Call for Grants

The intent of this document is to encourage organizations with a focus in continuing medical education (CME) for healthcare professionals to submit an application for funding that is related to Targeting EGFR Exon 20 in Non-Small Cell Lung Cancer: Addressing Key Challenges in Diagnostic and Therapeutic Strategies.

Please note that applications must be submitted in English

**Date:** November 23, 2020  
**From:** Global Medical Affairs, Takeda Oncology  
**Re:** Targeting EGFR Exon 20 in Non-Small Cell Lung Cancer: Addressing Key Challenges in Diagnostic and Therapeutic Strategies

**Therapeutic area:** EGFR Exon 20 Non-Small Cell Lung Cancer

**Background:** The mission of the Takeda Oncology Call for Grants program is to partner with qualified organizations to meet unmet educational needs, encourage improvement in patient outcomes, and/or promote excellence in patient care. The initiatives funded are independent, meaning that projects are the full responsibility of the recipient organization. Takeda has no influence over any aspect of the project and only asks for reports about the results and impact of the projects in order to share them publicly.

**Eligibility:** Collaborations within institutions, and between different organizations, are encouraged. All partners must have a relevant role, with the requesting organization being the primary contact with Takeda and responsible for ensuring the grant agreement is adhered to. All funding will be awarded to the requesting organization. For collaborative applications, all partners must submit a letter describing their competencies, experience and roles within the project.

**Educational objective:** While the discovery of predictive biomarkers, such as epidermal growth factor receptor (EGFR), has led to an improvement in overall survival by identifying subgroups of patients who benefit from targeted treatment, a need remains for optimal diagnostic and therapeutic strategies for EGFR exon 20 insertion-mutant Non-Small Cell Lung Cancer (NSCLC). The purpose of this call for grants is to support educational programs designed to 1) enhance healthcare professional’s (HCPs) knowledge of EGFR exon 20 insertion-mutant NSCLC biology, 2) highlight the need for diagnostic testing, and 3) how to optimally diagnose and treat patients who harbor EGFR exon 20 insertion-mutant NSCLC.

**Specific EGFR Exon 20 NSCLC topics of interest for this call for grants:**

- Education on strategies for optimal diagnosis of EGFR exon 20 insertions and clarity of reporting
- Disease awareness on exon 20 insertion mutations including biology and epidemiology
- Therapeutic strategies to target EGFR exon 20 insertions

The goal of this Call for Grants Program is to build HCP knowledge of EGFR exon 20 insertions and treatment options for patients, to educate pathologists and oncologists on the different testing
modalities and the benefits and limitations of each test, and to educate on current and emerging therapeutic strategies in the treatment paradigm for exon 20 EGFR NSCLC.

Summary of healthcare gaps:

Lung cancer is the leading cause of cancer mortality worldwide, with NSCLC comprising the vast majority of all lung malignancies. Among individuals diagnosed with NSCLC, the EGFR mutation is present in about 15% of people with lung cancer in the United States, and the number increases to 35% to 50% in people of East Asian descent (Zhang 2016). Mutations in EGFR occur predominantly in exons 18-21, with exon 19 deletions and exon 21 L858R mutation considered “classical” mutations accounting for ≈ 85% of EGFR mutations. And rare mutations account for the remaining 15% of EGFR mutations in NSCLC. Of these, EGFR exon 20 insertions, account for ≈2% of all NSCLC mutations. Currently, EGFR TKIs are used to treat both classical and rare mutations; however, the majority of NSCLC patients harboring EGFR exon 20 insertions are resistant to TKI therapy and have poor response rates. The overall response rate (ORR) in patients with exon 20 mutations receiving first- and second-generation TKIs is < 10%, with a median progression free survival (PFS) of < 3 months (Harrison 2020, O’Kane 2017, Wu 2011). This shows a high unmet need for a targeted treatment specifically for patients with NSCLC with EGFR exon 20 insertions that can improve outcome.

Because exon 20 insertion EGFR driven disease is not sensitive to classic EGFR TKIs, there is also a need to accurately diagnose patients to ensure the best therapeutic outcomes. Molecular testing for EGFR exon 20 insertions is another key unmet need; prompt and accurate testing is important to determine appropriate treatments and improve treatment outcomes. Polymerase chain reaction (PCR) and next-generation sequencing (NGS) assays are the most commonly used testing methods (NCCN 2020, Lindeman 2013, Lindeman 2018, Planchard 2018). PCR testing methods can only detect up to 50% of EGFR exon 20 insertions, while NGS-based tests can sequence multiple genes across multiple samples simultaneously and can detect novel variants (Illumina 2020). They are more comprehensive than PCR and can detect all EGFR exon 20 insertions (Khoo 2015, Riess 2018). Current guidelines recommend testing all patients with NSCLC for certain driver mutations, including EGFR, at diagnosis but do not specify the inclusion of tests specifically for EGFR exon 20 insertions (NCCN 2020, Lindeman 2013, Lindeman 2018, Planchard 2018). Thus, education around both testing modalities and the limitations of PCR testing for detecting exon 20 insertions is vital for pathologists and oncologists. And patients who have been initially tested by PCR, should be retested to ensure detection of exon 20 insertions. In addition to molecular testing, clarity of reporting is essential. Research shows that >80% of oncologists review at least the first two pages of the report but many commonly make treatment decisions based on the first summary page (Takeda Data on File). Thus, oncologists may be overlooking NGS exon specific results. Properly identifying patients with EGFR exon 20 insertions at diagnosis can help ensure that patients receive an appropriate targeted therapy.

Target audience: We welcome applications that target oncologists, pathologists, histologists, pulmonologists, and other healthcare specialties that interact with patients who harbor EGFR Exon 20 NSCLC. Priority will be given to those applications that primarily target physicians (oncologists/pulmonologists) and pathologists.

Educational format: Both virtual live and online formats are accepted. Innovative learning formats that assist pathologists to use appropriate diagnostic strategies and educate physicians on different
therapeutic strategies to target EGFR exon 20 insertions and the safety and efficacy profiles of these agents.

Outcomes measures: The educational evaluation plan must be designed to objectively measure improvements in HCP knowledge and competence (level 3 and above). Ideally, the evaluation plan will include quantitative and qualitative evidence that the educational program has had an impact on HCP behavior.

References


Takeda Data on File.


Submission requirements: When responding, please follow the established guidelines for the Takeda medical education grant submission process. All applications must be submitted at http://www.takedaoncology.com/partnerships/grants--donations/

The education must be accredited by the appropriate accrediting bodies, be fully compliant with ACCME criteria and the Standards for Commercial Support and must be in accordance with the U.S. Food and Drug Administration’s Guidance on Industry-Supported Scientific and Educational Activities. If accepted, must attest to the terms, conditions and purposes of an educational grant as described in the Takeda letter of agreement.

Geographic region: United States and Global

Length of proposed project: 12 months

Expected approximate monetary range of awarded proposals: Individual projects requesting up to $400,000 will be considered. The amount of the grant Takeda Oncology will fund for any project will depend on the Review Committee’s evaluation of the proposal and costs involved and will be stated clearly in the approval notification.

Preference will be given to proposals that address ALL of the following:

1. Overview of requesting organization: Please describe the organization requesting the grant, including its history, current mission, a list of key officers and staff who will direct the program; and descriptions of any other participating organizations/partners. Describe any experience your organization has in working in this area.
2. Abstract: Please provide a summary (750-word maximum) of your proposed project, including a brief assessment of needs in the target population.
3. Goals and implementation plan: Provide a clear description of program goals, implementation plan, target audience, and an anticipated timeline of project activities and milestones. Please indicate whether the project will be integrated into an existing program; if yes, please describe the existing program, how this project will be integrated, and the additional impact that is expected if funding is awarded.
4. Budget: Please provide a detailed itemized budget for the proposed project. Please also include a narrative justification for the requested amount.
5. Reach and impact: Please describe the planned reach for your program, as well as the estimated impact the program will have on your intended audience. Please involve any currently available baseline data.
6. Collaboration: If your project is collaborative in nature, please describe the roles and capabilities of each partner.
7. Evaluation: Specify how you will define and measure success for each of the proposed activities; indicate how the program will be measured and evaluated, and how results will be reported.
8. **Reporting:** Please specify the descriptive and evaluative reporting results that you will provide. For projects that are funded for longer than six-months, interim reporting is required. A final report is due at the end of the funded activities, including reporting of funding used to inform reconciliation of unused funding.

9. **Sustainability/replicability:** Describe any plans to broadly disseminate the proposed program’s results and ensure sustainability beyond the funding period. Describe how the proposed program could serve as a model in other geographic regions or to serve different populations.

10. **Terms and conditions:** Please take note that every Call for Grants released by Takeda Oncology is governed by specific terms and conditions. Please review these terms and conditions, posted here [LINK TO TERMS AND CONDITIONS].

11. **Additional submission requirements:**
- Letter of commitment from any partner organizations
- Most recent audited financial statement
- IRS 501(c)(3) letter (if applicable)
- Current annual report
- Current operating budget
- Biographies of key staff

**Key dates:**
- Call for Grants release date: 11/23/2020
- Full proposal deadline: 1/15/2021
- Review of proposals by review committee starts: 1/18/2021
- Anticipated proposal notification date: 2/1/2021

Grants will be distributed following the execution of a fully signed Letter of Agreement.

**How to submit:** Instructions on submitting can be found at: http://www.takedaoncology.com/partnerships/grants--donations/

**Questions:** If you have any questions, please direct them in writing to Monica Raziq, Manager Congresses, Outreach and Medical Education (monica.raziq@takeda.com) with the subject line “(Call for Grants EGFR Exon 20 NSCLC)”.