Novartis Office of Grants & Education
Request for Proposal (RFP) - Professional Medical Education

The Novartis Office of Grants & Education supports independent high-quality medical educational programs which provide fair-balanced, evidence-based, current scientific information to healthcare professionals to positively improve patient care. Activities should have an educational focus, be independent of commercial bias and be non-promotional in nature. We will perform these duties in compliance with laws, regulations and guidelines as established by the ACCME, PhRMA Code, OIG, other regulatory agencies and in compliance with Novartis guidelines and policies

Key Dates:	RFP Issued: January 13, 2023 ***Applications Due to Novartis: February 17, 2023 by 5 PM EST*** Notification of Grant Decisions: March - April 2023 Educational Programming Starts: Q2-Early Q3 2023
Therapeutic Area:	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Educational Need:	PNH, a life-threatening condition and rare hematological disorder, is characterized by complement-mediated hemolysis, bone marrow failure (BMF), and severe thrombophilia (Risitano AM, 2012). PNH patients are affected by a clonal expansion of hematopoietic stem cells (HSCs) bearing a somatic mutation in the phosphatidylinositol N-acetylglucosaminyltransferase subunit A (PIGA) gene whose product is required for the first step in GPI anchor synthesis (Miyata T, 1994). PNH is a rare acquired hemolytic disorder that affects an estimated 7.3 to 15.9 people/million individuals worldwide (Petropoulou AD, 2010). In the United States, it is estimated that around 14,000 individuals are affected with PNH. The clinical spectrum of PNH varies and includes anemia, thrombosis, smooth muscle dystonia, fatigue, hemoglobinuria, chronic kidney disease and pulmonary hypertension. Anemia in PNH is often multifactorial, and a result of the combination of intravascular and/or extravascular hemolysis and from various degrees of bone marrow failure. In patients with hemolytic PNH, intravascular hemolysis with moderate to severe anemia, increased reticulocytes, and markedly increased levels of lactate dehydrogenase (LDH) are common (Hill A, 2017). Currently, the only curative therapy for PNH is hematopoietic stem cell transplantation (HSCT). However, its indication is limited predominantly to PNH with severe bone marrow failure such as patients with Severe Aplastic Anemia-PNH syndrome (De Latour RP, 2012). The risk of treatment-related mortality after SCT is relatively high, with graft-versus host disease (GvHD) accounting for most of the transplant-related deaths. The International Bone Marrow Transplant Registry (IBMTR) reported a 2-year survival probability of 56% in HLA-identical sibling transplants for PNH patients with the majority of the deaths in this study occurring within one year of transplantation (Brodsky RA, 2010). Due to the high risk of mortality with HSCT, standard of care (SoC) treatment consists of humanized monoclonal antibodies inhibiting protein C5 of the

	complement system; eculizumab and ravulizumab (engineered from eculizumab with prolonged dosing interval) are currently the two approved anti-C5 antibody therapies for the treatment of PNH. Although the anti-C5 antibody therapy is generally effective in treating intravascular hemolysis (IVH), there remains a high unmet medical need for these patients due to extravascular hemolysis. Such non-/partial responder patients remain anemic and transfusion dependent, even though their transfusion requirements may decrease. Despite having serum LDH at or near normal levels, these patients continue to suffer from mild to moderate chronic anemia, related symptoms and potential long-term consequences, thus greatly impacting the patients' quality of life (QoL).
Geographic Scope:	Primary geography of interest: United States (National, Regional, and/or Local) Note: Applications for this RFP must be US focused for the audience, expert faculty, educational needs, and standards of care.
Project Description:	The Novartis Office of Grants & Education has identified the need for innovative continuing medical education programs that strive to optimize patient outcomes through education on: • The safety and efficacy profiles of the emerging therapies targeting the proximal complement pathways • The mechanism of action/mechanism of disease with new inhibitors targeting the proximal complement pathways • Adverse event management strategies with PNH therapies to ensure optimal patient outcomes and adherence The Novartis Office of Grants & Education is seeking to support: • Live/Virtual community-based educational series of case-based programs held in community hospitals, heme/onc academic centers, along with an enduring component. • Live/Virtual programs with enduring component (stand alone or in conjunction with PNH related medical societies, congresses) • Web-based programs (i.e. expert commentary, virtual tumor boards, interactive cases, etc.) • Highlights of ASH Note: Program placement is independent of Novartis. Program placement should reflect nationwide distribution in locations in which patients with PNH obtain treatment.
Target Audience:	• Hematologists/Oncologists, Academic & Community Oncologists, Bone Marrow Failure Experts, Nurses, Fellows, Physician Assistants, Pharmacists • Educational providers should include target number of participants. Further, please include details on proposed audience recruitment. Programs with a global reach are welcomed. Please clearly specify this in your proposal. Please note: Novartis will not participate in the distribution of invitations to the CME/CE event.

Available Funding:	Multiple single-support or multi-support initiatives may be funded; Up to $300,000 in total support is available
Submission Requirements:	Grant applications must be submitted by the Accredited Provider (or the Office of CME if from an Academic Institution) electronically via the Novartis Grants Central Station website: www.ngcs.novartis.com *by* ***5 PM EST on Feb 17, 2023*** *to be considered*. The grant application should include "RFP Response" within the Program Title [example: "RFP Response: *Program Title*"]. Proposals that include collaborations with third parties, including (but not limited to), medical societies, health education companies/centers, not-for-profit organizations, and academic institutions, are encouraged, as appropriate.

For grant request submission information, FAQs, and eligibility criteria, please visit:
https://www.novartis.us/corporate-responsibility/external-funding

If you have any questions regarding this RFP, you should only contact The Novartis Office of Grants & Education via email at: grants.office@novartis.com.
[Please title the subject of your email: "RFP Paroxysmal Nocturnal Hemoglobinuria 2023"].
Please submit under Hemolytic Anemias in the Grants System