To Compare Efficacy and Safety of CMAB007 and Xolair® in Patients With Chronic Spontaneous Urticaria

NCT06365879

Status	RECRUITING
Phase	Phase 3
Sponsor	Taizhou Mabtech Pharmaceutical Co.,Ltd
Enrollment	392 participants

Key Eligibility Criteria

Inclusion (10)

- Male or female patients 15 to 75 years old (both inclusive).
- Diagnosis of CSU refractory to H1AH, as defined by all of the following:
- Diagnosis of CSU at the time of screening, urticaria history e 6 months at the time of randomization
- The presence of itch and hives for e 6 consecutive weeks within half year prior to randomization despite use of H1AH treatment during this time period;
- 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 (22)

- Chronic inducible urticaria. This includes but is not limited to: dermatographism (factitious urticaria), cold, heat, solar, delayed pressure, aquagenic, cholinergic or contact urticarias. Any of the following diseases, which may have symptoms of urticaria and/or angioedema: urticarial vasculitis, erythema multiforme, mastocytosis, hereditary or acquired angioedema, etc.
- Suffer from other chronic pruritic dermatosis that may confound the results: atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, psoriasis, etc.
- CSU patients who had difficulty breathing episodes due to angioedema in the past six months.
- Previous treatment with omalizumab within one year prior to signing the informed consent.
- Hypersensitivity to omalizumab, study drug excipients or other biosimilars, or have a history of severe drug allergy or anaphylactic shock.

... and 17 more (see full listing online)

Locations (1 total)

Huashan Hospital, Shanghai, China