

A Phase 1 Trial to Evaluate the Safety, Tolerability, Pharmacodynamics, Pharmacokinetics, and Immunogenicity of VIS171 in Participants With Autoimmune Disease(s)

NCT06799520

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| Status | RECRUITING |
| Phase | Phase 1 |
| Sponsor | Otsuka Pharmaceutical Development & Commercialization, Inc. |
| Enrollment | 30 participants |

Key Eligibility Criteria

Inclusion (10)

- Estimated glomerular filtration rate (eGFR) >30 milliliters/minute/1.73 square meters (mL/min/1.73 m²) at the screening visit.
 - For SLE participants:
 - Participant has a confirmed diagnosis of SLE according to European League Against Rheumatism/American College of Rheumatology SLE classification criteria e 24 weeks prior to signing the informed consent form (ICF).
 - For AA participants:
 - Current scalp involvement between 25% and 95%, inclusive (Severity of Alopecia Tool [SALT] score between 25 and 95, inclusive), at screening.
- ... and 5 more (see full listing online)

Exclusion (11)

- Receipt of high-dose corticosteroid therapy within 4 weeks prior to screening as either (a) intravenous (IV) pulse corticosteroid therapy or (b) daily oral corticosteroid therapy of e 1 milligrams per kilogram (mg/kg) or up to 40 milligrams per day (mg/day) prednisone (or equivalent).
 - Receipt of blood products within 6 months prior to screening.
 - Previous exposure to VIS171 or any other drug targeting interleukins (IL)-2 or the IL-2 receptor or T regulatory cells.
 - History of or current diagnosis of catastrophic or severe anti-phospholipid syndrome (APS) within 1 year prior to signing ICF. SLE participants with APS adequately controlled by anticoagulant are eligible. SLE participants who are found to be triple positive for anti-phospholipid antibodies at screening (without clinical APS) will be excluded unless they are on stable anti-thrombotic therapy.
 - Known primary immunodeficiency disorder.
- ... and 6 more (see full listing online)

Locations (6 total)

Visterra Investigational Site, Sofia, Bulgaria
Visterra Investigational Site, Chisinau, Moldova
Visterra Investigational Site, Bucharest, Romania
... and 3 more locations