

Seattle Genetics & Astellas – Call For Grant Applications (CGA UC 2001)

Independent Medical Education Programs

Therapeutic Area: Oncology
Disease State: Urothelial Carcinoma (UC)
CGA Name: UC 2001
Release Date: Jan. 27, 2020

Eligibility Requirements

General	U.S. based provider that is accredited to provide CME/CE and in good standing (e.g. ACCME, ANCC, ACPE, etc.).
Geographical Scope	United States
Grant Submission Timeframe:	January 27 th - February 24 th , 2020
Specific Area of Interest	<p>The purpose of this <i>Call for Grant Application (CGA)</i> is to encourage organizations to submit grant applications for independent education designed to enhance understanding of increasingly complex treatment options and close educational gaps in UC. Activity design may be live, enduring or multi-format, including satellite symposia at annual professional conferences or regional meeting series. Knowledge gaps in UC which have been identified in the public healthcare landscape include:</p> <ul style="list-style-type: none">• Timely identification and management of side effects associated with administration of therapies used to treat locally advanced or metastatic urothelial cancer who have previously received a checkpoint inhibitor and a platinum-containing chemotherapy, if eligible.
Monetary Range:	Individual requests up to \$175,000.00 will be considered. The amount of any grant funding may vary from the amount requested. Multi-supported educational activities are preferred.
Target Audience:	Oncology Infusion Nurses, NPs/PAs, and Pharmacists who manage the treatment of patients with UC.
Target Performance Timeframe:	April 2020 – April 2021

Purpose:

Seattle Genetics and Astellas, (collectively, the Companies) are committed to supporting innovative, high quality, independent medical education (IME) for healthcare professionals that addresses unmet medical educational needs, fosters clinical excellence, and improves health outcomes in our therapeutic areas of interest.

The intent of this CGA is to encourage organizations to submit grant requests for IME activities that, if funded, will address the following educational needs and practice gaps, which have been independently determined by the companies:

- Effectively identify and manage side effects of therapies used to treat mUC.

When responding to this CGA, please adhere to the following principles in addition to the established guidelines for the Seattle Genetics IME grant application process. All applications must be submitted online through the Seattle Genetics Grant Management System, accessible at www.seattlegenetics.com/gms. The Companies will jointly review submissions in response to this CGA.

Background

Bladder cancer is the sixth most common cancer in the United States, with an estimated 80,000 cases to be diagnosed in 2017. UC accounts for 90% of bladder tumors in the US.¹ While most patients present with non-muscle-invasive disease, many will progress to more advanced muscle-invasive or metastatic disease. For those with more advanced illness, treatment outcomes have remained poor with typical 5-year survival rates in the range of ≤15%.²

Recent approvals of immune checkpoint inhibitors agents in metastatic UC has rapidly changed the treatment paradigm for a difficult-to-treat disease. While immune checkpoint inhibitors have improved outcomes in UC, the majority of patients do not respond.³ Therefore, a high medical need remains across the different lines of therapy and particularly for patients previously treated with a checkpoint inhibitor. New and emerging treatment strategies may offer additional therapeutic options to address the unmet needs of these patients.⁴

Outcomes Measures:

Applications should include a detailed plan to provide quantitative evidence to show that the educational initiative had impact on healthcare provider knowledge, competence, and/or performance outcomes (Moore outcome level 3 - 5). Ideally, the evaluation plan will include quantitative and qualitative evidence that the intervention(s) has had an impact on health care professional behavior. Additionally, the Companies request that reports be provided for interim and final outcomes and the impact of the project.

Additional Eligibility Requirements:

The IME must be accredited and fully compliant with the criteria and/or standards of commercial support for ACCME, AAFP, AOA, ACPE, ANCC, AANP, or NCCPA. Furthermore, the IME must be educational and non-promotional in nature and will be planned, designed and implemented in accordance with the U.S. Food and Drug Administration’s Guidance on Industry-Supported Scientific and Educational Activities ("Policy Statement").

Grant Submission Instructions:

Submission Directions	Application Process	Deadlines
Step 1	Organizations who meet the eligibility criteria and are interested in submitting a full grant application in response to this CGA may do so at www.seattlegenetics.com/gms and select “Independent Medical Education”. Organizations are asked to title the start of their grant with “CGA UC 2001: [include your grant title]”	February 24 th , 2020
Step 2	Anticipated notification of decisions via email will occur*	Mid- March 2020
Questions	If you have any questions regarding this Call for Grants, please direct them in writing to Lori Carpenter at grants@seagen.com , with the subject line “CGA UC 2001”.	

* There have been no pre-determined approvals, nor any identified preferred educational providers. All submissions will be reviewed equally and thoroughly.

Other submission Information:

- Grants will not be provided to individuals.
- The Companies adhere to the guidelines of the Accreditation Council for Continuing Medical Education (ACCME) and FDA Guidance for Industry-Supported Scientific and Educational Activities and do not influence or control the content of any IME it supports.
- The Companies will consider providing funding only for IME that is balanced and scientifically rigorous.
- Any type of funding provided by the Companies may not be tied in any way to the use, purchase, prescription or recommendation of any current or future Seattle Genetics or Astellas product.

Terms and Conditions:

1. All grant applications received in response to this CGA will be jointly reviewed by both Seattle Genetics and Astellas in accordance with the Companies respective policies and guidelines.
2. This CGA does not commit the Companies to award a grant or to pay any costs incurred in the preparation of a response to this request.
3. The Companies reserve the right to approve or deny any or all applications received as a result of this request or to cancel, in part or in its entirety, this CGA.
4. All communications about the CGA must be sent to Seattle Genetics IME at www.seattlegenetics.com/gms. For compliance reasons, and in fairness to all providers, all communications about this CGA must come exclusively to Seattle Genetics' department of Medical Education. Failure to comply will automatically disqualify providers.
5. Applicant and/or educational partner (if applicable) shall have complete control over the content, development and implementation of the IME and/or materials, including, if applicable, the selection of faculty.
6. Failure to follow instructions within this CGA may result in a denial of the grant application.

Transparency: Seattle Genetics, at its sole discretion, has the right to disclose the details of funded independent medical education activities, including those that may be required by federal, state, and/or local laws and regulations. This disclosure may include, but shall not be limited to, details of the activity and the grant amount. The information may be disclosed to the public in a manner including, but not limited to, disclosure on the Seattle Genetics' website.

References:

1. Siegel RL, Miller KD, Jemal A. *Cancer statistics*, 2017. *CA Cancer J Clin*. 2017;67(1):7–30.
2. Park JC, Citrin DE, Agarwal PK, Apolo AB. *Multimodal management of muscle invasive bladder cancer*. *Curr Probl Cancer*. 2014;38(3):80–108
3. Dietrich B, Srinivas S. *Urothelial carcinoma: the evolving landscape of immunotherapy for patients with advanced disease*. *Research and Reports in Urology*. 2018;10:7-16. doi:10.2147/RRU.S125635.
4. Rosenberg, JE, et al. *Pivotal Trial of Enfortumab Vedotin in Urothelial Carcinoma After Platinum and Anti-Programmed Death 1/Programmed Death Ligand 1 Therapy*. *J Clin Oncol*. 2019 Oct 10;37(29):2592-2600.