



Repair of Diabetic Damage by Stromal Cell Administration

What is REDDSTAR?

Millions of patients with diabetes mellitus in the EU use prescription drugs to control their blood glucose levels. Poor control of blood glucose levels can lead to a number of complications, including: nephropathy (kidney disease), retinopathy (retinal disease), cardiomyopathy (heart disease), neuropathy (peripheral nerve dysfunction), impaired bone repair and wound ulceration. At present, there are few therapeutic options available to control diabetic complications.

REDDSTAR is an EU FP7 project focused on examining whether Mesenchymal Stromal Cells (MSC, from adult bone marrow) can safely control glycaemia and alleviate damage caused by six different diabetic complications.

What has REDDSTAR achieved?

The REDDSTAR project began on 1 November 2012 and finishes on 31 October 2016. As part of our work we have successfully evaluated the effects of 3 MSC cell types in different models of diabetes. The team has generated exciting pre-clinical results, demonstrating the positive effects of a novel MSC cell type (ORBCEL-M) on blood glucose, kidney disease, neuropathy and wound healing. The diabetic nephropathy data from REDDSTAR has already led to further research in H2020 project Nephstrom. In addition, our work has demonstrated the immunomodulatory effects of ORBCEL-M, in a pre-clinical model of diabetic cardiomyopathy. We have also seen its beneficial effect in ischaemic and diabetic retinopathy.

Based on our positive pre-clinical results, an independent panel at the Steno Diabetes Centre

selected treatment of diabetic ulcers with ORBCEL-M for further exploration in a Phase 1b clinical trial. The Danish Medicines Agency (DKMA) and Danish National Committee on Health Research Ethics (NVK) recently approved the REDDSTAR Clinical trial authorisation application (CTA) to conduct this study.

Within REDDSTAR we have also developed and validated a novel benchtop cell sorter, the MACSQuant Tyto. The MACSQuant® Tyto™ is a high-speed, 10-parameter microchip-based cell sorter in a fully closed cartridge system, which offers rapid, multi-colour flow sorting with high purity and ease of use.

How will REDDSTAR help?

Non-healing, neuro-ischaemic diabetic foot ulcers (DFU) are very common and present a significant burden on an individual's health and on healthcare systems. Despite current treatment strategies, there is a high prevalence of non-healing ulcers and amputation. Foot ulcers can affect 12% to 25% of people with diabetes mellitus throughout their lives. Right now there are more than 5 million patients in the US and EU suffering with non-healing DFU.

REDDSTAR pre-clinical studies have highlighted the potential for a novel therapeutic product for people suffering with DFU, delivering improved wound healing and reduced healing time. The team is currently exploring options for the conduct of a Phase 1b trial arising from REDDSTAR, to investigate the treatment of diabetic ulcers with ORBCEL-M. The partners are committed to taking this next essential step towards novel clinical treatments for diabetic complications, with potential benefits for millions of patients worldwide.

REDDSTAR has generated exciting and novel results, with prospects far beyond the life of the project. Our findings have the potential to significantly impact the management and treatment of diabetes in the future, with benefits for patients, clinicians, researchers, pharmaceutical companies, health systems and for the general public.



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Who is REDDSTAR?

The REDDSTAR consortium is a network of diabetes specialists, regenerative medicine researchers, biotech industrialists and clinicians, led by the National University of Ireland, Galway (Prof Timothy O'Brien).



Find out more about REDDSTAR on the project website:
<http://www.REDDSTAR.eu/>

Patients: Information about diabetes which may be of interest to patients can be found here <http://www.REDDSTAR.eu/project/patients/> and here <http://www.REDDSTAR.eu/project/steno-diabetes-center-videos/>

Scientists: Academics, researchers and medical professionals may want to access the project publications listed here: <http://www.REDDSTAR.eu/scientific/publications/>

Industry: The project's industry brochure can be found here <http://www.REDDSTAR.eu/project/industry/>

Media: Press releases and information of interest to the media are set out here <http://www.REDDSTAR.eu/news/press-releases/>



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