



Spectrum Pharmaceuticals

A Biopharmaceutical Company Developing Targeted and Novel Therapies in Oncology

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December 22, 2020 | Poziotinib Update

Safe Harbor Statement

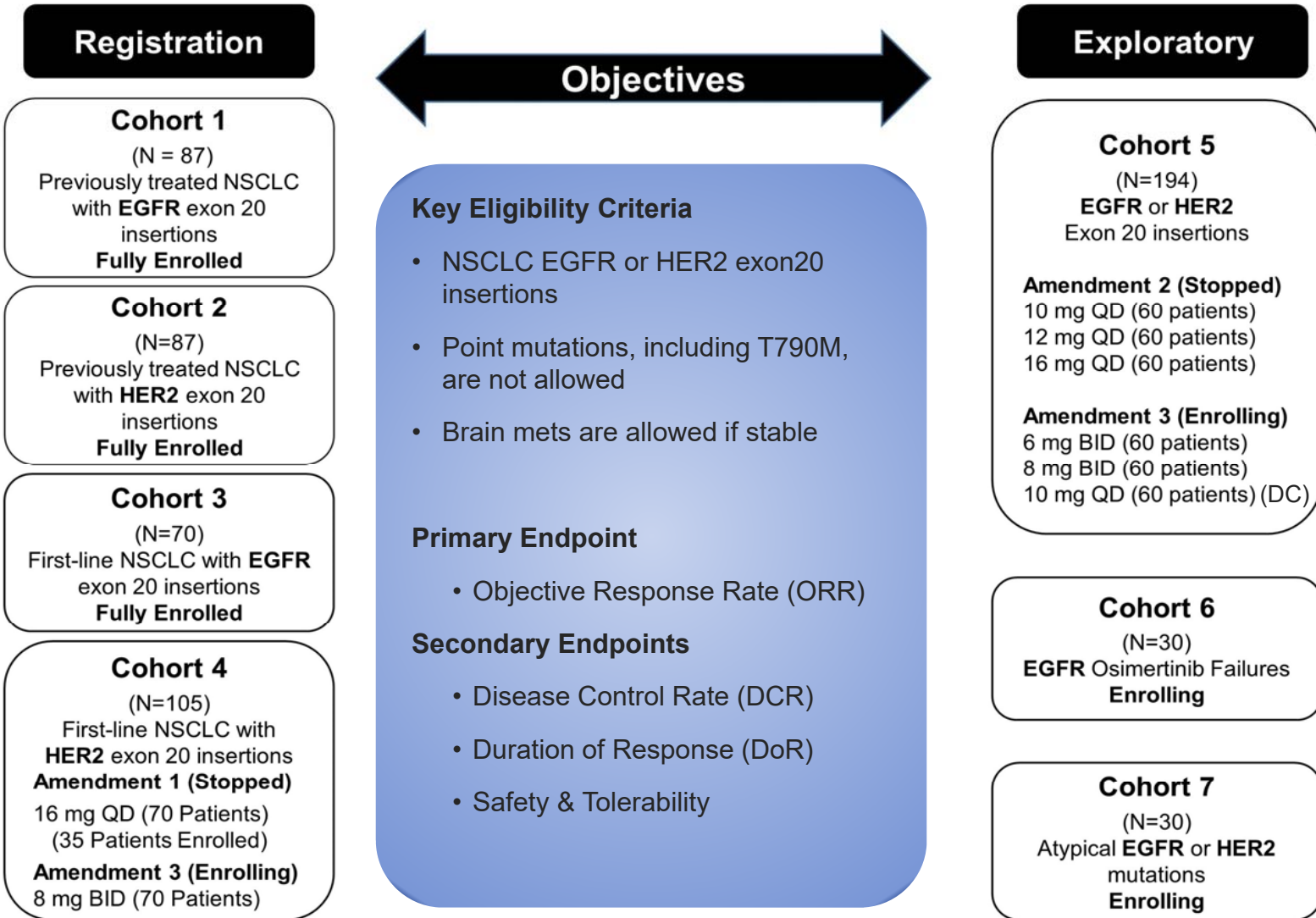
This presentation contains forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include but are not limited to statements that relate to our business and its future, our strategy, the success of our drug candidates, the safety and efficacy of our drug products, product approvals, market potential, product sales, revenue, development, regulatory and approval timelines, product launches, product acquisitions, capital resources and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact.

Risks that could cause actual results to differ include the possibility that our existing and new drug candidates may not prove safe or effective, the possibility that our existing and new drug candidates may not receive approval from the FDA and other regulatory agencies in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that price and other competitive pressures may make the marketing and sale of our drugs not commercially feasible, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of sustained revenue history, our limited experience in establishing strategic alliances, our limited marketing experience, our customer concentration, the possibility for fluctuations in customer orders, evolving market dynamics, our dependence on third parties for clinical trials, manufacturing, distribution, information and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this presentation except as required by law.

Today's Announcement

- FDA agrees to the submission of an NDA for poziotinib
 - **Indication:** Non-small cell lung cancer (NSCLC) in previously treated patients with HER2 exon 20 insertion mutations
 - **Timing:** Submission planned for 2021
- Cohort 3 of the ZENITH20 clinical study, which enrolled first-line NSCLC patients with EGFR exon 20 insertion mutations at 16mg QD, did not meet its primary endpoint (ORR)
- Poziotinib preliminary data from BID dosing in Cohort 5 demonstrates meaningful improvement in tolerability

ZENITH20 Study Design



FDA Agrees that Cohort 2 can be the Basis of NDA Submission

Cohort 2 met Primary Efficacy Endpoint: Observed lower bound of 18.9% exceeded the pre-specified lower bound of 17%

	Intent to treat (N=90) N (%)
Objective Response Rate (ORR) 95% Confidence Interval	27.8% (18.9 – 38.2%)
Disease Control Rate (DCR=CR+PR+SD)	70%
Duration of Response, Median (months)	5.1
Progression-free Survival, Median (months)	5.5

NDA submission planned in 2021

Safety Profile for Cohort 2 In-line with TKIs

- Safety profile was in-line with the type of adverse events seen with other second-generation EGFR TKIs
- Grade 3 incidence of rash was 30%
- Grade 3 incidence of diarrhea was 26%
- 11 patients (12%) permanently discontinued study due to adverse events

Primary Endpoint in Cohort 3 Not Met

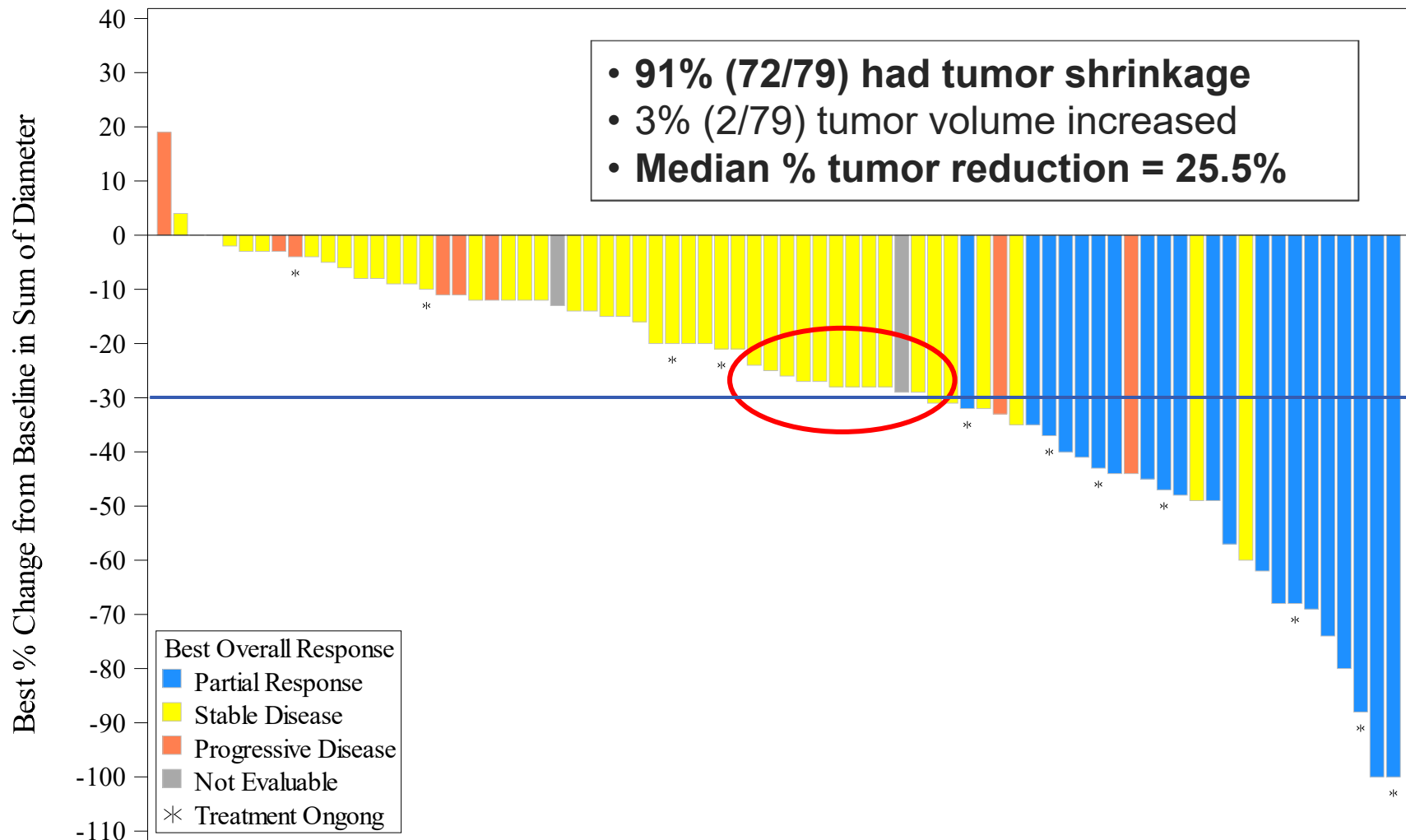
	Intent to Treat (N=79)
Objective Response Rate (ORR), n (%)	22 (27.8%)
95% Confidence Interval %	18.4% – 39.1%
Disease Control Rate (DCR), n (%)	68 (86.1%)
Median Duration of Response (months) *	6.5
Median Progression-free Survival (months) *	7.2
Median time of follow up of all patients (months) *	9.2

* Based on Kaplan-Meier estimate

Primary Efficacy criteria: 95% lower bound of ORR > 20%

Waterfall Plot - Cohort 3

Best Change from Baseline in Tumor Volume

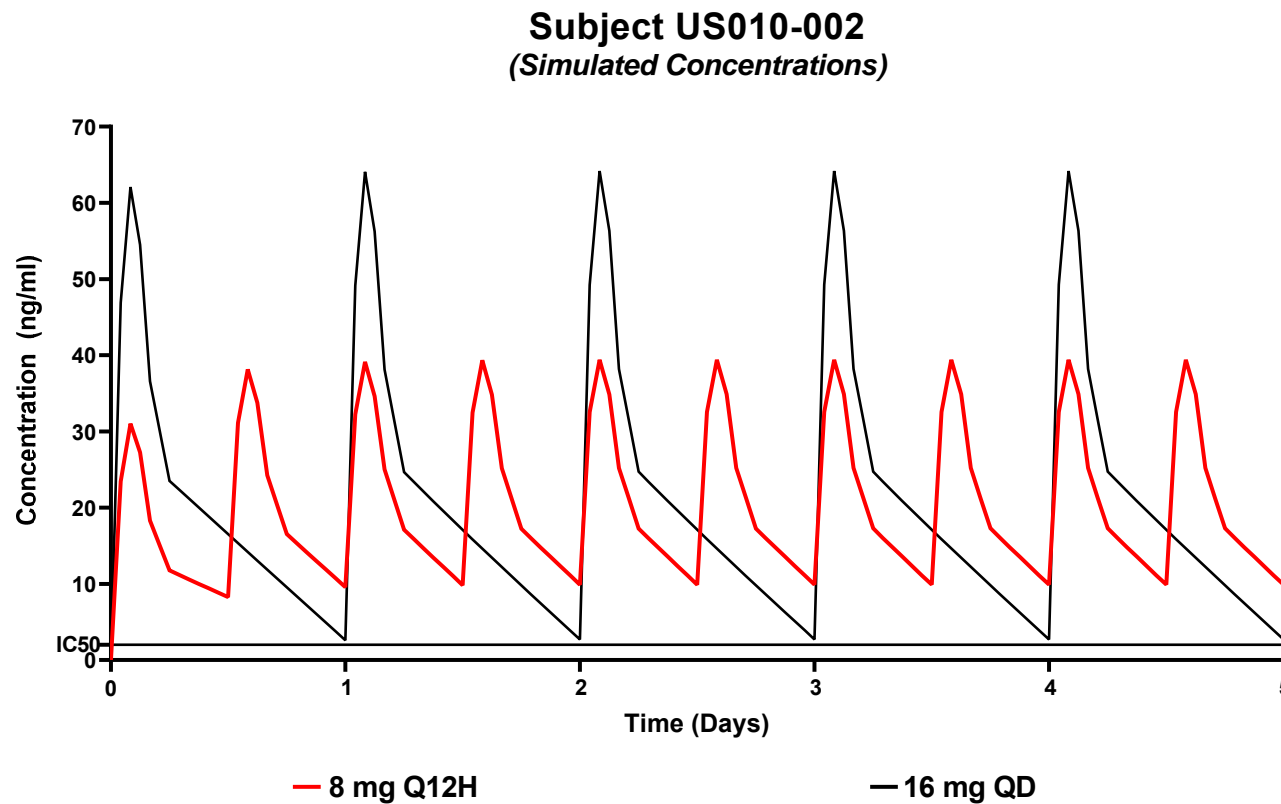


Summary of Treatment-Related Adverse Events

	N=79 n (%)
Any Treatment-related AE	78 (99)
Grade 3 Treatment-related AE	64 (81)
Any Treatment-related Serious AE	12 (15)
Permanently discontinued due to AE	6 (8%)

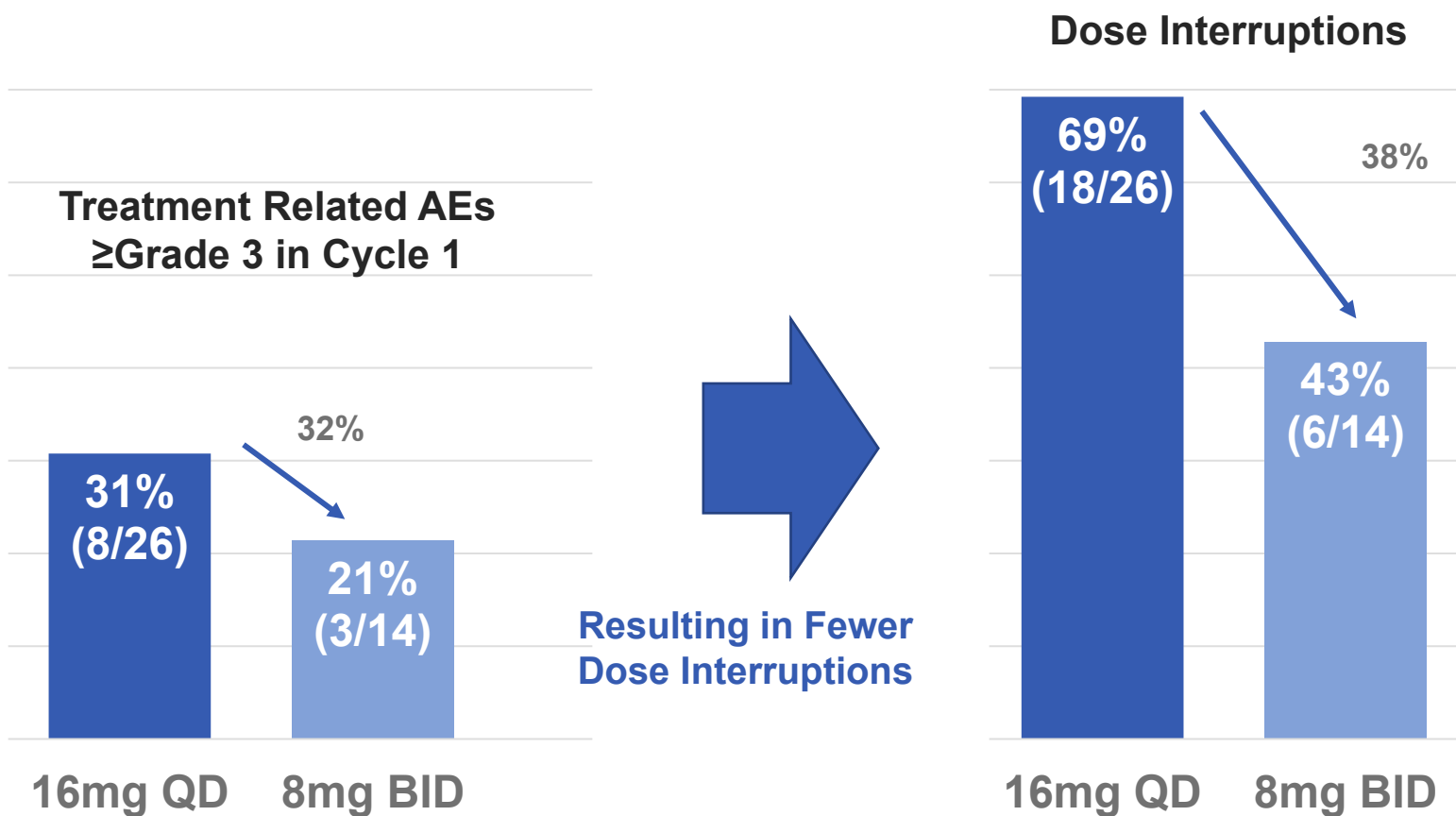
Preferred Term	N=79 n (%)		
	Any Grade	Grade 3	Grade 4 or 5
Diarrhea	68 (86)	18 (23)	0
Paronychia	53 (67)	7 (9)	0
Rash	51 (65)	26 (33)	0
Stomatitis	40 (51)	10 (13)	0
Pneumonitis	1 (1)	0	1 (1)

Hypothesis: BID Dosing Would Increase Tolerability Leading to Increased Dose Intensity



- Pozi plasma $\frac{1}{2}$ life is 7.9 hours
- BID dosing
 - Decreases Cmax
 - Maintains Ctough above IC50
- Pozi IC50 4nM (2ng/ml)-T790m

Cohort 5*: BID Dosing Improved Tolerability



*Cohort 5 enrolling, preliminary data as reported by investigator.

Summary

- NDA submission for poziotinib planned for 2021
- Cohort 2 data will be the basis for the NDA in previously treated NSCLC patients with HER2 exon 20 insertion mutations
- Cohort 3 demonstrated anti-tumor activity but did not meet the primary end point
- Cohort 5 – Preliminary data from 8 mg BID dosing meaningfully improved tolerability leading to fewer dose interruptions
- The preliminary findings of BID dosing could benefit the entire poziotinib program including both EGFR and HER2 exon 20 insertion mutations