Proposal Evaluation Form

EUROPEAN COMMISSION

Horizon 2020 - Research and Innovation Framework Programme

Evaluation Summary Report

Call: H2020-SMEINST-2-2016-2017
Funding scheme: SME-2
Proposal number: 806595
Proposal acronym: EuroXpand
Duration (months): 36
Proposal title: EUROpean clinical validation of a new ex vivo eXpanded stem cell theraPy for cArdiac regeNeration after acute myocarDial infarction: EUROXPAND
Activity: SMEInst-05-2016-2017

N.	Proposer name	Country	Total Cost	%	Grant Requested	%
1	CELLPROTHERA	FR	5,000,000	100.00%	5,000,000	100.00%
	Total:		5,000,000		5,000,000	

Abstract:
Heart failure (HF) after acute myocardial infarction (AMI) remains the first cause of death in developed countries, above cancer, with a life expectancy less than 5 years. With an overall cost of 83 billion euros per year worldwide , HF represents a global public-health issue. Treatments following AMI are still characterised by burdensome surgical procedures and post-operative treatments which both fail to prevent HF development. In this context, CellProthera, founded in 2008, developed an innovative technology based on the discoveries of its founder, Pr. Hénon, who has worked on stem cells for more than 35 years. Unlike its competitors, CellProthera has already demonstrated the efficacy and the safety of its cell therapy, thanks to a successful Proof of Concept study. The clinical outcomes indicated an excellent safety profile associated with an outstanding long-term recovery of the cardiac function, facilitating socio-professional reinsertion. The process used during the pilot phase could not be patented nor industrialised, limiting its availability to all patients. Hence, Cellprothera has developed a patented cell expansion automate StemXpand®, combined with StemPack® Kit creating an innovative business model, and a new cell therapy process less invasive, more affordable, and decreasing health costs related to HF in the order of 50 to 75%. With the efficacy demonstration of the new process through EuroXpand project, Cellprothera's cell therapy could become the reference treatment to prevent HF after AMI. This way, CellProthera will be in possession of all the assets required to achieve a leader position in HF prevention, after AMI. Indeed, with a potential of millions patients / year worldwide, Cellprothera's total turnover is expected to reach 1,9 billion euros in 2021, associated to the creation of at least 40 direct jobs by 2022 and several thousands of indirect jobs, particularly in Cell Therapy Centres.

Evaluation Summary Report

Evaluation Result

Total score: 14.18 (Threshold: 12)

Form information

Indicative Appraisal Scale per Sub-Criterion:
- Very Good to Excellent (4.5 – 5)
- Good to Very Good (3.5 – 4.49)
- Fair to Good (2.5 – 3.49)
- Insufficient to Fair (1.5 – 2.49)
- Insufficient (0-1.49)

Operational Capacity

Status: **Operational Capacity: Yes**

If NO, please indicate the partner(s) concerned, and provide a short explanation. In any case, evaluate the full proposal, taking into account all partners and activities.

Not provided

Criterion 1 - Impact

Score: **4.78** (Threshold: 4/5.00 , Weight: 100.00%)

The expected impacts listed in the work programme under the relevant topic:

The proposal describes in a realistic and relevant way how the innovation has the potential to boost the growth of the applying company.
Very Good to Excellent (4.5 – 5)

Enhancing innovation capacity:

The proposal demonstrates the alignment with the overall strategy of the participating SME(s) and the need for commercial and management experience, including understanding of the financial and organizational requirements for commercial exploitation as well as key third parties needed

Strengthening the competitiveness and growth of companies and create new market opportunities:

A European added value has been taken into account in the following aspects: a) the assessment of the market, b) the analysis of the competition, c) the impact on EU/global challenges.
Very Good to Excellent (4.5 – 5)

The proposal indicates in a convincing way that there will be demand/market (willingness to pay) for the innovation when the product /solution is introduced into the market.
Very Good to Excellent (4.5 – 5)

The targeted users or user groups of the final product/application, and their needs, are well described and the proposal provides a realistic description of why the identified groups will have an interest in using/buying the product/application, compared to current solutions available.
Very Good to Excellent (4.5 – 5)

Address issues related to climate change or the environment, or bring other important benefits for society (not already covered above):

The proposal adequately addresses issues related to climate change or the environment, or brings other important benefits for society.
Very Good to Excellent (4.5 – 5)

Quality of the proposed measures to exploit and disseminate the project results, and communicate the project activities to different target audiences:

The applicant has made a thorough competition analysis including a) description of competitors and competing products or services, and b) reasons to buy the proposed innovation rather than alternatives.
Very Good to Excellent (4.5 – 5)

The commercialisation strategy is described in a realistic and relevant way, including approximate time to market/deployment. Activities to be further developed after phase 2, including additional dissemination measures, are well outlined.
Very Good to Excellent (4.5 – 5)

Measures to ensure "freedom to operate" (possibility of commercial exploitation) are realistic and there is a convincing strategy of knowledge protection, including current IPR filing status, IPR ownership and licensing issues. Regulatory and/or standard requirements are well addressed.
Good to Very Good (3.5 – 4.49)

Overall assessment of the Impact criterion

(25% weight in the assessment of this criterion)
Very Good to Excellent (4.5 – 5)

Criterion 2 - Excellence

Score: **4.70** (Threshold: 3/5.00 , Weight: 100.00%)

Clarity and pertinence of the objectives:

The objectives for the project as well as the approach and activities to be developed are consistent with the expected impact (commercialisation/deployment). Specifications for the outcome of the project and criteria for success are well defined.
Very Good to Excellent (4.5 – 5)

Credibility of the proposed methodology:

The expected performances of the innovation are convincing and have the potential to be relevant in terms of value for money.
Very Good to Excellent (4.5 – 5)

Soundness of the concept, including appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge:

The proposal reflects a very good understanding of both risks and opportunities related to a successful market introduction of the innovation, from a technical, commercial and regulatory point of view.
Very Good to Excellent (4.5 – 5)

The feasibility assessment (developed under Phase I or through other means) demonstrates the technological/practical/economic viability of the innovation.
Very Good to Excellent (4.5 – 5)

Extent that the proposed work is beyond the state of the art, and demonstrates innovation potential:

With the proposed innovation, the company aims to explore new market opportunities addressing EU/global challenges.
Very Good to Excellent (4.5 – 5)

The current stage of development (TRL 6 - see note 1- or similar for non-technological innovations) is well described. The steps planned to take this innovation to the market are clearly outlined.
Note 1: Please see part G of the General Annexes. (N.B.: In the case of SMEInst-05-2016-2017, the Technology Readiness Levels indication does not apply)
Very Good to Excellent (4.5 – 5)

The proposal makes a realistic comparison with the current state-of-the-art solutions, including costs, environmental benefits, gender dimension- see note 2-, ease-of-use and other features.
Note 2:In relation to the project content, e.g. gender studies, clinical trials, etc.
Good to Very Good (3.5 – 4.49)

Overall assessment of the Excellence criterion

(25% weight in the assessment of this criterion)
Very Good to Excellent (4.5 – 5)

Criterion 3 - Quality and efficiency of implementation

Score: **4.70** (Threshold: 3/5.00 , Weight: 100.00%)

Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables:

The proposal demonstrates that the project has the relevant resources (personnel, facilities, networks, etc.) to develop its activities in the most suitable conditions. If relevant, describes in a realistic way how key stakeholders / partners / subcontractors could be involved and why and how they were selected (subcontractors must be selected using the best-value-for-money principles). (Where relevant-participants in a consortium are complementary).
Very Good to Excellent (4.5 – 5)

Complementarity of the participants and extend to which the consortium as a whole brings together the necessary expertise:

The team has relevant technical/scientific knowledge/management experience, and a very good understanding of the relevant market aspects for the particular innovation. If relevant, the proposal includes a plan to acquire missing competences, namely through partnerships or subcontracting (subcontractors must be selected using the best-value-for-money principles).
Very Good to Excellent (4.5 – 5)

Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role:

Taking the project's ambition and objectives into account, the proposal includes a realistic time frame and a comprehensive implementation description.
Very Good to Excellent (4.5 – 5)

The work package descriptions and major deliverables and milestones are realistic and relevant, including appropriateness of the allocation of tasks and resources, risk and innovation management.
Very Good to Excellent (4.5 – 5)

Overall assessment of the Quality and Efficiency of Implementation Criterion

(25% weight in the assessment of this criterion)
Very Good to Excellent (4.5 – 5)

Subcontracting

Subcontracting is acceptable in terms of 'best value for money': (only for NON-SMEInst-05-2016-2017: Supporting innovative SMEs in the healthcare biotechnology sector projects) except for task(s):

N.B.: A blank section means either a positive assessment of all your subcontracting tasks or that your proposal does not foresee any subcontracting activities.

Scope of the proposal

Status: **Yes**

Comments:

Not provided

Use of human embryonic stem cells (hESC)

Does this proposal involve the use of hESC?

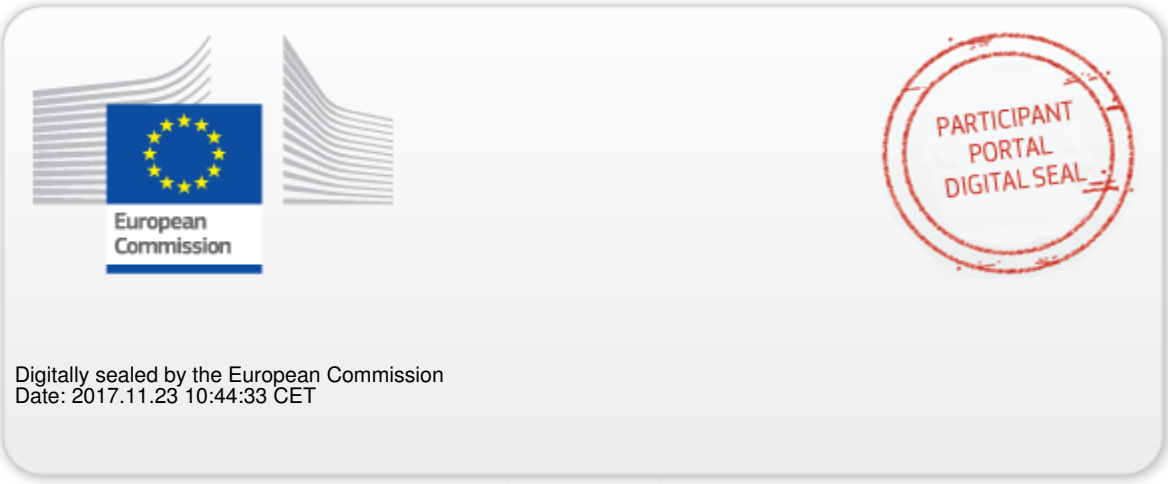
No

If yes, please state whether the use of hESC is, or is not, in your opinion, necessary to achieve the scientific objectives of the proposal and the reasons why. Alternatively, please also state if it cannot be assessed whether the use of hESC is necessary or not because of a lack of information.

Not provided

Overall comments

Not provided



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