**MASTER SERVICES AGREEMENT**

**Made and effective as of the date of the Effective Date**

**by and between:**

**TRB CHEMEDICA INTERNATIONAL S.A.**, a Swiss company with registered office at Route des Jeunes 33bis, 1227 Carouge (GA), Switzerland, on its behalf, and on behalf of any of its parent, subsidiary or Affiliated Company (hereinafter “**TRB**”),

And

**INSTITUTE OF ANIMAL PHYSIOLOGY AND GENETICS CAS, v. v. i. (IAPG)**, a public research institution located at Rumburská 89, 277 21 Liběchov, Czech Republic (hereinafter “**IAPG**”),

TRB and IAPG shall hereinafter also individually be referred to as a “**Party**” and collectively as “**Parties**” to this Agreement.

\* \* \* \* \*

**Whereas**, TRB is a pharmaceutical company specialized in the development, manufacturing and commercialization of pharmaceutical products and medical devices in therapeutic areas such as rheumatology, ophthalmology and neurology;

**Whereas**, TRB has expertise and possesses know-how and proprietary rights with respect to the development and manufacturing of GMP-grade porcine gangliosides active pharmaceutical ingredient (hereinafter “**GM1**”) and pharmaceutical product containing GM1 (“**Product**”);

**Whereas**, IAPG is a public research institution specialized in top-level basic research in physiology, genetics, ecology and evolution on a wide range of topics, from biomedical to biodiversity-oriented, and has launched the Pig Models of Disease Centre (PIGMOD Centre) for the performance of research on the nature of diseases of the nervous system and cancer, with focus on studying the Huntington's disease, spinal cord injury and human melanoma, identification of new biomarkers and validation of therapeutic procedures in these diseases;

**Whereas**, TRB would like to perform certain pre-clinical studies with GM1 (the “**Studies**” as defined herein), to be conducted at IAPG’s PIGMOD Centre;

**Whereas**, TRB would like to entrust IAPG, which accepts, with the performance of Services as defined herein for the conduct of the Studies, in accordance with the applicable laws and regulations, the animal study protocol (“**Protocol**”) and the terms and conditions of this Agreement;

**Now therefore**, in consideration of the mutual covenants and the promises contained herein,

**It has been agreed as follows:**

1. **DEFINITIONS AND INTERPRETATION**
	1. **Definitions.** Unless otherwise expressly indicated in this Agreement, the following terms shall have the following meanings:

“**Affiliate**” or “**Affiliated Company**” of TRB means any entity company, corporation, firm, partnership or other entity which is directly or indirectly Controlling, Controlled or is under common Control with TRB, where “**Control**” means the power, direct or indirect, to direct or cause the direction of the management and policies of such entity, whether by contract, through the by-laws of the aforementioned entities or otherwise.

“**Agreement**” means this agreement, any appendices attached hereto, and any amendments made at a later date by the Parties.

“**Animal**” shall mean any animal used for the purpose of the Studies.

“**Applicable Laws**” means any statute, law (including but not limited to 246/1992 Coll.

ACT of the Czech National Council of 15 April 1992 on the Protection of Animals Against Cruelty), regulation, ordinance, rule, judgment, rule of law, order, decree, ruling, by-law, approval of any Competent Authority, directive (including but not limited to Directive 2010/63/EU on the protection of animals used for scientific purposes), guideline, policy, clearance, requirement or other governmental restriction or any similar form of decision or determination by, or any interpretation or administration having the force of law of any of the foregoing by any competent authority having jurisdiction over the matter in question, including International Council for Harmonisation (“**ICH**”) guidelines and Competent Authorities’ and/or Ethics Committees’ Codes of Practice, applicable to the relevant activities of a Party under this Agreement, as amended from time to time and whether in effect as of the date of this Agreement or at any time thereafter.

“**Codes of Practice**” means the applicable Codes of Practice used by the relevant Competent Authority and/or Ethics Committee and which specify the regulations, guidelines and standards on animal care and use for scientific purposes.

“**Competent Authorities**” means the competent official and regulatory authorities in charge of licensing, approving, registering and/or issuing a notice of compliance pertinent to the performance of clinical and animal studies, manufacturing, marketing, sale, use and/or distribution of pharmaceutical products and/or medical devices.

“**Effective Date**” means the date this Agreement shall become effective and namely the date of signature of the last Party signing this Agreement.

“**Ethics Committee**” means the relevant organism in charge of **(i)** governing the ethical conduct of people whose work involves the use of animals for scientific purposes, and **(ii)** ensuring that all care and use of animals is conducted in compliance with the applicable Code(s) of Practice.

“**GM1**” shall mean the investigational active pharmaceutical ingredient subject of the Studies.

“**IAPG’s Know-How**” shall mean all know-how, Intellectual Property, data and experience owned by IAPG prior to the Effective Date and/or generated outside the context of the performance of the Studies.

“**IAPG’s Results**” shall mean any and all Results arising out of, or in connection with, IAPG’s Know-How, to the extent that such Results do not include the Materials, TRB’s Confidential Information or their use or any application, and are not specific to the Materials and susceptible of application in other products, whether patentable or not.

“**IAPG Studies File**” shall mean the file to be maintained by IAPG in accordance with Applicable Laws, containing any and all documents and data in connection with the Studies.

“**Intellectual Property Rights**” means, collectively, all of the following intangible legal rights, whether or not filed, perfected, registered or recorded and whether now or hereafter existing, filed, issued or acquired: **(i)** inventions, patents, patent disclosures, patent rights, including any and all continuations, continuations-in-part, divisionals, reissues, reexaminations, utility models, industrial designs and design patents or any extensions thereof, **(ii)** rights associated with works of authorship, including without limitation, copyrights, copyright applications and copyright registrations, **(iii)** rights in trademarks, trademark registrations and applications thereof, trade names, service marks, service names, logos, or trade dress, **(iv)** rights relating to the protection of formulae, trade secrets, know-how and Confidential Information, and **(v)** all other intellectual or proprietary rights.

“**Materials**” means **(i)** the agreed quantities of GM1, **(ii)** analytical kits, and **(iii)** antibodies which TRB is to provide to IAPG for the performance of the Studies.

“**Materials IP**” means all Intellectual Property and embodiments thereof as well as know-how including but not limited to formulation, regulatory dossiers, manufacturing know-how and data in connection with GM1 and/or the Materials and/or the Product, owned or Controlled by TRB or its Affiliates as of the Effective Date or thereafter.

“**Material Related Results**” shall mean any and all results arising out of, in connection with, or as a result of the use of Materials and/or TRB’s Confidential Information, irrespective of whether such results are patentable or not, excluding IAPG’s Results.

“**Protocol**” shall mean the description of the Studies established upon common agreement between the Parties, which shall be attached in due course to this Agreement as **Appendix Nr. 1**, and which may be amended as necessary by the Parties upon mutual agreement.

“**Results**” shall mean any and all results (including data and inventions) that are obtained by IAPG arising out of or in connection with the execution of the Studies.

“**Services**” means the activities to be carried out by IAPG in connection with the Studies for and on behalf of TRB which are further specified in **Appendix Nr. 1** and in the relevant Work Order(s).

“**Studies**” shall mean the preclinical investigations to be conducted with GM1, the Materials and the Animals at the Study Site in accordance with the Protocol, the terms and conditions set forth herein, any and all Competent Authorities’ and/or Ethics Committees’ requirements, as well as any and all Applicable Laws.

“**Study Site**” shall mean the research facility where the Studies shall be conducted, and namely IAPG’s PIGMOD Centre.

“**Third Party**” means any person or entity, other than the Parties hereto.

“**Work Order(s)**” means the written document(s) (e.g. quotations) signed by both Parties hereto describing the Services, the applicable timelines and financial terms for which a template Work Order is attached in **Appendix Nr. 2** hereto and which Work Orders shall be attached by reference to this Agreement.

* 1. **Interpretation.** In this Agreement, unless otherwise specified words denoting the singular will include the plural and vice versa and words denoting any gender will include all genders.
1. **SCOPE OF THE AGREEMENT**
	1. **Services.**

TRB hereby entrusts IAPG, which accepts, with the performance of the Services for the conduct of the Studies in accordance with the Protocol, the Work Orders, any and all Applicable Laws, in particular any relevant Codes of Practice, the terms and conditions set forth hereunder, as well as any other instructions provided in due course by TRB to IAPG. For the avoidance of any doubt, the Work Orders shall be subject to and shall be performed in accordance with the terms of this Agreement.

At a minimum, a Work Order shall include and describe the following:

1. The scope of Services, including but not limited to, if applicable, specific responsibilities and deliverables to be provided; and
2. The timelines for the performance of the Services; and
3. The corresponding fees for the Services (detailed quotation) and the relevant invoicing and payment terms.

In the event that either Party requires any revisions or modifications to be made to the content of the Services, such request shall be made in writing to the other Party. Amendments to the Agreement and/or the Services shall be agreed upon in writing and signed by both Parties hereto.

To the extent any terms set forth in a Work Order shall conflict with the terms set forth in this Agreement, the terms of this Agreement shall control, unless the conflicting terms in this Agreement are specifically referenced in the Work Order and stated to be superseded (but then only with respect to the matter so specified).

* 1. **Timelines.**

The Services shall be completed within the timelines set forth in the relevant Work Order. If any of the tasks detailed in the Work Order cannot be completed within the timelines initially agreed upon between the Parties hereto, IAPG shall promptly inform TRB thereof and the Parties shall discuss in good faith in order to adjust the initial planning.

IAPG shall use all reasonable means to fulfill its obligations under this Agreement and to perform the Services subject of the Work Orders.

Notwithstanding the aforesaid, TRB shall be entitled to cancel any tasks or Services to be performed under a Work Order free of charge provided that TRB notifies IAPG thereof at least thirty (30) calendar days before the scheduled beginning of Services or a particular task.

* 1. **Deliverables.**

IAPG shall prepare and maintain complete and accurate written records, accounts, notes, reports and data of the Services in the form suitable to TRB and/or requested by TRB in writing (hereinafter “**Deliverables**”). Any and all Deliverables, except accounting documents, shall be drafted in English. Upon TRB’s request, a written report shall be provided upon completion of a particular task and/or phase specified in a Work Order.

* 1. **Records.**

IAPG shall keep all materials, data, documentation and records pertaining to the Services during the term of this Agreement and for a period of five (5) years from the effective date of termination or expiration of this Agreement, or as otherwise foreseen by Applicable Laws.

Upon expiration of the above-mentioned period and unless otherwise agreed in writing between the Parties, IAPG shall automatically transfer, at TRB’s expense, such material and records to TRB or to any Third Party designated in writing by TRB, except in case TRB confirms in writing that it can be destroyed by IAPG.

* 1. **Publications.**

IAPG is not entitled to make publications of the results and/or data generated and/or prepared at the occasion of the performance of Services for the conduct of the Studies unless approved in writing beforehand by TRB.

* 1. **Publicity.**

Neither Party is entitled to use the name, symbols or marks of the other Party in any advertising or publicity material or make any form of representation or statement in relation to the Studies without the other Party’s prior written approval.

1. **OBLIGATIONS OF THE PARTIES**
	1. **Protocol.**

TRB undertakes to provide the first draft of the Protocol to IAPG. The latter shall review the draft Protocol and provide its comments, if any, to TRB within a timeline agreed upon between the Parties. In consideration of IAPG’s comments and observations on the first draft Protocol, a revised draft shall be prepared in collaboration between the Parties and finalized upon mutual agreement.

* 1. **Submissions to and relations with the Competent Authorities and the Ethics Committee.**

IAPG undertakes to provide its best efforts to obtain and maintain any necessary approval from the relevant Ethics Committee to carry out the Studies in compliance with the Applicable Laws.

The Parties hereby acknowledge that the Studies shall not commence until all necessary approvals from the Ethics Committee have been obtained in writing.

During the term of this Agreement, IAPG shall promptly inform TRB in writing of any and all information, question and/or requirement of the Ethics Committee and the Competent Authorities, if applicable, in connection with the Studies. IAPG shall send any and all replies and/or communication to the Ethics Committee and the Competent Authorities upon TRB’s prior written approval.

* 1. **Selection of Animals.**

IAPG shall use its best efforts to select for the Studies the number of Animals specified in the Protocol, in compliance with the relevant Competent Authority’s or Ethics Committee’s Codes of Practice and fulfilling the inclusion and exclusion criteria within the timelines specified in **Appendix Nr. 1** hereto.

IAPG shall, without any undue delay, inform TRB in writing of any issue in relation to the selection of Animals. In such case, the Parties shall discuss and use their best efforts in order to determine upon common agreement the measures to remediate such issue.

* 1. **Animal Welfare.**

The Parties acknowledge and agree that animal welfare is an important issue for ethical reasons as well as for the sake of quality of studies, and that high standards of animal care should be applied at all times. IAPG represents and warrants to follow all relevant local as well as international standards related to the care, welfare, and ethical treatment of the Animals, and to comply with any and all Ethics Committee’s requirements and Applicable Laws. IAPG shall immediately notify TRB in the event of any issues in relation to animal welfare or bioethical concerns that occur during the conduct of the Studies, and the Parties agree to cooperate to address any such issues and concerns in a diligent manner.

* 1. **Conduct of the Studies.**

IAPG undertakes to perform the Services for the conduct of the Studies in accordance with the Protocol attached as **Appendix Nr. 1** hereto and within the timelines set forth in the relevant Work Orders.

The Studies shall be conducted at IAPG’s Study Site.

Unless otherwise specifically agreed in the relevant Work Order, TRB undertakes to provide IAPG, as soon as possible, with:

1. The Materials;
2. The relevant GM1 information;
3. Any and all information necessary for IAPG to perform its obligations herein.
	1. **Supply and handling of the Materials.**

TRB shall supply to IAPG the Materials in accordance with the terms and conditions set forth in this Agreement in order for IAPG to fulfill its obligations hereunder.

TRB and IAPG shall agree upon the exact date of delivery of the Materials to IAPG. TRB shall deliver the Materials to the Study Site and shall ensure that the Materials are transported to IAPG in appropriate conditions. For the sake of clarity, TRB’s obligation of delivery of Materials hereunder shall be deemed fully fulfilled when the Materials are delivered to the Study Site.

IAPG shall confirm reception of the Materials and notify TRB of any issue regarding the quantity or state of the Materials within twenty-four (24) hours as from the reception of the Materials.

* 1. **Conditions of Use of Materials.**

TRB hereby grants to IAPG a temporary, non-exclusive right to use the Materials for the performance of the Studies, to the exclusion of any other use not specifically agreed upon in writing by and between the Parties. Consequently, IAPG is not entitled to use the Materials for any other purpose than the performance of the Studies or within a scope exceeding the perimeter of the Studies without TRB’s specific prior and written consent.

Except as otherwise provided in this Agreement, the Materials may not be used for or in relation to any other research than the Studies conducted by IAPG, in particular when such research is involving the participation of a Third Party. Under no circumstances may IAPG use the Materials for any commercial purpose.

The Materials shall be used in accordance with the highest standards of skill and care and IAPG shall ensure compliance with any Applicable Laws governing the handling, storage and use of the Materials. IAPG agrees not to use the Materials for research involving human subjects or clinical trials without TRB’s prior written consent.

All use of the Materials by IAPG in the frame of the Studies shall be carried out by IAPG’s qualified collaborators on a need-to-know basis and subject to the provisions of Section 7 – Confidentiality of this Agreement.

Except to the extent necessary for the performance of the Studies, IAPG shall not otherwise analyze or have other analyzes performed on the Materials. IAPG shall not disassemble or reverse engineer Materials or any portions thereof to determine their chemical composition, microscopic structure or method of manufacturing, without TRB’s specific and prior written consent.

IAPG is not allowed to transport, ship or send the Materials to a destination other than the Study Site as defined hereinabove.

In the event it appears that modifications or derivatives have been made on the Materials (in whole or in part), IAPG shall immediately notify TRB of this operation and items resulting from such modification or alteration of the Materials shall be provided to TRB promptly upon TRB’s request.

* 1. **Materials storage.**

IAPG undertakes to hold an accurate inventory of the Materials at all times. Upon TRB’s reasonable request, IAPG shall promptly communicate such inventory to TRB.

IAPG undertakes to receive, store and handle the Materials in appropriate conditions and in compliance with any and all Applicable Laws.

* 1. **IAPG Studies File and reports.**

IAPG shall prepare and maintain complete and accurate study files and other documents and reports required by Applicable Laws, including (but not limited to) written records, accounts, notes, reports and data of the Studies, such as but not limited to the IAPG Studies File.

The IAPG Studies File, as well as any and all other documents and reports required by Applicable Laws, shall be readily available at all times in case of inspection by the Competent Authorities and/or the Ethics Committee and/or audits conducted by TRB, or any Third Party mandated by TRB.

IAPG shall retain, in full compliance with the Applicable Laws, during the term of this Agreement and for a duration in consideration of Applicable Laws, any and all written records, accounts, notes, reports and data generated at the occasion of the performance of the Studies.

Upon expiration of the above-mentioned period, and unless otherwise agreed in writing between the Parties, IAPG shall automatically transfer, at TRB’s expense, such material and records to TRB or to any Third Party designated in writing by TRB, except in case TRB confirms in writing that it can be destroyed by IAPG.

* 1. **Departures and violation of the Protocol.**

IAPG may not implement any deviation from, or changes of, the Protocol without TRB’s written agreement, except where necessary to eliminate any immediate hazard(s) to Animals and/or IAPG’s qualified collaborators, or when the change(s) involves only logistical or administrative aspects of the Studies (e.g. change in monitor(s), change of telephone number(s)).

IAPG may implement a deviation from, or a change of, the Protocol in order to eliminate any immediate hazard(s) to Animals and/or IAPG’s qualified collaborators. As soon as reasonably possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed Protocol amendment(s) should be submitted to TRB for agreement.

IAPG shall promptly report any deviation from or change of the Protocol to TRB, as well as any intention to deviate from the Protocol, even if such deviation is unavoidable.

* 1. **Unexpected adverse events.**

IAPG shall report to TRB any unexpected adverse events occurring during the Studies within the timelines defined in the Competent Authority’s and/or Ethics Committee’s Code of Practice and the Protocol, and shall cooperate with TRB, to the extent applicable, for the reporting of any unexpected adverse events to the Competent Authority and/or the Ethics Committee and as required by TRB.

Detailed/ specific terms and conditions pertaining to the collection, storage, transmission and reporting requirements of the safety information generated during the Studies shall be performed in accordance with the Protocol and the Competent Authority’s and/or Ethics Committee’s Code of Practice.

IAPG shall take all necessary measures, in consultation with TRB, to protect Animals at risk following the occurrence or discovery of an unexpected adverse event.

* 1. **Compliance with Applicable Laws.**

IAPG shall perform the Services for the conduct of the Studies in accordance with the terms of this Agreement and in compliance with any and all Applicable Laws and generally accepted standards in the industry or as otherwise specifically agreed upon by the Parties in writing.

Except as otherwise specifically stated herein, IAPG shall not subcontract the performance of the Services to any Third Party without TRB’s specific prior written consent. For the avoidance of any doubt, IAPG is and remains at all times fully responsible and liable for its subcontractors’ acts, errors and/or omissions.

1. **AUDITS AND INSPECTIONS**
	1. **Audits.**

At any time during the term of this Agreement, TRB and/or any Third Party designated by TRB shall have the right to perform free of charge on-site or remote audits of IAPG upon thirty (30) days prior written notice, and during regular working hours.

Notwithstanding the foregoing, TRB and/or any Third Party designated by TRB shall have the right to perform free of charge on-site ‘for cause’ audits of IAPG without limitation of frequency, upon reasonable prior written notice, and during regular working hours.

IAPG shall guarantee access to the auditors during any and all compliance audits to any and all premises, documents and equipment involved in the Services and/or the Studies.

IAPG undertakes to provide its best efforts to carry out any and all actions stated in any corrective action and preventive action plans established by the Parties upon completion of an audit.

* 1. **Inspections.**

IAPG shall promptly provide TRB with the outcome of any and all inspections of IAPG by the Competent Authorities and/or the Ethics Committee.

1. **FINANCIALS**

TRB shall bear any and all costs related to the conduct of the Studies and the performance of the Services. Unless otherwise agreed in writing, the total costs for the conduct and completion of the Studies and provisions of related Services are specified in **Appendix Nr. 1** and further detailed in the relevant Work Orders.

Payment of the Studies’ costs and Services fees shall be made in accordance with the payment terms in the Work Orders.

1. **DATA, IP OWNERSHIP AND STUDIES RESULTS**
	1. IAPG hereby specifically acknowledges that TRB is the sole holder of any and all rights pertaining to the Studies and/or GM1 and/or the Materials.
	2. No right, title or interest is granted, whether expressly or by implication, to any technology or intellectual property rights owned by either Party other than pursuant to the terms of this Agreement. Each Party hereby reserves all rights not expressly granted under this Agreement.
	3. All the Materials and all related intellectual property rights shall remain the property of TRB, and no license on the Materials, Materials IP and Confidential Information is granted to IAPG under this Agreement, other than to use such Materials and Confidential Information for the Studies.
	4. The Parties hereby expressly agree that the right to use the Materials, Materials IP and the Confidential Information as granted under this Agreement may not, under any circumstances, be construed as expressly or implicitly providing IAPG with any ownership right or title, or option or license, whatsoever, over the Materials, Materials IP and TRB’s Confidential Information.
	5. The intellectual property generated during the Studies by IAPG other than in connection with the Materials IP will be the property of IAPG. For the sake of clarity, IAPG shall be the exclusive owner of IAPG’s Know-How and IAPG’s Results to the extent that such IAPG’s Results do not contain Materials and/or Materials Related Results. IAPG shall remain the owner of all its knowledge, concepts, research results, inventions, software and other information obtained before, after or outside the performance of this Agreement.
	6. Any documents and data provided by TRB to IAPG regarding the Services and/or the Studies and/or the Materials prepared by IAPG at the occasion of the performance of its obligations hereunder (hereinafter collectively referred to as “**Services Data**”) shall only be used by IAPG in order to perform its obligations hereunder. Any Services Data, whether or not generated by IAPG, is and shall remain the exclusive property of TRB and nothing contained in this Agreement shall be construed as granting IAPG any rights on such Services Data. It is hereby specifically stated that IAPG may not apply for any intellectual property rights on the Studies and/or the Materials and/or the Services Data without TRB’s explicit prior written agreement.
	7. Any improvement or invention, whether or not patentable, conceived or reduced to practice by IAPG in the frame of this Agreement shall become the sole and exclusive property of TRB (hereinafter referred to as the “**Improvements**”). IAPG hereby assigns and undertakes to cause its collaborators to assign to TRB all rights, title and interest in and to any such Improvements. TRB shall be the sole owner of all the rights to such Improvements in any form and in all fields of use known or hereafter existing. In the event TRB decides to file one or more patent applications covering any such Improvements, IAPG shall, at TRB’s request and expense, assist TRB in the preparation and prosecution of such patent application(s) and shall execute all documents deemed necessary by TRB for the filing thereof and/or the vesting in TRB of all title thereto.
	8. If any claim, action, cause of action or demand is asserted against IAPG and/or TRB based upon the contention that the Studies and/or GM1 and/or the Materials infringes any intellectual property right of any Third Party, the Party receiving the notice of such infringement action shall promptly give written notice to the other of the existence of such infringement action. The Parties agree to collaborate in order to defend their interests and to keep each other informed about all legal, technical and commercial information which may be necessary in such a defence.
2. **CONFIDENTIALITY**
	1. Shall be deemed confidential any information in whatever form (written, oral, visual and electronic, including but not limited to samples) related to the Studies, the Materials and in particular GM1, TRB’s products and in particular the Product, the Services and either Party’s business in general, including but not limited to the Services Data, the IAPG Studies File, the Improvements as well as know-how, technical, scientific, business, financial and other information, data, software, drawings, specifications, methods, models, plans, designs, materials, patent applications, product applications, processes, manufacturing technology and alike, communicated by one Party to the other Party (hereafter referred to as “**Confidential Information**”).

The Party disclosing Confidential Information shall hereinafter be referred to as the “**Disclosing Party**”, and the Party receiving such Confidential Information shall hereinafter be referred to as the “**Receiving Party**”.

* 1. The obligations of confidentiality will not apply to Confidential Information for which the Receiving Party can show by written records that this information **(a)** is or became publicly known through no act, omission or breach of this Section 7 by the Receiving Party; or **(b)** was already in the Receiving Party’s possession in written form prior to disclosure by the Disclosing Party; or **(c)** was received by the Receiving Party from a Third Party who did not obtain such information directly or indirectly from the Disclosing Party or who was duly authorized to disclose it; or **(d)** is required to be disclosed by valid written judicial order, provided reasonable advance notice is given to the Disclosing Party so that it may have the opportunity to intercede in such process to obtain an appropriate protective order or other reliable assurance that confidential treatment shall be accorded to the Confidential Information.
	2. The Receiving Party will not use any part of the Confidential Information for any purpose other than to fulfil their obligations under this Agreement. Notwithstanding the aforesaid, TRB shall be free to disclose the Confidential Information received from IAPG **(i)** to any Competent Authority and/or **(ii)** to the Ethics Committee and/or **(iii)** to any Third Party provided such disclosure is necessary for the use, registration, marketing, distribution and/or promotion of TRB’s products.

It is hereby specifically stated that the provisions of this Section 7 shall survive the termination of the Agreement and shall remain valid and enforceable for a period of ten (10) years after the termination or non-renewal of this Agreement.

1. **TERM**

This Agreement will commence on the Effective Date and shall remain in full force and effect until full completion of the Studies and related Services unless terminated earlier pursuant to Section 9 below.

1. **TERMINATION**
	1. This Agreement may be terminated at any time by registered written notice to the other Party:
	2. By either Party with immediate effect in case of material breach of any of its obligations hereunder by the other Party not having been remedied within sixty (60) days after receiving written notice requiring such breach to be remedied; or
	3. By either Party with immediate effect in case of occurrence of Force Majeure following the terms set forth in Section 10 hereafter; or
	4. By TRB with immediate effect if IAPG is prevented from performing the Services in connection with the Studies by reason of legal, administrative, regulatory or judicial decision; or
	5. By TRB with immediate effect if TRB decides to stop the Studies for commercial, technical, strategic, safety or efficacy reasons.
	6. No claims for indemnity or compensation can be lodged under the law of this Agreement solely by reason of termination of the present Agreement, save where these claims are based on breach of contract by one of the Parties hereto.
	7. Upon any termination of this Agreement and except as otherwise specifically stated otherwise in this Agreement:
2. IAPG shall, in accordance with Section 3.9. hereunder, keep all GM1 information, Product information, data, documentation and records (including but not limited to the Services Data and the IAPG Studies File) pertaining to the Studies during the term of this Agreement and for a period required by Applicable Laws. Upon expiration of the aforementioned period, and unless otherwise agreed in writing between the Parties, IAPG shall automatically transfer, at TRB’s expense, such records to TRB except in case TRB confirms in writing it can be destroyed by IAPG.
3. Unless otherwise agreed in writing, each Party shall immediately cease to use the other Party’s Confidential Information. Furthermore and except as otherwise specifically stated herein, each Party shall, as per the other Party’s written request, either **(a)** return, or **(b)** destroy the other Party’s Confidential Information disclosed under this Agreement within one (1) month after expiry or termination of this Agreement, except for copies the Parties are legally bound to retain for documentation purposes.
4. IAPG shall ensure, at TRB’s costs, a proper safety follow-up of the Animals to which GM1 has already been administered before the effective date of termination, in accordance with the Protocol and the Applicable Laws.
	1. Upon termination of this Agreement, TRB shall pay IAPG for the Services already performed before the effective date of termination and for the cost of Animals’ follow-up to be performed upon termination of this Agreement in accordance with the payment terms specified in the relevant Work Order(s). Such payment shall be made by TRB upon full completion by IAPG of its obligations set forth in Section 9.3. here-above.
	2. This Section 9 shall remain in force and effect after termination of the present Agreement until all obligations which occurred under this Section 9 are fulfilled.
5. **FORCE MAJEURE**
	1. Neither Party shall be held liable for failure to perform or delay in performing obligations set forth in this Agreement, and neither Party shall be deemed in breach or default of its obligations, if, to the extent and for so long as, such failure, delay, breach or default is due to an event of Force Majeure. The affected Party shall notify the other Party immediately upon the occurrence of the Force Majeure event and shall nevertheless use its best commercially reasonable efforts to fulfill its obligations hereunder.
	2. For the purpose of this Agreement, Force Majeure as used herein shall mean any cause(s) reasonably beyond the control of the affected Party without its fault or negligence, including without limitation, acts of God; acts of war; terrorism; riot or civil commotion; acts of a governmental body or agency including but not limited to in case of epidemic or pandemic; fire, flood or storm; failure of public utilities or of carriers.
	3. If such Force Majeure event prevents either Party from fulfilling its obligations under this Agreement for more than ninety (90) days, then the other Party shall have the right to terminate this Agreement immediately in accordance with the provisions of Section 9.1. (b) here-above.
6. **LIABILITY/ INDEMNIFICATION – LIMITATION OF LIABILITY**
	1. **Liability/ Indemnification.**

Each Party shall indemnify and hold harmless the other Party, its Affiliates, directors, officers, employees and agents from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including but not limited to reasonable attorneys’ fees) arising out of or resulting from **(a)** any breach of its representations, warranties or obligations set forth in this Agreement, or **(b)** any negligent or willful misconduct in the performance of this Agreement.

TRB shall indemnify and hold harmless IAPG and its collaborators from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including but not limited to reasonable attorneys’ fees) arising out of or resulting from injury or death of Animals due to natural causes following the administration and/or use of GM1 during or as a result of or in connection with the Services.

* 1. **Limitation of Liability.** Under no circumstances shall either Party be liable to the other Party for loss of revenues, loss of profits, loss of business or consequential, indirect, exemplary, special or punitive damages of any nature, whether such liability is asserted on the basis of contract, tort (including negligence or strict liability) or otherwise, and whether or not the possibility of such damages is foreseeable; provided that this exclusion shall not apply to **(i)** a breach of a Party’s confidentiality obligations, and/or **(ii)** a Party’s gross negligence or willful misconduct and/or **(iii)** injury or death of Animals involved in the Services to the extent death was not caused by administration of GM1 or performance of the Services and/or **(iv)** any matter for which it would be unlawful for such Party to exclude or attempt to exclude its liability.
1. **INSURANCE**

Each Party represents that it has and shall maintain throughout the term of this Agreement an appropriate insurance policy covering its obligations hereunder. A certificate evidencing such policy and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability shall be provided by either Party to the other Party upon request.

1. **GENERAL DECLARATIONS, WARRANTIES AND COMMITMENTS**
	1. Each Party represents and warrants to the other Party as follows, which representations and warranties shall be true at the Effective Date and throughout the term of this Agreement:
2. It has full corporate power and authority and has taken all corporate actions necessary to enter into and perform this Agreement; and
3. No contracts, commitments or agreements of any nature exist, and none will be entered into during the term of this Agreement, that impair or inhibit its ability to perform its obligations hereunder; and
4. No judgment, decree, order or award of any board, tribunal, court, governmental body, including any Competent Authority or arbitrator having jurisdiction over it exists, that impairs or inhibits its ability to perform its obligations hereunder; and
5. To conduct its activities in a manner that will reflect favorably at all times on the other Party and its reputation and not participate (alone or otherwise) in any illegal, deceptive or unethical advertising or other unfair practices, and
6. To diligently perform all of its obligations hereunder.
	1. IAPG represents and warrants to TRB as follows:
7. It has the professional skills, expertise and knowledge to perform the Services, and
8. It is duly authorized to conduct animal studies, and in particular the Studies, and, to this end, declares that it has obtained and undertakes to maintain during the entire term of this Agreement any and all necessary licenses, certifications, permissions, authorizations, consents and permits with respect to any and all Applicable Laws and any Competent Authorities’ and Ethics Committee’s requirements needed to carry out its obligations hereunder. IAPG undertakes to provide TRB with a copy of any such necessary authorizations upon TRB’s request, and
9. That **(i)** neither IAPG nor any of IAPG’s collaborators involved in the conduct of the Studies has been debarred by any relevant administration; **(ii)** no debarred person will be employed by IAPG for the conduct of the Studies during the entire term of this Agreement; **(iii)** should IAPG become aware that IAPG and/or any of IAPG’s collaborators involved in the conduct of the Studies is, or is in the process of, being debarred, IAPG shall immediately notify TRB, and
10. To ensure that the Study Site is in compliance with any and all Applicable Laws and Ethics Committee’s requirements.
	1. **Processing of Personal Data.**
11. The Parties agree that each will comply with their respective obligations as required under the provisions of Applicable Laws on data protection and privacy, including without limitation the EU Regulation 2016/679 (the “**General Data Protection Regulation**” or “**GDPR**”) and the Swiss “**Federal Act on Data Protection**” or “**nFADP**”. In the event a Party (the “**Processing Party**”) is to process personal data on behalf of the other Party (the “**Data Controller**”), the Parties shall enter into a separate Personal Data Processor Agreement, in a form provided by TRB.
12. GDPR requires that TRB provides IAPG and/or its representatives notice that TRB and its group companies may use IAPG’s and/or such representatives’ personal data provided in this Agreement for administration, reimbursement, and internal evaluation purposes. TRB will process the personal data to the extent necessary to fulfil TRB’s duties under this Agreement and for the purpose of TRB’s legitimate interest as contractor. TRB may share the representatives’ personal data within the TRB group and with TRB’s service providers and agents. Such sharing may include transfer to third countries, i.e. countries outside the EU/EEA area. When transferring the representatives’ personal data to third countries, TRB will ensure that the transfer is subject to appropriate safeguards and that the representatives’ rights are protected. Typically, TRB will enter into standard contractual clauses adopted by the EU Commission with companies in third countries receiving personal data from TRB. TRB applies different retention periods for different categories of personal data. When processing of the representatives’ personal data is no longer necessary in relation to the purpose for which it was collected, TRB will erase the personal data. The representatives have the right to access the personal data that TRB processes concerning the representatives and to request that TRB rectifies any inaccurate personal data and, under certain circumstances, request erasure and/or restriction of processing of the personal data. The representatives have the right to object to processing and to receive the processed personal data in a structured, commonly used and machine-readable format and have the right to transmit that data to another controller. The representatives also have the right to lodge a complaint to the local supervisory authority regarding how TRB processes such representatives’ personal data. IAPG undertakes to share the information provided under this Section 13 with all representatives engaged by or on its behalf in connection with this Agreement and whose personal data will be shared with TRB.
13. **ASSIGNMENT**

The Parties undertake not to transfer the present Agreement or any obligations thereof to any Third Party without the prior written consent of the other Party, except if such assignment arises under a transaction in which the assigning Party is selling its entire business or a substantial part of business to which this Agreement relates or that Party is being acquired or merging with a Third Party.

This Agreement will be binding upon and inure to the benefit of any Affiliates, subsidiaries, and successors and/or permitted assignees of a Party hereto.

1. **GOVERNING LAW / JURISDICTION**

This Agreement shall be governed by and construed in all respects in accordance with the laws of Switzerland, notwithstanding any conflicts of law provisions.

In the event of any dispute arising out of or in connection with the execution or interpretation of this Agreement, the authorized representatives of the Parties shall meet and seek to resolve in good faith such dispute amicably within a period of sixty (60) days from the first notification of a dispute.

In case the Parties fail to settle the dispute amicably within the above stated term of sixty (60) days, any proceeding under or related to this Agreement shall be brought solely and exclusively in the competent court of Geneva, Switzerland, and the Parties expressly agree to the exclusive venue and jurisdiction of such courts.

1. **FINAL PROVISIONS**
	1. **Notices.** Any notices required or permitted to be given under any of the provisions of this Agreement shall be made in writing either through email or registered mail, with acknowledgment of receipt. Notices shall be deemed to be served on and received by the other Party on the next day of transmission if sent through email and on the fifth day from date of dispatch if sent through registered mail.
	2. **Independent Contractor.** The relationship hereby established between the Parties is solely that of independent contractors; this Agreement shall not create an agency, partnership, joint venture, or employer/ employee relationship, and nothing hereunder shall be deemed to authorize either Party to act for, represent, or bind the other except as expressly provided in this Agreement.
	3. **Entire Agreement.** This Agreement, together with any appendices hereto, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supersedes, merges, terminates and otherwise renders null and void (a) any and all prior agreements, understandings, and communications, written or oral, with respect thereto.

Except as otherwise expressly agreed in writing by the Parties hereto, to the extent that any appendix or any document issued in connection with the Agreement contains terms or conditions that conflict with provisions of this Agreement, then such conflicting terms or conditions of such appendix or such document shall be deemed null and void, and the provisions of the Agreement shall control.

* 1. **Amendments.** Except as otherwise provided expressly herein, no modification, amendment, supplement or waiver of any of the provisions of this Agreement shall be valid unless in writing signed by both Parties hereto.
	2. **No Waiver.** The failure of either Party at any time to require performance by the other Party of any provision of this Agreement shall in no way affect the right of such Party to require performance of that provision, and any waiver by either Party of any breach of any provision of this Agreement shall not be construed as a waiver of any continuing or succeeding breach of such provision, a waiver of the provision itself, or a waiver of any right under this Agreement.
	3. **Severability.** The validity of this Agreement as a whole shall not be affected by any of its provisions being or becoming invalid or unenforceable for any reason whatsoever, except to the extent necessary to avoid an unjust or inequitable result.
	4. **Survival.** Provisions of the Agreement which by their nature should apply beyond their terms will remain in force after any termination or expiration of this Agreement.
	5. **Headings.** The headings and captions contained herein are for convenience only and not for interpretation of the Agreement.
	6. **Language.** This Agreement has been established in English language. The language in all the Agreement shall be in all cases constructed simply according to its fair meaning and not strictly for or against of the Parties.

**IN WITNESS WHEREOF** the Parties hereto have caused this Agreement in duplicate originals to be entered into by their duly authorized representatives as of the Effective Date.

**TRB CHEMEDICA INSTITUTE OF ANIMAL PHYSIOLOGY**

**INTERNATIONAL S.A. AND GENETICS CAS, v. v. i. (IAPG)**

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By: Alessandro Di Napoli By: Ing. Michal Kubelka, CSc.

Title: President Title: Director

Date: 25. 4. 2024 Date: 17. 5. 2024

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

By: Dr. Leila Nobs, PhD

Title: Corporate Scientific Director/

 Responsible Person

Date: 24. 4. 2024

**APPENDIX Nr. 1 – PROTOCOL**

**Attached to and forming part of the Master Services Agreement**

**effective as of the Effective Date**

**APPENDIX Nr. 2 – WORK ORDERS**

**Attached to and forming part of the Master Services Agreement**

**effective as of the Effective Date.**