

Partnering Opportunity

Profile Status: Published

Research & Development Request

EIC Pilot Fast Track To Innovation: Italian innovative start up in the healthcare sector seeks industrial and research partners to complete the consortium

Summary

An Italian innovative start up is preparing a project proposal for a Fast Track to Innovation. The company develops a novel formulation of dermatological cream containing tissue regenerative factors present in human platelets for the treatment of skin ulcers, including serious disorders, such as diabetic foot ulcers, pressure and leg ulcers. The start-up seeks two different partners: a contract manufacturing organization and a contract research organisation via research cooperation agreement.

Creation Date	13 November 2019
Last Update	13 November 2019
Expiration Date	10 January 2020
Reference	RDIT20191113001
Public Link	https://een.ec.europa.eu/tools/services/PRO/Profile/Detail/06e76d4b-4165-443e-9fca-1a3d1a3d4d35

Details

Description

The coordinator of the project is an innovative start-up, located in Milan, developer of highly effective (in terms of care-duration), accessible (in terms of distribution) and reliable (in terms of results achieved if compared with the state-of-the-art solutions) pharmaceutical cream, aimed at people affected by diabetic foot ulcers, pressure ulcers and leg ulcers.

The project is addressed to validate the dermatologic cream formulation through the performance of pre-clinical and clinical tests and the development of the medical device to administer the cream. Moreover, it aims to develop regulatory and dissemination activities that will lead, at the end of the three project years, to reach the target set in the product business plan, that is the preparation of all activities necessary to transfer the production process to manufacturing companies of the pharmaceutical sector.

This project has already involved 3 partners from Italy and Spain. The Italian start up is seeking additional partners to apply for the Fast Track to innovation call.

The sought partners should complete the roadmap needed to enter in the healthcare market with a disruptive product.

In order to complete the consortium, partners with the following profiles will be evaluated:

1. **CONTRACT MANUFACTURING ORGANIZATION (CMO):** to perform a controlled randomized clinical trial to obtain pre-regulatory authorization by the European Medicines Agency (EMA). The CMO will produce of the first batch of prototype state product (2000 units) to carry out the pre-clinical (200 units) and clinical studies (1800 units).
2. **CONTRACT RESEARCH ORGANIZATION (CRO):** to develop a pilot line of dermatological cream production complying with Good Manufacturing Practice (GMP) standards. The CRO will perform the study on the Efficacy and safety of Cord Blood Platelet-Gel (CBP-G) in patients with chronic neuropathic Diabetic Ulcers in a prospective randomized, open blinded endpoint (PROBE), phase II, multicenter study.

Due to the Fast Track to Innovation programme characteristics, the company will not evaluate any Italian or Spanish candidates for this project proposal.

Official deadline for the call: 19/02/2020

Deadline for expressions of interest: 10/01/2020

Estimated duration of the project: 3 years

Advantages and Innovations

The innovation potential of the project regards:

- 1) the use of several thousands of 'healthy and safe' blood units, from umbilical cord and adults' donors, available at hospitals but regrettably wasted (with significant cost and ethical concern);
- 2) the provision of a single-dose, home self-administered biopharmaceutical drug for the treatment of skin ulcers that will reduce hospitalization costs and improve the quality of life of a large number of patients.

Technical Specification or Expertise Sought

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Stage of Development

Under development/lab tested

Comments Regarding Stage of Development

The project is moving to the "laboratory to market" phase having reached a level of maturity close to market at TRL6.

This has been achieved through several stages:

(TRL1) the pro-angiogenic and reparative role of blood platelet lysates has been demonstrated

in early publications and recognized in numerous scientific papers
(TRL2) completed proteomic studies on cord blood platelet lysates confirming the high pro-angiogenic feature of neonatal platelets (even higher than that of lysates obtained from adult blood platelets)
(TRL3) documented clinical effectiveness of platelet gel obtained from placental blood in patients with devastating skin ulcers like those observed in epidermolysis bullosa
(TRL4, TRL5) validation and laboratory testing of a lyophilization procedure for the long- term storage at room temperature of the basic material used for the preparation of the dermatological cream
(TRL6) development of a cream formulation that is made by dissolving the lyophilized platelet lysate in proper solvents. An administration route has also been designed based on single use cream doses prepared at the moment of use by the patient that guarantees better shelf life of the lysate and easier administration. The cream and administration route have been evaluated in a relevant clinical environment to ensure efficacy and compatibility with clinical pathways in the treatment of chronic ulcers.

IPR Status

Patents granted

Comment Regarding IPR status

IP assets consist of three patent families:

1. Italian patent application n. IT2008MI01316 (now granted). The application has been extended internationally through the PCT application WO2010007502 (A2). The patent family is currently granted in Europe (DE, ES, FR, GB, IT, PL and TR) and US.
2. International patent application WO2016193924 A2 The PCT application has been nationalised in EP, US, CN, CA, RU, IR, IN, EG, MY and SA (still pending).
3. Italian patent application n. 102019000005978

Keywords

Technology

06001015 Pharmaceutical Products / Drugs

Market

05003005 Drug delivery and other equipment
05007002 Pharmaceuticals/fine chemicals

NACE

M.72.1.9 Other research and experimental development on natural sciences and engineering

Network Contact

Issuing Partner

ZACHODNIOPOMORSKI UNIWERSYTET TECHNOLOGICZNY W SZCZECINIE

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Open for EOI : **Yes**

Dissemination

Relevant Sector Groups

Healthcare

Client

Type and Size of Organisation Behind the Profile

Industry SME <= 10

Year Established

2016

Turnover

<1M

Already Engaged in Trans-National Cooperation

Yes

Languages Spoken

English
Spanish
Italian

Client Country

Italy

Partner Sought

Type and Role of Partner Sought

In order to complete the consortium the company is looking for:

1.CONTRACT MANUFACTURING ORGANIZATION (CMO)

Characteristics: Private for profit entity working in GMP conditions (Good Manufacturing Practices standard), able to perform the liophilization of cord blood platelet lysate and formulation of single dose dermatological cream based on liophilized Cord Blood; responsible of labelling and primary and secondary packaging

2.CONTRACT RESEARCH ORGANIZATION (CRO)

Characteristics: Certified For Profit European CRO; Development of protocol for the Phase 2 and 3 Randomized Clinical Multicenter Study "Efficacy and safety of Cord Blood Platelet-Gel (CBP-G) in patients with chronic neuropathic Diabetic Ulcers: a prospective randomized open blinded endpoint (PROBE); Primary outcomes: sample size comparison of dermatologic cream with standard of care.

The primary objective of this study will be to assess the incidence of complete wound closure after 12 weeks treatment with CBP-G in patients with diabetic foot ulcers.

The secondary objectives of this study will be:

- o Time to achieve complete wound closure
- o Percentage reduction in total ulcer surface area at each visit
- o Incidence of complete wound healing at week 6
- o Incidence and frequency of treatment-emergent adverse events (TEAEs) following 12 weeks of treatment
- o Wound-related infections
- o Changes in standard laboratory parameters

Type and Size of Partner Sought

University,R&D Institution,>500 MNE,251-500,SME 51-250,>500

Type of Partnership Considered

Research cooperation agreement

Program - Call

Framework Program

H2020

Call title and identifier

EIC Pilot Fast Track To Innovation

Coordinator Required

No

Deadline for EOI

10 Jan 2020

Ref: RDIT20191113001

Deadline of the Call

19 Feb 2020

Project Duration

156 week(s)

Weblink to the Call

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/eic-fti-2018-2020;freeTextSearchKeyword=;typeCodes=0,1;statusCodes=31094501,31094502;programCode=null;programDivisionCode=null;focusAreaCode=null;crossCutting>

Project Title and Acronym

Platelet LYSate based DERMal formulation for the treatment of skin ulcers (LYSADERM)