

# Extension Study of the Phase 3 Clinical Study of GZR18 Injection for Weight Loss

NCT07292441

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Status	RECRUITING
Phase	Phase 3
Sponsor	Gan & Lee Pharmaceuticals.
Enrollment	500 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Subjects who participated in the original study, completed the last dose at W50, EOT visit at W52 and safety follow-up visit at W55 of either original study, with last dose at W50 e 24 mg (including blinded dose of placebo).
- Subjects with BMI  $\geq 18.5$  kg/m<sup>2</sup> at W55 of the original study and before randomization at Visit 2 (V2) of this study, who are assessed by the investigator as suitable for participating in this study.
- Subjects of childbearing potential with no birth plan from the signing of ICF to 8 weeks after the last dose, willingness to take effective contraceptive measures, and no plan for sperm or ovum donation. Non-lactating women of childbearing potential (WOCBP) with a negative pregnancy test result before randomization at V2 in this study.
- Able to understand the procedures and methods of this study, willing and able to maintain a regular diet and exercise lifestyle during the study period, willing and able to undergo subcutaneous injections of the investigational medicinal product (IMP), and willing to sign the ICF voluntarily.
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### Exclusion (6)

- Subjects who used Semaglutide (Wegovy®) in the original study.
- Subjects with a previous diagnosis of any type of diabetes mellitus (excluding gestational diabetes mellitus).
- Subjects with FPG  $\geq 7.0$  mmol/L or HbA1c  $\geq 6.5\%$  in the central laboratory test at W52 visit of the original study.
- Subjects who plan to participate in another clinical study of an investigational medicinal product or device, or receive drug or non-drug therapies that affect body weight (excluding diet and exercise control) before completing all scheduled assessments in this clinical study.
- Subjects with any other factors (including but not limited to previous compliance in the original study) that may affect the efficacy or safety evaluation of this study as judged by the investigator.

... and 1 more (see full listing online)

## Locations (2 total)

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Study site 01, Beijing, Beijing Municipality, China  
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