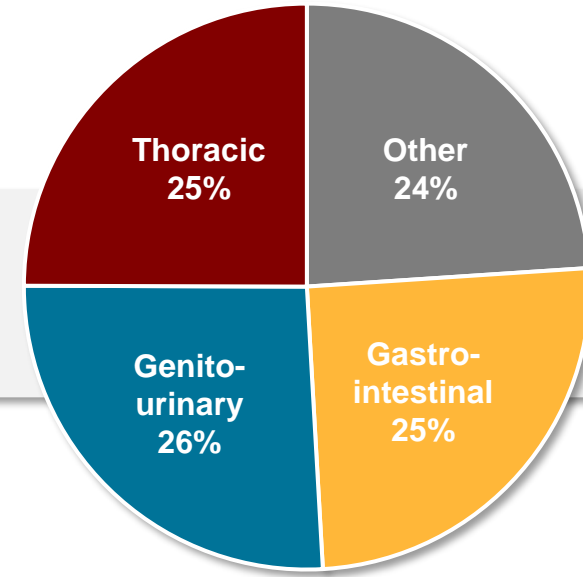
Real-World Analysis of TSC1 and TSC2 Patient Population¹

- 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)



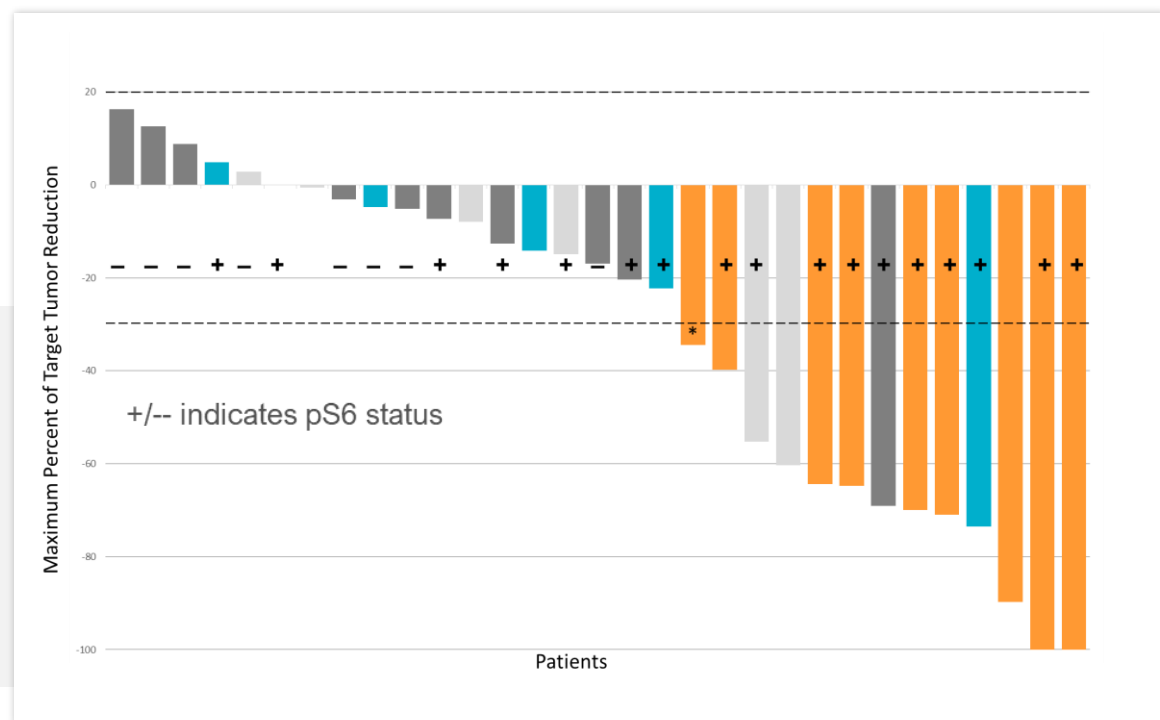
Tumor Clusters
% Patients (n=16,000)



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

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



Best Overall Responses Patients with NGS* (N=25)

	<i>TSC1/TSC2</i> n = 14	Non <i>TSC1/TSC2</i> 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

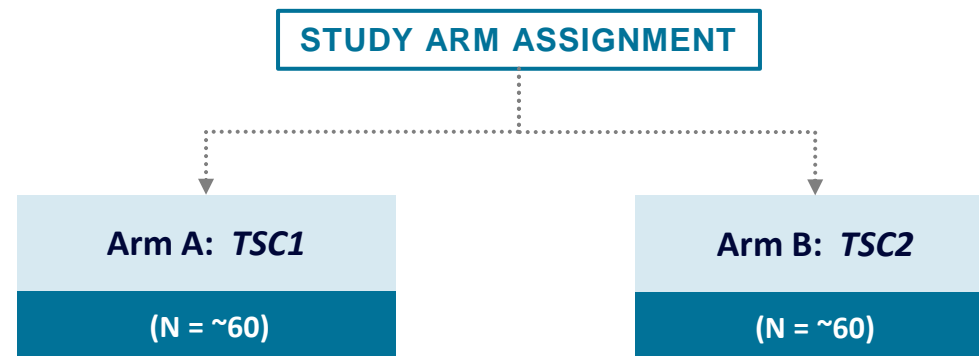
PRECISION1: Registration Directed Tumor-Agnostic Trial of *nab-sirolimus* in *TSC1* or *TSC2* Inactivating Alterations

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)
≥ 3 rd Line (%)	15 (79)	15 (83)
≥ 5 th 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

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

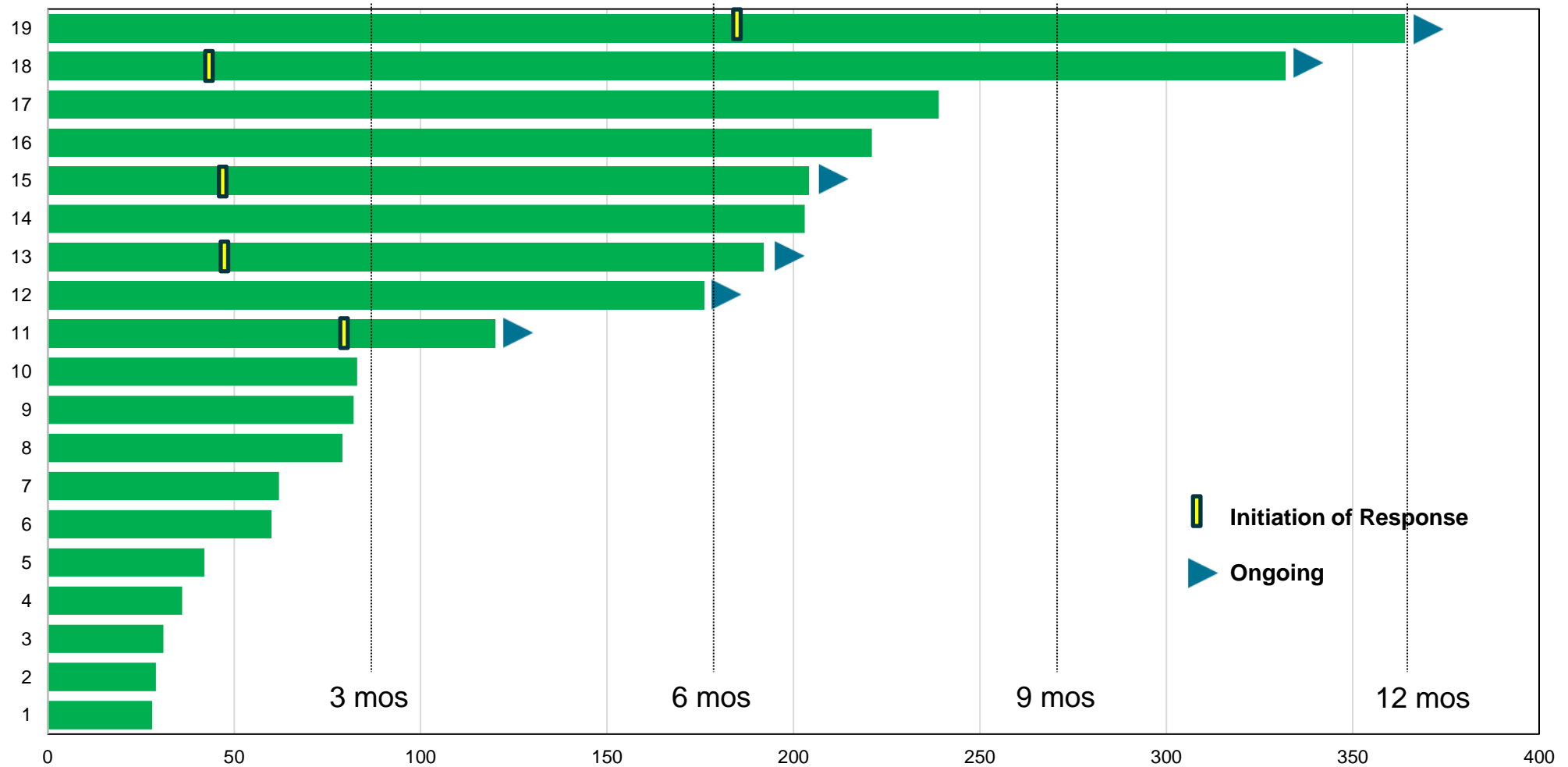
	Efficacy Evaluable ¹ (N=19) ²
Response	
Partial Response³ (n, %)	5 (26)
Stable Disease (SD) (n, %)	
SD	9 (47)
SD ≥ 6 mos	3 (16)
Progressive Disease (PD) (n,%)	5 (26)
Clinical Benefit Rate (n,%) (PR+SD ≥ 6 mos)	8 (42)
Duration of Response (median)	NE
Time to Response	
Median – mos	1.4

¹ By Investigator Assessment

² Three patients without post-baseline assessment not included

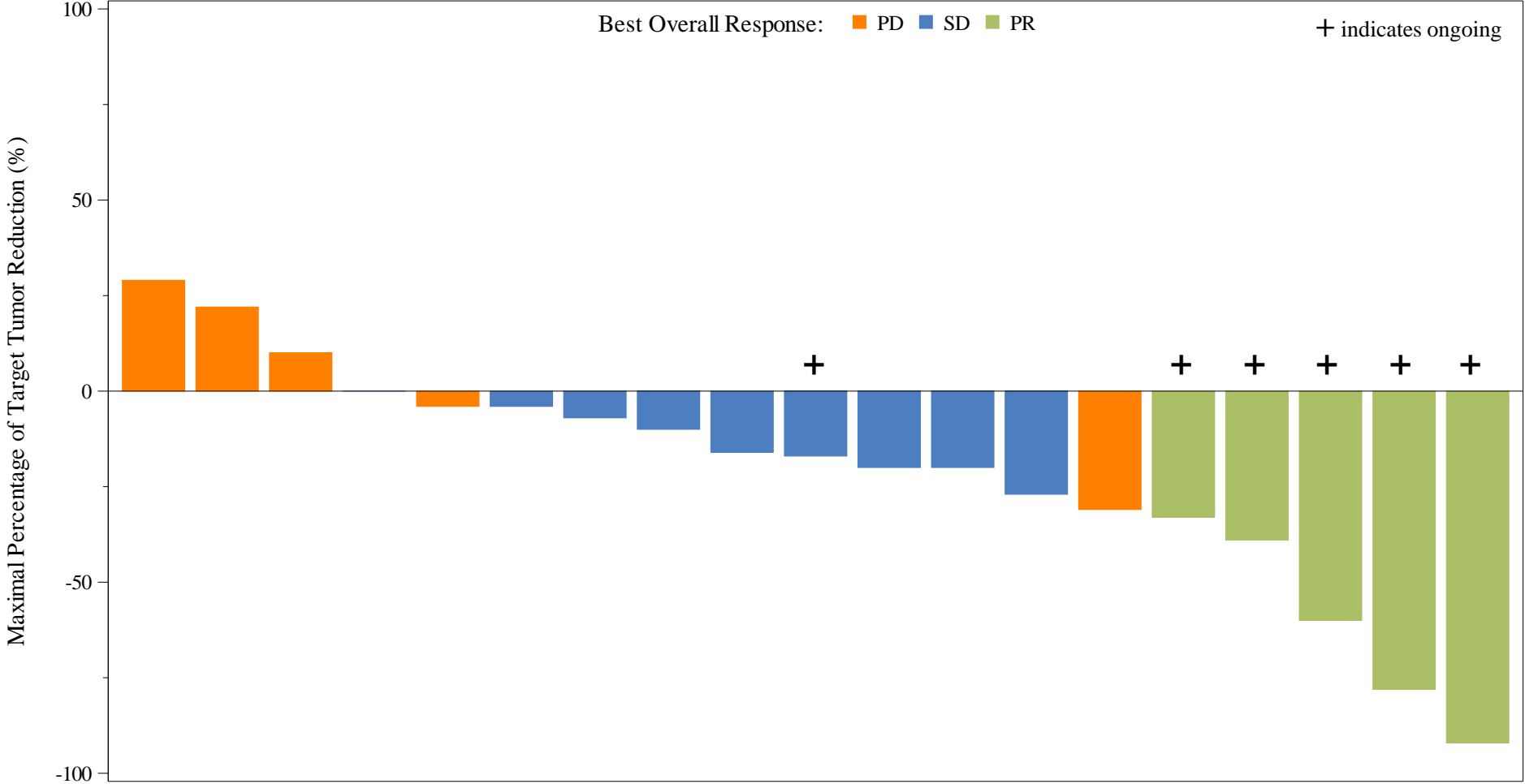
³ One unconfirmed PR, patient on treatment and awaiting confirmatory scan

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

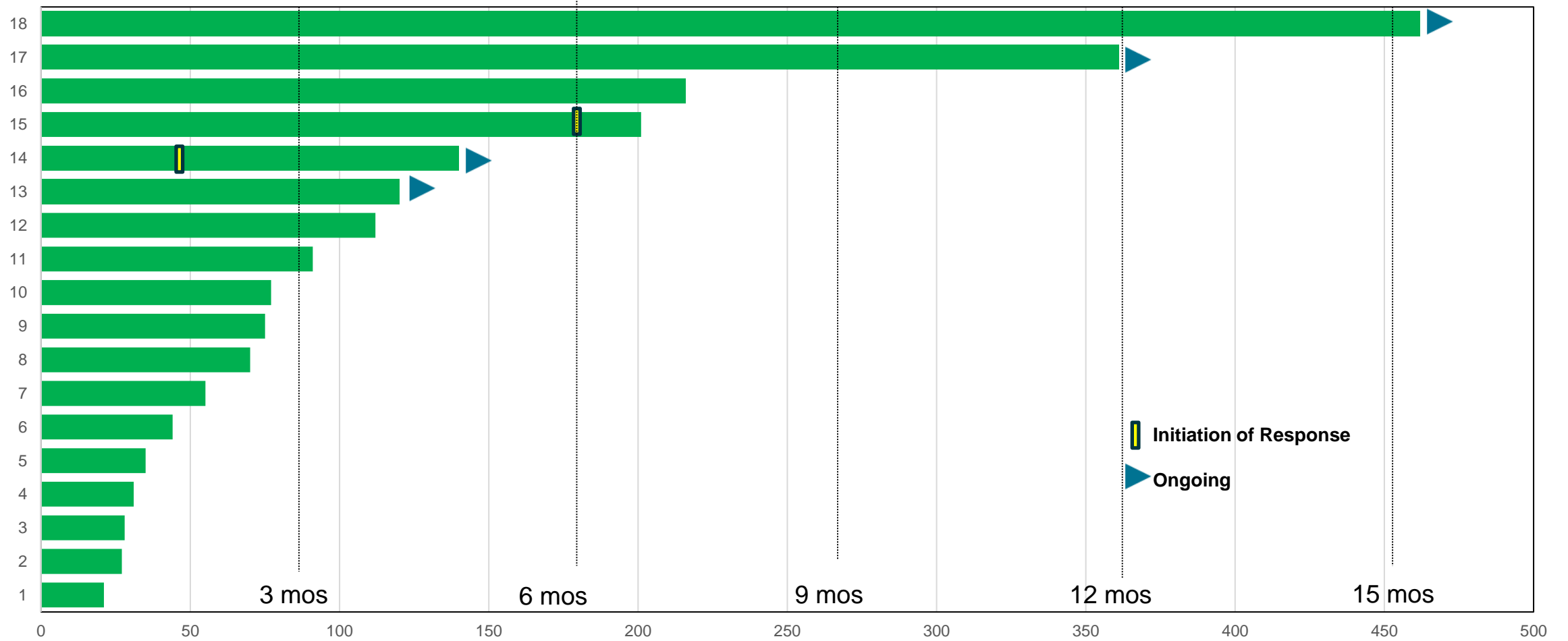
TSC2 Inactivating Alterations: Efficacy

	Efficacy Evaluable ¹ (N=18)
Response	
Partial Response² (n, %)	2 (11)
Stable Disease (n, %)	
SD	12 (67)
SD ≥ 6 mos	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

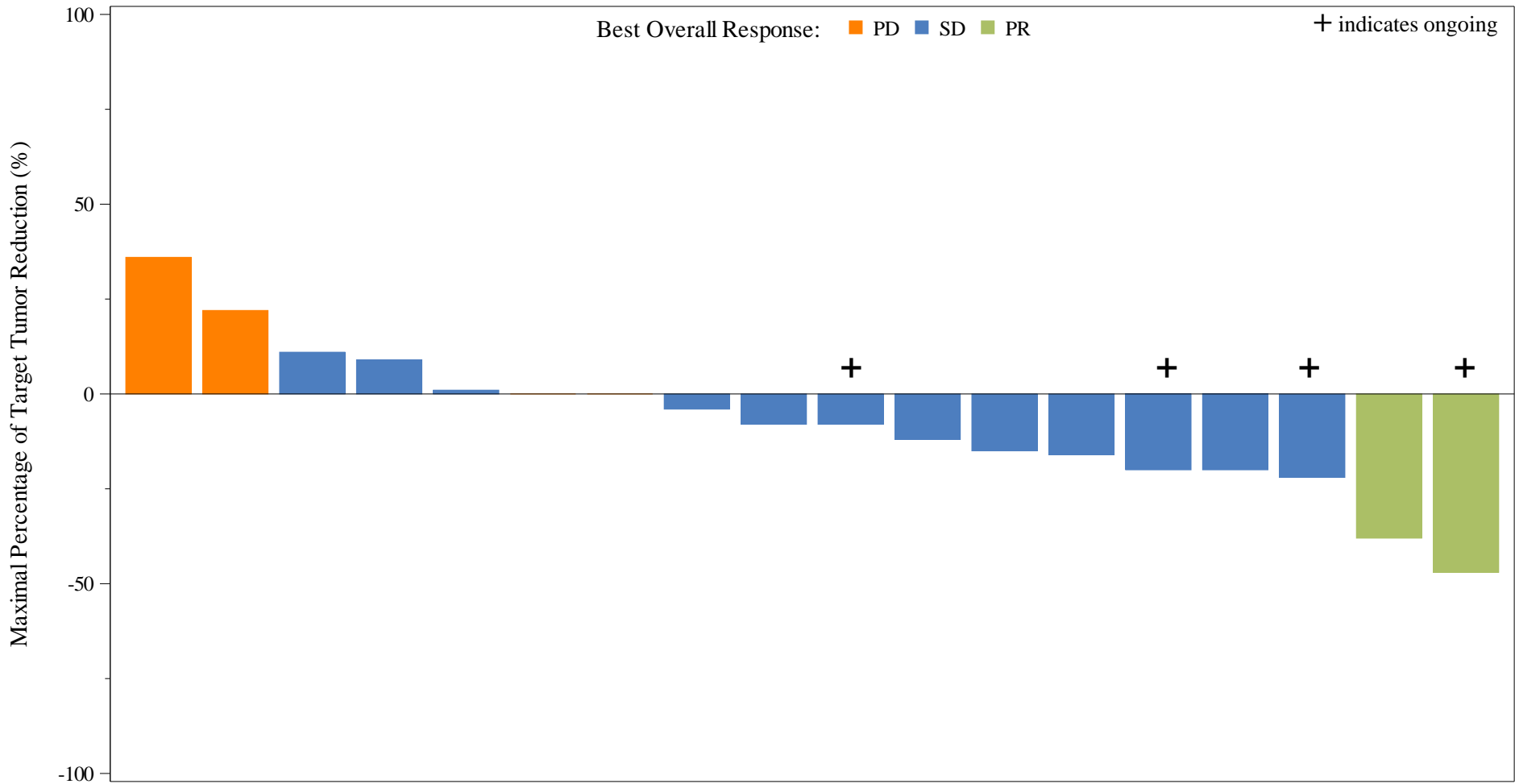
² One unconfirmed PR with a single PR assessment

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 \geq 5th line

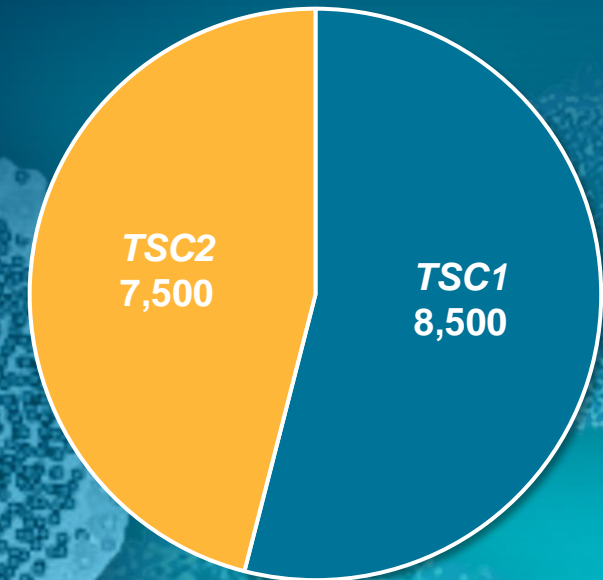
PRECISION1: Safety Conclusions

- 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**

Annual new US cancer cases by TSC alterations
Patients (n=16,000)



Completed and Upcoming PRECISION1 Milestones





Thank You

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