

Regenerative medicine for the treatment of heart disease

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HIGHLIGHTS

- ✓ An effective tool for drug screening in heart disease models
- ✓ Regenerative medicine for the treatment of heart disease
- ✓ A potential biological patch for post-infarct scars
- ✓ A new technology for the generation of mature human cardiomyocytes

TECH STATUS

- ✓ TRL: Preclinical Studies
- ✓ IP: Patent Application EP18382391.3

Problem to be solved

During last decades, much effort has been directed toward using stem cell therapy for cardiac regeneration. Although it has been demonstrated to be feasible and safe in animal models, the results have not been the same for patients. Heart transplant is the only therapy capable of restoring heart function after Acute Myocardial Infarction. However, transplantation is dependent on the number of donors and rejection reactions. Thus, there is an urgent need to find an alternative useful therapy.

Background

The main problems using stem cell therapy in cardiac regeneration include: the big surface of the scar to be repaired, the low retention degree of administered cells and the limited survival of implanted cells. For this reason, therapeutic efforts are being refocused on Cardiac Tissue Engineering (CTE), which uses scaffolds (either biological or synthetic) and stem cells, directly injected into the infarct zone. Although researchers are obtaining

good preclinical results, these are not being translated to clinical assays.

One of the critical points to generate a functional myocardium is the use of scaffolds with high similarity to the native myocardium. For this reason, the authors of the presented technology use decellularized scaffolds from heart biopsies. Another common problem in transplants is the reaction of immune response. To avoid it, the authors have used multipotent mesenchymal stem cells (because of their regenerative and immunomodulatory activity) and iPS (reprogramming somatic cells towards pluripotency by defined factors).

Technology

The authors have developed two exploitable technologies:

1. A system that allows the generation of mature human cardiomyocytes. The technology is based on bioreactors that enable 3D culture of patient-derived-iPS.

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2. A cardiopatch recovered by cardiomyocytes that could be used for human therapies in patients with heart damage.

Applications

One application for this technology is the in vitro use of a cardiac construct for the screening or evaluation of compounds for cardioprotective or cardiotoxic properties, and for cardiac disease modeling.

The present invention also represents a new therapeutic option for patients with acute myocardial infarction, which present post-infarct scars. CTE products could be implanted in damaged myocardium and shrink simultaneously with healthy tissue. At that moment, an improvement in contractile strength would occur, as well as in patient's life quality and life expectancy.

Technology status

Preclinical studies have been completed, demonstrating the efficacy in reproducing cardiomyocytes. Future work: CTE products, generated under GMP conditions and following AEMPS policies, which consist of 2 elements: decellularized scaffolds (biocompatible and highly similar to native myocardium) and cellular component (Wharton's Jelly-derived Mesenchymal Stem Cells or iPS).

Preclinical studies have to be completed, demonstrating the security and efficacy of CTE products (in vitro and in vivo - mice and pork). It is expected to reduce infarct size and to improve the functionality. A pilot study is being prepared to be performed in patients. IP status: Patent application in June 2018.

Market Opportunity

IDIBELL Technology Portfolio Ref. 17ARC001

Heart failure is the first cause of dead worldwide. The pathology causes from 12 to 15 millions of visits each year and is responsible of 6,5 millions of



hospitalizations per year. As the pathology is more prevalent in elderly population and population is ageing fast, the incidence of heart failure is increasing yearly.

It is the pathology that causes major Healthcare costs. According to a report by GlobalData, the heart failure market is expected to witness a compound annual growth rate of 15.7%, from \$3.7bn in 2016 to \$16.1bn by 2026.

Existing heart failure therapies have been effective in slowing the progression of the disease and reducing mortality and morbidity. The success of these therapies, however, is mostly limited to the reduction of ejection fraction (HF-REF). Novel therapies could have a significant impact in worldwide Healthcare systems economics. The major competitors are Novartis, Amgen, AstraZeneca, Sanofi and Merck.

Business Opportunity

IDIBELL is seeking a company partner to further develop the technology through a license agreement or an establishment of a Spin-off company.

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