advicenne

ARENA2

Decentralized Clinical Research Trial for Patients with Primary Distal Renal Tubular Acidosis (dRTA)

ARENA2 Phase 3 Study – USA and Canada

- Actively recruiting patients with inherited dRTA
- 12-week duration, randomized withdrawal design
- Virtual study design – allowing for study participation without hospitalization

Pivotal Study Objective

Compare the efficacy of ADV7103 versus placebo in preventing metabolic acidosis, defined as 2 consecutive serum bicarbonate levels < 18 mEq/L for subjects ≥ 4 years old and < 17 mEq/L for subjects < 4 years old, during the Withdrawal Period.

Long-term Extension Study

Patients completing Phase 3 have long-term access to ADV7103

Inclusion criteria

- Female or male patients ≥ 6 months of age and ≤ 65 years
- A previous diagnosis of primary dRTA based on documented history of non-anion gap, hypokalemic, hyperchloremic metabolic acidosis
- Requiring ≥ 0.9 mEq/kg/day of alkali therapy to maintain serum bicarbonate levels

Exclusion criteria

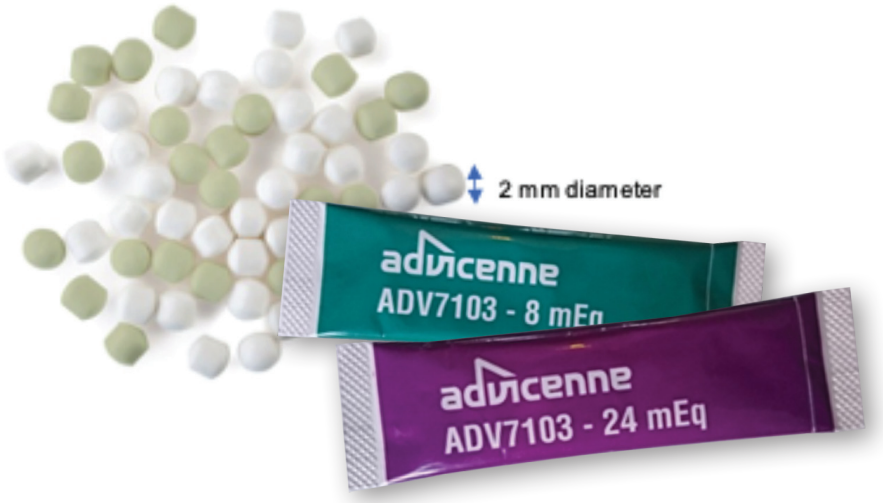
- Acquired /Secondary dRTA
- eGFR <60 mL/min/1.73m^2
- Patient has evidence of proximal tubule dysfunction
- Patients requiring contraindicated medication

If you are interested to learn more about the ARENA2 trial or have a patient that is interested to participate contact:

ARENA2info@advicenne.com

About ADV7103

ADV7103 is an innovative prolonged-release oral granule combining the advantages of potassium citrate and potassium bicarbonate designed to improve treatment effectiveness with twice daily dosing.



Principal Investigator: Larry Greenbaum, MD, PhD

ClinicalTrials.gov Identifier NCT03644706

Results of European Phase 3 Trial Comparing ADV7103 to Standard of Care