Proposal Evaluation Form

EUROPEAN COMMISSION

Horizon 2020 - Research and Innovation Framework Programme

Evaluation Summary Report

Call: H2020-PHC-2014-single-stage_RTD
Funding scheme: Research and Innovation action
Proposal number: 643384
Proposal acronym: APOSEC
Duration (months): 54
Proposal title: Clinical Trial testing of APOSEC(TM) as a Regenerative Medicine
Activity: PHC-15-2014

N.	Proposer name	Country	Total Cost	%	Grant Requested	%
1	[redacted]	AT	1,431,968	23.25%	1,431,968	23.25%
2	[redacted]	AT	975,098	15.83%	975,098	15.83%
3	Apoptosience AG	AT	1,940,316	31.50%	1,940,316	31.50%
4	[redacted]	AT	436,500	7.09%	436,500	7.09%
5	[redacted]	DE	551,688	8.96%	551,688	8.96%
6	[redacted]	DK	204,128	3.31%	204,128	3.31%
7	[redacted]	ES	156,913	2.55%	156,913	2.55%
8	[redacted]	RO	150,221	2.44%	150,221	2.44%
9	[redacted]	PL	145,688	2.37%	145,688	2.37%
10	[redacted]	SK	166,745	2.71%	166,745	2.71%
	Total:		6,159,265		6,159,265	

Abstract:
The objective of the APOSEC project is to achieve clinical proof-of-concept by performing clinical Phase I & II studies utilising the patent and trademark protected drug product APOSEC. Authorisation for APOSEC production has already been granted by the relevant Austrian regulatory body (AGES) and complementary studies on toxicology, efficacy and mode of action will ensure full compliance and readiness to swiftly move into Phase III trials at the completion of the proposed H2020 project. The results gained within these trials will provide first-in-man evidence of the ground-breaking potential of APOSEC to provide new therapies to millions of sufferers in modern society worldwide in the fields of wound healing (e.g. for chronic skin wounds and diabetic ulcers) and acute Myocardial Infarction (AMI). The specific objectives are 1. To develop potency and stability assays, to validate its shelf life and to produce sufficient APOSEC for the clinical trials. 2. To conduct toxicology and safety pharmacology studies to assess the safety of the medicinal drug candidate in animal models in order to address preclinical and toxicological matters raised by regulatory authorities. 3. To conduct Phase I topical and systemic clinical trials of APOSEC in healthy subjects. 4. To conduct a Phase II randomised, double blind prospective clinical trial utilising APOSEC as topical treatment for Diabetic foot ulcer. 5. To conduct a Phase I-II clinical trial to determine the safety of a single intravenous application of APOSEC in patients with ST-elevation myocardial infarction (STEMI) as an upstream therapy before primary percutaneous coronary intervention (PCI). 6. To perform parallel, mode of action research for APOSEC to optimise the dosage and the frequency of application for Phase I, II and later on Phase III clinical trials. 7. To promote the APOSEC project and its results widely and effectively to relevant stakeholder groups to fulfil both dissemination and exploitation strategies.

Evaluation Summary Report

Evaluation Result

Total score: 3.50 (Threshold: 12.00)

Form information

SCORING

Scores must be in the range 0-5.

Interpretation of the score:

***0– The proposal fails to address the criterion** or cannot be assessed due to missing or incomplete information.*

***1– Poor.** The criterion is inadequately addressed, or there are serious inherent weaknesses.*

***2– Fair.** The proposal broadly addresses the criterion, but there are significant weaknesses.*

***3– Good.** The proposal addresses the criterion well, but a number of shortcomings are present.*

***4– Very good.** The proposal addresses the criterion very well, but a small number of shortcomings are present.*

***5– Excellent.** The proposal successfully addresses all relevant aspects of the criterion.Any shortcomings are minor.*

Criterion 1 - Excellence

Score: **3.50** (Threshold: 4.00/- , Weight: -)

Note: The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work programme. If a proposal is partly out of scope, this must be reflected in the scoring, and explained in the comments.
Clarity and pertinence of the objectives

Credibility of the proposed approach
Soundness of the concept, including trans-disciplinary considerations, where relevant
Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art (e.g. ground-breaking objectives, novel concepts and approaches)

The consortium behind the APOSEC trial is seeking a clinical proof-of-concept of APOSEC™ in treatment of non-healing wounds and acute myocardial infarction. APOSEC is lyophilized mixture of active paracrine components secreted from apoptotic cultured peripheral white blood cells (PBMC). Apoptosis is induced by gamma-irradiation. APOSEC was tested on clinically relevant animal models of wound healing in a species-specific manner, including large animals, and the treatment resulted in a significant improvement compared to controls. Consortium partners published several reports in peer-reviewed journals. Published data on wound healing are solid and reflect a meticulous approach in validation of the new product toward clinical application.

The proposal suffers from several weaknesses: First, more preliminary evidence of a functional recovery following use of APOSEC in the animal model for acute myocardial infarction (AMI) is needed. Second, proceeding with studies in two completely different indication fields appears much too ambitious. In addition, evaluation of toxicological and safety pharmacological properties of APOSEC as a medicinal product for topical and systemic application should have been done before this application. Also, it remains unclear how well the upstream delivery of the product will be in AMI patients before percutaneous coronary intervention.

Criterion 2 - Impact

Score: **.00** (Threshold: 4.00/- , Weight: -)

Note: The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level:
The expected impacts listed in the work programme under the relevant topic
Enhancing innovation capacity and integration of new knowledge
Strengthening the competitiveness and growth of companies by developing innovations meeting the needs of European and global markets, and where relevant, by delivering such innovations to the markets
Any other environmental and socially important impacts
Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant

Criterion 2 not evaluated due to Criterion 1 falling below threshold.

Criterion 3 - Quality and efficiency of the implementation

Score: **.00** (Threshold: 3.00/- , Weight: -)

Note: The following aspects will be taken into account:
Coherence and effectiveness of the work plan, including appropriateness of the allocation of tasks and resources
Complementarity of the participants within the consortium (when relevant)
Appropriateness of the management structures and procedures, including risk and innovation management

Criterion 3 not evaluated due to Criterion 1 falling below threshold.

Operational Capacity

Status: **Operational Capacity: Yes**

Not provided

Proposal content corresponds, wholly or in part, to the topic description against which it is submitted, in the relevant work programme part

Status: **Yes**

Not provided

Overall comments

Not provided