LUPUS RELATED INNOVATIVE CLINICAL TRIALS & RESEARCH STUDIES

ENROLLMENT OPENING SOON

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2024 Lupus Medical and Educational Symposium

May 9, 2024 11 am - 6 pm

Beechwood Hotel- 363 Plantation Street Worcester, MA 01655

APS ACTION STUDY 1

Antiphospholipid Syndrome Alliance for Clinical Trials and International Networking ("APS ACTION") International Clinical Database and Repository

PRINCIPAL INVESTIGATOR

Dr. Elena Gkrouzman, MD, Co-Director, Assistant Professor of Medicine
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BACKGROUND

Antiphospholipid antibody (aPL) positivity occurs in approximately one-third of patients with systemic lupus erythematosus and also in patients without known connective tissue diseases.

Patients with aPL-related clinical events (thromboembolic disease, recurrent pregnancy loss) and medium-to-high titer aPL are diagnosed with Antiphospholipid Syndrome (APS) and are, conventionally, treated with life-long anticoagulation.

There is currently no clear consensus on diagnosis of equivocal cases and long-term treatment, which is due to lack of large-scale registries and randomized controlled studies of aPL-positive patients.

OBJECTIVES OF THE STUDY

To establish an international secure, web-based clinical database and repository of aPL-positive patients so that the natural course of at least 2000 patients can be followed over 10 years.

APS ACTION is the first and only international APS network that has been created to design and conduct well designed clinical trials.

Our hope is that the APS ACTION International Clinical Database and Repository will significantly address gaps by supporting and promoting aPL-related basic science and clinical research internationally.

STUDY PERIOD

Planning to enroll at least 2000 patients internationally to be followed over 10 years.

SELECT –SLE STUDY 2

SELECT-SLE: A Phase 3 Program to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus (SLE)

PRINCIPAL INVESTIGATOR

Dr. Roberto Caricchio, MD

BACKGROUND

Upadacitinib, a JAK inhibitor, is approved in more than 70 countries for at least one of the following indications: RA,PsA, AS, nr-axSpA, UC, AD, and CD. A completed Phase 2 SLE Study M19-130 demonstrated the efficacy of Upadacitinib 30 mg QD in achieving the primary endpoint of SRI-4 and glucocorticoid dose ≤10 mg QD versus placebo at Week 24 in moderately to severely active SLE despite background therapy. This was supported by secondary and other efficacy endpoints that showed a benefit of Upadacitinib 30 mg QD compared to placebo at 48 weeks in reduction of overall flares, delayed time to first flare, BICLA, SRI-4, LLDAS, tender or swollen joint count, and skin activity as measured by CLASI.

OBJECTIVES OF THE STUDY

The primary efficacy objective is to demonstrate superiority of Upadacitinib compared to placebo with respect to the primary endpoint in adult subjects with moderately to severely active SLE despite background therapy.

The secondary efficacy objectives are to demonstrate superiority of Upadacitinib compared with placebo with respect to the secondary endpoints for the following categories: SLE disease activity, SLE flares, reduction of glucocorticoid dose, patient-reported outcomes, and damage.

STUDY PERIOD

The program will consist of two independent randomized, double blinded, and placebo-controlled studies (Study 1 and Study 2) followed by a single combined double-blind long-term extension for both studies together (Study 3).

The Phase 3 program is comprised of a 42-day Screening Period, a 52-week placebo-controlled, double-blind treatment period (Study 1 and Study 2), a 52-week re-randomized double-blind extension treatment period (Study 3), and a 30-day follow-up period.

NKARTA STUDY 3

A Phase 1 Study of NKX019, a CD19 Chimeric Antigen Receptor Natural Killer (CAR NK) Cell Therapy, in Subjects with Autoimmune Disease

PRINCIPAL INVESTIGATOR

Dr. Roberto Caricchio, MD, (in collaboration with Divisions of Hematology and Nephrology)
Director
Chief, Division of Rheumatology, Myles J. McDonough Chair in Rheumatology, Professor of Medicine. Email : Lupus.Caricchio@umassmed.edu

BACKGROUND

NKX019 is a chimeric antigen receptor natural killer (CAR NK) cell therapy that targets B cells. NK cells are lymphocytes which help destroy infected and diseased cells in your body. NKX019 is engineered by collecting NK cells from healthy donor blood and modified with a CAR designed to target CD19, a protein found on the surface of B cells. CD19 plays a role in several cancers and autoimmune diseases including SLE.

Natural killer (CAR NK) cell therapy, is currently being studied in Oncology, but this is the first time the therapy will be evaluated in lupus nephritis, an inflammation of the kidney caused by lupus.

OBJECTIVES OF THE STUDY

- The multi-center, open label, dose escalation clinical trial will assess the safety and clinical activity of NKX019 in patients with refractory lupus nephritis (LN).
- Safety and tolerability of NKX019, administered after lymphodepletion (LD)
- Assess clinical activity of NKX019 in subjects with systemic lupus erythematosus (SLE) and with active LN

STUDY PERIOD

Patients will receive a three-dose cycle of NKX019 at 1 billion or 1.5 billion cells per dose on Days 0, 7 and 14 following LD with single agent cyclophosphamide, an agent with an established safety profile in SLE and LN.

The study is designed to enroll up to 12 patients, with the first patient expected to be enrolled in the first half of 2024.

The potential of cell therapy to reset the immune system and provide long-term, drug-free remissions for patients with severe autoimmune disease may represent the biggest medical breakthrough in the last 50 years of rheumatology," said Roberto Caricchio, M.D., the Myles J. McDonough Chair in Rheumatology, Professor of Medicine, and Chief of the Division of Rheumatology in the Department of Medicine at the University of Massachusetts Chan Medical School. "**Patients with lupus nephritis have limited treatment options, and the early results with cell therapy suggest that we may be defining a new era of treatment**."

Source : https://ir.nkartatx.com/news-releases/news-release-details/nkarta-receives-fda-clearance-ind-application-nkx019-lupus

For more information about the studies, please contact our study coordinators:

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