UCB, Inc Medical Educational Grants
Medical Affairs
Request for Proposal (RFP)

RFP Title: Evolution of MOGAD with a focus on the new proposed diagnostic criteria

Background:	UCB, Inc., is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. Myelin oligodendrocyte glycoprotein antibody-associated disease referred to as MOGAD is an autoimmune, antibody-mediated, demyelinating disorder caused by autoantibodies that target MOG glycoprotein located on the surface of myelin sheath & oligodendrocytes in the CNS. Autoantibodies against MOG induce oligodendrocyte cell damage after entering the CNS, leading to demyelination of the myelin sheath. The disease presents as optic neuritis (ON), transverse myelitis (TM), and/or encephalomyelitis in adults and more commonly as acute disseminated encephalomyelitis (ADEM) in children. MOGAD can present as a monophasic (up to ~55%) or relapsing (44–83%) disease course across adult and pediatric population. Nearly half (47%) of patients develop permanent neurological deficits and over a third (37%) experience long-term severe visual impairment or functional blindness. Although increasingly recognized as a distinct disease entity separate from NMOSD (Neuromyelitis Optica spectrum disorders) and MS (Multiple Sclerosis) an official MOGAD diagnosis can take from months to years from onset as not all neurologists are familiar with the disease, and it often gets misdiagnosed. However, similar to NMOSD, MOGAD preferentially targets the optic nerve and spinal cord, and severe attacks can lead to blindness and paralysis. The MOG antibody test itself can take several weeks to process and there is a knowledge gap even amongst neurologists with regards to the evolving understanding of MOGAD disease from pathological to disease classification. Generally, intravenous high dose corticosteroid (IV HDC) and PLEX are used to treat acute attacks, although IVIg can also be used, particularly in pediatric patients. Immunosuppressant therapy; has been shown to reduce the relapse rate in MOGAD. There are no currently approved therapies or randomized controlled trials (RCTs) for MOGAD. Given these knowledge gaps and complexities, clinicians face challenges in diagnosis and in determining which patients should start with chronic maintenance therapy and when to start treatment for prevention of relapses of MOGAD. Microlearning tools involve presenting data in small bite-sized units and short-term learning activities, which are organized in a series format to allow for continuous learning. Mobile platform is the best engagement platform as it is available all the time, hence the URL based CME platform available on all traditional digital interface should be customized for mobile interface for ease of access through multiple digital channels

Overall Gaps in Care:	Following are the current gaps in care identified in literature and through interviews with HCPs and patients, however all of these cannot be addressed in a single initiative, the specific area of focus for this particular RFP are mentioned in the next portion. **<u>Awareness of disease and its pathology</u>** 1. Limited population-based data on the epidemiology of MOGAD in relation to different geographical areas and ethnicities. 2. Exact pathophysiology and disease course of MOGAD remains unclear. Currently, there is limited understanding of the predictors of relapse in MOGAD. 3. When patients present with their first attack, it is difficult to predict who will have a monophasic illness and who will develop relapsing disease. 4. Predictors of relapse and long-term outcome are not well understood yet 5. MOGAD is not yet recognised/ classified as a distinct disease entity system [WHO ICD-10&11] **<u>Delays in diagnosis</u>** 1. Currently no formal criteria constituted for diagnosis of MOGAD, correct diagnosis can be delayed by weeks to years 2. Access to accurate & reproducible assay for MOG Antibody is limited and inconsistent. The exact relationship between antibody titers and relapse risk is also unclear. 3. Need to educate clinicians on the brain imaging features and MRI lesion evolution of MOGAD to help differentiate it versus NMO and MS . 4. Differentiation of MOGAD versus MS and NMO on basis of its clinical presentation, MRI and antibody testing is key to prevent misdiagnosis **<u>Gaps in treatment</u>** 1. Current treatments used have no randomized clinical trial data. There is unmet medical need for approved MOGAD treatments to help prevent relapse. 2. No standard treatment guidelines for treatment of MOGAD. 3. Because of the risk of disability, identifying patients at risk of relapse, and treating them early is a key unmet need.
Specific Gaps of Interest of this RFP:	The proposed consensus diagnostic criterion for MOGAD developed by international panel for MOGAD was published in Lancet Neurology in January 2023 (Banwell B. et al). This collates the current understanding & best practices from centers of excellence for neuroimmunological diseases. This could impact the way in which MOGAD is diagnosed and will help in increasing the recognition of MOGAD as a separate disease entity. Hence there is a need to 1. Create awareness and discussion regarding the **new proposed diagnostic criteria** of MOGAD 2. Raise disease awareness for early patient referral to centers of excellence of neuro-immunological diseases 3. Awareness and updates regarding the diagnostic tools (MOG antibody test and MRI features) 4. Increase awareness around current treatment landscape and gaps in treatment from patient perspective It is our intent to financially support an independently developed comprehensive proposal that will create awareness of the new MOGAD diagnostic criteria and improve target health care provider knowledge and skills in identifying, diagnosing, and

	differentiating MOGAD versus other demyelinating CNS conditions and understand the gaps in treatment for these MOGAD patients
Eligibility Criteria:	• The program should target the US geographic region. The education must be accredited and abide by ACCME standards. • The education must offer credit and meet the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP, or ADA CERP or other recognized accrediting body. • The educational program could be an online CME or could be based on microlearning principles spanning over the 3-4 modular episodes of 10-12 min each with a continuity of theme, overall involving 1-2 top experts as speakers and availability customized to mobile platform. The program will be run for minimum of 6 months in US during 2023 . • Please share your governance and compliance processes around the CCPA /GDPR. • If accepted, the provider must attest to the terms, conditions and purposes of an educational grant as described in the electronic UCB letter of agreement. See the FAQ document in the Grants section at https://www.ucb.com/our-company/funding/usa for the UCB letter of agreement content.
Clinical Area:	MOGAD (Myelin Oligodendrocyte Glycoprotein Antibody Associated Disease) and its differential diagnosis
Target Audience:	The virtual/digital educational program should facilitate learning of US HCPs working in Neurology with 100% from primary target audience **Primary Target Audience:** neuroimmunology experts, neurologists with MS expertise, pediatric neurologists, neuro-ophthalmologists
Outcomes:	1. Participation metrics (number of targeted HCPs initiating & completing all modules) 2. Satisfaction ratings with qualitative feedback 3. Minimum outcome measurement level will demonstrate learner competence (practical application and conceptual understanding). • Minimum levels for measured outcomes will be set at Moore level 3 (knowledge acquisition) and Moore level 4 (competence). Where applicable level 5 outcomes (performance improvement) can be proposed. The proposed methodology for collecting and analyzing outcomes measures should be described. 4. Based on the learning outcomes obtained from this learning activity, a methodology should be proposed for identifying persisting learning gaps that need further consideration in future learning activities. 5. A methodology for measuring long-term knowledge retention should be proposed.
Expected Budget Range of Applications:	The anticipated program cost is expected to be achievable with a budget of no more than $ 150,000. The final awarded amount will depend upon the review panel's evaluation of the proposal and costs involved.
Key Dates:	**RFP release date:** 21st Feb 2023 **Proposal Deadline:** 14th March 2023 *Please note the deadline is midnight Eastern Time* **Review of Proposals by Review Panel:** 28th March 2023 **Anticipated Proposal Notification Date:** 1st April 2023

	Period of Performance: 1st June May to 30th Nov 2023 Please note an interim progress report will be requested depending upon timelines of the program.
Submission Instructions:	Submit applications online through the UCB eRequest system which can be accessed by following the link in the Grants section at https://www.ucb.com/our-company/funding/usa. Follow this link to submit a grant request: https://erequest.ucb.com/ Applicants must register for the UCB eRequest system if you are not a current registrant. Select **UCB.MOGAD01.Feb2023** in the RFP Number field in the application and include **UCB.MOGAD01.Feb2023** within the Request Title as well. Select **Neurology** as the **Therapeutic Area** and **Other Neurology** as the **Indication**(s). Complete all required sections of the online application and upload the proposal. Approvals and denials will be communicated to the applicant via the eRequest system by email by the dates provided above.
Application Section Requirements:	• Learning objectives • Needs assessment with classification of identified gaps into knowledge, skills, attitudes optionally performance according to the Moore levels of outcomes based planning • Intended outcome level to be achieved according to the Moore Scale • Activity type and delivery format following instructional design principles • Audience • Line-item budget (template provided on application) Document uploads for inclusion: 1. A formal dated Letter of Request for the funding 2. A comprehensive learning needs assessment plan 3. Detailed program plan 4. Accreditation certificate(s) 5. W-9 for payee organization 6. Outcomes measures plan Be sure to review the FAQ document at the USA Funding website https://www.ucb.com/our-company/funding/usa for other application information.
Questions:	Please direct any questions that you may have to the UCB Grants Office at grants@ucb.com

References:

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3. Sechi E, Cacciaguerra L, Chen JJ,Mariotto S, Fadda G, Dinoto A,Lopez-Chiriboga AS, Pittock SJ and Flanagan EP. MyelinOligodendrocyte Glycoprotein Antibody-Associated Disease (MOGAD): A Review of Clinical and MRI Features, Diagnosis, and Management. Front. Neurol. 2022; 13:885218. doi:10.3389/fneur.2022.885218
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5. Hennes EM, Baumann M, Lechner C, Rostásy K. MOG Spectrum Disorders and Role of MOG-Antibodies in Clinical Practice. Neuropediatrics. 2018 Feb;49(1):3-11. doi: 10.1055/s-0037-1604404. Epub 2017 Aug 31. PMID: 28859212.
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7. Epstein SE, Levin S, et al. Myelin oligodendrocyte glycoprotein (MOG) antibody-mediated disease: The difficulty of predicting relapses Mult Scler Relat Disord 2021 Nov;56:103229. doi: 10.1016/j.msard.2021.103229. Epub 2021
8. Asseyer S, Henke E, et.al. Pain, depression, and quality of life in adults with MOG-antibody-associated disease. Eur J Neurol. 2021 May;28(5):1645-1658. doi: 10.1111/ene.14729. Epub 2021 Feb 11. PMID: 33423336.