Trial in Progress: A Phase Ib, Open-label, Single-arm Trial of Autologous Natural Tumor-Infiltrating Lymphocyte Injection (GC101) in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) (MIZAR-005)

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Background

Lung cancer is the leading cause of cancer incidence and mortality in China [1,2]. Non-small cell lung cancer (NSCLC) accounts for 80–85% of cases, and ~70% are diagnosed at advanced stages with a 5-year survival rate of only ~15% [3]. For oncogene-driven NSCLC, targeted therapies have improved outcomes, but resistance inevitably develops. For oncogene-negative NSCLC, immunotherapies and chemotherapy provide limited benefit after failure of first-line treatment. Tumor-infiltrating lymphocyte (TIL) therapy has shown promise in solid tumors [4-7], but conventional regimens require high-dose IL-2 and intensive lymphodepletion, leading to substantial toxicity [8-11]. GC101 is an optimized TIL product generated by a novel culture method that enables low-intensity preconditioning and eliminates the need for post-infusion IL-2. Early data from a phase I trial in gynecological cancers with GC101 demonstrated encouraging safety and efficacy [12]. Here we present the design of MIZAR-005, a phase Ib trial evaluating GC101 in advanced NSCLC

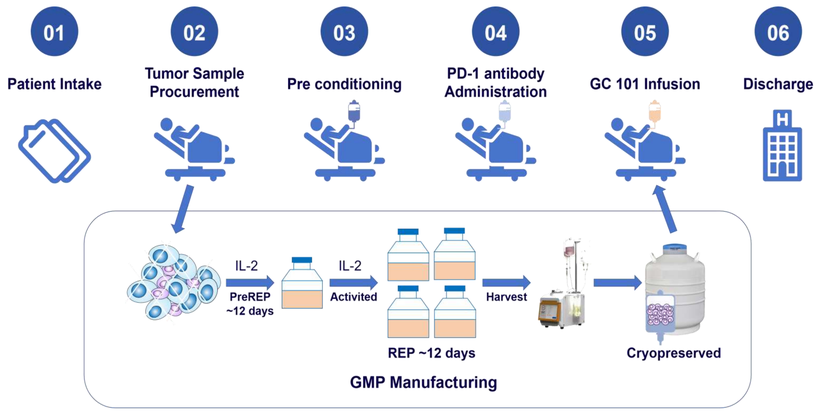


Figure 1. TIL therapy procedure

Objective

To evaluate the safety and efficacy of GC101 (autologous natural TIL injection) in patients with advanced NSCLC who have progressed on prior standard therapy.

Study Design and Treatment Regimen

MIZAR-005 (NCT06473961) is a phase Ib, open-label, single-arm, multicenter trial enrolling 40 patients with advanced NSCLC. The study is recruiting at Shanghai Chest Hospital (lead site) since 31 July 2025.

Eligible patients undergo tumor resection for TIL generation. Following low-intensity preconditioning (one of three optional regimens, no IL-2), patients receive a single infusion of GC101 at doses ranging from 5 × 10^9 to 45 × 10^9 cells (±20%). PD-1 blockade (sintilimab 100 mg or 200 mg) is administered prior to infusion and then every 6 weeks for up to 5 doses, with possible continuation beyond 5 doses if clinically beneficial. Follow-up continues until 1 year or disease progression.

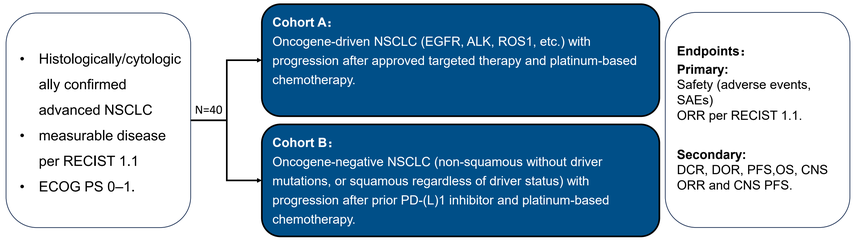
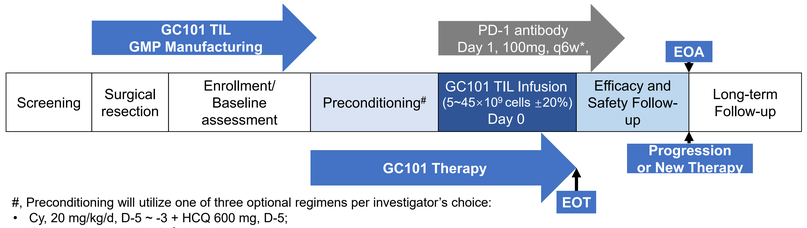


Figure 2. MIZAR-005 Trial Design



#, Preconditioning will utilize one of three optional regimens per investigator's choice:
- Cy, 20 mg/kg/d, D-5 ~ -3 + HCQ 600 mg, D-5;
- Gemcitabine, 1250 mg/m^2 , D-1;
- Gemcitabine, 1250 mg/m^2 , D-1 + HCQ 600 mg, D-1.

*, Sintilimab, 100 mg or 200 mg per investigator's choice, is administered prior to TIL infusion and then every 6 weeks for a planned total of 5 doses, with follow-up until 1year or disease progression.

Figure 3. Treatment Schema

Endpoints

Primary:
Safety (adverse events, SAEs) and objective response rate (ORR) per RECIST 1.1.

Secondary:
Disease control rate (DCR), duration of response (DOR), progression-free survival (PFS), overall survival (OS), CNS ORR and CNS PFS.

Exploratory:
TCR sequencing dynamics, immunophenotyping (TBNK, cytokines), quality of life (EORTC QLQ-C30).

Key Eligibility Criteria

- Age 18–75 years, ECOG PS 0–1
- Histologically/cytologically confirmed advanced NSCLC meeting cohort-specific prior treatment requirements
- Resectable lesion(s) for TIL generation (≥150 mm^3)
- At least one measurable lesion per RECIST 1.1 post-resection
- Adequate organ function

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Disclosures

- This study and poster are sponsored by Shanghai Juncell Therapeutics Co., Ltd.
- HJ, WZ, and YX are employees of Shanghai Juncell Therapeutics Co., Ltd.

Ethics Approval

The study was approved by the institutional review board at each site and was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines of National Medical Products Administration.

Abbreviations

AE, adverse event; CY, cyclophosphamide; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EOA, End of assessment; EOS, end of study; EOT, End of treatment; GMP, Good Manufacturing Practice; HCQ, hydroxychloroquine; HNSCC, head and neck squamous cell carcinoma; IL-2, interleukin-2; IND, Investigational New Drug ; NMPA, National Medical Products Administration; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein-1; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; SAE, serious adverse event; TIL, tumor-infiltrating lymphocyte.

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