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Status of the ongoing SORENTO clinical trial: Assessing efficacy and safety of high-exposure octreotide subcutaneous depot in patients with GEP-NET

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BACKGROUND

Somatostatin receptor ligands (SRLs) are first-line standard of care therapies for gastroenteropancreatic neuroendocrine tumors (GEP-NET), showing efficacy in tumor/symptom control with an established safety profile. However, disease progression usually occurs despite standard-dose SRL treatment, requiring more aggressive and potentially more toxic therapies. Retrospective/non-randomized data suggest higher-dose SRLs may benefit patients with GEP-NET who do not respond to standard-dose treatment, providing improved disease control. Octreotide subcutaneous depot (CAM2029) is a novel, long-acting, high-exposure formulation. Clinical trials showed ~500% higher octreotide bioavailability with CAM2029 versus octreotide long-acting release (LAR), and maintenance/reduction of NET symptoms. Prospective, randomized trial data are needed to confirm efficacy/safety of alternative high-exposure SRLs, such as CAM2029, versus standard-dose SRLs including octreotide LAR and lanreotide Autogel (ATG).

METHODS

SORENTO (NCT05050942) is a randomized, multicenter, open-label, active-controlled phase 3 trial, aiming to enroll 302 adults with GEP-NET. Key eligibility criteria: advanced, well-differentiated NET of GEP/presumed GEP origin; ≥1 measurable somatostatin receptor-positive lesion (by nuclear imaging) according to RECIST 1.1; no/<6 months consecutive treatment with long-acting SRLs. Notably, patients with Grade 3 GEP-NET are eligible (unlike in the CLARINET/PROMID trials). Patients will be randomized 1:1 to CAM2029 20mg every two weeks or active comparator (octreotide LAR 30mg intramuscular or lanreotide ATG 120mg SC, every four weeks). CAM2029 self/carer-administration is permitted after appropriate training and supervised administrations. Randomization stratified by histological grade; tumor origin; intended comparator.

The primary outcome is progression free survival (PFS; time from randomization to first documented disease progression [RECIST 1.1] or death), assessed by a Blinded Independent Review Committee. The study is powered to detect a 0.65 hazard ratio. Key secondary outcomes are overall survival; response rate; rescue medication use; patient satisfaction; adverse events. After primary PFS analysis, overall survival will be followed for up to 2 years. If the primary endpoint of CAM2029 superiority is met, the comparator group may switch to CAM2029. Patients in any group experiencing progressive disease in the randomized period may enter an open-label extension with intensified CAM2029 treatment to investigate effects of higher-frequency dosing. Readout will occur following 194 PFS events.

RESULTS

Enrollment began Nov-2021. As of Jun-2023, 183 patients have been randomized across the 95 open sites in Australia (newly added country), Belgium, Canada, France, Germany, Hungary, Israel, Italy, the Netherlands, Romania, Spain, and the United States.

CONCLUSIONS

This novel head-to-head superiority trial is anticipated to demonstrate potential benefits of CAM2029 as a first-line therapy in patients with well-differentiated GEP-NET.

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