**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 all 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

**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.