Letter of Agreement (LOA): Grant

# GRANT LETTER OF AGREEMENT (the "Agreement") No. 20064-G-INF

#### **Statement of Purpose**

**Detská fakultná nemocnica s poliklinikou Banska Bystrica** ("Applicant") has submitted a grant request application to **Biogen MA**, **Inc.** ("Biogen"), (each a "Party" and together the "Parties") to seek funding for the project entitled, "**The reconstruction of hospital, specifically paediatric clinic**" ("Project") to begin on **October 17, 2021** by the Applicant, as further described in the Grant request **ID#20064-G-INF** ("Grant Application").

#### **Grant Award**

Biogen hereby awards this grant of EUR 10,420.00 ("Grant") to the Applicant to be used as follows:

Biogen agrees to provide the Applicant a lump sum of **EUR 10,420.00** as a grant for the use described more fully in the Grant Application.

The amount of the Grant is based on a budget provided to Biogen in the Grant Application and is based on a good faith estimate of the actual costs of the Project.

The Parties acknowledge and agree that this Grant is not being given in exchange for any explicit or implicit agreement to purchase, prescribe, recommend, influence, or provide favorable formulary status for any Biogen product. The amount of the Grant has not been determined in a manner that takes into account the volume or value of referrals.

#### Independence

The Applicant must ensure that all decisions regarding the identification of Project needs, determination of objectives, selection of methods, selection and development of content, and the selection of service providers or personnel, speakers, moderators, chairpersons, planning committee personnel (herein referred to collectively as "Faculty"), and all other persons in a position to control the design and execution of the Project are independent of any commercial influence or bias. Neither Biogen nor its affiliates, distributors or agents shall direct the design or execution of the Project. The Applicant will independently make the selection of the Faculty for the Project.

# <u>Disclosure of Financial Relationships and Program Funding Support</u>

The Applicant will ensure meaningful disclosure to the audience prior to the beginning of the Project of: 1) Biogen funding of the Project, without mention of product trade names or product messages; and, 2) any significant relationship between the Applicant and Biogen, and/or between individual Faculty and Biogen. For individuals with no relevant financial relationships, the audience must be informed that no relevant financial relationships exist. In addition, the Applicant shall acknowledge support from Biogen in program brochures, syllabi, and other Project materials, without any use of Biogen logo(s).

## **Promotional Activities**

No promotional activities will be permitted at the same time or in the same room or obligate path as the Project. Arrangement for commercial exhibits or advertisements will not influence planning or interfere with the Project, nor will they be a condition of the provision of commercial support for the Project. The nature and scheduling of any social event or meal held in connection with the Project is at the sole discretion of the Applicant. The Applicant agrees to ensure that any social event or meal held in connection with the Project is modest, does not compete with, nor take precedence over, the Project.

# **Objectivity & Balance**



The Applicant will make every effort to ensure, if applicable, that the Project is non-promotional and any references to pharmaceutical products, including Biogen's products, are objectively selected and presented with a balanced view that is without commercial bias for or against such products. The Applicant shall use generic names for all products discussed in connection with the Project. The title of the Project shall adequately reflect the purpose, content, and scope of the Project. The Project shall include discussion of multiple treatment options and will not focus on a single product or regimen unless existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies.

# <u>Limitations on Data and Discussion of Unapproved Uses</u>

The Applicant will ensure that the Project provide truthful and non-misleading information according to local regulations, including meaningful disclosure of limitations on data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). The Applicant will require that Faculty disclose when a product is not approved in the host country for the use under discussion.

## **Audience Selection and Opportunities for Debate**

The audience for the Project will not be selected by any Biogen representative, or reflect Biogen's sales or marketing goals. The Applicant will ensure meaningful opportunities for questioning and scientific debate.

## **Enduring Materials**

Biogen will not distribute any enduring materials (e.g., printed, recorded, or computer-based materials) that are developed through support of this Project. Requests from healthcare professionals for information regarding this Project will be forwarded to the Applicant, and the Applicant will be responsible for dissemination of any enduring materials relating to this Project.

#### **Use of Contributed Funds**

Funds will be in the form of a Grant made payable to the Applicant or the Applicant's designee. The Applicant must make all decisions regarding the disposition and disbursement of Biogen support hereunder, and no additional funds outside those noted in the Grant Application will be provided by Biogen to the Applicant. Biogen may, at its discretion, require the Applicant to provide written documentation regarding accounting of the funds awarded by Biogen for the Project as well as full reconciliation of Grant. Failure of the Applicant to meet any conditions or contingencies in the Grant Application, this Agreement or which have otherwise been communicated by Biogen may render this Agreement null and void.

The Applicant may collect additional funds from third parties for the Project under the obligation that the collected funds will not be in excess of the anticipated total costs of the Project. The Applicant confirms that the Grant does not overlap with regular financing of its activities from any public institution or governmental authority, and with financial support received by other third parties. The Applicant furthermore acknowledges that the Grant will not be used to finance any research activities that involve Biogen products or medicinal products from other companies, nor any other Investigator Initiated/Sponsored Trials. The Applicant warrants that the Grant shall not be used to finance any activities related to hospitality, gifts, or payments for HCP educational event related costs (e.g. congress attendance) unless explicitly set forth and detailed within Grant Application.

# **Compliance with Applicable Standards**

The Applicant will comply with and assure that all Applicant contractors comply with all relevant requirements of: 1) the U.S. Food and Drug Administration Final Guidance on Industry-Supported Scientific and Educational Activities; 2) the American Medical Association Guidelines on Gifts to Physicians (Opinion 8.061 and all clarifying addendums) and Continuing Medical Education (Opinion 9.011); 3) PhRMA Code on Interactions with Healthcare Professionals; 4) Office of the Inspector General guidance, including the Compliance Program Guidance for Pharmaceutical Manufacturers; 5) the U.S. Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b and any similar anti-kickback laws,



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or the corresponding provisions of any future laws and the United States Foreign Corrupt Practices Act, the UK Bribery Act 2010 and the OECD Convention on Combatting Bribery of Foreign Public Officials in International Business Transactions and 6) all other similar and applicable laws and regulations in the country of the Applicant's registered seat and 7) all other relevant standards and guidelines.

The Applicant represents and warrants to Biogen that any payment to contractors or other agents working on behalf of Applicant as part of the Project (i) represents the fair market value, (ii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Biogen product or as a reward for past behavior, and (iii) is in compliance with all applicable laws and regulations, including the local laws and regulations of the country of the recipient.

Biogen will not be responsible from any deviation from relevant standards that is not the direct fault of Biogen. Biogen hereby acknowledges that it has no ownership of the Project.

#### **Firewalls**

The Applicant has disclosed all relevant information concerning its current and previous relationships, financial and otherwise, with Biogen, as well as those of any of its contractors, as part of the proposal submitted to Biogen in support of this Grant. To the extent applicable, the Applicant certifies that for each organization, an appropriate separation exists between the part of the organization that provides marketing or promotional services to Biogen and the part of the organization receiving the Grant.

# **Excluded Individuals/Entities**

The Applicant noted hereby certifies that to the best of its knowledge, none of its employees or subcontractors is on the Office of Inspector General's List of Excluded Individuals/Entities or has been debarred, excluded, or is otherwise ineligible to participate in Federal healthcare programs.

# **Provider Responsibilities**

In the event that Applicant is unable to carry out the Project as fully described in the Grant Application, including changes to the (a) date(s), (b) scope, and/or (c) method of delivering the Project, etc. Applicant shall notify Biogen immediately and provide a detailed explanation, in writing, of the reason(s) for such change. Any changes must be approved by Biogen prior to implementation. Any changes that occur without prior notification will constitute a breach of this Agreement and may render the Applicant ineligible to receive future grants or other funding from Biogen.

## **Confidentiality**

The Parties anticipate that under this Agreement it may be necessary for one Party to transfer to the other Party information of a confidential or proprietary nature ("Confidential Information"). As such, all such transfers and disclosures of information shall be governed by the confidentiality and non-disclosure provisions hereunder. The Parties agree that the existence and terms of this Agreement shall be deemed Confidential Information and, as such, shall not be disclosed to any third party without both Parties' prior express written consent, or as required by law.

As used in this Agreement, the term "Confidential Information" shall mean all trade secrets or confidential or proprietary information provided by either Party, or one of its representatives, to the other, or its representatives.

Confidential Information does not include information that: (1) is approved for release by the written authorization of the non-disclosing Party; (2) the disclosing Party can show was already in its possession at the time of disclosure; (3) is or becomes publicly available by other than unauthorized disclosure by the disclosing Party; (4) is received by the disclosing Party from a third party who is rightfully in possession of such information free of any obligation to maintain its confidentiality; or (5) is independently developed by an employee, agent, or contractor of the disclosing





Party without access to the Confidential Information.

The Parties agree that, except as required by judicial order or governmental laws or regulations, the Confidential Information of Biogen shall be used by Applicant solely for the purpose of fulfilling any responsibilities agreed to by the Parties under the terms of this Agreement. Each Party agrees to hold the Confidential Information of the other Party in confidence by security measures, devices, and procedures equal to those used by it in securing its own confidential documents. The Parties further agree that the Confidential Information of Biogen shall be disclosed only to those officers, employees, and representatives of Applicant who need to know such Confidential Information for the purposes of fulfilling any responsibilities agreed to by the Parties under the terms of this Agreement; it being understood that such officers, employees, and representatives shall be bound by the terms of this Agreement and Applicant shall be liable for any breaches by its officers, employees, and representatives.

#### Liability

Biogen shall not be liable for any loss, injury, or damage incurred by Applicant or by a third party as a result of activities funded under the Project, including any loss, injury, or damage resulting from a negligent or willful act or omission by Applicant. Applicant shall indemnify and hold Biogen harmless from any liability, loss, cost, and expense (including, but not limited to, attorneys' fees and costs) incurred by Biogen as a result of Applicant's negligent or willful act or omission.

# **Disclosures/Reporting**

The Parties acknowledge and agree that Biogen may have certain disclosure and reporting obligations pursuant to applicable federal and state laws and regulations and institutional policies, including, without limitation, the disclosure/reporting of the Grant, and Applicant hereby authorizes Biogen to make such disclosures. Upon Biogen's request, Applicant may be asked to complete and submit to Biogen, interim and final progress or status reports, final budget reconciliation, and transparency reporting information for the Project. Applicant agrees to fully cooperate with Biogen to ensure that Biogen can meet its reporting obligations in a timely manner.

As a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA") and of science industries, the codes adopted by the EFPIA and science industries, including the Swiss Pharma-Kooperations-Kodex (Pharmaceutical Cooperation Code) (Internet link: <a href="www.scienceindustries.ch">www.scienceindustries.ch</a>), apply to Biogen as to many other pharmaceutical companies. These oblige the participating companies to publish on their publicly accessible company web-sites payments in kind as defined in the above codes. To comply with these obligations, Biogen will collect, record and publish information concerning payments in kind to the Applicant in accordance with the following principles.

"Payments in kind" are defined as every direct or indirect transfer of value in cash or in kind or by other means, that can be allocated to the following categories according to the Pharma-Kooperations-Kodex: donations and grants, funding research and development, including but not limited to studies, clinical studies and non-interventional studies, non-monetary benefits in connection with participation in medical training and conferences, including participation/registration fees, sponsorship contracts and travel and subsistence expenses, service and consultancy fees and other payments in kind.

In particular, but not exclusively, the following data is specified as "information" according to the Pharma-Kooperations-Kodex: the sums granted, names and business addresses of the professionals and/or organizations in the health care system, type of non-monetary benefits, the respective reporting periods and the grounds for/purposes of the grant of monetary advantages.

Publication is per calendar year (for the first time in 2016 for payments in kind made in 2015). The data shall remain publicly accessible for at least three (3) years.

# Audit Rights and Reconciliation of Expenses/Evaluation of Activity

The Applicant agrees to verify the manner in which the Grant is used. Within **ninety (90) days** of the completion



of the last activity described in the Grant Application, Applicant shall furnish: 1) a written statement verifying that the Project occurred; 2) a reconciliation of expenditures supported by the Grant as submitted in the Grant Application; and, 3) a final outcomes report or summary of the Project; 4) the aggregated summary results of the activity evaluations, if any.

Applicant must return to Biogen unexpended funds greater than one hundred (100) USD dollars, or any funds not utilized as stated and agreed upon, immediately. If Applicant fails to provide a timely reconciliation and/or fails to return any applicable unused funds, Applicant shall be ineligible to receive a decision on any pending requests until such reconciliation and/or return of funds has been received.

Upon reasonable advance notice, Applicant shall make available to Biogen and its designated representatives and regulatory agencies, during normal business hours, for the purpose of inspection, audit and reproduction, complete copies of financial and other records, including, but not limited to, receipts and invoices, documenting Applicant and each of their permitted subcontractors', expenses and costs related to the Project.

#### **Publicity Rights**

Applicant hereby grants permission to Biogen to publicly disclose all aspects of this Grant, including, but not limited to, the name of the Applicant and the Grant amount.

Biogen hereby grants permission to Applicant to disclose Biogen's role as a funder of this Grant, but Applicant agrees not to utilize Biogen's logo in any such disclosure and not to provide Biogen, in connection with this Grant, with any promotional benefits or forms of recognition that would typically be associated with sponsorship opportunities, as opposed to grants.

## **Data Privacy**

In accordance with applicable data protection laws, Biogen processes Personal Data (meaning any information relating to an identified or identifiable natural person) Applicant may provide to Biogen in order to fulfill and perform its obligations under this Agreement and also to comply with its legal obligations. Where necessary, Biogen may transfer Personal Data to other companies in its group and may also engage third party service providers (e.g. IT service providers) to process Personal Data Applicant may provide on its behalf. Biogen will ensure that all recipients are contractually (e.g. by Standard Contractual Clauses) and/or legally obliged to comply with privacy standards in accordance with data protection law. These transfers may include transfers Biogen retains Personal Data Applicant may provide for no longer than is necessary for the purposes for which it is collected. Data Subjects (as defined below) whose Personal Data Applicant provides to Biogen may contact Biogen if they would like to access Personal Data Applicant may provide or require information about the Personal Data that Biogen holds. They may object to the processing of the Personal Data for legitimate reasons and they may also request the correction or erasure of it. Some of these rights are limited by applicable data protection law and we have the right to collect, process and hold Applicant's personal data to perform our legal obligations. Should they feel it necessary, they also have the right to lodge a complaint with their data protection authority. If Applicant has questions about our processing of Personal Data, Applicant can contact Biogen's Global Privacy Office at <a href="mailto:privacy@biogen.com">privacy@biogen.com</a>.

The Applicant's signature at the end of this Agreement represents his/her consent to the collection, processing and transmission of the Personal Data of the Applicant provided to Biogen, in compliance with applicable data protection laws.

"Data Subject" is a person who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.



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# **Terms & Terminations**

This Agreement may be immediately terminated at any time by Biogen or the Applicant upon at least thirty (30) days advance written notice to the other Party in the event the other Party materially breaches this Agreement. In such event, the non-breaching Party shall notify the Party in breach of such breach in writing.

In the event, that the applicable legislation, jurisdiction or a Government authority decision, in accordance with the Applicant's country, could render this Agreement or any transaction based upon it being found a violation of applicable law or would otherwise have a material adverse effect on one of the Parties if the Agreement would remain in effect, each Party shall have the right to terminate this Agreement and rescind from or not fulfill any of its obligations.

Notwithstanding any liability of the Applicant under applicable law in case of termination by Biogen, Applicant will refund to Biogen the amount of Grant received by Biogen, unless Biogen instructs Applicant to refund a smaller amount. If any portion of the Grant has not been expended or allocated in accordance with the Project at the time of termination or expiration, the Applicant shall consult with Biogen to determine Biogen's wishes for an alternative use of the remaining portion.

#### Miscellaneous

This Agreement including any applicable appendices attached hereto as integral parts of this Agreement constitute the entire Agreement between the Parties with respect to the subject matter hereof and supersede all prior and contemporaneous oral, written and other Agreements between the Parties.

The rights and obligations of the Parties hereunder shall inure to the benefit of, and shall be binding upon, their respective successors and assigns. This Agreement may not be assigned by the Applicant without the prior written consent of Biogen. This Agreement may only be amended in writing, duly signed by the Parties hereto.

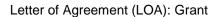
In the event any part of this Agreement shall be held illegal, void or ineffective, the remaining portions hereof shall remain in force and effect. If any of the terms or conditions of this Agreement are in conflict with any applicable laws or rules for professional conduct, then such terms or conditions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform to such laws or rules.

This Agreement constitutes the entire agreement between the Parties relating to the Grant and supersedes all other agreements, express or implied, between the Parties as to its subject matter. This Agreement may be modified only by a writing signed by both Parties which states it is an amendment to this Agreement. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, United States.

#### Counterparts

This Agreement (i) may be signed in counterparts, each of which shall constitute an original and all of which, taken together, shall constitute a single agreement binding on all Parties, and (ii) will be considered executed by a Party when the signature of such Party is delivered physically or by email or facsimile transmission to the other Party or Parties, as appropriate. The Parties agree that any signature delivered by email or facsimile transmission shall have the same force and effect as an original signature.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year last set forth below.





APPLICANT

Pogusined by:

Rep. Stirres Organization's Authorized Signer

Juraj Gallo Name:

Title: ing.

Date: 05-10-2021

Biogen Docusigned by:

Biographic bentative

Rachel McDonnell Name:

Title: Director, Grants Management & Strategic Giving

Date: 05-0ct-2021