



Levicept Starts First-in-Human Phase I Trial of LEVI-04, A Novel Fusion Protein Therapy for Chronic Pain

Sandwich, UK – DATE – Levicept Ltd., an asset-centric biotechnology company focused on the development of LEVI-04, a first-in-class treatment for chronic pain indications, today announces that it has commenced its Phase I trial of LEVI-04 in healthy volunteers and osteoarthritis patients at Hammersmith Medical Research, London UK.

LEVI-04 is a proprietary p75 neurotrophin receptor fusion protein (p75NTR-Fc) being developed by Levicept as a once-a-month injectable for the treatment of osteoarthritis and chronic pain. It modulates the nerve growth factor (NGF) pathway, clinically proven to provide effective analgesia.

NGF is elevated in chronic pain, and inhibitors are efficacious in reducing pain in conditions such as osteoarthritis, back pain and cancer pain. However, anti-NGF antibodies (e.g. tanezumab, fulranumab) have side effects in some patients, such as rapid progression of osteoarthritis, resulting in early joint replacement. In pre-clinical models of osteoarthritis, LEVI-04 provides analgesia equivalent to that achieved with anti-NGF antibody treatment, but without rapid progression of osteoarthritis. LEVI-04 treatment restores neurotrophin homeostasis by providing stable binding proteins for the excess neurotrophins present in chronic pain states. Unlike anti-NGF antibodies that ablate NGF signalling, LEVI-04 reduces NGF activity to provide analgesia while maintaining the neurotrophin function required for cartilage and bone repair.

Simon Westbrook, CEO of Levicept, and the named inventor on the patent for p75NTR-Fc, originally developed at Pfizer, said: "Studies to date indicate that LEVI-04 overcomes the shortcomings of anti-NGF antibodies; offering the same profound analgesia but without the negative effects of complete NGF removal. We believe that LEVI-04 could provide a meaningful benefit for the billion patients with chronic pain worldwide, who have limited treatment options."

There remains a large, unmet medical need for safe and effective analgesics. Non-steroidal anti-inflammatory drugs (NSAIDs) and opiates are currently the most widely used drugs to treat pain and inflammation associated with osteoarthritis. However, both classes of analgesics are limited by adverse side effects. NSAIDs are associated with impaired platelet function, increased cardiovascular liability and gastrointestinal adverse effects, and opiates can be highly addictive. It is estimated, if developed to a high safety standard, the market opportunity for anti-NGFs is worth in excess of \$10 billion (Holmes 2012 Nature Reviews Drug Discovery 11: 337).

Further information on the trial can be found [here](#).

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About Levicept

Levicept is a biopharmaceutical company focused solely on the preclinical and clinical development of LEVI-04 as treatment for osteoarthritis and chronic pain. Levicept is based in Sandwich, UK. LEVI-04 was originally discovered at Pfizer by Levicept's founder and CEO, Simon Westbrook, who subsequently acquired the asset following the closure of Pfizer's research site. Levicept received seed funding from Index Ventures, now Medicxi, in 2012, enabling the Company to deliver research test agent for preclinical studies, and preclinical proof-of-concept data demonstrating efficacy and safety. Levicept was awarded a £2.4 million grant by Innovate UK, the UK's innovation agency in April 2014. The Company raised a further £10 million in September 2014 with Advent and Glide, to develop LEVI-04 to proof-of-concept first-in-human clinical trials. For more information please visit the website at www.levicept.com.

About Medicxi

Medicxi is based in London, Geneva and Jersey. The Company's mission is to invest across the full healthcare continuum. Medicxi was established by the former Index Ventures life sciences team. Medicxi manages the legacy life science portfolio of Index Ventures as well as the new funds launched as Medicxi, Medicxi Ventures 1 (MV1) and Medicxi Growth 1 (MG1) focusing on early-stage and late-stage investments in life sciences.

GSK, Johnson & Johnson and Novartis, three of the world's largest pharmaceutical companies back Medicxi along with Verily, an Alphabet company. These companies, whilst participating in the SABs of the funds, do not receive any preferential rights to the portfolio companies.

Medicxi's team has been investing in life sciences for over 20 years and has backed many successful companies, including Genmab (Nasdaq Copenhagen: GEN), PanGenetics (sold to AbbVie), Molecular Partners (SWX: MOLN), XO1 (sold to Janssen) Egalet (Nasdaq: EGLT), Minerva Neurosciences (Nasdaq: NERV) and Versartis (NASDAQ: VSAR).

Please see <https://www.medicxi.com/> for more information.

About Advent Life Sciences

Advent Life Sciences funds and invests in early- and mid-stage life sciences companies that have a first- or best-in-class approach to unmet medical needs. The investing team consists of experienced professionals, each with extensive scientific, medical and operational experience, a long-standing record of entrepreneurial and investment success in the US and Europe, and is particularly focused on supporting entrepreneurs and founders to take innovative new medical entities from concept to approval. The firm invests in a range of sectors within life sciences, principally drug discovery, enabling technologies and med tech, always with an emphasis on innovative, paradigm-changing approaches. Advent Life Sciences has a presence in the UK, US and France. For more information, please visit <http://www.AdventLS.com>.

About Gilde Healthcare

Gilde Healthcare is a specialized European healthcare investor managing two business lines: a venture & growth capital fund and a lower mid-market buy-out fund.

Gilde Healthcare's venture & growth capital fund invests in therapeutics, medtech, diagnostics and digital health. The portfolio companies are based in Europe and North America.

Gilde Healthcare's lower mid-market buy-out fund invests in profitable European healthcare services companies with a focus on the Netherlands, Belgium and Germany. The portfolio consists of healthcare providers, suppliers of medical products and other service providers in the healthcare market.

Since 2001 Gilde Healthcare has raised €800 million (\$900 million) for its specialized funds. www.gildehealthcare.com

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