

Safety, Tolerability, Pharmacokinetic, and Pharmacodynamic Study in Healthy Male and Female Subjects and Safety, Tolerability, Pharmacokinetics, and Pilot Efficacy Biomarkers in Subjects With Cold Agglutinin Disease

NCT05318534

Status	RECRUITING
Phase	Phase 1
Sponsor	Gliknik Inc.
Enrollment	70 participants

Key Eligibility Criteria

Inclusion (21)

- Healthy female or male subjects who, at the time of screening, are between the ages of 18 and 65 years, inclusive.
- Females will not be pregnant or lactating, and females of childbearing potential and males will agree to use contraception.
- Body mass index of 18.0 to 32.0 kg/m², inclusive; and a total body weight > 50 kg up to a maximum of 110 kg.
- Study subjects must have received a quadrivalent meningococcal conjugate vaccine (meningococcal serogroups A, C, W, and Y) within the past 5 years or vaccination a minimum of 14 days prior to initial study drug administration.
- The subject must be capable of understanding the investigational nature, potential risks and benefits of the study and capable of providing valid informed consent.

... and 16 more (see full listing online)

Exclusion (6)

- History of any clinically significant (as determined by the investigator) cardiac, endocrine, hematological, hepatic, immunological, metabolic, urological, pulmonary, neurological, dermatological, psychiatric, renal, or other major disease.
- Evidence of clinically significant medical condition or other condition that might significantly interfere with the absorption, distribution, metabolism, or excretion of study drug, or place the subject at an unacceptable risk as a participant in this study.
- Signs and symptoms of, or diagnosis consistent with a chronic autoimmune disorder and/or positive antinuclear antibodies (ANA) test by indirect immunofluorescence confirmed by ANA titer \geq 1:160.
- Documented history of autoimmune disease, or history of a syndrome that required systemic steroids or immunosuppressive medications, except for subjects with vitiligo or resolved childhood asthma/atopy.
- Any underlying medical condition that, in the opinion of the investigator, renders the subject a poor candidate for this study or could confound the results of the study or put the subject at undue risk.

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

Locations (1 total)

Fortrea Clinical Research Unit Ltd, Leeds, United Kingdom