Call for Grant Notification Topic: Live CME Symposium & online enduring at the annual AIBD 2017 and Crohn’s & Colitis Congress 2018 educational conferences

Identifier to enter into the title of the grant application: Please reference one of the codes below in the “Activity Title” field on the Takeda Educational Grant online application form.

CGA-IBD-AIBD 2017

CGA-IBD-Crohn’s & Colitis Congress 2018

Therapeutic Area: Gastroenterology, IBD

Issue Date: July 17th, 2017

Deadline for Submission: For AIBD: August 25th, 2017; For Crohn’s & Colitis Congress 2018: August 31st, 2018

Award Decision Date: Approvals and denials will be communicated via standard email notifications no later than September 15th, 2017

1. Purpose: Takeda is seeking to support independent educational grants for live CME symposium at the annual AIBD 2017 and Crohn’s & Colitis Congress 2018 designed to improve clinical decisions, patient care and outcomes for people with moderate to severe Ulcerative Colitis (UC). The programs supported should focus on addressing challenges that exist in the management of UC, such as: complexity of treating UC, myths and misconceptions, individualizing treatment and effectively treating patients with moderate to severe disease based on safety/efficacy profiles of available therapies.

2. Focus Area:

There are gaps in the care of UC that include: unknown cause, non uniform therapeutic response, fear of adverse events (from therapies, cancer and surgery) and a variety of misperceptions that may influence management strategies and limit opportunities for improving patient outcomes. (1-9)

First misperception is that UC is commonly regarded as more benign than Crohn’s Disease (CD). (10) However, despite continuing advances in the treatment of UC, approximately half of patients do not achieve sustained clinical remission, and ~15% of patients undergo a colectomy within 20 years after UC diagnosis. (11-12) Furthermore, approximately 50% of patient’s progress to more extensive disease within the first two years of diagnosis and consequences of disease progression include: proximal extension of disease, strictureing, pseudopolyposis, dysmotility, anorectal dysfunction and impaired permeability. (18-20) Patients with UC are also at risk for developing colorectal cancer (CRC). (3)

Second, many patients who respond to corticosteroid therapy remain steroid dependent. (13) Despite clinicians’ general understanding of the detrimental side effects of corticosteroid, these continue to be used excessively in UC. (26) Blood clots, heightened risk of infection, diabetes mellitus, hypertension, cataracts and depression have been associated with long term use of corticosteroids. (4-8) Bone loss and fractures are among the most serious side effects associated with chronic steroid therapy. (14)
Third, there is a general assumption that colectomy can cure the disease and normal life can be restored. (12) However, colectomy often results in consequences that negatively impact a patient’s daily life. (9)

Fourth, symptoms are not a reliable indicator of disease assessment. Mucosal healing (MH) is now considered as a major treatment goal in clinical trials and clinical practice for patients UC. (27) MH is associated with sustained clinical remission, steroid-free remission, and reduced rates of hospitalization and surgery. (23) A systematic review and meta analysis of studies comparing long term outcomes of patients with MH with those without MH illustrated that MH was associated with long term clinical remission, avoidance of colectomy and corticosteroid free remission. (24)

Lastly, 5ASAS historically have been the initial treatment for UC followed by immune modulators and biologic therapies if remission is not achieved. (15-17) However, instead of delaying appropriate therapy in patients with moderate to severe disease, an earlier effective therapy may be more appropriate. (Ryan, Rutgeerts) To aid in the complexity of therapeutic decision making, clinicians should be familiar with the dangers of periodic courses of corticosteroids and the AGA Carepathway for UC and risk/benefit profiles of available steroid sparing therapies. (27)

In conclusion, optimizing current treatment options, reducing frequent corticosteroid usage and employing systematic care pathways may improve health care professionals’ ability to individualize treatment to achieve disease modifying goals, prevent disease progression, meet evolving quality improvement indicators and improve patient outcomes (12).

3. Funding: Budget should demonstrate fiscal responsibility and cost effectiveness.

4. Criteria applied to assess applications:
   - Quality of needs assessment, educational design and evaluation plan
   - Project scope alignment with proposal objectives
   - Plan for Dissemination of findings and sustainability of interventions
   - Budget

5. Submission process and requirements:

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.

Proposals should be structured based on below format to ensure standardization and evaluation of all responses. All the sections listed below must be included in the proposal, in the order presented, with the Section Number listed.

The responses shall be submitted in the following format:
   - Section 1 – Executive Summary
   - Section 2 – Your Organizational Profile: This section should provide a brief overview of your organization, past experience, and pertinent information.
• Section 3 – Background: This section must include a well-referenced needs assessment that demonstrates the specific gaps and barriers of the intended target audience; where appropriate demonstration of need using real world data and established national measures used. Additionally, information about the how the needs were identified must be presented.

• Section 4 – Proposed Activities: This section should clearly define the target audience, measurable learning objectives or measures and rationale for the program design. Proposals should outline how the content will be developed, by whom, and the methods to ensure complete, accurate and evidence-based information. The activities should be linked to specific gaps identified in the guidance provided in Section 3.

• Section 5 – Implementation Plan: This section should include roles and responsibilities of all parties, selection criteria, identification of partners or outside vendors for any part of the implementation plan, Letters of Support from partners if applicable, and timeline of key milestones of the program.

• Section 6 -- Outcomes and Evaluation Plan: This section should describe specifically the outcomes model utilized (i.e. Moore’s, TELMS or other): measures, methodology, measurement design, statistical analysis, and reporting. At minimum, the educational evaluation plan must be designed to objectively measure improvements in knowledge and competence. Preference will be given to programs that align to objectives, outcomes, and measures properly and provide as much detail regarding the metrics that will be captured and reported.

• Section 7- Reporting & Dissemination Plan – This section should include information about the potential contents of the report, frequency of reporting throughout the funding period (interim and final reports) as well as a plan for disseminating findings as best practices (journal articles, newsletters, conference abstracts etc.).

• Section 8 – Budget: This section should include a detailed budget with rationale including breakdown of costs associated with management of the program, content development and out-of-pockets.

• Section 9 – Appendices: Any additional and relevant information should be attached as an appendix. This may include results of similar programs or examples of previous programs or contingency plan for implementation.

6. References:


21. Ryan Ungaro, Saurabh Mehandru, Patrick B Allen, Laurent Peyrin-Biroulet, Jean-Frédéric Colombel UC Lancet review


