

P2.100: A phase 1b/2, open-label study of SNB-101, a nanoparticle formulation of SN-38, in patients with extensive-stage small cell lung cancer

Young Hwan Park,² Jaehong Kim,² BOJAN ZARIC¹

¹INSTITUTE FOR PULMONARY DISEASES OF VOJVODINA, FACULTY OF MEDICINE, UNIVERSITY OF NOVI SAD, NOVI SAD, SERBIA; ²SN BIOSCIENCE, SEONGNAM, KOREA

Correspondence: Prof Dr Bojan Zarić, MD, PhD | BOJAN.ZARIC@mf.uns.ac.rs



IASLC 2026 World
Conference on Lung Cancer

SEPTEMBER 12 – 15, 2026
SEOUL, REPUBLIC OF KOREA

INTRODUCTION

- Extensive-stage small cell lung cancer (ES-SCLC)** is an aggressive malignancy with poor prognosis and limited treatment options following progression on platinum-based chemotherapy with or without immunotherapy. Although irinotecan-based regimens have demonstrated antitumor activity in SCLC, clinical use of SN-38, the active metabolite of irinotecan, is limited by poor solubility and an unfavorable pharmacokinetic profile.¹⁻³
- SNB-101** is a lyophilized nanoparticle formulation of SN-38 developed using polymer micelle technology to enable intravenous administration and improve systemic exposure. In a prior phase 1 study in patients with advanced solid tumors, dose escalation was completed without identification of a maximum tolerated dose, supporting further evaluation of SNB-101 at higher dose levels.
- SNB-101-101 (NCT07391813)** is a Phase 1/2, Open-Label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics and Efficacy of SNB-101, Extensive Stage Small Cell Lung Cancer.⁴

METHODS

Design

- SNB-101-101 (NCT07391813)** is a Phase 1/2 open-label, dose escalation and dose optimization study of SNB-101 as a single agent to assess safety, tolerability, pharmacokinetics and efficacy.⁵ (Figure 1)
- SNB-101 is administered intravenously on Days 1 and 15 of each 28-day cycle until progressive disease, unacceptable toxicity, death or consent withdrawal.
- Phase 1 dose escalation:** A standard 3+3 design will enroll 3–6 patients with ES-SCLC per cohort at 50, 60, and 70 mg/m². Intermediate dose levels of 55 and 65 mg/m² may be explored if needed.
- Dose selection:** The SRC will review the totality of safety, efficacy, dose-intensity, PK, exposure–response, and modeling and simulation data. Selected cohorts may be expanded to support selection of two doses for randomized evaluation.
- Phase 2 dose optimization:** Approximately 40 patients will be randomized 1:1 to two selected dose levels (20 patients per arm). The optimized dose will be determined based on the totality of Phase 1 and Phase 2 data.
- UGT1A1 variant carriers:** Patients with selected UGT1A1 poor-metabolizer genotypes will start at a 30% reduced dose in Cycle 1, with escalation to the full assigned dose from Cycle 2 based on tolerability and emerging PK data.

Patients

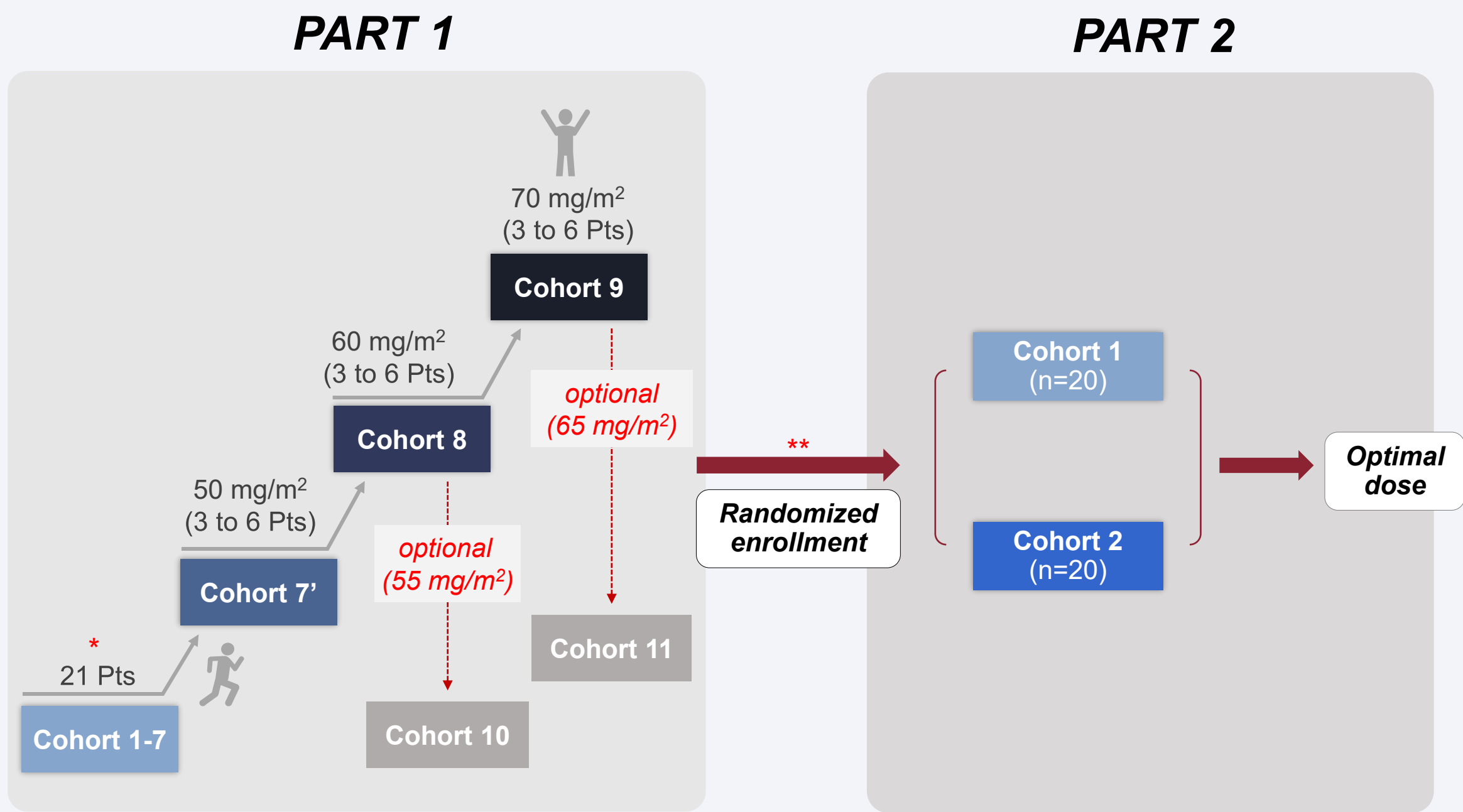
- Adults ≥18 years of age with cytologically or histologically confirmed small cell lung cancer which is locally advanced or metastatic and has progressed on or after standard therapy for advanced disease containing platinum-based therapy plus etoposide with or without atezolizumab or durvalumab immunotherapy and is not suitable for complete surgical resection.
- Participants with CNS or brain metastases who have completed treatment and recovered from the acute phase of radiation therapy or surgery.
- Measurable/evaluable disease (RECIST v1.1).
- ECOG performance status 0/1.

Assessments

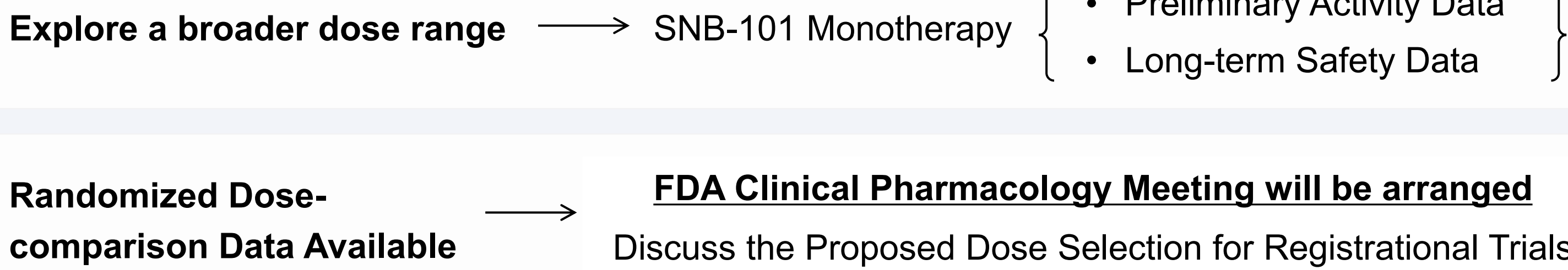
- Key safety evaluations** includes physical examinations, vital signs, ECGs, clinical safety laboratory assessments, and (S)AEs.
- Efficacy** will be assessed via CT scans (abdomen/pelvic, chest) performed at screening and every 8 weeks (±7 days) for tumor assessment:
 - Tumor assessments** will be used to calculate efficacy endpoints, including ORR, DCR, PFS, and DoR. OS and Survival at 12 months
 - Response** will be assessed by the local reviewer for the Phase 1 dose escalation study and by both the local reviewer and the central reviewer for the phase 2 dose optimization study, using RECIST v1.1. Study outcomes for Phase 2 will be based on the central review(BICR).
- Blood samples for PK analysis will be collected intensively during cycle 1 (single-dose PK sampling) and cycle 3 (multiple-dose PK sampling) after the first dose on Day 1. Sparse blood samples for PK analysis will be collected during cycle 2 and 4.
- Plasma concentrations** of Irinotecan/SNB-38 (encapsulated and free), SN-38G will be determined using validated LC/MS/MS analysis.

DOSE OPTIMIZATION STRATEGY

Figure 1. Phase 1/ 2 Dose Escalation and Optimization



Dose Optimization Approach



* 7 Dose level completed with pretreated solid cancer patients from Korea
** Select two Dose levels to expand with additional patients for dose optimization

RESULTS of 0204-001 patient

PATIENT DEMOGRAPHICS & BASELINE

Age / Sex	74 years / Male
ECOG PS	Grade 1
Stage	Stage IV
UGT1A1 Status	Negative (wild-type)
Assigned Dose	Cohort 7 (96.5 mg)

CLINICAL HISTORY

25 AUG 2025	Initial diagnosis	Stage IV SCLC
SEP–NOV 2025	1L systemic chemotherapy	Cisplatin + etoposide (4 cycles) Best response: stable disease
27 FEB 2026	Palliative radiotherapy	VTH9–VTH11 (8 Gy × 1)
30 MAR 2026	Disease recurrence	Documented after first-line therapy
12 MAY 2026	SNB-101 initiation (C1D1)	96.5 mg administered

ANTI-TUMOR ACTIVITY (RECIST v1.1)

BEST OVERALL RESPONSE

STABLE DISEASE

–19.4%

165 mm → 133 mm (–32 mm)

- First assessment: 08 Jul 2026
- Four of five target lesions decreased in size
- Largest lesion-level decrease: –40.9%
- One adrenal lesion increased from 21 to 25 mm

KEY OBSERVATION

At the first assessment, this patient had stable disease with a 19.4% decrease in the sum of target-lesion diameters. Grade 2 neutropenia resolved without dose modification.

Individual patient experience (n=1); descriptive only.

SAFETY, TOLERABILITY & CURRENT STATUS

ADVERSE EVENT

- Grade 2 neutropenia (non-serious) 22–25 Jun 2026
- Probable/likely relationship
- Recovered; no dose modification

TREATMENT STATUS

- ONGOING as of Aug 2026
- Same dose maintained
- C4D1 planned: 12 Aug 2026

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ACKNOWLEDGEMENTS

The authors would like to thank all patients and their caregivers, and all site investigators and study staff who participated in the study.

This research was supported by Korea Drug Development Fund funded by Ministry of Science and ICT, Ministry of Trade, Industry, and Resources and Ministry of Health and Welfare (Grant No. 2710093021, RS-2025-02073050, Republic of Korea)