

Innovacell includes first patients in study for urocell®

A total of 245 patients will be treated during Phase IIb – the study will evaluate the effectiveness and determine the optimal dose for treatment.

Innsbruck – "First patient in" is the call from the Innsbruck firm, Innovacell Biotechnologie AG, as the first patient was recruited at the MHAT Plovdiv clinic in Bulgaria for the Phase IIb study of the advanced therapy medicinal product, urocell®. The clinical study will be conducted, beside Bulgaria, in the Czech Republic, Germany, Poland and Romania at more than 50 clinics.

"Altogether in this controlled clinical study, some 245 patients will participate. The study objective is to determine the optimal dose for treatment and to evaluate the effectiveness in the indication of Stress Urinary Incontinence," explained Innovacell CEO, Ekkehart Steinhuber. Initial evidential results are expected for the fourth quarter of 2010. Innovacell is investing 10 million Euro in the Phase IIb study.

Innovative therapy

urocell® is based on an innovative therapy concept for the treatment of bladder weakness, aimed at people with damaged sphincters. In contrast to earlier types of therapy, that rely either on "bulking" methods or on surgical "lifting" of the urogenital tract, urocell® is based on the principle of the body's own ability to regenerate the sphincter muscle by using the patient's own muscle cells.

Phase IIb study

Immediately after completion of the Phase IIb study, Innovacell will start with the Phase III study. Said Steinhuber: "Its findings will be available in 2011. When the results are established, we will apply for an EU-Marketing Authorisation at the European Medicines Agency (EMA) in London."

Since 2007, the European Union has laid down a set procedure for the clinical development of tissue engineered products – it covers the pre-clinical stage up to the Phase III study, after which permission to market can be granted. After 30 December 2012 – the end of the

transition period for the use of products which were on the market before a set date – no further marketing will be allowed without this centralized EU permission.

Information on Innovacell Biotechnologie AG

Innovacell Biotechnologie AG is an innovative biotechnology company that develops personalized cell therapies for treatment of incontinence. Innovacell is running multinational clinical trials for its two ‘tissue-engineered’ products in development, urocell® and rectocell®. Using Innovacell’s innovative ‘ultrasound-guided’ injector, patients benefit from a minimally invasive surgery. More than 500 patients have been treated since 2002. Shareholders are institutional and private investors and the management team. Chairman of the supervisory board is Dr Harald Poettinger, CEO of Hypo Equity Management AG, Austria.

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