



Intercytex

KING'S COLLEGE LONDON, INTERCYTEX AND DEBRA BEGIN PHASE II TRIAL WITH ICX-RHY IN PATIENTS WITH SEVERE GENETIC SKIN DISORDER, RDEB AT GUY'S HOSPITAL, LONDON

London, Manchester and Crowthorne, UK, 15 March 2011..... King's College London; the regenerative medicine company Intercytex; and the patient charity DEBRA, announce the start of a Phase II trial with the Intercytex therapy ICX-RHY to treat skin erosions in patients suffering from the severe genetic skin disorder Recessive Dystrophic Epidermolysis Bullosa (RDEB). In such patients the skin blisters at the slightest knock or rub, causing painful, open wounds which result in scarring and fusion of fingers.

The placebo controlled trial will involve 20 RDEB patients. It will be led by Professor John McGrath, Professor of Molecular Dermatology at King's College London and Honorary Consultant Dermatologist at Guy's and St Thomas' NHS Foundation Trust, London, who will administer a single series of ICX-RHY injections or placebo around the margins of several selected skin erosions. The injections will take place at the Clinical Research Facilities at Guy's Hospital. Patients will then be assessed initially over a three month period to measure end points including time to wound closure, wound recurrence and erosion pain. The trial, which is scheduled for completion early in the autumn, is funded jointly by Intercytex, The Technology Strategy Board and DEBRA.

Professor McGrath has already used ICX-RHY successfully to treat 14 EB patients on a compassionate use basis. Commenting on the start of the trial, Prof McGrath said 'Finding out whether a new treatment can help people with EB heal their wounds faster makes this an important clinical trial. We plan to test cells called "fibroblasts" to see if injection into the skin affects wound healing. The trial represents a significant step forward in taking research from the laboratory to the clinic.'

Melissa Smith was born with RDEB and has lived with the condition for over 24 years. Melissa took part in preliminary studies with the therapy and is now preparing to participate in the Phase II trial. Commenting on her involvement, Melissa said 'I am firmly committed to helping with these trials. When you have EB you live in constant pain. There is, of course, additional pain from the trial treatment but its short term and the therapy could offer such hope long term for me and others who live with EB.'

Ben Merrett, CEO of DEBRA, added: 'Some forms of EB, like RDEB, can be very debilitating and there is a high unmet medical need for an effective treatment. Judging

by the initial patient reaction to ICX-RHY, this could be an exciting step forward in treating the disease and make a significant, long-term difference to people who lead very difficult lives.'

'I am delighted that ICX-RHY has shown such early promise in a small number of RDEB patients' commented Dr Kemp, Intercytex's Chief Executive Officer. 'ICX-RHY is designated an Orphan Product in the EU and this trial marks a very significant step towards obtaining Regulatory Approval for the treatment. In the meantime we are actively looking at ways we can make this material available to other patients who are not able to be part of this trial. In addition to EB patients, ICX-RHY has also shown to have the potential to help heal burn and trauma scars and we are also trialling it in these indications.'

One in 227 people have a defective gene that causes EB and the disease affects around 1 in 17,000 live births. It is estimated that there are half a million sufferers world wide and 5,000 people with EB in the UK. RDEB is one of the more severe, debilitating forms of the disease, with a prevalence of around 2 in 100,000.

ICX-RHY is a suspension of human dermal fibroblasts (HDFs, which are naturally derived skin cells) in cell storage medium, for injection into the skin. The newly introduced HDFs are thought to repair the extracellular matrix to improve skin structure and function.

ICX-RHY is designated as one of the first Advanced Therapy Medicinal Products (ATMP) by the European Medical Agency and has already been used in clinical trials and compassionate use programmes in over 100 patients in a variety of indications.

PHOTOGRAPHS ARE AVAILABLE ON REQUEST

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Notes to Editors

Intercytex was founded in 2000 and it is now owned by a private concern, Regenerative Solutions Ltd. Alongside its work with DEBRA and EB patients, the company is assessing the potential of ICX-RHY to treat patients with burn scars, trauma scars and acne. The company is based in Alderley Edge, south of Manchester and currently employs ten people. See www.intercytexas.com

King's College London is one of the top 25 universities in the world (2010 QS international world rankings) and The *Sunday Times* 'University of the Year 2010/11'. King's has an outstanding reputation for cutting-edge research and is in the top seven UK universities for research earnings. King's Health Partners Academic Health Sciences Centre (AHSC) is a pioneering global collaboration between King's College London and three of London's most successful NHS Foundation Trusts (Guy's and St Thomas', King's College Hospital and South London and Maudsley NHS Foundation Trusts). www.kingshealthpartners.org.

DEBRA provides a team of nurses and social care staff to work directly with people affected by EB. The charity also commissions world-leading research into the condition with the aim of finding effective treatments and, ultimately, a cure for EB. EB has a number of distinct forms: at its mildest, blistering is confined to the hands and feet and in more severe cases, the whole body is affected. In its worst form EB is fatal in infancy. www.debra.org.uk

The Technology Strategy Board is a business-led government body which works to create economic growth by ensuring that the UK is a global leader in innovation.

Sponsored by the Department for Business, Innovation and Skills (BIS), the Technology Strategy Board brings together business, research and the public sector, supporting and accelerating the development of innovative products and services to meet market needs, tackle major societal challenges and help build the future economy. For more information please visit www.innovateuk.org.