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 managing patients with Hodgkin Lymphoma and Peripheral T Cell Lymphoma.

Please note that applications must be submitted in English

Date: 01/10/2021
From: Global Medical Affairs, Takeda Oncology
Re: Managing Patients with Hodgkin Lymphoma or Peripheral T Cell Lymphoma
Therapeutic area: Hodgkin Lymphoma and Peripheral T cell Lymphoma

Background: The mission of the Takeda Oncology Call for Grants program is to communicate with qualified organizations on potential unmet educational needs, in order to 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 institutions/organizations 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 involved parties must submit a letter describing their competencies, experience, and roles within the project.

Education Topics of Interest:

- Hodgkin Lymphoma (HL) and Peripheral T Cell Lymphoma (PTCL), common subtypes, disease states including the unmet needs of their treatment
- First line treatment options of both advanced HL and common PTCL subtypes
- Disease characteristics that place patients at a high-risk for relapse
- Relapsed/Refractory treatment options of both HL and PTCL including retreatment and combining various mechanisms of action
- The role of real-world evidence (RWE) in treatment selection

The goal for this call for grants program is to educate healthcare professionals on the treatment options for HL and PTCL.

Summary of healthcare gaps:
Hodgkin Lymphoma:

Hodgkin lymphoma (HL), a relatively uncommon B cell malignancy, has the second highest societal burden of all malignancies (Hanly et al., 2014). This high societal burden is due to the relatively young age of many patients and lost productivity due to premature mortality. In 40 – 48% of newly diagnosed HL patients this disease has already reached an advanced stage (stage III/IV disease or earlier stage disease with high-risk features) (Bray et al., 2018; Global Cancer Observatory; Engert et al., 2005). Multi-

agent chemotherapy regimens are a mainstay therapy in the first-line, second-line, and salvage treatment of patients with advanced HL (NCCN 2020; Eichenauer et al., 2014). Up to 30% of HL patients with advanced-stage disease fail frontline therapy, which is associated with poor outcomes (Mounier et al. 2014; Carde et al., 2016; Engert et al., 2009; Viviani et al., 2011). The salvage therapy options for patients with advanced HL are limited and associated with substantial treatment burden. For most patients with R/R HL, salvage treatment choices are not optimal, and often consist of high-dose chemotherapy followed by autologous stem cell transplant (ASCT) (NCCN 2020; Eichenauer et al., 2014; Majhail et al., 2006).

Pre-transplant risk factors have been identified that place a patient at a high risk for failing ASCT. Disease-related and patient-related pre-transplant risk factors may increase the chance of early post-transplant progression or death (Josting et al., 2010, Sureda et al., 2005, Moskowitz et al., 2001, Devillier et al., 2012). Increasing numbers of risk factors further elevate the risk of relapse following ASCT (Moskowitz et al., 2001; Josting et al., 2010). Effective pre-transplant treatment options that achieve CR are needed to improve the success of transplant (Czyz et al., 2004; Devillier et al., 2012). Novel agents are also investigated to improve the outcomes of ASCT. Recent approaches for salvage therapy combine novel agents and classical chemotherapy to increase the amount of patients achieving a CR pre-transplant (Voorhees et al., 2020; Castagna et al., 2020; Moskowitz et al., 2019). Consolidative therapy after ASCT for patients with increased risk for relapse demonstrated reduction in the risk of progression after ASCT (Moskowitz et al., 2018).

Several novel agents are approved by EMA and FDA for treatment of r/r HL in different lines of therapy (Vassilakopoulos et al., 2020). The application of the novel agents as monotherapy improved the prognosis of r/r HL patients (Kallam et al., 2019). Open questions remain, such as if efficacy can be further improved by combining several novel agents or what the optimal sequencing of traditional chemotherapy regimens, the different novel agents, ASCT, and allo SCT will be in the future (Wang et al., 2018; Voorhees et al., 2020). As not all these questions are investigated in clinical trials, evidence from RWE is of increasing importance for treatment decisions in r/r HL (Vassilakopoulos et al., 2020; Bair et al., 2017).

Peripheral T- cell Lymphoma:

Peripheral T-cell lymphoma (PTCL) includes a rare, heterogeneous group of lymphoid malignancies that originate from mature, post-thymic T cells. PTCLs account for less than 20% of non-Hodgkin Lymphoma (Hildyard et al., 2017). The most common PTCL subtypes, including PTCL-not otherwise specified (PTCL-NOS), angioimmunoblastic T-cell lymphoma (AITL), and ALCL (anaplastic large cell lymphoma), represent over half of PTCL cases and tend to be treated similarly with multi-agent chemotherapy (usually CHOP or CHOEP) (Vose et al., 2008: d'Amore et al., 2015). Prognosis in PTCL varies widely by subtype, and the low incidence of some subtypes can make prognostic assessment difficult (Vose et al., 2008). CD30 is variably expressed in PTCL subtypes and measurement can inform diagnosis and treatment decisions (Swerdlow et al., 2016; Dearden et al., 2011).

Traditionally, PTCLs have been treated with anthracycline-containing regimens that are associated with poor long-term survival (Fisher et al., 1993; Jagadeesh et al., 2014). The curative effects of chemotherapy regimens as a frontline PTCL treatment is generally dismal, and both CHOP and CHOEP show similar therapeutic effects, with CHOEP presenting significantly increased AEs compared with

CHOP (Deng et al., 2019; Mak et al., 2013). Novel agents showed durable responses, translating into better survival in FL treatment of PTCL (Horwitz et al., 2019).

Target audience: We welcome applications that primarily target hematology oncologists and other health care professional that interact with Hodgkin Lymphoma and Peripheral T cell Lymphoma patients.

Educational format: Hybrid symposium at EHA with an online enduring component. Any variety of approaches to the symposium will be considered including, but not limited to: case-based learning, didactic learning, and/or roundtable discussions.

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

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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: Global, with a focus on Europe

Length of proposed project: Hybrid symposium at EHA with a 12 month online enduring component

Expected approximate monetary range of awarded proposals:
The total available budget related to this call for grants is approximately $220,000. Grants of varying budgets up to $220,000 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. **Please note, the symposium slot at EHA will be pre-purchased by Takeda. Providers do not need to include a slot fee. Date and time will be shared when confirmed by EHA.**

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 the following terms and conditions:
    - All grant applications received in response to this Call for Grants will be kept confidential reviewed in accordance with all Takeda policies and guidelines.
    - This CGA does not commit Takeda to fund any Call for Grants submission, or the costs associated with such submissions.
    - Takeda reserves the right to cancel, in part or in its entirety, this Call for Grants.
    - For compliance reasons, and in fairness to all providers, all communications about this Call for Grants must come exclusively to Takeda's Department of Medical Education. Failure to comply will automatically disqualify providers.
    - Failure to follow the instructions within this Call for Grants will result in a denial
11. **Additional submission requirements:**
    - Letter of commitment from any partner organizations

- IRS 501(c)(3) letter (if applicable)
- Current operating budget

Key dates:

Full proposal deadline: [02/17/2022]
Review of proposals by review committee starts: [02/18/2022]
Anticipated proposal notification date: [02/28/2022]

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 Sarah Willette, Manager Congresses, Outreach and Medical Education (Sarah.Willette@takeda.com) with the subject line "(Call for Grants Lymphomas EHA)".