

Seattle Genetics – Call For Grant Applications (CGA mBC 1901)

Independent Medical Education Programs

Therapeutic Area: Oncology
Disease State: Breast Cancer
CGA Name: mBC 1901
Release Date: March 15th, 2019

Eligibility Requirements

General	U.S. Based Provider
Geographical Scope	United States
Grant Submission Timeframe:	March 15 th – April 12 th , 2019
Specific Area of Interest	<p>The purpose of this <i>Call for Grant Applications (CGA)</i> is to encourage organizations to submit grant applications for an in-depth independent educational needs assessment(s) designed to assess and understand the rapidly evolving educational needs of HCPs responsible for treatment decisions for patients with hormone receptor-positive 2 metastatic breast cancer (HER2+ mBC), including:</p> <ul style="list-style-type: none">• Understanding of current and future treatment options in in patients with HER 2+ mBC with or without brain metastases• Awareness and understanding of emerging therapeutic options for patients with HER 2+ mBC who have failed two or more lines of therapy• Awareness and understanding of differences in mechanism of action, efficacy, tolerability, and safety profiles of novel agents in HER2+ mBC <p>The completed needs assessment must be made publicly available to ensure that the community at large benefits from this endeavor.</p>
Monetary Range:	Individual requests up to \$150,000 will be considered. The amount of any grant funded may vary from the amount requested. Multi-supported initiatives are recommended.
Target Audience:	HCPs responsible for treatment decisions for patients with HER2+ mBC in patients with or without brain metastases
Target Performance Completion:	September 1, 2019

Purpose:

Seattle Genetics is committed to supporting innovative, high quality, independent medical education (IME) activities 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 proposals for conducting a national independent educational needs assessment that, if funded, will summarize the knowledge, competence, and/or performance gaps that exists within the

current and future treatment landscape of hormone receptor-positive 2 metastatic breast cancer (HER2+ mBC). The funded initiative should also include a research-based education plan that will address problems in practice and/or patient care identified in its findings. Additionally, the plan should include but are not limited to, the following components:

- Learning objectives based on identified gaps and provider type (MD, APN/PA, etc.)
- Methods to address the gaps identified
- Learning formats preferred by healthcare providers
- Barriers to best practices at individual and system levels
- Regional and socioeconomic variation in response

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

Breast cancer is the most common cancer in American women after skin cancer. Approximately 260,000 new cases of breast cancer are diagnosed and 42,000 deaths occur in the US each year.¹ HER2 positivity accounts for about 15–20% of breast cancers.²

While survival rate for patients with breast cancer remains high, many will progress to more advanced or metastatic disease. For those with more advanced illness, treatment outcomes have remained poor with typical 5-year survival rates in the range of 15-26%.³⁻⁵ Historically, HER2+ breast cancer tends to be more aggressive and more likely to recur than HER2- breast cancer.^{6,7} Throughout the course of HER2+ metastatic breast cancer, approximately 30% to 50% of patients will develop brain metastases.⁸⁻¹³ HER2+ breast cancer patients with brain metastases are a high-risk population associated with unfavorable prognosis and neurological symptoms that can result in a significant reduction in quality of life.¹³⁻¹⁵

Despite advances in the management of patients with HER2+ metastatic breast cancer with monoclonal antibodies and taxane combinations, most patients will ultimately progress.^{16,17} Continued use of HER2-targeting therapies is an accepted treatment strategy for third- or greater lines of therapy for patients with HER2+ metastatic breast cancer, however, there is no established standard of care for these patients.^{18,19} For patients with brain metastases, there is no FDA approved systemic treatment option, leaving patients to rely on the use of local therapies such as radiation therapy, which may be associated with cognitive dysfunction.^{15, 20} Therefore, a high medical need remains across the different lines of therapy and particularly for patients previously treated with two or more lines of therapy and those with brain metastases. New and emerging treatment strategies may offer additional therapeutic options to address the unmet needs of these patients.

Additional Eligibility Requirements:

The independent educational needs assessment 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 mBC 1901: [include your grant title]"	April 12, 2019
Step 2	Anticipated notification of decisions via email will occur*	May 1, 2019
Questions	If you have any questions regarding this Call for Grants, please direct them in writing to Nicole Schroeder at grants@seagen.com , with the subject line "CGA mBC 1901."	

* *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 product.

Terms and Conditions:

1. All grant applications received in response to this CGA will be reviewed by Seattle Genetics 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:

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2. Loibl S, Gianni L. HER2-positive breast cancer. *Lancet*. 2017;389: 2415-2429.
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8. Duchnowska R, Loibl S, Jassem J. Tyrosine kinase inhibitors for brain metastases in HER2-positive breast cancer. *Cancer Treat Rev*. 2018;67:71-77.
9. Witzel I, et al. Breast cancer brain metastases: biology and new clinical perspectives. *Breast Cancer Res*. 2016;18(8):1-9.
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13. Mounsey LA, Deal AM, Keith KC, et al. Changing Natural History of HER2-Positive Breast Cancer Metastatic to the Brain in the Era of New Targeted Therapies. *Clin Breast Cancer*. 2018;18(1):29-37.
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17. Swain SM, Kim SB, Cortes J, et al. Pertuzumab, trastuzumab, and docetaxel for HER2-positive metastatic breast cancer (CLEOPATRA study): overall survival results from a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol*. 2013;14:461-471.
18. National Comprehensive Cancer Network (NCCN) clinical practice guidelines in oncology. Breast cancer. Version 3.2018 – October 25, 2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on January 28, 2019.
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20. Kotecha R, Gondi V, Ahluwalia MS, Brastianos PK, Mehta MP. Recent Advances in managing brain metastasis [Version 1; Referees: 2 Approved]. *F1000Res*. 2018;7:1-9.