# Doctor's Note — Clinical Trial Summary

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## TRIAL

### HS-IT101 Injection Versus Chemotherapy in the Treatment of Advanced Melanoma

NCT ID: NCT07406724 Phase: PHASE2 Sponsor: Qingdao Sino-Cell Biomedicine Co., Ltd. Status: Not Yet Recruiting

## SUMMARY

This is a multicenter, randomized controlled, open-label Phase II clinical study designed to evaluate the efficacy and safety of HS-IT101 Injection versus the investigator's choice of chemotherapy in participants with advanced melanoma. A total of 90 participants are planned to be enrolled, and eligible participants will be randomly assigned to the experimental group or control group at a 1:1 ratio. The experimental group will receive a single administration of autologous tumor-infiltrating lymphocyte therapy, while the control group will receive chemotherapy regimens selected by the research physicians. Efficacy and safety evaluations will be conducted for all enrolled participants throughout the study.

## KEY ELIGIBILITY CRITERIA

- 1. Participants aged 18 to 75 years, inclusive.
- 2. Patients with cytologically or histologically confirmed unresectable advanced, recurrent, or metastatic melanoma (excluding uveal melanoma), who have experienced disease progression after failure of systemic therapy recommended in the 2025 CSCO Guidelines.
- 3. Disease Progression Following Anti-PD-1 Therapy.
- 4. At least one tumor lesion not treated with radiotherapy or other local therapies within 28 days prior to resection, suitable for autologous tumor-infiltrating lymphocyte (TIL) preparation, with a minimum tissue weight of e0.050 g.
- 5. At least one measurable tumor lesion per RECIST 1.1 after tumor tissue sampling.
- 6. ECOG performance status d 1.
- 7. Expected survival e 3 months.
- 8. Adequate organ and bone marrow function as confirmed by screening assessments.
- 9. Documented by echocardiography showing left ventricular ejection fraction (LVEF) e50% Absence of arrhythmia requiring therapeutic intervention Electrocardiogram (ECG) criteria QT interval corrected by Frederica's formula (QTcF) d470 ms Baseline peripheral oxygen saturation (SpO,) \>91% in room air.
- 10. Adverse reactions from prior therapy have resolved to CTCAE v5.0 grade d1 before randomization, except for hypothyroidism and alopecia judged by the investigator as non-safety concerns.

Total sites: 0 | 0 currently recruiting