CONTEXTE

Low back pain (LBP) is **the most common cause for disability in individuals aged 45 years or younger**. Hence, the **World Health Organisation** has included LBP in its list of twelve priority diseases. Degenerative disc disease is the most common cause of chronic LBP.

More than

70 million Europeans

are affected by DDD

100 million euros

DDD costs per year

***DDD** is **a serious medical and social problem** causing chronic back pain, sciatica, spinal stenos, impairs mobility and the quality of life.*

No efficient therapy available

Combining physical and medical therapies can temporally relieve pain in most of the cases and chronic cases often receive surgery.

THE PROJECT

Encouraging results in phase 1 and 2a trials suggest that cell-based, **regenerative therapies may prevent those problems**. Patients exhibited rapid and progressive improvement of functional pain indexes by **50 % within 6 months** and **by 65 % to 78 % over 1 year** a**fter intradiscal administration of autologous BM-MSCs** (bone marrow mesenchymal stromal cells).

EXPECTED OUTCOMES

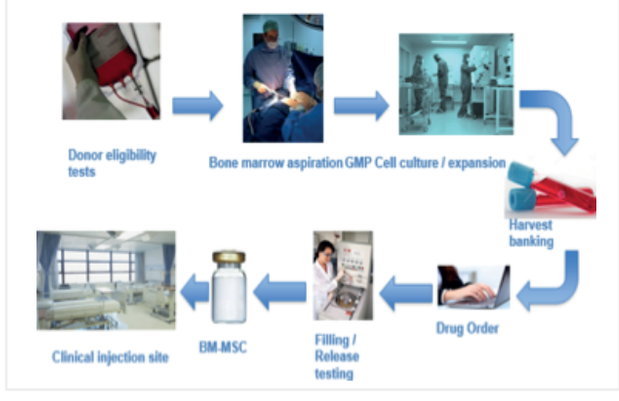
- RESPINE will ensure that the treatment of LBP will be **available to a large population in the EU**.
- It is estimated that approximately **300-1000 patients within the EU will be treated** annually during the first three years after launching the RESPINE product.
- RESPINE impacts are expected to **improve lifelong health and well-being of all patients** by reducing pain, disability, and eliminating or delaying the need for prosthetic implants or other surgeries.

CHU MONTPELLIER CENTRE HOSPITALIER UNIVERSITAIRE

European Commission

RESPINE OBJECTIVES

- RESPINE aims to **validate this advanced cellular therapy** through a phase 2b, randomized, double blind, controlled clinical trial in order to define the efficacy of an allogeneic MSC therapy. The goal is to **bring therapy to the clinic** in order to rapidly (within 3 months) and sustainably (at least 24 months) **improve DDD patient's quality of life relieving pain and disability**.
- RESPINE's ambition is to **use an allogeneic MSC** based cell therapy. One potential advantage of allogeneic cells resides in the possibility of their use as **an "of-the-shelf" therapeutic** agent, avoiding the need that the treated patient undergoes bone marrow aspiration.
- RESPINE aims to **deliver a simple**, **non-invasive**, **standard operating procedure** that will be easy to use by clinicians in secondary care hospitals and clinical centres throughout Europe and the world.



RESPINE partners

RESPINE is a project coordinated by the Montpellier University Hospital and brings together partners across Europe.

France

Centre Hospitalier Universitaire de Montpellier (Coordinator)
Université de Montpellier
Univercelle-Biosolutions, Toulouse
Centre National des Recherches Scientifiques (CNRS), Toulouse
Assistance Publique-Hôpitaux de Paris
Centre Hospitalier Universitaire de Nantes
Centre Hospitalier Universitaire de Rennes
European Clinical Research Infrastructure Network, Paris

Spain

University of Navarra
Valladolid University Hospital
Citospin, Valladolid
ITRT, Barcelone

Germany

BG Klinikum Bergmannstrost, Halle

Italy

Università Campus Bio-Medico di Roma

Ireland

National University of Ireland, Galway

RESPINE has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement 732163.

PROJECT FACTS

EC contribution: **5,555,836.25 €**

Duration: **4 years**

Starting date: **01/01/2017**

FOR FURTHER INFORMATION, PLEASE VISIT OUR WEBSITE:

http://www.chu-montpellier.fr/fr/respine/projet/

or **CONTACT THE PROJECT COORDINATOR:**

respine@chu-montpellier.fr

WANT TO PARTICIPATE? CONTACT:

etude.respine@gmail.com

Conception et réalisation : 06/18

RESPINE's aim is to develop an effective therapy against Degenerative Disc Disease (DDD) using mesenchymal stromal cells (MSC)