

#P2.351: Nelmastobart plus docetaxel in advanced NSCLC: initial safety and efficacy from a single-arm phase 2 study (STCUBE-004; NCT07306624)

ABSTRACT

Lung cancer remains the leading cause of cancer-related mortality worldwide. Non-small cell lung cancer (NSCLC) accounts for approximately 80–85% of cases, and many patients are diagnosed with advanced-stage disease. First-line outcomes have improved with immune checkpoint inhibitors (ICIs), alone or combined with platinum-based chemotherapy, and with targeted therapies in tumors harboring actionable genomic alterations (AGA). Nevertheless, most patients eventually progress, and effective options are limited after platinum-based chemotherapy and ICI therapy and, in patients with AGA, after prior targeted therapy. Docetaxel remains a standard option in this setting but is associated with modest response rates, underscoring the need for combination strategies. BTN1A1 is a novel immune checkpoint associated with tumor immune evasion that is preferentially expressed in tumor cells and minimally expressed in normal tissues and immune cells. Nelmastobart (hSTC810) is a first-in-class humanized IgG4 monoclonal antibody that selectively binds dimerized and glycosylated BTN1A1 and restore antitumor immune responses. STCUBE-004 is a single-arm phase 2 study evaluating the efficacy and safety of Nelmastobart plus docetaxel in patients with BTN1A1-positive (tumor proportion score $\geq 50\%$) advanced or metastatic NSCLC.

INTRODUCTION

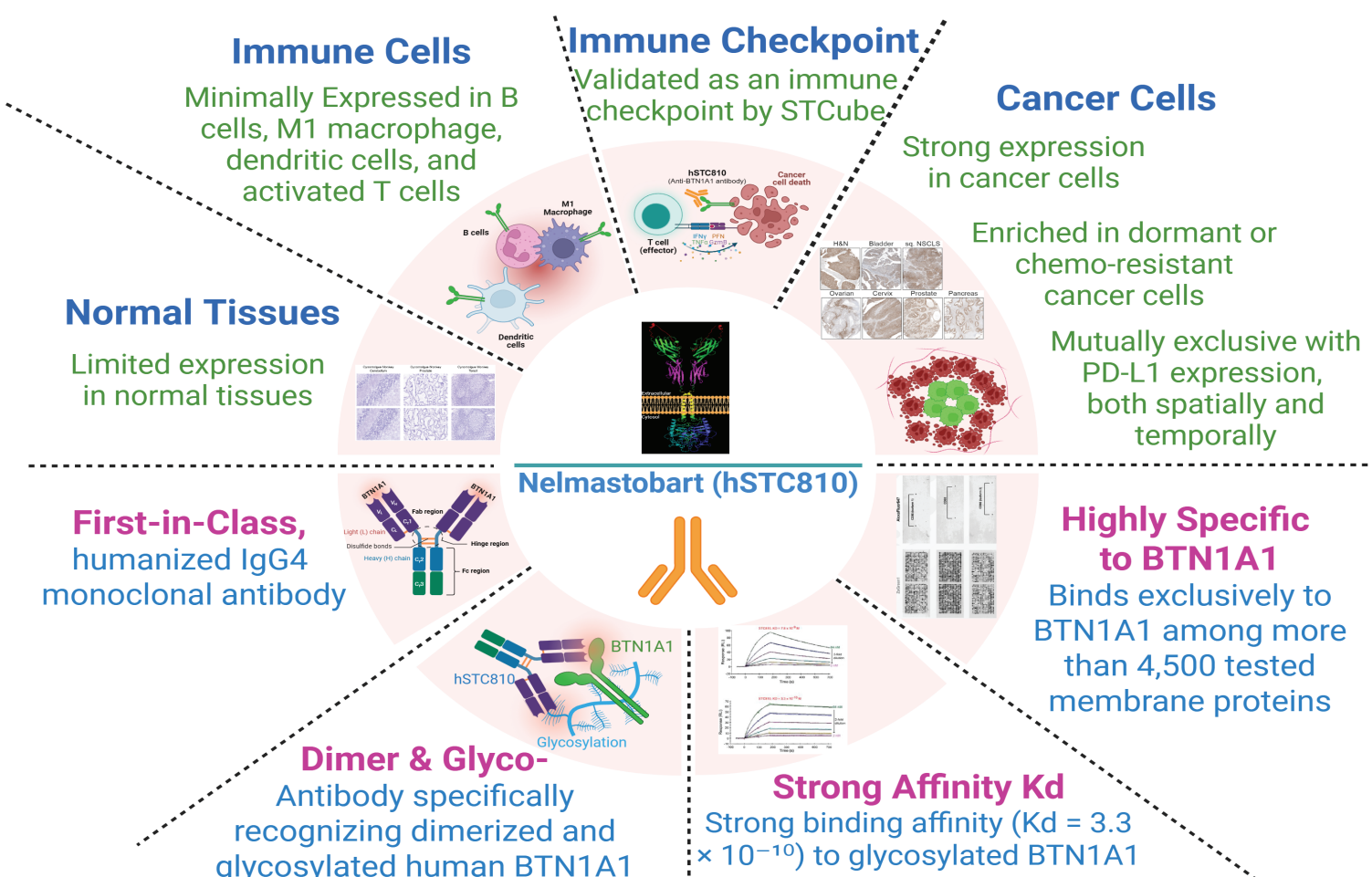
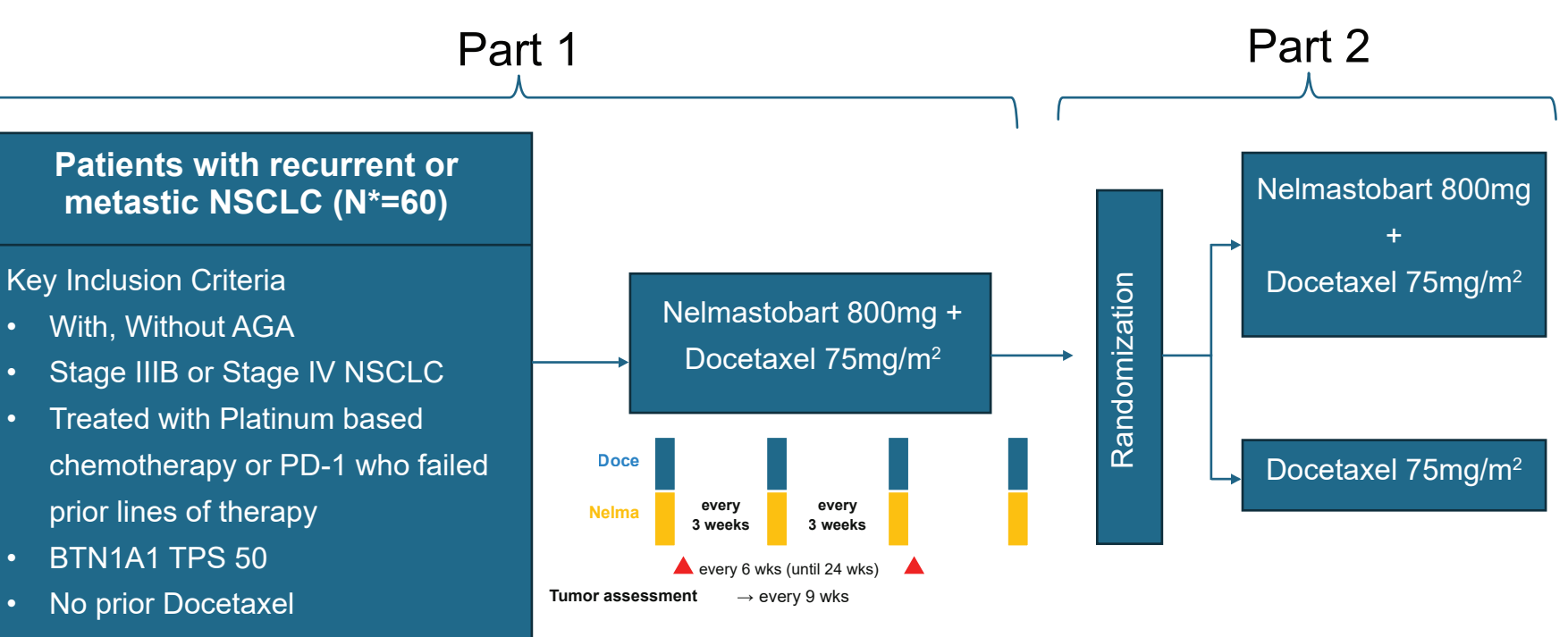


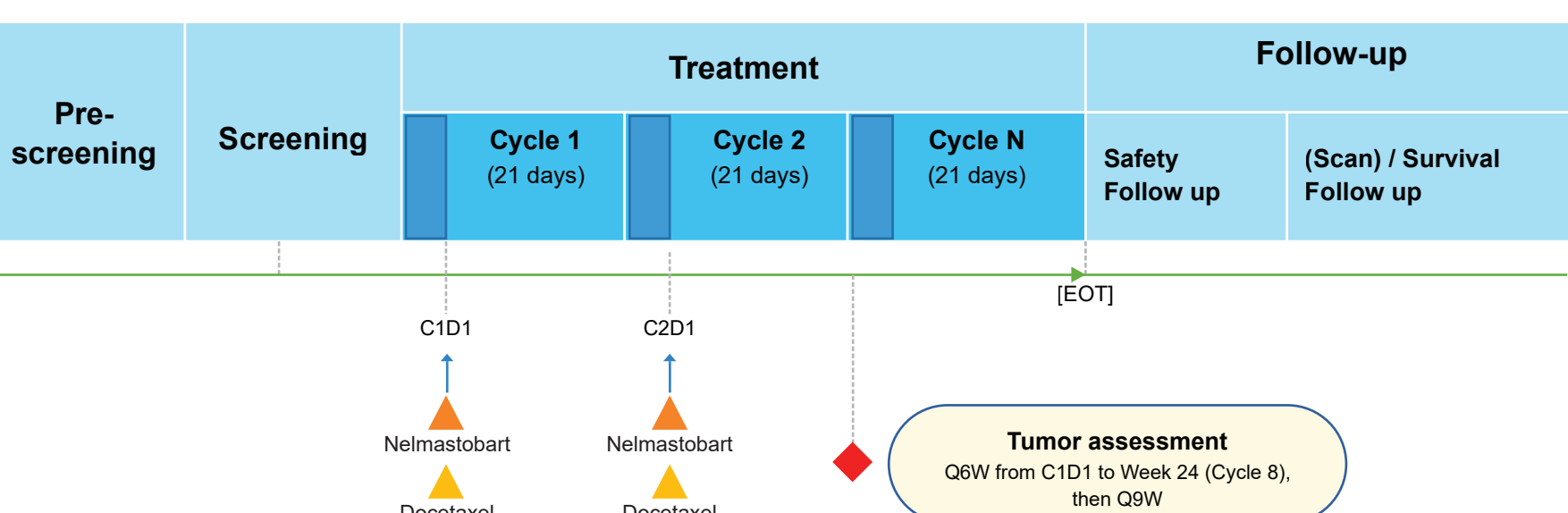
Figure 1. Biological characteristics of BTN1A1 and mechanism of action of Nelmastobart (hSTC810).

BTN1A1 is highly expressed in cancer cells but minimally present in normal tissues and immune cells. Nelmastobart specifically binds glycosylated BTN1A1 with high affinity and selectivity, supporting its development as a novel immune checkpoint inhibitor.

METHODS



Part 1 is a single arm trial where mPFS from 62 subjects who are administered with Nelmastobart 800mg combined with Docetaxel 75mg/m² will be tested against the mPFS from historical control of Docetaxel monotherapy. Safety and efficacy data from Part 1 will be evaluated concurrently to assess the feasibility of a subsequent two arm, randomized Part 2 study. Purpose of part 2 is to further assess and compare the mPFS of each arm.



Study Objectives

- Primary endpoint**
 - mPFS based on RECIST v1.1 assessed by central reviewer
- Secondary endpoints (Efficacy)**
 - mPFS based on RECIST v1.1 assessed by investigator
 - PFS rate at 6 months based on RECIST v1.1 assessed by investigator and central reviewer
 - DCR, BOR, ORR (Confirmed and unconfirmed) based on RECIST v1.1 assessed by investigator and central reviewer

- Other Secondary endpoints**
 - Safety
 - Pharmacokinetics
- Exploratory endpoints**
 - Efficacy endpoints based on iRECIST
 - Immune cell profiling

RESULTS

Baseline Demographics

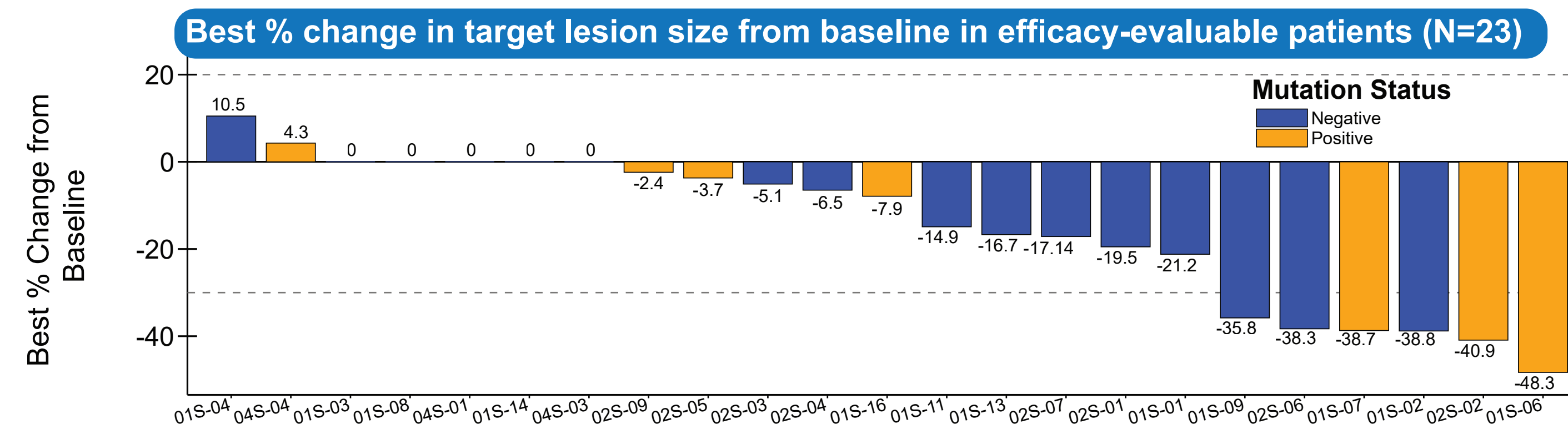
Parameter	Number (N=34)	Parameter	Number (N=34)	Parameter	Number (N=34)
Median age	64	ECOG performance status		PD-L1 status	
Female gender	9			0	15
Histology				1~49	14
Squamous	12	0	7	≥ 50	5
Non squamous	22	1	27		
Smoking history		Mutation status		Prior systemic therapy	
Ever	25	EGFR mutant	10	immunotherapy	28
Never	9	Other mutant	2	Targeted therapy	14
Unknown	0	Negative (Wild type)	22	Nonplatinum chemotherapy	30

Safety & Efficacy

TRAE, N=34 Subject n, %	Related to Nelmastobart		Related to Docetaxel		Related to Both	
	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3
Myalgia	11 (32.4%)	2 (5.9%)	9 (26.5%)	2 (5.9%)	1 (2.9%)	
Anemia	6 (17.6%)		6 (17.6%)	2 (5.9%)		
Asthenia	5 (14.7%)		1 (2.9%)		4 (11.8%)	2 (5.9%)
Anorexia	4 (11.8%)		3 (8.8%)	1 (2.9%)	1 (2.9%)	
Vomiting	4 (11.8%)		3 (8.8%)	1 (2.9%)		
Drug induced pneumonitis	2 (5.9%)	1 (2.9%)	1 (2.9%)	1 (2.9%)		
Dyspnea	2 (5.9%)	1 (2.9%)	1 (2.9%)	1 (2.9%)		
Neutropenia	2 (5.9%)		2 (5.9%)	2 (5.9%)		
Pneumonia	2 (5.9%)		2 (5.9%)	1 (2.9%)		
General edema	1 (2.9%)	1 (2.9%)	1 (2.9%)			
Hypokalemia	1 (2.9%)		1 (2.9%)	1 (2.9%)		

* Grade ≥ 3 Nelmastobart related General edema and drug-induced pneumonitis eventually resolved after adequate concomitant treatment.

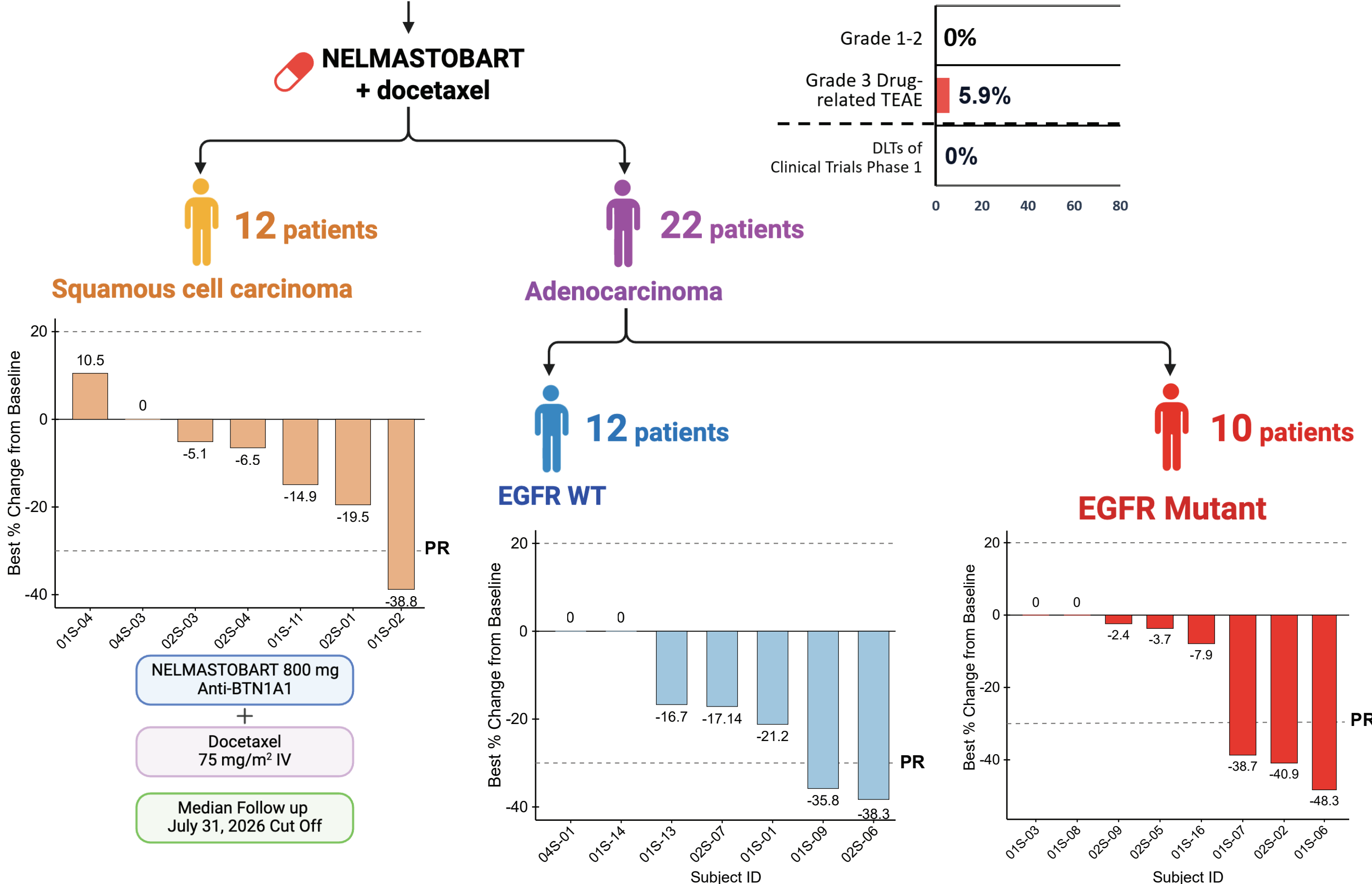
* Causality of General edema was assessed as Nelmastobart related, but changed to both IP related later on.



STCUBE-004 phase 2
34 treated patients

Treatment Related ILD Events

0% 10 of Patients with EGFR-Mutated



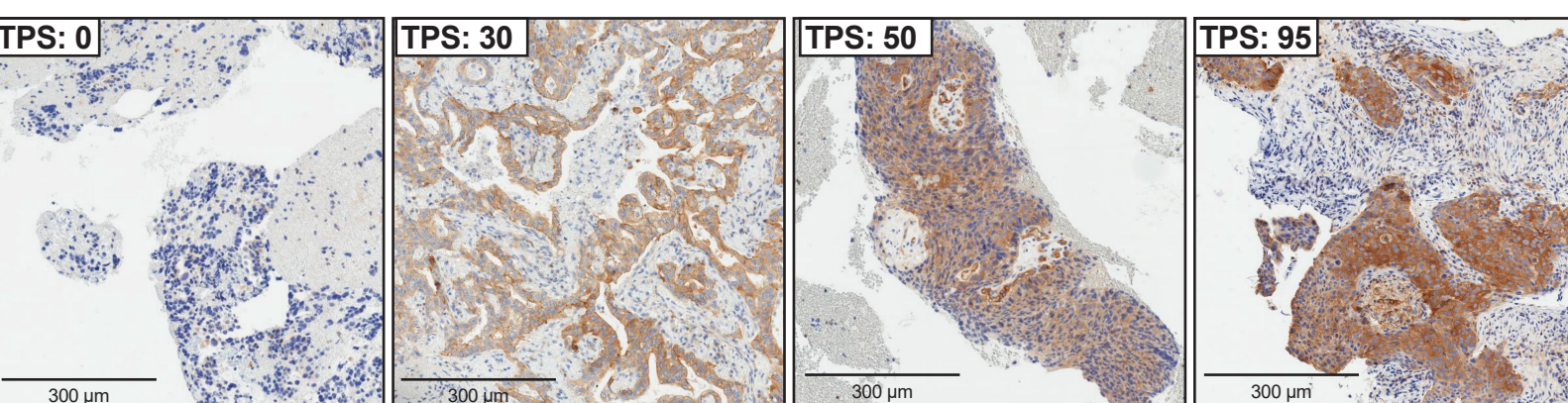
Efficacy (Continued)

As of July 31st 2026, median follow up duration was 3.5 months and 23 subjects had at least 1 post-base line radiologic tumor assessments.

Investigator assessment N = 23 n, %	
BOR	
CR	0 (0.0%)
PR	6 (26.1%)
SD	14 (60.9%)
PD	3 (13.0%)
ORR	6 (26.1%)
DCR	20 (87.0%)

Due to limited number of tumor assessments by BICR at the time of data cut off, only the response rate was provided for the BICR results.

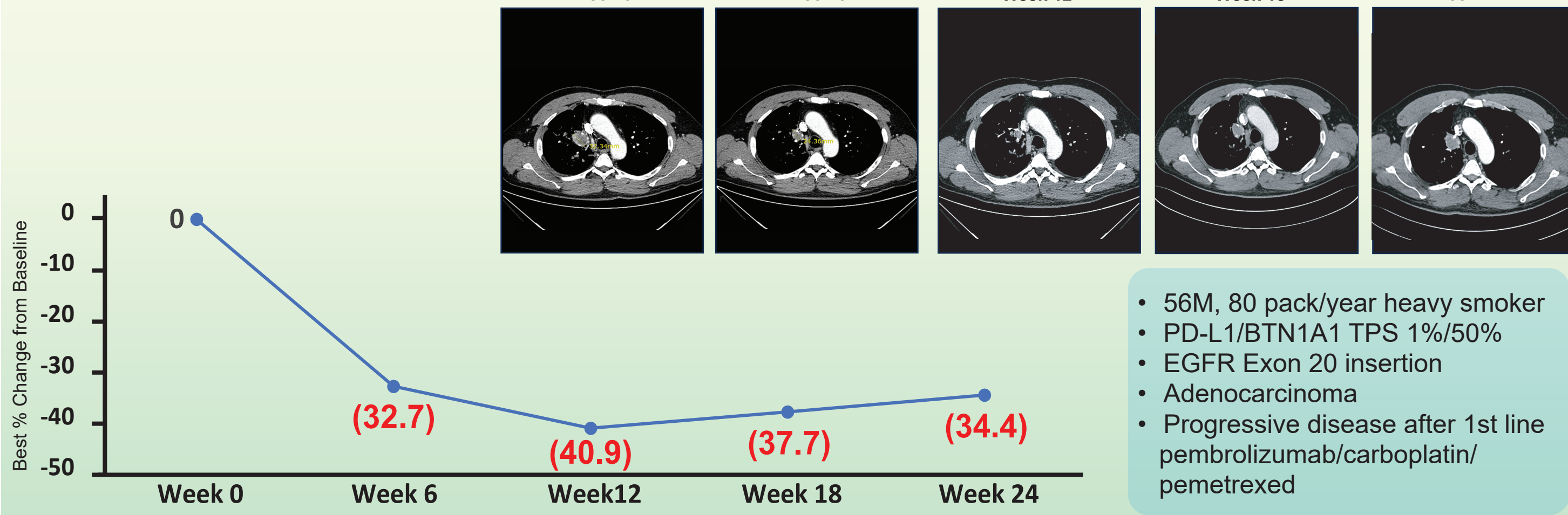
BICR assessment N = 9 n, %	
BOR	
CR	0 (0.0%)
PR	2 (22.2%)
SD	7 (77.8%)
PD	0 (0.0%)
ORR	2 (22.2%)
DCR	9 (100.0%)



The four images on the left displays representative images of BTN1A1 staining results (TPS: 0, 30, 50, 95) obtained via IHC performed by LogOne. This study aimed to evaluate the efficacy of combination therapy involving Nelmastobart and docetaxel, and the analysis was conducted on patients with BTN1A1 TPS values reaching 50.

Representative Clinical Response in an EGFR-Mutant Patient

Advanced EGFR mutant patient with rapid and durable response to Nelmastobart and Docetaxel combination



CONCLUSION

- Nelmastobart 800 mg plus docetaxel 75 mg/m² was safe and tolerable in patients with BTN1A1-positive (TPS $\geq 50\%$) advanced or metastatic NSCLC who had progressed on prior platinum-based chemotherapy and/or immunotherapy (N=34).
- The most frequent treatment-related adverse event was myalgia (32.4%); most events were attributed to docetaxel and were consistent with its established profile. Grade ≥ 3 events attributed to Nelmastobart were uncommon (general edema and drug-induced pneumonitis, 1 patient [2.9%] each) and resolved with appropriate management.
- Preliminary antitumor activity was observed: among 23 efficacy-evaluable patients (data cutoff July 31st, 2026; median follow-up 3.5 months), investigator-assessed ORR was 26.1% (6/23, all partial responses) and DCR was 87.0% (20/23).
- Early BICR-assessed results in the 9 patients evaluated to date were directionally consistent (ORR 22.2%; no progressive disease).
- Tumor shrinkage was observed across histologic and molecular subgroups. A subset of patients with actionable genomic alterations (AGA) showed deeper tumor shrinkage or more prolonged disease control than AGA-negative patients, including the deepest response observed (-48.3%); these exploratory findings are hypothesis-generating and support further evaluation in AGA-positive populations.
- Interpretation is limited by the small sample size and short follow-up, which leave a high proportion of patients not yet evaluable — particularly by BICR. The primary endpoint of BICR-assessed median PFS is not yet mature; complete enrollment of all 62 patients and longer follow-up are required.
- Exploratory pharmacodynamic analyses (cytokine and immune cell profiling) and the correlation between BTN1A1 and PD-L1 expression are ongoing and may identify predictive biomarkers to guide patient selection and future combination strategies.

ACKNOWLEDGEMENT

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