



CORPORATE PRESS RELEASE

NORGINE AND INNOVACELL ENTER INTO AN EXCLUSIVE LICENSING AGREEMENT FOR ICEF15 – AN INNOVATIVE PERSONALISED CELL THERAPY TO TREAT FAECAL INCONTINENCE

17 December 2013, 07:00 AM GMT: Norgine B.V. (“Norgine”) and Innovacell today announced they have entered into a collaboration and exclusive licensing agreement for Europe*, SADAC and MENA regions for ICEF15. Through this collaboration Innovacell will co-develop ICEF15 with Norgine, and Norgine will commercialise the product through its sales and marketing operations. The start of the ICEF15 phase IIb clinical trial is imminent and it is anticipated that the first patient will be dosed in Q1 2014.

ICEF15 is developed for both men and women suffering from faecal incontinence with sphincter weakness or damage. ICEF15 is a personalised cell-based product concept based upon proliferating autologous myoblasts from a biopsy taken from the patients’ own muscle. The patient’s proliferated muscle cells are re-injected into the patient’s external anal sphincter muscle, using Innovacell’s proprietary injection device, thereby regenerating the muscle’s full functionality.

Data from a phase I/II clinical trial have shown a rapid reduction in the symptoms of faecal incontinence as well as an improvement in the quality of life.ⁱ In addition, data from a retrospective study (5 years - post treatment) show that ICEF15 has a lasting effect.ⁱⁱ

ICEF15 has the potential to become the first-choice treatment over current therapies, including surgery. This one off procedure could also offer a once in a lifetime treatment option.

There is a significant unmet medical need for treating faecal incontinence. It is estimated that in major European countries, around 5 per cent of all adult men and women will suffer from faecal incontinence.ⁱⁱⁱ There is a strong association between increasing age and faecal incontinence, but also it suggested that women are at greater risk of faecal incontinence and that the cause of this is primarily related to childbirth.^{iv}

Ekkehart Steinhuber, CEO at Innovacell said, “By partnering with Norgine, Innovacell is accessing demonstrated gastroenterology and commercial expertise and capabilities that will accelerate development and market entry of ICEF15 in Europe, SADAC and MENA. ICEF15 could help many patients to overcome faecal incontinence, a very debilitating condition, and regain their quality of life.”

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Peter Stein, CEO at Norgine said, “Our collaboration with Innovacell is a major step forward in developing a truly innovative therapy in a disease area in which we have strong expertise. Faecal incontinence is a common and distressing condition that may severely restrict patients’ activities and through the development and marketing of ICEF15, we hope to offer a novel and long life lasting treatment option.”

He added: “ICEF15 is a strong addition to our portfolio. Our approach to partnering is flexible and our efforts are always focused to find and work with partners who have complementary skills and a shared vision for improving healthcare. Partnering is a key priority for our long-term growth and success as an independent and leading pan-European specialty pharmaceutical company.”

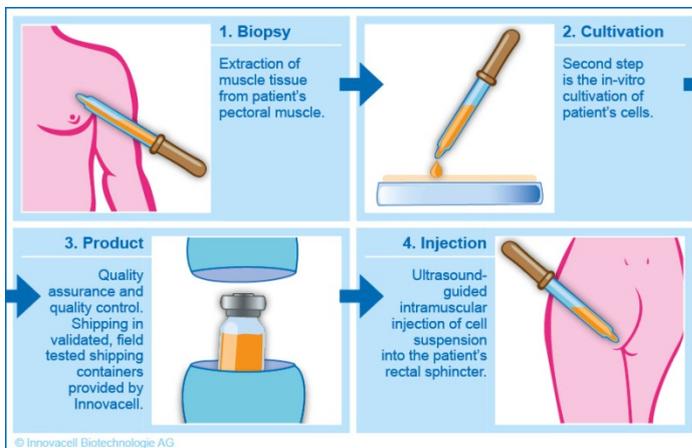
Financial terms are not disclosed.

Ends

* with the exception of Russia and Turkey

Notes to editors

ICEF15



About Faecal Incontinence

Patients with faecal incontinence (FI) can be broadly split into two main segments: those with passive FI (in the context of the sphincter being intact); and traumatic FI (where the sphincter is no longer intact and there is injury/damage in the physiological structure of the external or/and internal sphincter).

About Norgine

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Norgine is a successful, independent European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2012, Norgine's net product sales were €250 million and the company employs over 1,000 people.

Norgine's focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in therapeutic areas such as gastroenterology, hepatology and critical and supportive care.

Norgine owns a manufacturing and development site in Hengoed, UK and a manufacturing site in Dreux, France. For more information: www.norgine.com.

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About Innovacell

Innovacell Biotechnologie AG is a privately-held Phase III biotechnology company based in Innsbruck, Austria. The company is engaged in the clinical development of autologous (i.e. patient's own cells), minimally invasive cell therapies. Innovacell's personalized products are potentially curative one-off treatments, which re-establish functionality of sphincter muscles in patients, i.e. with stress urinary incontinence (SUI) or fecal incontinence (FI).

Innovacell's products are highly innovative in terms of composition and methodology.

Innovacell owns and operates one of the biggest manufacturing facilities for the expansion of autologous cells in Europe. For more information: <http://www.innovacell.com>.

Innovacell's supervisory board is chaired by the experienced financial expert, Dr. Harald Pöttinger, CEO of Alpine Equity Management AG, based in Bregenz, Austria.

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References

ⁱ Prof. A. Frudinger et al. Muscle-derived cell injection to treat anal incontinence due to obstetric trauma: pilot study with 1 year follow-up. Gut 2010;59:55–61. doi:10.1136/gut.2009.181347

ⁱⁱ Prof. A. Frudinger. Zelltherapie bei Stuhlinkontinenz – ein neues, vielversprechendes Therpiekonzept. Interdisziplinärer Beckenbodenkongress, Germany. Presented on 14 Sept. 2013

ⁱⁱⁱ Michael Probst et al. Dtsch Arztebl Int 2010; 107(34–35): 596–601

^{iv} S. Perry et al. Prevalence of faecal incontinence in adults aged 40 years or more living in the community. Gut 2002;50:480–484