Study to Assess Safety, Efficacy, and Cellular Kinetics of YTB323 in Generalized Myasthenia Gravis

NCT06704269

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Novartis Pharmaceuticals
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (9)

- Confirmed gMG diagnosis supported by the following:
- Documented report of positive serology testing for either AChR antibodies or MuSK antibodies at screening AND at least one of the following:
- History of abnormal neuromuscular transmission test demonstrated by repetitive nerve stimulation or single-fiber electromyography
- History of positive acetylcholinesterase inhibitor test
- Improvement in MG signs on an oral acetylcholinesterase inhibitor as assessed by the treating physician

... and 4 more (see full listing online)

Exclusion (6)

- Exclusively ocular myasthenia gravis (MGFA I), mild symptoms (MGFA II), or severe bulbar disease or MG crisis, MGFA Class IVb or V at screening
- History of bone marrow/hematopoietic stem cell or solid organ transplantation.
- Clinically significant active, opportunistic, chronic or recurrent infection (including positive for hepatitis B or hepatitis C) confirmed by clinical evidence, imaging, or positive laboratory tests one month prior to leukapheresis
- Other uncontrolled disease states, such as asthma, or inflammatory bowel disease, where flares are commonly treated with oral or parenteral corticosteroids, at screening
- Participants with a known immunodeficiency syndrome (AIDS, hereditary immune deficiency, drug induced immune deficiency), or tested positive for HIV antibody, at screening

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

Locations (10 total)

Univ Cali Irvine ALS Neuromuscular, Orange, California, United States
Wake Forest Univ School of Medicine, Winston-Salem, North Carolina, United States
Houston Methodist Hospital, Houston, Texas, United States
... and 7 more locations