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## ***AGREEMENT***

*between*

**ACTELION Pharmaceuticals Ltd**, Gewerbestrasse 16, CH-4123 Allschwil, Switzerland (hereafter referred to as "ACTELION")

and

***Applicant***, \_\_\_\_\_ (hereafter referred to as "APPLICANT")

and

***Institution***, \_\_\_\_\_ (hereafter referred to as "INSTITUTION")

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## ACTELION ENDOTHELIN RESEARCH AWARD

The Actelion Endothelin Research Award (hereafter the “AERA”) is a grant-based program supported by ACTELION dedicated to the advancement of endothelin science and is committed to providing financial support to research projects in this field.

INSTITUTION is engaged in research projects in the field of endothelin science (hereafter referred to as the “Project”).

The parties hereto agree as follows:

### **Project Summary**

Title

First Name

Name

Institution

Project Title

Submission number

Grant awards

Funds disbursed over

Proposed start date

Estimated completion date

APPLICANT is hereby designated as the Sponsor Investigator of this Project according to Good Clinical Practice (hereafter referred to as “GCP”) definitions in accordance with the terms defined in the Protocol (see application).

The role of ACTELION under this Agreement is limited to the financial support outlined in Section 16. ACTELION exerts no control over, and has no responsibility in the Project or its outcome. Therefore, ACTELION does not assume any Sponsor obligation according to the principles of GCP.

### **1. Protocol**

The Protocol of the Project (hereafter referred to as the “Protocol”) will be performed under the supervision and responsibility of INSTITUTION. The Protocol is an integral part of this agreement (Exhibit A). It is essential that the Project is carried out exactly in accordance with the terms of the corresponding Protocol accepted by the AERA Steering Committee and with the content of the AERA Charter. Any amendments,

revisions or modifications to the Protocol must be in writing and agreed upon by both Parties prior to implementation.

## **2. Start and End Dates of Project**

The Project shall commence no later than 6 months after approval and must be completed within 12 months of commencement. Failure to initiate the Project within this period will result in the possible withdrawal of the grant.

## **3. Scientific Reports**

On **XXX**, six months after the project has started, the AERA requires an interim scientific report that should be sufficiently comprehensive to indicate the Project's accomplishments. Copies of reprints, abstracts or manuscripts in press must be included with the scientific report. The payment of the second grant instalment is contingent upon receipt of a satisfactory interim scientific report.

On **XXX**, the completion of the grant period, the AERA requires a final scientific report that should be sufficiently comprehensive to indicate the Project's accomplishments. Copies of reprints, abstracts or manuscripts in press must be included with the final scientific report.

The payment of the final grant installment is contingent upon receipt of a satisfactory final scientific report. ACTELION has the right to publish the final scientific report free of charge and without any limitation in the AERA Annual Report and/or on the AERA homepage. In case the APPLICANT reports unpublished data, these will not be published in the AERA Annual report or homepage by ACTELION without the agreement of the APPLICANT.

All final scientific reports must be submitted within 60 (sixty) days of the above-mentioned termination date of the grant.

Scientific reports are essential to the function of the AERA. Failure to submit reports could affect funding from the AERA.

## **4. Representation and Warranties**

By signing this Agreement, APPLICANT and INSTITUTION individually represent, warrant and agree to and with ACTELION that:

- a) INSTITUTION recommends APPLICANT for the grant;
- b) any information provided by APPLICANT or INSTITUTION is accurate, not misleading and consistent with the policy of INSTITUTION;
- c) APPLICANT has not been barred from applying to any other research-funding organization for reasons of breach of standards of ethics or integrity;

- d) any research carried out with funds from the AERA respects all grant application requirements of the AERA and complies with the ethical conduct of research as expressed in the AERA charter as published on the AERA homepage ([www.endothelin.org](http://www.endothelin.org)) on the date of signing the Agreement; and as expressed in the latest version of the World Medical Association Declaration of Helsinki (available on the AERA homepage and on <http://www.wma.net>);
- e) the Project has been approved without any restriction by INSTITUTION regarding Biosafety and safety of Human Subjects;
- f) the Project will be carried out in accordance with GCP;
- g) any trial will be conducted according to the Regulations of INSTITUTION;
- h) the Regulations of INSTITUTION are in accordance with the applicable laws and regulations as well as local and international human and animal ethical standards (latest version of the World Medical Association Declaration of Helsinki);
- i) APPLICANT acts within the scope of his/her employment when pursuing the Project;
- k) APPLICANT shall be in charge of implementing the Project and be responsible for any Project related activities, such as data management (e.g. data entry, validation, coherence controls), auditing, intermediary and/or final data analysis and preparation of the scientific reports and final publication.

## **5. Covenants of the INSTITUTION**

INSTITUTION undertakes with ACTELION that INSTITUTION shall:

- a) provide adequate accommodation and research facilities for the duration of the grant;
- b) provide APPLICANT with a suitable affiliation which will allow successful completion of the Project;
- c) administer any grant or award received hereunder according to the policies of the AERA as set out in the AERA Charter;
- d) investigate by appropriate procedures any allegations of conduct inconsistent with AERA's policies and proactively take corrective action.
- e) report to ACTELION the results of any investigation coming to the conclusion that an APPLICANT has infringed any policy of the AERA;
- f) immediately notify ACTELION if the Project cannot be executed as proposed and return the unused money to ACTELION;

- g) immediately notify ACTELION if APPLICANT leaves INSTITUTION. It shall then be up to the AERA Steering Committee to decide whether and/or how to continue with the Project;

## **6. Adverse events**

APPLICANT and INSTITUTION are obliged to report any SAE's to ACTELION Drug Safety within 24 hours. ACTELION or its representatives will provide an SAE report form and related instructions to the APPLICANT and INSTITUTION.

It is understood that APPLICANT and INSTITUTION will notify their Ethics Review Committee of all such events.

ACTELION or its representatives undertakes to notify APPLICANT and INSTITUTION of all serious unexpected adverse events, which occur during the course of a similar study in any other location and are reported in an expedited manner to the health authorities.

## **7. Confidentiality**

Prior to or during the course of the Project, ACTELION or its representatives may provide APPLICANT and INSTITUTION with confidential information, which may not be disclosed to anyone else without prior approval of ACTELION in writing. Such confidential information will be clearly identified as confidential at the time of disclosure.

Specifically excepted from this is all information that:

- a) was previously known by APPLICANT and INSTITUTION as evidenced by written records;
- b) is publicly disclosed except by breach of this Agreement either prior or subsequent to APPLICANT's and INSTITUTION's receipt of such information;
- c) is rightfully received by APPLICANT and INSTITUTION from a third party without an obligation of confidence;
- d) is required by statute or judicial process to be disclosed

INSTITUTION will take any possible steps to the effect that his/her collaborators will be under the same secrecy obligation.

The provisions of this Section 6 shall survive termination of this Agreement for a period of three (3) years.

## **8. Ethics Review Committee Approval**

Written approval for the Protocol and Protocol amendment and the content of the patient information/consent form must be obtained by APPLICANT from a properly constituted Institutional Review Board (IRB) prior to the commencement of the Project.

## **9. Clinical Trial Application to Health Authorities**

A clinical trial application (CTA) must be submitted by the APPLICANT to “Health Authority”.

## **10. Patient Consent**

Written informed consent must be obtained from each patient enrolling in the Project prior to the commencement of his/her participation in the Project. The method of explanation to the patient and the obtaining of their consent should comply with the ICH Guidelines, with local law and/or the ethical principles in the amended Declaration of Helsinki, whichever represents the greater protection for the individual.

## **11. Early Termination**

It is AERA’s intention that the Project is carried out to its conclusion, but APPLICANT must be aware that for a number of reasons, the Project may need to be stopped prior to its conclusion. ACTELION, therefore, reserves the right to terminate this Agreement:

- a) immediately upon a substantial breach of the terms either of the Agreement or the conduct of the Protocol;
- b) in the event of irregularities in the method by which the Project is carried out and although capable of being rectified, are not rectified within 30 days of notice from ACTELION requiring this.
- c) Immediately, if this is necessary in the interests of health and safety of the Project subjects/patients, or as a result of any government authority or court of law.

APPLICANT may terminate the agreement upon thirty (30) days written notice if he/she becomes, for any reason, unable to perform or complete the Project.

If ACTELION unilaterally terminates this Agreement, or if the APPLICANT is unable to complete the Project for reasons beyond APPLICANT’s control, ACTELION will pay APPLICANT and INSTITUTION pro-rata compensation and any related additional non-cancellable costs APPLICANT and INSTITUTION incurred.

ACTELION may demand the reimbursement of funds, which have been or will be or appear to be used – in ACTELION’s discretion - contrary to the aims of the AERA or in contravention of agreed conditions.

## **12. Publication of data**

APPLICANT will inform ACTELION of any Project results in a timely manner and must keep available Project related results to share with scientific community through presentations at any time.

APPLICANT will not publish or disclose information concerning the Project to any third party without first providing ACTELION with a copy of any manuscript, abstract or other document disclosing such information at least sixty (60) days prior to submission thereof to a publisher or to any third party, for the purpose of allowing ACTELION to protect any proprietary information or intellectual property of ACTELION which might be contained in such information. INSTITUTION shall be responsible for compliance by INSTITUTION's staff with the obligations under this Section 11, as well as all other obligations under this Agreement. Neither party will, without the prior written consent of the other party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the other party or party's employee or agent.

### **13. Intellectual Property Rights**

APPLICANT agrees that any Intellectual Property Rights (as defined below) that may arise under this Agreement shall belong to ACTELION and hereby assigns all of APPLICANT's right, title, and interest in such Intellectual Property Rights to ACTELION. APPLICANT agrees to execute such documents and take such actions as ACTELION may reasonably request (at ACTELION's expense) to memorialize and secure such Intellectual Property Rights. For purposes of this Agreement, the term "Intellectual Property Rights" shall mean any rights and know-how existing now or in the future under patent law, copyright law, trade secret law, and any and all similar proprietary rights.

### **14. Exclusion of Liability**

In no event shall ACTELION, its officers, employees, or agents (and their respective successors, heirs and assigns) be liable for any use by APPLICANT or the Project subject/patients, or for any loss, claim, damage or liability, of whatever kind or nature, which may arise in connection with this Agreement.

## **15. Indemnification**

APPLICANT and INSTITUTION shall indemnify, defend, and hold harmless ACTELION, its officers employees, and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys fees and expenses of litigation) incurred by or imposed upon any of the Indemnitees in connection with any claims, suits, actions, demands or judgments arising out of any theory of liability (including without limitation actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) which may arise in connection with this Agreement. However, such indemnification shall not apply to any liability, damage, loss, or expense to the extent directly attributable to the settlement of a claim, suit, action, or demand by Indemnitees without the prior written approval of APPLICANT and INSTITUTION, such approval not to be unreasonably withheld or delayed.

The Indemnitees agree to provide APPLICANT and INSTITUTION with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement. APPLICANT and INSTITUTION agree, at their own expense, to provide attorneys reasonably acceptable to ACTELION to defend against any such claim. With respect to any claim covered by the indemnification contained in Section 14 above, Indemnitees shall cooperate fully with APPLICANT and INSTITUTION in such defense and will permit APPLICANT and INSTITUTION to conduct and control such defense and the disposition of such claim, suit or action (including all decisions relative to litigation, appeal, and settlement); provided, however, that any Indemnitee shall have the right to retain its own counsel, at the expense of APPLICANT and INSTITUTION, if representation of such Indemnitee by the counsel retained by APPLICANT and INSTITUTION would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel. APPLICANT and INSTITUTION agrees to keep ACTELION informed of the progress in the defense and disposition of such claim and to consult with ACTELION with regard to any proposed settlement.

## **16. Insurance**

APPLICANT and INSTITUTION represent and warrant that he/it has all necessary (liability) insurance required in order to perform the Project and to indemnify ACTELION pursuant to Section 14 here above. APPLICANT and INSTITUTION shall provide ACTELION with a copy of the relevant insurance policy prior to the initiation of the Project. APPLICANT and INSTITUTION shall notify ACTELION of any changes in the relevant insurance coverage.

## **17. Finance**

All funds will be disbursed in Swiss Francs (CHF).

Project will be funded by XXX CHF.

CHF XX.-- [50%] will be paid at the end of the month in which the grant term starts.

CHF XX.-- [40%] will be paid on XXX, at the latest, contingent upon the satisfactory receipt of the interim scientific report by the AERA Support Team.

CHF XX.-- [10%] will be paid on XXX, at the latest, contingent upon the satisfactory receipt of the final scientific report by the AERA Support Team.

The payment of the second and the third grant installments is contingent upon receipt of satisfactory scientific reports.

INSTITUTION and APPLICANT will not use more than ten percent (10%) of the grant award from the AERA for Project overhead costs.

## **18. Transferability**

If APPLICANT leaves his/her employment with INSTITUTION, ACTELION has the exclusive right to transfer this Agreement and all rights and responsibilities thereto appertaining, without limitation, in its sole discretion, to the APPLICANT's new employer/new INSTITUTION.

## **19. Applicable Law and Place of Jurisdiction**

This Agreement shall be interpreted and construed in accordance with the laws of Switzerland. In case of controversies, which cannot be settled amicably, the matter shall be brought before the competent courts of Basel-City, Switzerland.

IN WITNESS THEREOF, the parties hereto have executed this Agreement in duplicate by proper persons duly authorized.

APPLICANT

**Date**

\_\_\_\_\_

**Signature**

\_\_\_\_\_

**Name**

\_\_\_\_\_

**Title**

\_\_\_\_\_

INSTITUTION

**Date**

\_\_\_\_\_

**Signature**

\_\_\_\_\_

**Name**

\_\_\_\_\_

**Title**

\_\_\_\_\_

ACTELION

**Date**

\_\_\_\_\_

\_\_\_\_\_

**Signature**

\_\_\_\_\_

\_\_\_\_\_

**Name**

\_\_\_\_\_

\_\_\_\_\_

**Title**

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Exhibit A: Protocol

SAMPLE