Doctor's Note — Clinical Trial Summary

Generated by FindMyCure.ai on November 25, 2026 | For discussion with your oncologist

TRIAL

HS-IT101 Injection Versus Chemotherapy in the Treatment of Advanced Melanoma - FASTIL-Mela02

NCT ID: NCT07406724 Phase: PHASE2 Sponsor: Hangzhou Huasai Biomedicine Co., Ltd. Status: 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.

ENROLLMENT CONTACT

Jun.Guo

Beijing Cancer Hospital

Beijing, China

Phone: 010-88121122

Email: guoj307@126.com

Total sites: 1 | 1 currently recruiting

This document is for informational purposes only and does not constitute medical advice. Always discuss clinical trial decisions with your oncologist. Data sourced from ClinicalTrials.gov (NCT07406724) and public sources. Generated by FindMyCure.ai.