PF614 Analgesic Activity in Acute Postoperative Pain (PF614-301)

NCT06602271

Status	RECRUITING
Phase	Phase 3
Sponsor	Ensysce Biosciences
Enrollment	320 participants

Key Eligibility Criteria

Inclusion (9)

- Participant must provide written informed consent prior to the initiation of any protocol specific procedures.
- Male or female participant, between 18 and 75 years of age, inclusive, at the time of Screening.
- Participant must be scheduled to undergo a full abdominoplasty procedure without liposuction with no collateral procedures.
- Participant must have physical status rated as I-II on the American Society of Anesthesiologists rating scale.
- Participant must have a body mass index (BMI) within 18.0 to 32.0 kg/m2, inclusive (minimum weight of at least 50.0 kg).

... and 4 more (see full listing online)

Exclusion (30)

- Participant has a history or presence of a clinically significant abnormality, as assessed by physical examination, medical history, electrocardiograms (ECGs; including a median QT interval corrected for heart rate \[Fridericia; QTcF interval\] of \>450 milliseconds if male or \>470 milliseconds if female at Screening and pre-operatively based on triplicate ECG; a repeat triplicate test is permitted and the median QTcF value will be used to determine eligibility), vital signs, or laboratory values, which, in the opinion of the investigator, would jeopardize the safety of the participant or the validity of the study results. Laboratory tests may be repeated once (one time) at Screening only, after approval by the medical monitor, if the investigator determines that the abnormal laboratory finding(s) was erroneous or caused by a temporary medical condition, for example, an acute infection, or by the temporary use of a prior medication.
- Participant has a significant cardiac (e.g., ischemia or infarct, complete bundle branch blocks, symptomatic arrhythmias or predominantly non-sinus-conducted rhythm), pulmonary, gastrointestinal, endocrine, metabolic (except diabetes mellitus \[A1c d7.0\]), neurological, or psychiatric disorder (resulting in disorientation, memory impairment or inability to report accurately; for instance, schizophrenia, Alzheimer's disease), or any other clinically significant disease that, in the investigator's opinion, may affect efficacy or safety assessments, or that may compromise participant safety during trial participation.
- Participant has a history of malignancy within the past 2 years, with the exception of basal cell carcinoma that has been treated and is no longer present.
- Participant has a history or presence of acute respiratory depression, moderate or severe chronic pulmonary disease, cor pulmonale, delirium tremens, central nervous system (CNS) depression, or increased cerebrospinal or intracranial pressure.
- Participant has a documented history of, or currently active, seizure disorder (excluding febrile seizures in childhood), or history of clinically significant head injury or syncope of unknown origin.

... and 25 more (see full listing online)

Locations (3 total)

CenExel / Atlanta Center for Medical Research (ACMR), Atlanta, Georgia, United States
HD Research - Memorial Hermann Surgery Center, Houston, Texas, United States
CenExel / JBR, Salt Lake City, Utah, United States