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**INVESTIGATOR INITIATED-SPONSORED CLINICAL RESEARCH  
AGREEMENT**

**between**

**AstraZeneca Czech Republic s.r.o.**

**and**

**Palacký University, Faculty of Physical Culture, Olomouc**

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**THIS AGREEMENT** is dated \_\_\_\_\_

**PARTIES:**

- (1) AstraZeneca Czech Republic s.r.o., a company incorporated in Czech Republic, whose registered office is at Prague 5, U Trezorky 921/2, Jinonice, 158 00, ID Nr. 63984482, registered in trade register of Municipal Court in Prague, file no. C 38105 (the “**Company**”);
- (2) Palacký University Olomouc, Faculty of Physical Culture, Trida Miru 117, Olomouc, 77111, ID Nr. 61989592, VAT ID: CZ61989592 (the “**Institution**”); and
- (3) [REDACTED] Department of Physiotherapy, Faculty of Physical Culture, Trida Miru 117, Olomouc, 77111 (the “**Principal Investigator**”),

together the “**Parties**” and each a “**Party**”.

**BACKGROUND**

- (a) The Institution and the Principal Investigator intends to initiate and conduct a Study entitled “The presence and the effect of frailty in patients with chronic obstructive pulmonary disease (COPD - 2B) on the level of daily physical activity, on postural stability and on a risk of falls”.
- (b) The Institution will assume the role of sponsor with respect to the Study. The Principal Investigator has agreed to take responsibility for the day-to-day conduct of the Study and to lead, train and supervise the Study Site Staff.
- (c) The Company is interested in the development of scientific knowledge in disease area in which the Company is active. The Company is not the sponsor of the Study, but is willing to support the Study on the terms and conditions set out below.

**AGREED TERMS**

**1. DEFINITIONS**

Unless otherwise specifically provided in this Agreement, capitalised terms shall have the meanings set forth in Appendix A.

**2. SUPPORT PROVIDED BY THE COMPANY**

- 2.1 The Company agrees to provide to the Institution the Financial Support on the terms set out in this Agreement.
- 2.2 The Institution and the Principal Investigator will be responsible for the initiation and conduct of the Study, and for all other Study and administrative costs. The Institution and the Principal Investigator shall disclose to the Company immediately any other support, including support from a public or government body or any inducements

(financial or otherwise), received in connection with this Agreement or their participation in the Study.

- 2.3 The Parties acknowledge that nothing in this Agreement is provided as or intended to be an inducement to prescribe, purchase, recommend, use, or dispense any of the Company's or its Affiliates' products.
- 2.4 Notwithstanding the support provided by the Company under this Agreement, for the purposes of compliance with Applicable Laws, the Institution and the Principal Investigator acknowledges that they are performing the Study independently of the Company, and the Company is not the sponsor of the Study and will not be identified as such.

### **3. RESPONSIBILITIES OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR**

- 3.1 The Principal Investigator and Institution agree to perform the Study in accordance with the Protocol, this Agreement, and all relevant Applicable Laws. They will:
  - 3.1.1 ensure that the Institution obtains and maintains, all regulatory and ethical authorisations and approvals required for the conduct of the Study in accordance with Applicable Laws;
  - 3.1.2 inform all relevant Regulatory Authorities and Ethics Committees of the Company's support of the Study;
  - 3.1.3 take all reasonable steps to ensure the health and well-being of the Subjects;
  - 3.1.4 ensure that they are appropriately qualified by training and expertise, and obtain and maintain all necessary licenses, approvals and authorisations, to enter into this Agreement and conduct the Study;
  - 3.1.5 provide appropriately qualified Study Site Staff, and ensure that the Study Site Staff are made aware of and comply with the terms of this Agreement;
  - 3.1.6 enter into written agreements with the Study Site(s) detailing their responsibilities and ensuring that they comply with the terms of this Agreement; and
  - 3.1.7 protect the personal data and personally identifiable information of any Subjects, and obtain consent with respect to any personal data processing or transfer required under this Agreement.
- 3.2 Institution and Principal Investigator will notify the Company immediately if the Principal Investigator ceases to discharge its duties as principal investigator or otherwise becomes unable to act or to continue to act as Principal Investigator.

- 3.3 At the request and expense of the Company, the Institution and Principal Investigator shall:
- 3.3.1 provide such assistance and cooperation as the Company may reasonably require to support any regulatory matter and/or interaction with a Regulatory Authority relating to the Study or the use of the Company's medicinal products; and
  - 3.3.2 notify the Company within seven (7) days of becoming aware of any investigation relating to or finding by a Regulatory Authority or any internal audit that the Study has been/is being conducted in breach or violation of any Applicable Laws, and/or any request made by a Regulatory Authority to audit or inspect the Study Data/Study Site and/or the activities of the Principal Investigator.

#### 4. FINANCIAL SUPPORT

- 4.1 The Company will provide the Institution with the support set out in Appendix B (the "**Financial Support**") for the purpose of supporting the arrangement, initiation, conduct and management of the Study. Payment will be provided in accordance with Appendix B.
- 4.2 Payment will not be made until the Company has received an invoice and documentation evidencing that the relevant milestone in Appendix B has been met. The Company shall pay the invoice within sixty (60) days of the date of receipt by the Company, PROVIDED THAT if any amount included in the invoice is disputed, the Company shall not be required to pay the disputed amount until the dispute is resolved in accordance with this Agreement.
- 4.3 The Parties acknowledge that the amounts to be paid by the Company under this Agreement are reasonable, represent the fair market value and are for services actually performed by Institution, Principal Investigator and/or Study Site Staff for the work supported by the Company under this Agreement and that neither the Institution, the Principal Investigator nor the Study Site Staff have received any other compensation or inducement from the Company in connection with the Agreement or their participation in the Study.
- 4.4 The Company will not be liable for the payment of any sums due after termination of this Agreement provided that the Company shall pay any sums due for payment up to the date of termination which have actually been incurred as a result of commitments reasonably and necessarily undertaken by the Institution and Principal Investigator. The Institution and the Principal Investigator shall take reasonable steps to mitigate such commitments. To the extent the Financial Support involves any advance payment of any sums in respect of Study set-up costs or expenses, if any such payments have been made in respect of work that has not been completed as at the date of termination, any

part of such sum not reasonably utilised shall be repaid to the Company within fourteen (14) days of receipt of written notice from the Company.

- 4.5 The Company shall deduct or withhold from the amounts payable any taxes that it is required by Applicable Laws to deduct or withhold. All payments made by the Company under this Agreement are inclusive of value added taxes, sales taxes or similar taxes. The Institution will be responsible for all such taxes with respect to payment of the Financial Support.

## **5. CHANGES TO THE PROTOCOL**

- 5.1 The Institution and the Principal Investigator will be responsible for developing the Protocol. In the event that changes to the Protocol are required by the Institution, a Regulatory Authority or an Ethics Committee, the Institution shall notify the Company at least seven (7) days in advance of the change being implemented, except in an emergency involving the health and well-being of Subjects, in which event notification to the Company will be made within seven (7) days of implementation. If such an amendment requires additional funding and/or materials, the Parties shall negotiate in good faith on corresponding amendment to the terms of this Agreement.
- 5.2 If the Company is of the reasonable opinion that the changes made to the Protocol are such that it can no longer support the Study, the Company may terminate this Agreement on written notice to all other Parties.

## **6. MATERIAL AND INFORMATION TO BE PROVIDED TO THE COMPANY**

- 6.1 The Principal Investigator and Institution agree to keep the Company informed of progress and substation developments in the conduct of the Study. In particular, the Principal Investigator and Institution shall ensure that the Company is promptly provided with:
- 6.1.1 a copy of the Ethics Committee approval and any approvals or authorisations for the Study, and notice of any withdrawal or amendment of such documents;
  - 6.1.2 a copy of the periodic or annual reports, including safety report and Ethics Committee updates, in advance of or at the same time as submission to Regulatory Authorities and/or the Ethics Committee;
  - 6.1.3 a status report every two (2) months in electronic or paper format throughout the duration of the Study, which shall summarise the work performed and the results achieved, including number of Subjects screened, enrolled, completed, withdrawn and/or in follow-up and identify any emerging safety related issues; and
  - 6.1.4 a copy of the Final Report as soon as it is available.

- 6.2 The Company shall have the right at its expense, and on reasonable advance notice, to use and publish for any purpose both the Final Report and the data contained in the Final Report (including submission to Regulatory Authorities), provided that the Institution and Principal Investigator's roles are appropriately acknowledged in any subsequent publication.
- 6.3 The Company shall have the right to examine all Study Data, documents and financial records relating to the Study in order to determine that the conduct of the Study is in compliance with the terms of this Agreement. In addition, at reasonable times, including on the completion or termination of the Study, the Company or its authorised representative may, at the Company's expense and on reasonable notice, inspect and audit Institution's and/or Principal Investigator's activities pursuant to this Agreement and the Study.

## **7. RIGHTS TO PUBLICATION**

- 7.1 The Institution and the Principal Investigator shall be entitled to publish the results of, or make presentations related to, the Study to the extent that such publications or presentations are consistent with academic standards, are not false or misleading, and are not for commercial purposes, subject to the procedures set forth below.
- 7.2 The Institution and/or Principal Investigator shall provide the Company with copies of any materials relating to the Study, the Study Data or the Developed Technologies that either intends to publish (or submit for publication, including, but not limited to, materials to be posted on clinical trial registries) or make any presentations relating to, at least thirty (30) days in advance of publication, submission or presentation.
- 7.3 At the request of the Company, the Institution and/or Principal Investigator:
- 7.3.1 shall not include in or shall remove from any proposed publication any Confidential Information; and
- 7.3.2 shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the Company receives the material to allow the Company to take such measures as the Company considers necessary to preserve its proprietary rights and/or protect its Confidential Information.
- 7.4 The Institution and the Principal Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Data or the Developed Technologies, as well as in any financial disclosure information relating to the Study: "This research was conducted with support from AstraZeneca Czech Republic s.r.o.". A copy of any publications and presentations relating to the Study shall be provided to the Company on publication or presentation, and the Company will be granted such rights or licenses as may be required to enable it to make copies of and distribute the publication or presentation as it considers necessary.

- 7.5 Subject to Clause 7.4, no Party shall mention or otherwise use the name, trade mark, trade name or logo of any other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party.
- 7.6 Transparency of clinical research is encouraged by the Company. Subject to Clauses 7.1 to 7.3, the Institution shall post the Study on clinical trial registries and publish the results on clinical trial results databases in such format and within such timelines as laid down by Applicable Laws. The Institution and Principal Investigator acknowledge and agree that the Company shall have the right to post the Study results (as set out in the Final Report) on one or more publicly accessible clinical trial registries and websites (including [www.AZClinicalTrials.com](http://www.AZClinicalTrials.com)), and/or to provide such results to the Regulatory Authorities.

## **8. COMPLIANCE, TRANSPARENCY, ANTI-BRIBERY ANTI-CORRUPTION AND CONFLICTS OF INTEREST**

- 8.1 The Parties will not offer or make any Payments or Transfers of Value to any official or other person, that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage, or to induce such official or other person to perform a function in violation of any statute, rule, or regulation.
- 8.2 The Institution and Principal Investigator warrant that neither they nor any of their officers or employees have engaged in any conduct that has resulted or may result in a criminal conviction, nor are currently excluded, debarred, suspended, or otherwise ineligible to participate in government health care programs in any country. Institution and Principal Investigator agree to notify the Company immediately in the event they become aware that they or any of their officers or employees are being investigated by any professional licensing body, or by any government, state or federal agency.
- 8.3 Institution and Principal Investigator acknowledge and agree that the Company and/or its Affiliates may publicly disclose information about certain Payments or Transfers of Value provided to them as required by Applicable Laws, including any Payments or Transfers of Value provided directly by the Company or indirectly through a contract research or site management organization. Certain Payments or Transfers of Value may also be disclosed on public websites. Institution and Principal Investigator shall provide any information needed to facilitate the disclosures set forth in this Clause 8.3 on request.
- 8.4 If any Party or any of their employees, agents, or sub-contractors commits any of the acts referred to in Clause 8.1 or any offence under the applicable transparency or anti-corruption laws in relation to this Agreement or the Study, or any breach of the warranty given in Clause 8.2, then any other Party shall be entitled, in addition to any other remedy available, to terminate this Agreement with immediate effect.
- 8.5 Any Payments or Transfers of Value relating to this Agreement must be made pursuant to written agreements. This may include an unbroken chain of written agreements which



link the Company with the Covered Recipient via third parties such as contract research organisations, instead of a single agreement between the Company and the Covered Recipient.

- 8.6 Institution and Principal Investigator declare that neither the Principal Investigator, nor his or her spouse nor any dependent children, have entered into and will not enter into any financial arrangements with the Company to hold financial interests in the Company that are required to be disclosed pursuant to the Applicable Laws, including but not limited to (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Study could be influenced by the outcome of the Study, (ii) any proprietary interest in the product being tested, (iii) any significant equity interest in the Company (as defined in the Applicable Laws); and (iv) any significant payments from the Company such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria. The Principal Investigator understands that such prohibitions relate to the period that the Principal Investigator is carrying out the Study. The Principal Investigator shall inform the Company immediately upon learning of the existence of any financial arrangement or interest between the Principal Investigator and the Company.
- 8.7 If during the term of this Agreement or within 2 years of its termination the Principal Investigator (i) joins or participates in any committee that sets formularies or develops clinical guidelines, or (ii) is involved in any decision or recommendation relating to the adoption of any products of the Company of its Affiliates for clinical use in any local or national health care service, the Principal Investigator will disclose to such committee the existence and nature of this Agreement and will follow the procedures set forth by the committee. The Principal Investigator further agrees to fully comply with all applicable disclosure obligations relating to the Principal Investigator's relationship with the Company that may be externally imposed on the Principal Investigator based on the requirements of any institution, medical committee or other medical or scientific organization with which the Principal Investigator is affiliated, and shall notify the Company of any such disclosures.

## **9. INTELLECTUAL PROPERTY**

- 9.1 Except as expressly set out in this Agreement, no Party shall acquire any right, title or interest in or to the Intellectual Property of any of the other Parties or their licensors.
- 9.2 The Institution and the Principal Investigator shall own all rights and title in and to the Study Data, provided that Institution and the Principal Investigator shall disclose all or any portion of the Study Data to the Company on request, and shall permit the Company to use the disclosed Study Data for any purpose.
- 9.3 The Institution and the Principal Investigator shall provide the Company upon completion of the Study with final report and grant to the Company non-exclusive, perpetual, worldwide license to use the final report in whole or part thereof by

publication or dissemination through electronic media including right to use parts of final report in Company's own works and publication and dissemination of these works.

## **10. CONFIDENTIAL INFORMATION**

- 10.1 Subject to Clause 10.2, each Party shall at all times keep confidential the Confidential Information. Each Party shall safeguard the other Party's Confidential Information with at least the same level of care as it affords to its own Confidential Information, and shall not use any other Party's Confidential Information for any purpose other than to perform its obligations under this Agreement. All Study Site Staff shall be bound by obligations of confidentiality at least as restrictive as those contained in this Agreement.
- 10.2 The obligations on each Party set out in Clause 10.1 shall survive for seven (7) years after the expiry or termination of this Agreement, but shall not apply to any information which:
- 10.2.1 was in that Party's possession (with full right to disclose) prior to receiving it from another Party, as demonstrated by written records;
  - 10.2.2 is public knowledge otherwise than as a result of any breach of this Clause or any similar Clause in any other relevant agreement; or
  - 10.2.3 it can demonstrate was developed independently without reference to the Confidential Information, or was received from a third party who had the right to disclose such information in a non-confidential manner.
- 10.3 Notwithstanding Clauses 10.1 and 10.2, a Party may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with Applicable Laws (including freedom of information legislation), provided always that (i) to the extent it is legally permitted to do so, the disclosing Party gives the affected Party as much notice of such disclosure as possible; and (ii) the disclosing Party complies with the affected Party's reasonable directions for taking legally available steps to resist or narrow such requirement (at the affected Party's reasonable expense) and in any event restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.
- 10.4 The Parties acknowledge that damages alone would not be an adequate remedy for the breach of any of the terms of Clause 10, and that in the event of a breach or threatened breach the Party that initially disclosed the Confidential Information shall be entitled to seek equitable relief and/or injunctive relief concerning any threatened or actual breach (in addition to any other rights and remedies it may have under this Agreement or otherwise).

## **11. INSURANCE**

- 11.1 Institution and Principal Investigator shall ensure that adequate provision is made by way of insurance or indemnity arrangements sufficient to meet their obligations and liabilities under this Agreement and the Applicable Laws, in particular towards Subjects for personal injury arising as a result of participation in the Study.

## **12. TERM AND TERMINATION**

- 12.1 This Agreement will remain in effect until the date on which the Company receives the Final Report or the date on which the Institution has received any/all payments due to it under this Agreement, whichever is the later.
- 12.2 The Institution and the Principal Investigator will notify the Company in writing of the completion or early termination of the Study within seven (7) days of such completion or early termination and, where termination occurs at a date earlier than provided under the Protocol, the reason for such termination.
- 12.3 In the event of early termination of this Agreement, the Parties shall use their commercially reasonable efforts to minimize any inconvenience or harm to the Subjects.
- 12.4 Any Party may terminate this Agreement without cause at any time by giving at least thirty (30) days prior written notice of such termination to all other Parties, or with immediate effect at any time upon written notice to all other Parties if:
- 12.4.1 on reasonable grounds it believes the Study should cease in the interest of the health, safety or well-being of Subjects;
  - 12.4.2 any other Party commits a material breach of any of its obligations under the Agreement and fails to remedy such breach (where possible) within thirty (30) days of written notice from a non-defaulting Party; or
  - 12.4.3 any step, application, order, proceeding or appointment is taken or made by or with respect to any other Party for distress, execution, composition or arrangement with creditors, winding up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, if that Party is unable to pay its debts or if any event occurs which, under the applicable law of any jurisdiction to which it is subject, has an effect similar to that of any of the events referred to in this Clause 12.4.3.
- 12.5 The following Clauses shall survive the termination or expiry of this Agreement to the extent necessary to preserve such rights and obligations:
- 12.5.1 Clause 3 (Responsibilities of the Institution and the Principal Investigator);

- 12.5.2 Clause 6 (Material and Information to be Provided to the Company);
- 12.5.3 Clause 7 (Review and Publication);
- 12.5.4 Clause 8 (Anti-Bribery and Anti-Corruption);
- 12.5.5 Clause 9 (Intellectual Property);
- 12.5.6 Clause 10 (Confidential Information);
- 12.5.7 Clause 11 (Insurance);
- 12.5.8 Clause 12.3 (Term and Termination); and
- 12.5.9 Clause 13 (General).

### **13. GENERAL**

- 13.1 No Party shall be liable to any other for any delay or non-performance of its obligations under this Agreement arising from any Force Majeure Event. In the event of a Party being so delayed or prevented from performing its obligations, such Party shall: (i) give notice in writing of such delay or prevention to the other Parties as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause of such delay or prevention and its estimated duration; (ii) use commercially reasonable efforts to mitigate the effects of such delay or prevention upon the performance of its obligations under this Agreement; and (iii) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention. If a Party is prevented from performing its obligations by a Force Majeure Event for more than 8 consecutive weeks either of the remaining Parties may terminate this Agreement immediately upon written notice to the other Parties.
- 13.2 The Principal Investigator and the Institution may not assign, delegate, sublicense or otherwise transfer any or all of their rights and obligations under this Agreement without the prior written consent of the other Parties. The Company shall be entitled to assign, delegate, sublicense or otherwise transfer its rights under this Agreement to any Affiliate. Any assignment in violation of this Agreement shall be null and void.
- 13.3 Nothing in this Agreement shall create, or be deemed to create a partnership, joint venture, employer/employee, contractor/contractee, or other relationship between the Parties other than the contractual relationship expressly provided for in this Agreement.
- 13.4 No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that (or any other) right or remedy, nor shall it preclude or restrict its further exercise. In addition, no single or partial exercise of any such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.

- 13.5 The Parties acknowledge and agree that they have reviewed, negotiated and jointly drafted this Agreement and that it should be construed without regard to the Party or Parties responsible for its preparation.
- 13.6 If any provision of this Agreement is held by any court or other competent authority to be illegal, invalid or unenforceable in whole or in part, this Agreement shall continue to be valid as to its other provisions, and if possible the affected provision should be modified to the minimum extent necessary to make it valid, legal and enforceable.
- 13.7 Any notice to be given by any Party under or in connection with this Agreement must be in writing in English and shall be: (a) delivered by hand or by courier; (b) sent by pre-paid recorded (i.e. signed for) post; or (c) sent by fax or by email [REDACTED] to the addresses set out at the start of this Agreement or such addresses or numbers as may be notified to the other Parties from time to time. Notices sent in accordance with this Clause are to be deemed to have been received (i) if delivered by hand or by courier, when left at the address referred to above; (ii) if sent by post, three business days after posting; (iii) if sent by fax or email, when transmitted.
- 13.8 This Agreement together with the Appendices (all of which are incorporated by reference) constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior agreements, whether written or oral, with respect to that subject matter.
- 13.9 Any amendment or modification to this Agreement must be in writing and signed by authorised representatives of each Party.
- 13.10 This Agreement may be executed in any number of counterparts all of which then together shall constitute one and the same agreement.
- 13.11 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of Czech Republic without regard to the conflicts of law principles thereof. The Parties irrevocably agree that the courts of Czech Republic shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter (including non-contractual disputes or claims).

**AGREED** by the Parties on the dates indicated below.

SIGNED for and on behalf of  
Palacky University Olomouc, Faculty of  
Physical Culture

SIGNED by

Signature

Signature

Name: doc. PhDr. Zbynek Svozil, Ph.D.

Date:

Title: Dean of the Faculty

10 -11- 2017

Date:

10 -11- 2017

SIGNED for and on behalf of  
AstraZeneca Czech Republic s.r.o.

Signature

Name: Gratiela Popescu

Title: Country President

Date: - 9 -11- 2017

## APPENDIX A - DEFINITIONS

“**Affiliate**” means any business entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party, with “control” meaning in the case of a company, direct or indirect ownership of 50% or more of the voting interest in such company, and in the case of a partnership the right to a share of more than half the assets, or of more than half the income of the partnership.

“**Applicable Laws**” means all applicable international, national, regional and local laws, rules, regulations and guidance including without limitation Regulatory Authority rules and regulations, decisions and industry codes (including any modification or re-enactment thereto) applicable to the Study and the activities or interactions under this Agreement, including International Conference on Harmonisation guidance on good clinical practice and all generally accepted standards of good clinical practice and good medical practice.

“**Confidential Information**” means (i) the terms of this Agreement; and (ii) any business, employee or customer information or data in any form which is disclosed or otherwise comes into possession of a Party, directly or indirectly, as a result of this Agreement and which is of a confidential or proprietary nature (including, without limitation, any information relating to business affairs, operations, products, processes, methodologies, formulae, plans, intentions, projections, know-how, Intellectual Property, trade secrets, market opportunities, suppliers, customers, marketing activities, sales, software, computer and telecommunications systems, costs and prices, wage rates, records, finances and personnel).

“**Developed Technology**” means any inventions, discoveries, improvements or developments made by Institution, Principal Investigator or any Study Site Staff (whether solely or jointly with others) in the course of or as a result of the Study and that are directly related to any medical product owned, commercialised, controlled or licensed by the Company or its Affiliates, or the use thereof.

“**Ethics Committee**” means the independent institutional, regional, national or supranational committee or review board-responsible for reviewing and approving/providing an opinion on the Protocol, the suitability of the investigator(s), the Study Site(s), the Subject recruitment materials and methods, and informed consent forms.

“**Final Report**” means the final report of the results of the Study which shall include, without limitation, the research objectives, methodology and therapies used and the medical/scientific results, or, as the case may be, a report of the data generated as of the date of the termination of the Study.

“**Force Majeure Event**” means any circumstance beyond a Party’s reasonable control, including acts of war or other action of military forces, terrorism, riot, civil commotion, sabotage, vandalism, accident, fire, flood, acts of God, strike, lock-out or other industrial disputes (whether or not involving employees of the relevant party) or legislative or administrative interference and which could not have been avoided or mitigated by the exercise of reasonable care by that Party.

**“Intellectual Property”** means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

**“Payment or Transfer of Value”** means a direct or indirect transfer of *anything* of value, whether cash or in kind in connection with the development or sale of medical products. “Value” shall mean the discernible economic value on the open market. A direct Payment or Transfer of Value is one made directly by a company for the benefit of a recipient. An indirect Payment or Transfer of Value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

**“Protocol”** means the study protocol with title “The presence and the effect of frailty in patients with Chronic Obstructive pulmonary disease (COPD - 2B) on the level of daily Physical Activity, on postural Stability and on a risk of falls (COMPASS STUDY)”, a copy of which was provided to the Company on 11.10.2017 and as may be amended from time to time by the Institution and the Principal Investigator in accordance with the terms of this Agreement.

**“Regulatory Authority”** means any international, national, regional or local agency, authority, department, inspectorate, minister, ministry official, parliament, public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement, the Study, or the Parties.

**“Study”** means the clinical study entitled “The presence and the effect of frailty in patients with Chronic Obstructive pulmonary disease (COPD - 2B) on the level of daily Physical Activity, on postural Stability and on a risk of falls (COMPASS STUDY)” conducted in accordance with the Protocol, with reference number ESR-17-13253.

**“Study Data”** means all records, accounts, notes, reports and data, and Ethics Committee and/or Regulatory Authority communications (submission, approvals and progress reports) collected, generated or used in connection with the Study by Institution or Principal Investigator (whether solely or jointly with others), whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as case report forms and all other reports and records necessary for the evaluation and reconstruction of the Study.

**“Study Site(s)”** means the premises occupied, owned and/or managed by the Institution and the Principal Investigator (including any sub-contracted sites) where Study related activities are conducted.

**“Study Site Staff”** means all those investigators, sub-investigators, employees, agents, students and others who are engaged by Institution and/or Principal Investigator in the conduct of the Study, including any such persons at Study Site.



**“Subject”** means a person recruited to participate in the Study in accordance with the Protocol.

## APPENDIX B - FINANCIAL SUPPORT

The Company will pay the Financial Support against invoices issued by the Institution at achievement of the following agreed milestones and in accordance with Clause 4.

<b>Milestone</b>	<b>Documentation</b>	<b>Amount</b>	<b>Estimated Time</b>
1. Milestone upon signature of the Agreement	Signed Agreement	122,500.00 Kc (30% of the funding is necessary to use for the purchase of the pedometers at the beginning of the study)	2017 Dec
2. Milestone – first subject enrolment		70,828.00 Kc	2018 Mar
3. Milestone – 50% of Subjects have been enrolled		70,828.00 Kc	2018 May
4. Milestone – last Subject enrolment		70,828.00 Kc	2018 Jun
5. Milestone – Final Report		59,115.00 Kc	2018 Oct

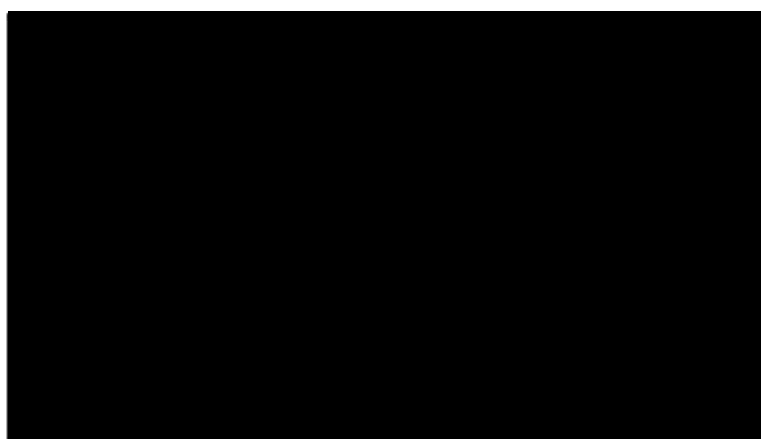
Payment of the Financial Support will be made to the following account, as specified by the Institution:

Bank Name:


Sorting Code:

Account No.:

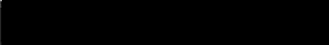
Account Name:




All invoices should be clearly marked with the Study number and D2287L00017 the correct purchase order number (supplied by the Company on signature of this Agreement) the relevant milestone/activity and associated budget on all invoices.

Invoices to be sent electronically to: 

Or by post to:

  
AstraZeneca Czech Republic s.r.o.  
U Trezorky 921/2  
Prague 5, Jinonice  
158 00  
Czech Republic

SIGNED for and on behalf of  
Palacky University Olomouc, Faculty of  
Physical Culture,

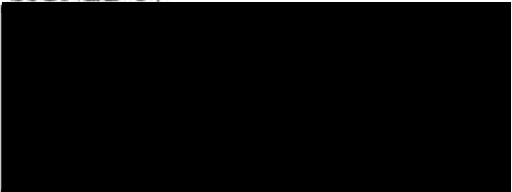
Signature 

Name: doc. PhDr. Zbynek Svozil, Ph.D.

Title: Dean of the Faculty

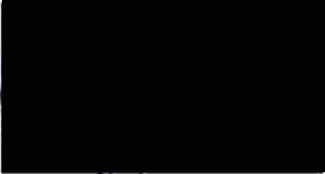
Date: 10 -11- 2017

SIGNED by

Signature 

Date: 10 -11- 2017

SIGNED for and on behalf of  
AstraZeneca Czech Republic s.r.o.

Signature 

Name: Gratiela Elena Popescu

Title: Country President

Date: - 9 -11- 2017