

# Actelion Endothelin Research Awards (AERA)

## *Charter*

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### **I. Introduction**

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- 1. Mission** The purpose of the Actelion Endothelin Research Awards (hereafter "AERA") is the advancement of clinical science in the field of endothelin research by supporting young clinical investigators at universities and research institutes.
- 2. Description** AERA was established by Actelion Pharmaceuticals Ltd (hereafter "Actelion") in 2006. Actelion committed to providing initial funding of 500,000 Swiss Francs (CHF) for one year. Further possible funding will be communicated on the AERA website ([www.endothelin.org](http://www.endothelin.org))
- The AERA is run as an autonomous and non-profit program.
- 3. Research focus** AERA encourages the exploration of new research in areas associated with the study of endothelin related to heart, lung and vascular diseases.
- 4. Publication of results** Results will be shared with the scientific community through presentations in scientific congresses and publications in general.

### **II. Structure**

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- 1. Steering Committee** There are 5-8 members on the Steering Committee (hereafter SC).
- SC members have been selected by Actelion and approved by the Chairman to ensure a wide variety of expertise, experience and opinion as well as representation throughout all Europe.
- SC members of the AERA will have the following duties and obligations:
1. To review applications and decide on the final distribution and size of grants to the applicants.
  2. To ensure a fair and timely grant application review, approval and award procedure.
  3. Strategic decisions and contribution to the improvement of the AERA.
- As of January 2009, SC members and their co-workers will not be allowed to apply for AERA grants. Also SC members are excluded from appearing as mentors or from being involved in any way in submitted projects.
- 2. Chairman** The Chairman has been appointed by Actelion.
- The Chairman of the AERA will have the following duties and obligations:
1. Interaction with Actelion during the initial set-up and finalisation of documents and procedures.
  2. Supervise implementation of the charter in order to maximise the AERA's objective of fostering clinical endothelin research.
  3. To provide direction and leadership to the AERA.
  4. To represent AERA in the scientific community and in public when this is appropriate, and to support public awareness of AERA and its objectives.

### **III. Grant Application Process**

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#### **1. Grants**

Funds allocated to each competition cycle will be distributed to successful applicants. Amounts available for each competition cycle will be announced on the AERA website ([www.endothelin.org](http://www.endothelin.org)).

Every awarded project will receive a maximum of 100,000 CHF.

#### **2. Timelines**

Timelines for application submissions and announcement of award winners will be communicated on the AERA website ([www.endothelin.org](http://www.endothelin.org)).

#### **3. Submission**

Letter of Intent applications (LOI) must be submitted electronically via the AERA website ([www.endothelin.org](http://www.endothelin.org)). Applicants must download the LOI application form and complete it in accordance with the accompanying guidelines. The completed form should be submitted within the provided deadline and in accordance with the guidelines and the AERA website ([www.endothelin.org](http://www.endothelin.org)).

Confidentiality of submitted data is guaranteed. Especially, no personal data or scientific results will be provided to third parties.

Once submitted, applications cannot be modified. Changes occurring after award are subject to approval by the SC.

By submitting the completed application form the principal investigator confirms to have read and understood the application guidelines, the AERA charter and the AERA Agreement for Grant Awards and confirms to agree to the content of these documents and to the conditions stated.

#### **4. Review**

The SC will evaluate submitted LOI applications according to the application guidelines.

Submitted applications and evaluations will be discussed by the SC and ranked according to the SC discussion outcomes.

Selected applicants will be invited to submit a full proposal within about four weeks from notification (a deadline will be provided).

Submitted full proposals will be evaluated and extensively discussed by the SC and ranked according to the SC discussion outcomes.

The number of awards will be determined depending on the funds available for grants. The top-ranked projects will be awarded.

Based on budget requests and available funds for grants, the SC will also decide on the size of awarded grants, which can differ from the amount requested by the applicant.

### **IV. Grant Awards**

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#### **1. Notification**

Both successful and non-successful applicants will be notified in writing.

AERA will not provide details of the review process. In particular, ranking, qualitative and quantitative evaluations, names of reviewers and criteria for award or rejection will not be communicated.

The notification letter may also include special terms or conditions which apply to all terms applicable.

## **2. Further conditions to funding**

AERA will support mentored, clinical, and investigator-initiated studies only. The sponsor responsibility has to be heard solely by the applicants and their institutions. Only clinical projects with patient involvement will be evaluated and considered for funding.

Drugs used in the submitted studies must have been approved in the country where the study will be conducted.

Receiving a grant in no way implies that the recipient is obliged to recommend or prescribe any Actelion products.

Award winners will be asked to provide supplementary documents, including but not limited to: Institutional Review Board or ethical committee approvals for the submitted study, complete clinical study protocols, samples of informed consent documents (if applicable).

Award winners and the institution where the study will be conducted will also be required to sign the AERA Agreement for Grant Awards, a sample of which can be found on the AERA website ([www.endothelin.org](http://www.endothelin.org)).

The signed agreement and requested documents are to be returned as specified in the notification letter not later than 90 days after the communication of the award. No funds will be disbursed prior to complete submission of the requested documents. Failure to submit requested documents as specified and within the given deadline may result in withdrawal of award.

## **3. Budget**

Budgets are to be submitted in CHF and should reflect realistic estimates of the funds required for the proposed research. Awards are made without assurance of continued support beyond the term designated.

The award is not necessarily designated to cover the total cost of the proposed research. The grantee institution is expected to provide the required physical facilities and administrative services normally available in a research institution. However, each grant may include a ten percent (10%) supplement for overheads, the disposition of which is the responsibility of the host institution and the applicant. If applying, overhead costs should be included in the submitted budget at the time of submission. It is assumed that the institution will permit the overhead allocation to be spent on the research project.

The AERA does not provide funds for the following items:

1. Institutional overheads above the 10% flat rate
2. Purchase of journals and books
3. Purchase of office furniture
4. Payments of dues and membership of professional societies
5. Recruitment and relocation expenses
6. Construction and maintenance of buildings
7. Payment of non-medical or personal services to patients
8. Purchases of reprints/copies

Travel related directly to the research project to communicate research findings is allowable up to a maximum of CHF 2,000 (as part of the submitted budget).

The AERA relies on the integrity of the applicants in assessing overlap between grants proposed and other grants held or being requested by the applicant. The AERA intends to fund independent research projects. Overlap between grant proposals submitted and research already being conducted by the applicant must

be specifically acknowledged by the applicant.

If a project designated for funding by the AERA is also funded by another agency the applicant must choose which grant to accept. If funding is awarded later by another institution, notification must be made to the SC, and the AERA will be entitled to withdraw the grant or the remaining part of it.

#### **4. Funds disbursement**

The SC will decide the manner in which an award will be disbursed. In principle, only a part of the amount awarded is paid by the end of the month in which the grant term commences as per the notification letter. The rest is paid contingent upon approval of a final report.

All funds are disbursed in CHF. An equivalent amount is transferred to the applicant in the local currency at the exchange rate of the day of transfer.

Funds are distributed over at least two instalments. An amount not less than 10% of the total grant awarded will be paid after a final report has been submitted by the applicants and approved by the SC.

If more than two instalments will be paid, further progress reports may be requested before proceeding with payment.

### **V. Eligibility and conduct of the study**

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#### **1. Eligibility**

Eligible principal investigators should:

1. Be engaged principally in clinical research aimed at understanding the role of endothelin in disease.
2. Have experience in the proposed research field as of the date of submission of the Letter of Intent, and no more than 5 years experience in their tenure track appointment or other comparable independent research appointment.
3. Preferentially be no higher than Assistant Professor.
4. Preferentially have a PhD or MD degree.

Principal investigators can submit only 1 research proposal per application round and cannot hold more than 1 grant at the time. Previously awarded projects have to be completed and successfully published as manuscripts in peer-reviewed journals in order to be eligible for further grant awards.

Grant funds cannot be awarded to principal investigators whose salaries are largely derived from commercial organisations in the pharmaceutical or allied industries.

Grant funds will always follow the principal investigator, if he or she changes institution, insofar as he or she can convince AERA that the project can be pursued as planned (including fulfilment of all contracts with the sponsoring institution).

Research projects must be carried out at an academic institution or research institute. Submissions from all countries except the USA are accepted (see AERA website for further information on the USA grant programme).

#### **2. Start and end dates**

Research should commence no later than 6 months after approval of the grant unless an alternative date for commencement has been approved by the SC. Failure to initiate the research within this period may result in withdrawal of the grant.

Funded projects should be completed within 12 months of commencement. Clinical follow-up after the 12-month limit is however allowed if properly

justified by the applicant and corroborated by outcomes and delivered data. A report must be provided after 12 months and the follow-up must be evaluated and approved by the SC. No further funding will be provided after the 12-month limit.

**3. Final reports** At the end of the grant period, the AERA requires a comprehensive final scientific report summarising the project's accomplishments and including copies of reprints, abstracts or manuscripts in press.

The payment of the final grant instalment is contingent upon approval of the final report by two (2) SC members.

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

Final reports are essential to the function of AERA. Failure to submit final reports may affect eligibility for future funding.

**4. Study conduct and ethics** The AERA is bound by its objectives to maintain and promulgate the highest ethical standards in clinical research and to maintain the highest standards in the conduct and assessment of such research.

All research involving human subjects should be performed in accordance with the latest version of the World Medical Association Declaration of Helsinki at the time of submission. Research proposals for human cloning will not be considered.

**5. Publication** Where a publication of the data and results generated by the grant-holder is foreseen, the full text of the manuscript or abstract shall be submitted to Actelion for consideration prior to submission to a scientific journal or prior to use in a public lecture or poster. Actelion shall have the right to provide comments on publication as mentioned in the agreement for grant awards.

**6. Patents / Commercial activities** The grant-holder shall make available to Actelion any and all data and results of his work to be performed under his AERA grant. All data and results are exclusively owned by and proprietary to Actelion. As to the said data and results, the same obligation regarding confidentiality as agreed upon as per the AERA Agreement for Grant Awards shall apply for the grant-holder as well.

**7. Equipment** All equipment covered by the AERA funds must be for the purposes of the funded research. Applicants must give a full description of all equipment including cost and technical data. The equipment will become the property of the host institution, which will be responsible for its accommodation, operating, servicing and insurance costs.

**8. Appropriate use of funds** The Steering Committee may demand reimbursement for funds used in a manner contrary to the aims of the AERA or in contravention of agreed conditions.

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*Finalised and approved on 20 March 2006. Changes and amendments done on 29 March 2006, 26 April 2006, 10 January 2007 and 8 January 2008, 19 January 2009.*