

CLINICAL STUDY AGREEMENT

This agreement is made and effective as of the date of **1st October 2016** (the "Effective Date") by and between:

Greiner Bio-One GmbH, having its legal office at [REDACTED]
(hereinafter referred to as "GBO")

And

Faculty Hospital in Pilsen, represented [REDACTED]

(hereinafter referred to as "PARTNER")

And

[REDACTED]
(hereinafter referred to as "STUDY LEADER")

-hereinafter together referred to as "Parties" and each as a "Party"-

PREAMBLE

WHEREAS, GBO has agreed to provide funding and support to PARTNER to conduct a clinical trial ("Study") as investigator according to a study plan [REDACTED] and any related amendments (the "Plan") entitled [REDACTED] attached hereto as Appendix A and incorporated herein by reference.

WHEREAS, PARTNER is equipped to undertake the Study under its own responsibility and under the direction of its employee [REDACTED] ("STUDY LEADER"), and PARTNER has agreed to perform the Study as investigator, on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants expressed herein, the Parties agree as follows:

1. Performance of Study

- 1.1 PARTNER agrees to use its best efforts and professional expertise to perform the Study in accordance with the Plan, including any subsequent Plan amendments, all applicable legal and regulatory requirements and in accordance with the terms and conditions of this Agreement.
- 1.2 The PARTNER retains the sole and complete regulatory responsibility as investigator of the Study, according to the applicable law.
- 1.3 In the event that STUDY LEADER becomes no longer affiliated with PARTNER, PARTNER shall provide written notice to GBO within three (3) weeks of such event. In such case, PARTNER shall designate a new, equally qualified STUDY LEADER and inform GBO thereof in writing.

2 Ethics Committee (EC)

- 2.1 PARTNER shall be responsible for obtaining approval of the Plan and its amendments, informed consent form, Study recruitment procedures (e.g. advertisements, financial compensation) and any other relevant documents in connection with the Study, from the competent Ethics Committee ("EC") prior to commencement of the Study. In the event the EC requires changes in the Plan or informed consent form, GBO will be informed.
- 2.2 PARTNER shall be responsible for ensuring that the informed consent form is signed by or on behalf of each human subject before the first Study related procedure. This informed consent document shall be the document approved by the EC, prior to the subject's participation in the Study.
- 2.3 PARTNER shall be responsible for fulfilling all other authorization formalities related to the conduct of the Study (such as submitting a clinical trial application) and if required, for obtaining the written authorization from the competent health authorities prior to commencement of the Study.

3 Adverse Event Reporting

- 3.1 As the sponsor of the Study, the PARTNER shall be solely responsible for complying, within the required timelines, with any safety reporting obligation towards the competent Health Authorities and the EC, as defined in the applicable laws and regulations.

4 Financial Contribution

- 4.1 As support for the Study, GBO will pay to PARTNER a financial compensation of [REDACTED] per [REDACTED] as required by the Plan, inclusive of overhead and exclusive of VAT (the "Financial Contribution").
- 4.2 Payment shall be made based on the actual completed [REDACTED] and procedure as required by the Plan, by the PARTNER. It is determined that there is a maximum of 100 study participants in this Study.

- 4.3 GBO shall pay invoice within thirty (30) days of receipt of the invoice. PARTNER will issue an invoice after the final study report has sent to GBO.
- 4.4 In case of early termination of this contract GBO is not obliged to may any further payment to the PARTNER.

5 Reporting of Results

- 5.1 PARTNER shall issue to GBO a final study report with a copy of all of the "Results" (defined as all information, know-how, results, inventions and other intellectual property identified or first reduced to practice or writing in the course of the Study as reported in accordance with this article 5), excluding any "Background" (defined as any information, techniques, know-how and materials regardless of the form or medium in which they are disclosed or stored that is provided by one Party to the other for use in the Study whether before or after the date of this Agreement), within ninety (90) days following (a) completion of the Study or (b) termination of this Agreement. Reports hereunder shall be sent to:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6 Compliance with Applicable Laws

- 6.1 PARTNER will conduct the Study and maintain records and data during and after the term of this Agreement in compliance with all applicable legal and regulatory requirements.
- 6.2 The Parties agree that the collection, processing and disclosure of personal data, such as patient health and medical information, and personal data related to any investigational staff (e.g., name, hospital or clinic address and phone number, curriculum vitae) (collectively, the "Data") is subject to compliance with applicable personal data protection and security laws and regulations. When collecting and processing personal data, PARTNER agrees to take appropriate measures to safeguard these data, to maintain the confidentiality of patient health and medical information, to properly inform the concerned data subjects about the collection and processing of their personal data, to grant data subjects reasonable access to their personal data and to prevent access by unauthorized persons.
- 6.3 After completion of the Study the Data and Results may be published by the Partner only after written consent of GBO.

7 Ownership - Confidentiality

- 7.1 All Data and Results, whether protected under intellectual property right or not, shall remain wholly and entirely the property of GBO, which may utilize the Results in any way it deems appropriate,

subject to and in accordance with applicable privacy laws.

- 7.2 The PARTNER guarantees that no third party intellectual property rights exist that might interfere with or prevent GBO from using Data and Results as contemplated by the Agreement and that no additional licenses, permissions, consents or payments with regard to third party intellectual property rights (including payments to collecting societies) are necessary in order for GBO to use the Data and Results as contemplated by the Agreement. The PARTNER shall fully indemnify and hold harmless GBO and/or its Affiliates (incl. their representatives, employees and/or agents) from and against any and all actions, demands, costs, charges, losses, claims and expenses suffered or incurred by GBO and/or its Affiliates (incl. their representatives, employees and/or agents) arising from any infringement or alleged infringement of any third party intellectual property rights.
- 7.3 All Background of the other Party and any other information concerning the Study supplied by one of the Parties to the other Party and not previously published (the "Confidential Information") are considered confidential and shall remain the sole property of the disclosing party. Both during and after the term of this Agreement, each Party will use diligent efforts to maintain in confidence and use only for the purposes contemplated in this Agreement information which is identified in the preceding sentence as confidential or which a reasonable person would conclude is the confidential and proprietary property of the disclosing party and which is disclosed by the disclosing party to the receiving party. The preceding obligation shall not apply to any information (a) which has been published through no fault of the receiving party, (b) which the disclosing party agrees in writing, may be used or disclosed, (c) which is published in accordance with article 7.3, or (d) that is developed independently at the receiving party by persons who had no direct or indirect access to Confidential Information, as shown by contemporaneous written records.

8 Insurance

- 8.1 It will be guaranteed that all Study participants are insured during, in conformance with applicable legal and regulatory requirements as well as comprehensive and professional liability insurance of reasonable policy limits, the performance of the Study (and following termination of the Study to cover any claims arising from the Study). The costs for participant insurance will be borne by GBO.

9 Warranties and Indemnification

- 9.1 PARTNER, being the investigator, agrees that neither GBO, nor any of its affiliates or subsidiaries, their respective officers, directors, or employees will bear any responsibility or liability for claims, losses, injuries, or other damages arising under this Agreement and the related Study, research, and/or meetings or publications regarding same, and shall fully indemnify and hold harmless GBO in this respect. GBO shall have no obligation of indemnification hereunder for any loss or damages arising out of the negligence or willful misconduct or failure to act of STUDY LEADER, PARTNER, their officers, agents, and/or employees in connection with the conduct of the Study.
- 9.2 Neither Party accepts any liability for any use which may be made by the other Party, nor for any reliance which may be placed by that other Party on any Results, Background, materials nor for

advice or information given in connection with any Results.

- 9.3 Except as expressly stated in this Agreement, the aggregate liability of each Party to the other arising in any other way out of the subject matter of this Agreement, the Study and the Results, will not exceed in total the Financial Compensation, and will not extend to any indirect damages or losses (for instance, loss of profits, loss of revenue, loss of data, loss of contracts or opportunity), even if the Party bringing the claim has advised the other of the possibility of those losses, or if they were within the other Party's contemplation.

10 Term and Termination

- 10.1 The term of this Agreement shall begin on the Effective Date stated above and shall end automatically on **31th December 2016**, or until earlier termination as herein provided.
- 10.2 This Agreement may be terminated by each Party at any time in the exercise of its reasonable discretion upon two (2) weeks prior written notice to the other Party. Upon such termination, PARTNER shall immediately notify other Study sites of such termination. Reasons for termination of this Agreement may include but are not limited to breach of contract by the other Party, e.g. in case of non-payment of the Financial Contribution set forth in article 4. In such case, PARTNER will provide GBO with the study report referred to in article 5.1 containing the Results obtained up to the termination (if any).
- 10.3 Notwithstanding the above, PARTNER may immediately terminate this Agreement and require that the Study be stopped if, within its reasonable judgment, such immediate termination is necessary based upon considerations of patient safety. This Agreement shall also automatically terminate if the authorization and approval to conduct the Study is rejected or withdrawn by the competent EC or regulatory authority. In this case, the Parties shall discuss in good faith the refunding of the Financial Contribution to GBO.
- 10.4 Upon early termination of this Agreement under article 10.2 or 10.3, PARTNER agrees to promptly terminate conduct of the Study to the extent medically permissible for any patients.
- 10.5 In case the Agreement or Study is early terminated by the PARTNER, PARTNER agrees to inform GBO in writing, outlying the reasons for such earlier termination.
- 10.6 The provisions of articles 6, 7, 9, 10 and 12 shall survive termination of this Agreement.

11 Force Majeure

- 11.1 If the performance by either Party of any of its obligations under this Agreement (except a payment obligation) is delayed or prevented by circumstances beyond its reasonable control, that Party will not be in breach of this Agreement because of that delay in performance. However, if the delay in performance is more than three (3) months, the other Party may terminate this Agreement with immediate effect by giving written notice to the other Party.

12 General

- 12.1 **Notices:** except of any operational communications and progress reporting as stipulated in article 5, all communication regarding this Agreement must be in writing and addressed to:

Greiner Bio-One GmbH



Faculty Hospital in Pilsen



- 12.2 **Illegal/unenforceable provisions:** If the whole or any part of any provision of this Agreement is void or unenforceable in any jurisdiction, the other provisions of this Agreement, and the rest of the void or unenforceable provision, will continue in force in that jurisdiction, and the validity and enforceability of that provision in any other jurisdiction will not be affected. The Parties shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the Parties.
- 12.3 **Waiver of rights:** If a Party fails to enforce, or delays in enforcing, an obligation of the other Party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.
- 12.4 **No agency:** Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the Parties, or the relationship between them of principal and agent. Neither Party has any authority to make any representation or commitment, or to incur any liability, on behalf of the other.
- 12.5 **Entire agreement:** This Agreement constitutes the entire agreement between the Parties relating to its subject matter and supersedes all prior arrangements, understandings, representation and communications, oral or written with respect to the subject matter.
- 12.6 **Amendments:** No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each Party's representative.
- 12.7 **Compliance:** It is expressly agreed that this Agreement has no relation to any potential purchase of MD- or IVD-products from GBO by STUDY LEADER, PARTNER, their officers, agents, and/or employees.
- 12.8 **Governing law:** This Agreement is governed by, and is to be construed in accordance with Czech Law, excluding any laws of conflict law. This Agreement shall be governed and enforced under the principles and laws of the Czech Republic. The Parties agree that all disputes and

claims arising from this Agreement or in accordance with it, and any breaches of this Agreement that cannot be settled amicably, shall be resolved by the courts of Czech Republic which have jurisdiction to decide any questions related to this Agreement.

- 12.9 None of the Parties shall use the name of any other Party for promotional purposes without prior written consent of the Party whose name is proposed to be used, nor shall either Party disclose the existence or substance of this Agreement except as required by law.
- 12.10 The Agreement is drawn up in English and in Czech languages whereas both versions are intended to consist of and exist as the same Agreement; provided, however, that the Czech language version of this Agreement shall control in the event of any dispute related to language.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

Kremsmunster, on

Pilsen,
on

Greiner Bio-One GmbH

Faculty Hospital in Pilsen

[REDACTED]

[REDACTED]

Exhibits:

Appendix .IA - study plan [REDACTED]