



Request for Investigator Initiated Study Proposals

Pertaining To:

Gastrointestinal Surgery Hypoglycemia

PURPOSE

Rezolute, Inc. (Rezolute), seeks Investigator Initiated Study proposals pertaining to “Gastrointestinal Surgery Hypoglycemia.”

OVERVIEW OF COMPANY

Rezolute is a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by a congenital or any acquired form of hyperinsulinism (HI). The Company’s investigational antibody therapy, ersodetug, has been studied in clinical trials, including two ongoing Phase III programs for congenital HI and tumor HI, and used in real-world cases for the treatment of refractory hypoglycemia due to a variety of causes of HI. Ersodetug (a fully humanized monoclonal antibody [mAb] of immunoglobulin G, subclass 2 [IgG2]) is given by IV infusion administered over at least 30 min (<60 min).

SUBJECT OF STUDY PROPOSALS REQUESTED

Rezolute seeks study proposals evaluating the use of ersodetug in “Gastrointestinal Surgery Hypoglycemia” to assess its impact on the frequency and severity of such hypoglycemia and overall glycemic stability.

“Gastrointestinal Surgery Hypoglycemia” would include the spectrum of persistent or recurrent hyperinsulinemic hypoglycemia syndromes occurring following gastric or upper gastrointestinal surgery, irrespective of the original surgical indication, including:

- All forms of bariatric/metabolic surgery, including Roux-N-Y or Vertical Sleeve Gastrectomy
- Gastrectomy for malignancy
- Upper GI reconstructive surgery
- Antrectomy/vagotomy
- Esophagectomy with gastric pull-up
- Nissen fundoplication
- Whipple and related pancreato-intestinal surgeries, with or without insulin dependent brittle diabetes; and
- Other procedures associated with altered nutrient transit and dysregulated insulin secretion.

Proposed studies must be U.S. only. Study results will enhance insights regarding this unmet need and may support potential new or expanded indications for ersodetug.

GENERAL

Proposals must be received by Friday, July 17, 2026, with selection of a study proposal targeted by August 2026. The study proposal selection process is a competitive process. Therefore, it is critical that specified deadlines are met.

In order to be considered by Rezolute a proposal must include:

- The name and address of the investigator(s) and the research entity or institution(s) seeking the funding.
- The name, address, and curriculum vitae or other documentation showing qualifications and expertise of the investigator(s) and the institution(s) where the proposed study would take place.
- The amount of monetary funding requested, including a detailed budget showing study costs, institutional expenses (e.g., overhead), plus any additional study-related budget information, and justification for each.
- A study protocol synopsis including study start and end dates, study population, proposed number of patients (up to 15), proposed endpoints (primary and exploratory), and high-level data management plan. Due to the rare nature of the associated conditions and small study size, open label study design is preferred.
- To help allocate drug quantity assessment, please provide the total number of planned enrollment, anticipated average weight of enrolled population, and whether enrollment is expected to be initiated in outpatient (i.e., biweekly dosing) or inpatient (i.e., weekly dosing) populations. Please include any institutional mandates regarding the use of any specific infusion devices.
- A sufficiently detailed timeline to reflect the key steps and timing associated with initiation of the study, completion of the study, full study report and anticipated publication plan of study results (manuscript, congress and/or other meetings)
- The signature of an authorized representative of the Grant Applicant.

Study proposals that do not meet these requirements will not be considered by Rezolute, and the submitter will be so notified.

RESPONSIBILITIES OF THE GRANT APPLICANT

The Grant Applicant is responsible for including in the proposal all necessary items required to meet deliverables as defined in this document. Missing budget items or other proposal-related information must be provided as requested by Rezolute before a proposal will be evaluated.

As part of the proposal, please describe the operational approach for the proposed study, including anticipated start-up timelines, key personnel and roles, plans for data collection, study reporting, compliance with Good Clinical Practices (GCP) and quality assurance, IRB information (institutional

or name of external IRB) and strategies to support efficient use of resources while maintaining scientific rigor.

PROCESS FOR SUBMISSION OF PROPOSALS

- A. All proposals must be received by July 17, 2026. Send proposals and/or relevant questions to the following REZOLUTE contact:

Primary Contacts:

Davelyn Eaves Hood, MD, MBA

VP, Medical & Patient Affairs

medical-affairs@rezolutebio.com

GRANT RECIPIENT SELECTION CRITERIA

The decision to award a grant will be based on the strength and quality of all aspects of a submitted proposal, and the Grant Applicant's responses to additional or follow-up questions by Rezolute.

GENERAL SELECTION CRITERIA:

- Focus of proposed study
- Quality and applicability of grant proposal, including protocol submitted
- Scientific merit and credibility of the investigator(s) and institution(s), as evidenced by relevant subject matter expertise, prior research accomplishments, and a track record of publishing methodologically robust studies in influential peer-reviewed journals.
- Availability and appropriateness of monetary funding and drug product quantity requested

Be sure to include the following information in your proposal document:

1. Contact and Logistical
 - a. Provide location and contact information.
 - b. Provide the location where the study will be performed and include any subcontractors or third-party vendor along with their responsible service and the relevant contact information.
 - c. Provide a current curriculum vitae of the investigator(s), a list of publications and presentations, and medical license information.
 - d. Provide confirmation regarding your ability to file and sponsor an investigator IND with FDA.
2. Please include any intended third-party contractor (I.e., CRO) that will be assigned responsibility for any service listed in this proposal.

3. Investigators should outline their plans for data management, analysis and dissemination of study results. As a condition of funding, Rezolute expects timely access to study outcomes, including interim updates as appropriate, a final study report, and access to anonymized study datasets necessary to verify reported findings and support scientific evaluation of study results, subject to applicable laws, regulations, institutional policies, and patient privacy requirements.