Title: A Double-Blind, Randomized, Placebo-Controlled Phase 2 Clinical Trial to Evaluate Safety and Efficacy of US-APR2020 in Subjects With Chronic Kidney Disease Stage IV

Type of Study: A double-blind, randomized, placebo-controlled Phase 2 clinical trial to evaluate safety and efficacy of US-APR2020 in subjects with Chronic Kidney Disease Stage IV

Patients: CKD IV (Volunteers participating on their own free will, prequalified and selected to participate based on prior medical history), subject to inclusion and exclusion criteria.

Measured Endpoints: at all visits

Primary End Point:

- Presence of adverse events in less than 10% of the study population, as a measure of safety.
- Arresting the decline of eGFR by 40% as per NKF-USFDA guidelines in the group treated with US-APR2020 as compared to the placebo

Secondary End Point: Interventional product US-APR2020 vs Placebo

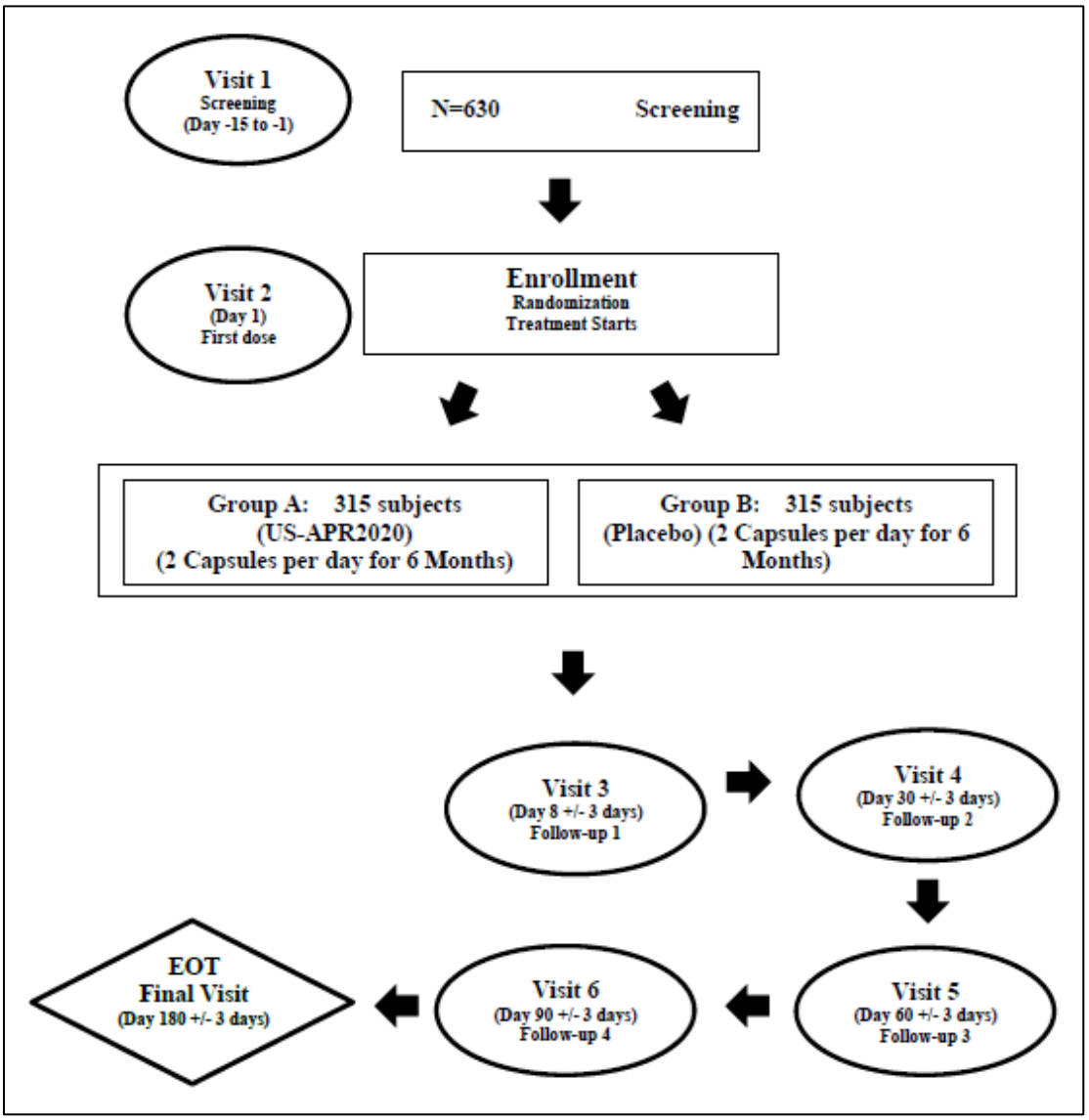
- Improvement in any of the basic blood uremic metabolic markers (BUN, Uric acid, creatinine)
- Improvement in any of the complete blood count (CBC) and hematology parameters.
- Reduction in C-Reactive Protein (CRP) levels.
- Percent change from baseline in rating scale (Modified SF36 QOL questionnaire) at 24-weeks.

Tertiary End Point:

- Evaluate possible exploratory biomarkers in the blood such as KIM-1, NGAL, IS, PCS, TMAO and other inflammatory/oxidative-stress markers like IL-6.
- Monitor mGFR (subject to availability of this test on the site).
- Monitor for fecal microbiome changes by using nucleic acid sequencing (subject to availability of this test on the site)

Study Design

This is a Randomized, Double Blind, Placebo-controlled, clinical trial in a, 6 month, (24 weeks) study in an outpatient setting.



Total Number of Visits: Seven (7)

Dosage Regimen:

Interventional product: 1 Capsule of US-APR2020, 2 times a day (90 billion CFUs /day)

Placebo: 1 Capsule of placebo (cream of corn and rice), 2 times a day