PRESS RELEASE

CAROCELL BIO

Carocell Bio receives ethical approval for human pre-clinical testing of its lead proprietary peptide in collaboration with Oxford clinical researcher

Testing this anti-inflammation approach to treat burns and scarring is a key step in therapeutic development and potential progression to clinical testing

DURHAM, NORTH CAROLINA - 17 May 2022 - Today, Carocell Bio has announced that it has received approval from the Health Research Authority (HRA) to test its lead candidate proprietary peptide JEL3108 in human burns and reconstructive surgery tissue samples. The approval, which was received alongside a favourable research ethics committee opinion, will permit ex vivo human preclinical testing at Buckinghamshire Healthcare NHS Trust. The preclinical study will test Carocell Bio's anti-inflammation approach to treating severe burns and preventing scar formation after surgery, based upon proprietary peptides that target the body's intracellular inflammation cascade.

The project is a collaboration with Professor Fadi Issa, Associate Professor of Burns and Plastic Surgery at the University of Oxford and Consultant Plastic Surgeon, Buckinghamshire Healthcare NHS Trust. Professor Issa is a world-leading researcher on the treatment of immune-mediated diseases including transplant rejection, with significant experience of the clinical management of burns and scars – an area of significant unmet clinical need.

So far, JEL3801's high selectivity for mitogen-activated protein kinase (MAPK, p38-alpha) has demonstrated the capability to potentially inhibit the intracellular inflammation cascade. Its 150-fold selectivity for p38-alpha over p38-beta, and 10,000-fold over other kinases could provide a much more targeted and possibly safer approach than those currently available. In combination with a specifically tailored nanoparticle topical delivery system, the peptides could facilitate a high rate of cell penetration through the skin's surface, rapidly delivering anti-inflammation effects where they are most required following skin damage.

Carocell Bio's CEO, Dr Mike Davies, said:
"Receiving ethical approval for these human ex-vivo studies is an important next stage in development – getting us even closer to clinical testing - and with that, to the possibility of impacting patients' lives. Our peptide-based approach has the potential to help treat devastating burns and also help prevent scar formation post-surgery. At Carocell Bio, we believe that an anti-inflammation approach is the most effective route by which to achieve this which is why this ex-vivo testing, with world-leading research Professor Issa, is incredibly exciting."

Professor Fadi Issa, Chief Investigator of the project, said: "We are excited to be initiating this pre-clinical research project with the Carocell Bio team. The company's approach to treating burns and scars addresses a current area of unmet clinical need. Scarring, from burns, surgery or other causes, can cause significant physical and mental challenges, yet has often been to-date overlooked as a medical issue in its own right. By being able to eliminate or reduce scarring soon after an operation or burn with the topical application of these first-in-class peptides, we might be able to improve the quality of life for many patients worldwide."

As part of the study, tissue will be collected from patients who have been burnt and are in need of an operation and controlled burns in patients undergoing reconstruction surgery, and treated with lead candidate JEL3108 to investigate whether the compounds can ‘switch off’ inflammation. Importantly, a small amount of the patients’ own healthy skin graft tissue will be used as a matched negative control. The ethical approval was granted by HRA and Health and Care Research Wales (HCRW).

The company has previously demonstrated efficacy of three of its proprietary peptides in a cellular model. In 2021, it announced it had received over USD $125,000 (almost GBP £100,000) in additional funding from Innovate UK to study the effect of the peptides in burns, and received USD $314,000 (GBP £250,000) seed investment from Deepbridge Capital.

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About Carocell Bio
Carocell Bio is the anti-inflammation therapeutics company developing new therapies for the active management of the inflammatory response, including scarring and burns. Headquartered in Durham, North Carolina, USA and Cheadle, UK, its pipeline peptide-based products are designed to interrupt the inflammatory cascade - potentially providing safer and novel therapeutic options for patients. Unfortunately, scarring is too often ignored, although the burden on the healthcare sector for scarring, burns and related skin conditions in the UK, US and internationally is significant, with USD $37 billion spent on treating existing scars in 2019.

The proprietary peptides driving Carocell Bio’s therapeutic pipeline, discovered by AstraZeneca, offer a novel anti-inflammatory mechanism that is highly selective for mitogen-activated protein kinase (MAPK, p38-alpha). It inhibits an important component in the intracellular inflammation cascade. The company’s lead peptide, JEL3108, binds in an advantageous way to its target and is highly selective, with greater than 150-fold selectivity for p38-alpha over p38-beta, and around 10,000-fold selectivity over other kinases, meaning that it delivers a very targeted and potentially safer treatment. Formulated with a nanoparticle delivery system to enhance cell penetration, the peptides are designed for topical delivery.

Carocell Bio is focused on increasing quality of life for millions of patients with its novel approach - creating significant impact by addressing an area of unmet clinical need. For more information, see www.carocellbio.com.

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