

A Study of Efficacy and Safety of TLL-018 in CSU Participants

NCT06396026

Status	RECRUITING
Phase	Phase 3
Sponsor	Hangzhou HighlightII Pharmaceutical Co., Ltd
Enrollment	436 participants

Key Eligibility Criteria

Inclusion (10)

- Aged between 18 and 75.
- Diagnosis of CSU refractory to second-generation H1-AH.
- CSU diagnosis for e 6 months.
- The presence of itch and hives despite current use of an approved dose of H1-AH prior to screening visit.
- UAS7 score (range 0-42) e 16 and itch component of UAS7 (range 0-21) e 8 during 7 days prior to randomization (Day 1).
- ... and 5 more (see full listing online)

Exclusion (18)

- Participants meeting Chinese Guidelines for Urticaria Diagnosis and Treatment with the following concomitant diseases cannot be enrolled:
- Clearly defined underlying etiology for chronic urticarias other than CSU. E.g. induced urticaria, including but not limited to artificial urticaria.
- Any disease, which may have symptoms of urticaria and/or angioedema, including but not limited to urticaria and vasculitis.
- Suffering from other chronic pruritic diseases that may affect the judgment of efficacy results, such as psoriasis, atopic dermatitis, etc.
- Previous malignancy, herpes zoster, active tuberculosis.
- ... and 13 more (see full listing online)

Locations (1 total)

Hospital for Skin Diseases, Institute of Dermatology, Chinese Academy of Medical Sciences, Nanjing, Jiangsu, China