Open-label Single-Center Study to Evaluate the Safety and Efficacy of Combining Rituximab and AB-101 in B-cell Associated Autoimmune Diseases.

NCT06581562

Status	RECRUITING
Phase	Phase 1
Sponsor	IRIS Research and Development, LLC
Enrollment	30 participants

Plain Language Summary

This study tests a combination of rituximab (which depletes certain immune cells called B-cells) and a new drug called AB-101 in people with autoimmune diseases where the immune system mistakenly attacks the body. The trial covers several conditions including lupus, rheumatoid arthritis, ANCA vasculitis, and myositis.

You may be eligible if...
- You are 18 or older
- You have been diagnosed with one of the targeted autoimmune diseases (e.g., lupus, rheumatoid arthritis, ANCA vasculitis, or myositis)
- Your disease has not been adequately controlled by prior treatments
- Women of childbearing age must agree to use contraception

You may NOT be eligible if...
- You have active, serious infection
- You have had prior treatment with rituximab or another B-cell depleting therapy recently
- You have severe organ damage from your autoimmune disease

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (50)

- Males or female subjects, e 18 years of age at the time of signing informed consent.
- Ability to understand the requirements of the study.
- Willingness to provide written informed consent.
- Willingness to comply with the study protocol procedures.
- Women of childbearing potential and all male participants must agree to use two acceptable methods of contraception together to avoid pregnancy. The following are examples of acceptable methods of contraception including:

... and 45 more (see full listing online)

Exclusion (28)

- \. Known hypersensitivity or contraindication to any drug products or any component of the drug products they plan to receive (e.g., cyclophosphamide, fludarabine, rituximab, AB-101).
- \. History of an anaphylactic reaction to parenteral administration of contrast agents, human or murine proteins or monoclonal antibodies or DMSO (Dimethyl sulfoxide).
- \. Prior treatment with any B-cell targeted therapy within 3 months of the start of the planned lymphodepletion regimen (e.g., rituximab or other anti-CD20, anti-CD19, anti-CD22 monoclonal antibodies) 6. Prior treatment with any autologous or allogeneic cell therapy approach using genetically modified immune cells (e.g., T, NK, macrophages, or gamma-delta T cells modified with chimeric antigen receptors (CAR)).

- \. Received any of the following within 6 months of the start of the planned lymphodepletion regimen:
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... and 23 more (see full listing online)

Locations (1 total)

IRIS Research and Development, LLC, Plantation, Florida, United States