# INVESTIGATOR INITIATED STUDY AGREEMENT

Abbott Brussels Coordination Center bvba, Da Vincilaan 11-F1, 1935 Zaventem, Belgium ("Abbott") desires to provide support to **Institute for Clinical and Experimental Medicine,** Vídeňská 1958/9, 140 21 Prague 4, Czech Republic, ID: 00023001, VAT: CZ00023001 ("<u>Institution</u>") for the restricted purpose of Institution's conduct of an investigator initiated study ("<u>Study</u>") effective as of the Effective date this Investigator Initiated Study Agreement (the "<u>Agreement</u>"). In consideration of the mutual promises set forth herein, the parties hereto agree as follows:

- 1. <u>Support</u>. Abbott will provide support for the Study as specified in **Exhibit A**.
- 2. Sponsor and Conduct of Study. Institution will sponsor and conduct the Study pursuant to the terms of this Agreement and in strict adherence to the protocol entitled "Safety and Feasibility of Transition to Anti-thrombotic Monotherapy with the HeartMate 3 LVAS: A prospective controlled study (MAGENTUM 2)" ("the "Protocol") attached hereto and incorporated herein by reference as Exhibit B. Institution shall have complete responsibility for all aspects of the conduct of the Study. If required by law and/or regulation, Institution shall submit the Protocol and any other required regulatory documents to the appropriate regulatory authority for review. In the event that the Protocol is modified, Institution must provide such modified Protocol to Abbott and obtain Abbott's written approval of continued support. If the modified Protocol requires changes to the Budget or other terms of this Agreement, a written amendment signed by the parties shall be made incorporating the modified Protocol and any necessary changes to this Agreement.
- 3. Investigator; Contact Information. ("Investigator") will be responsible on Institution's behalf for the conduct of the Study. If Investigator is not available to conduct the Study for any reason, Abbott may terminate this Agreement immediately. Institution's contact(s) at Abbott will be service or Sr. Director Medical Affairs, phone or whomever Abbott may designate in writing. Abbott's contact(s) at Institution will be service or Whomever Abbott may designate in writing. Institution represents and warrants that Investigator is an employee of Institution. If Investigator leaves Institution's employment during the Term (as defined below), then Institution will promptly notify Abbott in writing.
- 4. Compliance with Law.
  - (a) Each of Institution and Investigator represents, warrants and covenants that it will conduct the Study and perform its obligations under this Agreement in compliance with all applicable laws, regulations and guidelines. In furtherance of the foregoing obligations, Institution will further ensure that an Institutional Review Board, an Independent Ethics Committee, or both, as applicable (collectively "<u>EC</u>"), established and constituted in accordance with applicable laws and regulations, approves and oversees the conduct of the Study. Institution will comply with the directives of the EC respecting the conduct of the Study, and will notify Abbott to the extent any such directives vary from the Protocol. Institution will promptly disclose to Abbott, any action or threatened action by the local regulatory authority or other agency that may affect marketing of the Study. Product(s) or continuation of the Study.
  - (b) Institution and Investigator agree that, if Study Product(s) or other Study materials are provided without charge by Abbott, and/or activities performed by Institution or Investigator is funded by Abbott, none of Institution, its agents or Investigator shall separately bill or seek reimbursement for such Study Product(s), other Study materials and/or activities from any third party including, without limitation, a subject, any private provider of insurance, or any government program. If the Study involves subjects whose Study Product(s) or other Study materials and/or activities performed by Institution or Investigator are covered under global payment systems, such as Diagnosis Related Groups, Institution will treat any such Study Product(s) or other Study materials that are provided without charge by Abbott, or activities that is funded by Abbott as part of the Study, under the billing procedures applicable to such payment system. Institution will further report receipt of such Study Product(s) to any government, other public or private insurance program, as may be required by law.
  - (c) Investigator understands and agrees that none of Investigator or any subinvestigator will receive any funds from Abbott in connection with the Study other than the funds paid to Institution according to the Budget.
- 5. <u>Adverse Events</u>. Investigator shall report adverse events that occur during the course of the Study directly to the competent regulatory authorities as required by and in accordance with the applicable law. In addition, Investigator shall report all unanticipated adverse device effects to Abbott within twenty-four (24) hours of learning of the event. The Investigator shall make available to Abbott promptly such records as may be necessary and pertinent to investigate any such serious adverse event, if specifically requested by Abbott. Abbott's contact for reporting serious adverse events shall be the individual identified in Section 3 (Investigator; Contact Information) hereof.
- 6. <u>Delivery of Progress Reports</u>. Upon the request of Abbott, Institution will submit oral or written reports on the progress of the Study. Within forty-five (45) days following the completion or termination of the Study, Institution will furnish Abbott with a final report detailing the results of the Study.

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 Auditing of Study Records and Data. Abbott reserves the right to periodically audit records and other data related to the Study during normal business hours. Institution may redact such records, source documents, and other data as may be legally required to protect subject confidentiality, consistent with Section 9 (Subject Confidentiality and Data Protection) of this Agreement. Institution shall retain the Study documents in accordance with the applicable laws, regulations and the Protocol.

## 8. Confidentiality.

- (a) During the Term of this Agreement, including any extensions thereof, and for a period of ten (10) years after the expiration or termination of this Agreement, Institution, its employees, including Investigator, agents, subcontractors and affiliates (collectively, "<u>Receiving Party</u>") shall not disclose Confidential Information (other than to Abbott or Abbott-designated parties) without Abbott's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Abbott shall remain in place for so long as the applicable Confidential Information provided to Receiving Party by or on behalf of Abbott, including but not limited to information about the Study Product(s), and all materials and information concerning Abbott or the Study or developed as a result of conducting the Study, except any portion thereof which:
  - (i) is known to the Receiving Party prior to receipt thereof under this Agreement, as evidenced by its written records;
  - (ii) is disclosed to the Receiving Party by a third party who has a right to make such disclosure in a non-confidential manner; or
  - (iii) is or becomes part of the public domain through no fault of the Receiving Party.
- (b) The Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Abbott's prior written approval.
- (c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Abbott prompt written notice (and in any case at least five (5) business days notice) to allow Abbott to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Abbott waives compliance with the terms of this Section 8, Receiving Party shall furnish only that portion of the Confidential Information which is legally required based on written opinion of legal counsel.
- (d) Receiving Party will not disclose to Abbott any information which is confidential or proprietary to a third party unless Institution has first obtained the prior written approval of such third party and Abbott.
- (e) Within thirty (30) days after the effective date of termination of this Agreement and at Abbott's direction, Institution will ensure Receiving Party returns or destroys all tangible materials that contain Abbott's Confidential Information.
- 9. Subject Confidentiality and Data Protection.
  - (a) The parties will comply with all applicable laws and regulations regarding Study subject confidentiality and data protection. Investigator will be responsible on behalf of the Institution for obtaining from each Study subject, prior to the Study subject's participation in the Study, a signed informed consent in a form approved in writing by the EC. Investigator shall also obtain in the informed consent or separate authorization document, permission for Abbott and Abbott's representatives involved with or evaluating the Study to access and obtain copies of the Study data. In addition, the Investigator must disclose to potential Study subjects that the Institution and Investigator are receiving funding and/or other support for the conduct of the Study.
  - (b) Where Institution and/or Investigator collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others, participating in or associated with the Study ("Personal Data"), in performing its obligations under this Agreement, it shall only do so in accordance with this Agreement and with all applicable laws. Institution and Investigator shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data. Institution and Investigator shall promptly inform Abbott about any unauthorized access to or disclosure of Personal Data ("Security Breach"), including the timing and nature of the Security Breach, and take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Institution will undertake to ensure that all necessary agreements are implemented and in place.
  - (c) Investigator acknowledges and consents to, and shall cause all subinvestigators for the Study to acknowledge and consent to, Abbott's collection, use, processing, and disclosure of Investigator's and sub-investigator's Personal Data including details of his/her name, address, qualifications and clinical trial experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), assessments by Abbott of Investigator's suitability for future studies, and for purposes of complying with applicable laws. Investigator understands and expressly agrees and shall cause all subinvestigators for the Study to expressly agree that this information may, if necessary for these purposes, be made

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available to ethics committees, government authorities and other companies within the Abbott group of companies located both in the country in which the Study is carried out and in other countries, including in the United States or elsewhere as required by applicable law or as necessary for the purposes of Good Clinical Practice or data protection audits or inspections.

- (d) The Parties agree that Institution shall act as a data controller and are obliged to comply with EU regulation 2016/679, general data protection regulation.
- 10. <u>Publicity</u>. Except for the requirements set forth in Section 12(c) (Publications and Presentations) of this Agreement, the Institution shall not and shall ensure Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Abbott in any publicity, advertising or information, which is disseminated to any third person or to the general public without Abbott's prior written approval. Institution and Investigator understand that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Abbott as required by law or regulation or where Abbott deems appropriate.
- 11. <u>Inventions</u>. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of any of the Study Product(s) if applicable, or results from conduct of the Study will be promptly disclosed to Abbott, assigned to Abbott and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott's request and at Abbott's expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott's name covering any of the foregoing.
- 12. Publications and Presentations.
  - (a) <u>Publication Requirements</u>. To foster the highest standards of conduct related to scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "<u>Publication(s)</u>"), Abbott is committed to transparency and ethical publication practices. If Investigator serves as an author on any Publication(s) emanating from the Study, Abbott advises compliance with the Recommendations for Scientific Publications attached hereto as **Exhibit C**.
  - (b) Procedures. If Institution or Investigator prepares a Publication(s) or any other public disclosure of Study results (collectively a "Study Results Disclosure"), Institution shall provide or shall require Investigator to provide Abbott, at least sixty (60) days prior to any submission of a Study Results Disclosure, with a draft of the same for Abbott's review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. Abbott shall return comments to Institution or Investigator shall delay any proposed Study Results Disclosure ("Review Period"). Furthermore, Institution or Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event Abbott so requests to enable Abbott to secure patent or other proprietary protection ("Delay Period"). Institution agrees and shall require Investigator to agree to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree to delete Abbott Confidential Information (other than the results of the Study generated hereunder) from any Study Results Disclosure. In the event that Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.
  - (c) Institution and Investigator agree to fully disclose Abbott's support of the Study to the extent required by applicable laws, regulations, and industry guidelines and to journals, congresses, or other entities, regardless of the journal's or congress' requirements. Institution agrees to include the following acknowledgement language when submitting the Study research results to congress' or other meetings and for publication in medical or other journals: "This research was supported by a grant from Abbott Laboratories." This language shall appear on all posters, as a sentence within abstracts and as an acknowledgment in all manuscripts and presentations, as well as in any financial disclosure information.
- 13. <u>Registration of Study</u>. Institution agrees to be fully compliant with all applicable laws rules and regulations relating to the registration of the Study and posting results of the Study. If applicable, Institution shall register the Study on any other registry with requirements consistent with the policy of the International Committee of Medical Journal Editors (De Angelis C, et al., Clinical trial registration: a statement from the International Committee of Medical Journal Editors, Ann Intern Med 2004; 141:477-8, as amended from time to time, the "ICMJE Policy"), in a manner consistent with Institution's guidelines regarding the ICMJE Policy.
- 14. Representations and Warranties.
  - (a) Institution represents and warrants that:
    - the terms of this Agreement are valid and binding obligations of Institution, and are not inconsistent with any other contractual or legal obligation it or Investigator may have or with Institution's policies and procedures or the policies and procedures of any institution or company with which each of Institution or Investigator is associated;

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- Institution's performance of the activities hereunder and acceptance of compensation, if applicable, (including the acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott approved meetings, which may be provided to Investigator) hereunder, is in compliance with all policies and procedures of Institution, and that Investigator's performance of such activities does not present a conflict of interest with Investigator's official duties;
- (iii) Investigator has received any required authorization, written or otherwise, from Institution for Investigator's performance of the activities;
- (iv) Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to, sufficient personnel and equipment, to efficiently and expeditiously perform the Study hereunder in a professional and competent manner and will utilize due diligence and devote the necessary personnel and equipment at all times to perform the Study hereunder in such a manner;
- (v) any subinvestigators used by Institution for the Study will be selected based upon a consideration of the following: (A) training and expertise in relevant fields; (B) appropriate research facilities; (C) experience with the relevant subject population so that the subinvestigator has a reasonably high likelihood of recruiting the appropriate research participants and following through to the completion of the Study; (D) prior scientific research or clinical experience; and (E) ability to conduct the Study in accordance with applicable legal and regulatory requirements;
- (vi) Investigator is not under investigation or subject to any disciplinary action by any medical board, and Investigator has a medical license, or equivalent, that has not been restricted or suspended by any medical board in any way. In the event that any of foregoing occurs, Investigator shall immediately notify Abbott, and Abbott shall have the right to immediately terminate this Agreement;
- (vii) neither Institution, Investigator, nor any of their agents, subcontractors or employees (including any sub-investigators) shall make or accept, directly or indirectly, any offer or promise or authorization of a bribe, kickback, payoff or other payment or gift intended to improperly influence any person including an agent, government official, political party or candidate for public office to exercise their discretionary authority or influence to benefit any party to this Agreement;
- (viii) neither Institution, Investigator, nor any of their agents, subcontractors or employees (including any sub-investigators) are currently, or have been within the past five (5) years debarred, disqualified, or excluded under any Applicable Law from: (i) providing goods or services to a regulated health care company, (ii) participating in clinical research, (iii) participating in a government procurement or non-procurement program, or (iv) participating in a reimbursed government-funded or financed healthcare program (each, a "Restriction"). Institution agrees to promptly notify Abbott if any such Restriction is proposed, pending or occurs during the Term. Upon receipt of notice, Abbott may elect, in its sole discretion, to immediately terminate this Agreement; and
- (ix) if any significant changes occur during the Term with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Institution or Investigator's involvement in this Agreement), Institution agrees to immediately notify Abbott in writing of any such changes.
- (b) Each party represents and warrants that Abbott's support of this Study is not intended to be, nor shall it be construed as, an inducement to purchase, prescribe, use, recommend, or provide a favorable formulary status for any Abbott product or product co-promoted or marketed by Abbott.

#### 15. Term and Termination.

- (a) This Agreement will be effective on the date of the last signature and becomes effective on the date of publication in the Register of Contracts based on the Act No. 340/2015 Coll., on Agreement Register as amended ("the Effective Date") and shall expire on the later of: (i) one (1) year from the Effective Date; or (ii) the date of completion of all the obligations of the parties hereunder (the "Term"), unless terminated earlier as provided in Section 15(b) below. Institution shall immediately notify Abbott in writing in the event the Study is terminated for any reason. Abbott takes note that Institution will publish this Agreement in Register of Contracts.
- (b) This Agreement may be terminated:
  - (i) by either Abbott or Institution upon written notice to the other party if: (*A*) the other party has breached a material term of this Agreement; or (*B*) in the event of termination of the Study by any governmental or regulatory authority;
  - (ii) by Abbott immediately upon written notice to Institution if: (A) the personal services of Investigator are not available, pursuant to Section 3 (Investigator; Contact Information) of this Agreement, (B) in Abbott's sole judgment, an adverse safety concern with respect to the Study Product(s) makes continued testing unadvisable, or (C) the Institution or

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Investigator breaches any of the representations and warranties as stated in **Section 14** (Representations and Warranties) of this Agreement; or

- (iii) by Abbott without cause upon at least thirty (30) days prior written notice to Institution.
- (c) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto.
- 16. <u>Liability</u>. The design of the Protocol, as well as all other aspects of the Study conduct (including, but not limited to, securing and maintaining all appropriate EC and legal/regulatory approvals) shall be solely Institution's responsibility. Abbott will not be responsible or liable for any losses, costs, damages, or other expenses arising out of or resulting from: (a) design, content, or implementation of the Protocol or use of any Abbott product in the Study, if applicable, or selection of Study subjects; or (b) any injury (whether or not Study related) to persons or damage to property involved in the Study.
- 17. <u>Insurance</u>. Institution agrees to maintain a policy or policies of insurance or self-insurance sufficient to satisfy its duties and obligations under this Agreement to the extent such duties and obligations are commercially insurable. Institution further agrees to provide written evidence of such insurance (including certificates of insurance or other evidence providing reasonable assurances) to Abbott within seven (7) business days following receipt of written request by Abbott.
- 18. <u>Independent Contractor</u>. Each of Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor, and neither Institution nor Investigator has the authority to bind or act on behalf of Abbott.
- 19. <u>Assignment</u>. Institution may not assign this Agreement to any other party, or subcontract any of its activities hereunder, without Abbott's prior written consent. Any attempted assignment without Abbott's prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation.
- 20. <u>Notices</u>. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answerback, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile:

If to Institution: Michal Stiborek Institute for Clinical and Experimental Medicine, Vídeňská 1958/9, 14021 Prague 4, Czech Republic Phone: Fax:	If to Investigator: Institute for Clinical and Experimental Medicine, Vídeňská 1958/9, 14021 Prague 4, Czech Republic Phone: Fax:
If to Abbott: Senior Director Medical Affairs, SJM/Abbott Brussels Coordination Ctr Da Vincilaan 11-F1 1935 Zaventem Phone: E-Mail :	with a copy to: Divisional Vice President & Associate General Counsel Corporate Legal Dept. 32CO, Bldg. AP6A Abbott Laboratories 100 Abbott Park Road Abbott Park, IL 60064-6011 U.S.A. Fax:

- 21. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between provisions of the Protocol and this Agreement or any exhibits hereto, the Protocol shall control with respect to matters of science, medical practice, and Study subject safety. In all other matters, the provisions of this Agreement shall control. None of this Agreement or any of its terms, including any attachment or exhibit hereto may be amended, restated or otherwise altered except by written agreement signed by the parties.
- 22. <u>Survival</u>. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.
- 23. <u>Severability</u>. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

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- 24. <u>Counterparts</u>. This Agreement is executed in 3 counterparts in Czech and English language version, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. In case of discrepancies between the Czech and English language version, Czech version shall prevail.
- 25. <u>Governing Law and Arbitration</u>. This Agreement shall be governed by and construed in accordance with the laws of Czech Republic, excluding its conflicts of laws provisions. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the parties, shall be settled by the courts of the Czech Republic. This Section shall survive termination or expiration of this Agreement.

**IN WITNESS WHEREOF**, the parties have caused this Investigator Initiated Study Agreement to be executed by their duly authorized representatives.

ABBOTT BRUSSELS COORDINATION CENTER	Institute for Clinical and Experimental Medicine
Ву:	Ву:
Name:	Name: Ing. Michal Stiborek, MBA
Title: Sr. Director Medical Affairs	Title: Director
Date:	Date:
Digitally signed by DN: dc=com, dc=oneabbott, ou=Common, ou=Provisioned, ou=Users, cn Reason: I agree to the terms defined by the placement of my signature on this document Date: 2020.05.26 15:31:46 +02'00'	Michal Stiborek Michal Stiborek   Stiborek Datum: 2020.05.29   14:07:42 +02'00'   I agree to be bound by the provisions of this Agreement.   By:

Attachments Exhibit A – Support provided by Abbott Exhibit B – Protocol Exhibit C – Recommendations for Scientific Publications IKEM

# EXHIBIT A

# SUPPORT PROVIDED BY ABBOTT

Type of support being provided:

- X Funds
- Products

Funds and Products

Other:

- 1. Institution and Investigator agree that, if Study Product(s) or other Study materials are provided without charge by Abbott, and/or activities performed by Institution or Investigator is funded by Abbott, none of Institution, its agents or Investigator shall separately bill or seek reimbursement for such Study Product(s), other Study materials and/or activities from any third party including, without limitation, a subject, any private provider of insurance, or any government program. If the Study involves subjects whose Study Product(s) or other Study materials and/or activities performed by Institution or Investigator are covered under global payment systems, such as Diagnosis Related Groups, Institution will treat any such Study Product(s) or other Study materials that are provided without charge by Abbott, or activities that is funded by Abbott as part of the Study, under the billing procedures applicable to such payment system. Institution will further report receipt of such Study Product(s) to any government, other public or private insurance program, as may be required by law.
- 2. Funding support:
  - (a) Abbott shall pay a maximum of Euro 35,000 for the conduct of this study, where 15-20 patients are expected to be enrolled in total. If the final milestone is not completed within twelve (12) months of the conclusion of the Study, Abbott will not be obligated to make the final milestone payment listed below. Payment shall be made upon Abbott's receipt and approval of an invoice in accordance to the following payment milestones:

Payment shall be made upon Abbott's receipt and approval of an invoice in accordance to the following payment milestones:

*(i)* Euro ten thousand (Euro 10,000) shall be paid within ninety (90) days of both full execution of the Agreement and Medical Ethics Committee approval;

(ii) Euro ten thousand (Euro 10,000) shall be paid within ninety (90) days after the 6-month follow-up of the first 10 subjects has been completed;

(iii) Euro one thousand (Euro 1,000) per each additional subject enrolled shall be paid within ninety (90) days after completion of the 6-month follow-up (min. of 15 and max. of 20 subjects in total);

(iv) Euro five thousand (Euro 5,000) shall be paid within ninety (90) days of Abbott's receipt and acceptance of a final summary report, manuscript, abstract or poster.

Subjects are defined as patients transitioned to a single anti-thrombotic therapy with Aspirin only (no Warfarin anticoagulation per structured protocols defined as "Safety and Feasibility of Anti-thrombotic Monotherapy with the HeartMate3 LVAS: A single center prospective controlled study" algorithm for gradually transitioned patients and as "Safety and Feasibility of Transition to Anti-thrombotic Monotherapy with the HeartMate3 LVAS: A prospective controlled study (MAGENTUM 2)" protocol for de novo patients).

- (b) Payments shall be made via bank transfer to the following: Česká národní banka, acc. number: 34534-42334041/0710, IBAN: CZ4007100345340042334041, SWIFT: CNBACZPP. Invoices shall be sent to: St Jude Medical Brussels Coordination Center bvba, Da Vincilaan 11-F1, 1935 Zaventem, Belgium.
- (c) The parties agree that (i) the amount of funding represents the fair market value to support the activities to be performed and the deliverables to be provided, as applicable; (ii) expenses contained in the Budget are reasonable and customary; and (iii) expenses related to travel are consistent with Abbott's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel).
- (d) In the event of termination of this Agreement by Abbott for any reason other than for Institution's breach, Abbott shall pay Institution for activities performed.

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- (e) All payments shall be made within ninety (90) days of Abbott's approval of an invoice detailing Institution's activities performed under this Agreement or incurrence of pass-through expenses, and only after full execution of this Agreement.
- (f) The final payment to be made under this Agreement will be accompanied by a financial reconciliation, taking into account the payment to be made in accordance with this Section 3. If, at the time of such financial reconciliation, the total amount Abbott has paid is less than the amount to which Institution is entitled hereunder, Abbott shall pay the amount due Institution at such time. Any overpayment due Abbott pursuant to this Agreement, as determined at the time of final reconciliation, shall be made payable to Abbott within forty five (45) days of Abbott's notice to Institution of such overpayment and sent to: the Controller, Brussels Coordination Center, Da Vincilaan 11-F, 1935 Zaventem, along with an explanation for such payment and accompanying support documentation for the remittance with a copy to the Abbott contact set forth in Section 3 (Investigator Contact Information) of the Agreement.
- (g) Investigator understands and agrees that none of Investigator or any subinvestigator will receive any funds from Abbott in connection with the Study other than the funds paid to Institution according to the Budget.

# EXHIBIT B

PROTOCOL

# EXHIBIT C

# RECOMMENDATIONS FOR SCIENTIFIC PUBLICATIONS

- 1. <u>Criteria for Authorship</u>. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit should be based on:
  - (a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
  - (b) Drafting or revising the article for important intellectual content; and
  - (c) Final approval of the version to be published.

A person should meet all three of the above criteria to warrant authorship.

- <u>Acknowledgement of Medical Writers and Other Contributors</u>. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, should be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.
- 3. <u>Conflict of Interest</u>. In the interest of transparency and maintaining the highest possible standards of conduct, authors should comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.
- 4. <u>Access to Data</u>. Institution or Investigator should provide all authors with the final protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. Institution or Investigator provide a copy of the clinical trial protocol and plan for statistical analysis when requested by a medical journal considering a submitted manuscript for publication.
- 5. <u>Redundant Publication</u>. Duplicate or redundant publication of the Study results in peer-reviewed journals is not recommended. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are acceptable. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is acceptable. Encore presentation of data, when permitted by scientific congress policy, is acceptable.