HEMA Biologics Request for Proposals

Eptacog beta for Surgical Procedures in Bleeding Disorder Patients other than Congenital Hemophilia

OR

Refractory Bleeding in Hospital Based Interventions for Patients without Bleeding Disorders

Competitive Grant Program

Overview

This competitive program seeks to generate new evidence in the management of patients with bleeding disorders *other than congenital hemophilia* undergoing minor/major surgical procedures OR in patients without bleeding disorders experiencing refractory bleeding during hospital-based interventions. Supported research projects should be focused on the effectiveness and/or safety of eptacog beta in one or both of these settings.

Geographic Scope/Location of Project

United States

Project Types and Area of Interest

Potential applicants are encouraged to identify and address data gaps relating to the populations and use settings outlined below:

Patient Populations

- Glanzmann's Thrombasthenia or other platelet disorders (i.e., Bernard Soulier Syndrome, Gray Platelet Disorder)
- Congenital Factor 7 Deficiency
- Acquired Hemophilia
- Non-bleeding disorder populations experiencing refractory bleeding during hospital-based interventions

Procedures/Use Settings:

In patients with bleeding disorders:

- Major procedures may include: orthopedic surgeries (joint replacement, fracture repair), hysterectomy, splenectomy, tumor resection, cardiac surgery, planned cesarean section, multiple dental extraction (i.e., wisdom teeth removal),etc.
- Minor procedures may include: single tooth extraction, circumcisions, port placements, skin biopsies, endoscopy with biopsy, etc.

In non-bleeding disorder patients undergoing the following hospital-based interventions:

- Trauma care
- Cardiothoracic surgery
- Post-partum hemorrhage treatment
- Other clinical scenarios with bleeding refractory to other measures where rFVIIa is deemed necessary

Research Objectives:
Considered proposals should seek to:

- Generate data on eptacog beta use for either a variety of procedures within a specific patient population or a more defined scope of procedures across patient populations.
- Study proposals must be scientifically well-designed
- The investigator must have technical and operational capabilities to conduct a study as a sponsor, including adequately trained staff to execute a study (GCP, etc.), be able to fulfill all regulatory requirements (including submitting an IND, writing of final study report, and manuscripts etc.)"
- Proposals should anticipate the inclusion of a reasonable number of patients (i.e., a minimum of 6-8) to generate data that can make a meaningful contribution to the field.

All proposals are also governed by the General Guidelines applicable to Hema grants
View full guidelines on HEMA Biologic's website

Key Milestones

- Application submission deadline: **July 15, 2025**
- Anticipated decision notification date: **August 1, 2025**
- Anticipated project start date: **September 1, 2025**

Funding Range and Project Length

The estimated total available budget related to this RFP is $450,000.

Individual projects requesting **up to $150,000** in monetary support will be considered. Award amounts include direct costs and institutional overhead costs (capped at 22% per HEMA policy).

Drug/compound requests may be requested in addition to monetary requests for this RFP.

Maximum project length is 2 years.

How to Apply

Send the following to grants@hemabio.com

1. IIR-Proposal-Form.pdf
2. Current CV for all potential investigators
3. Proposed Budget (1-page tabular description of direct and overhead costs). *The proposed budget should also include requested quantities of study drug to be provided in kind, if applicable.*
4. One-page synopsis of the proposed research study:
    - Description and Justification of Study
    - Eligibility
    - Sample Size
    - Objectives/Endpoints
    - Proposed Dosing
    - Key Assessments/Data to be Collected
5. HEMA policy requires a letter from the academic or hospital department chairman authorizing the research project

Review and Approval Process

- Grant requests received in response to this RFP will be reviewed by HEMA to make final grant decisions.
- Applicants may be asked for additional clarification during the review period.
- All applicants will be notified via email by the dates noted above.
- Funding of approved grants will be subject to finalization of contractual agreements which requires a complete, final protocol to be appended.