



Levicept Completes Recruitment in Phase II Clinical Trial of Neurotrophin Modulator, LEVI-04

Study of Novel Biological Agent for Chronic Pain in Patients with Osteoarthritis

Sandwich, UK – 13 December 2023 – Levicept Ltd, a biotechnology company focused on the development of LEVI-04, a first-in-class treatment for chronic pain indications, today announces it has completed recruitment in its Phase II clinical trial of LEVI-04, a novel neurotrophin-modulating biological agent. Top line data are expected to be announced in late first half of 2024.

The multiple arm, multicentre, prospective, randomized, double-blind, placebo-controlled, Phase II study enrolled more than 500 participants with pain due to osteoarthritis of the knee ([ClinicalTrials.gov ID: NCT05618782](https://clinicaltrials.gov/ct2/show/study/NCT05618782)). The trial was designed to evaluate the efficacy, safety and tolerability of five, monthly, infusions of LEVI-04 as compared to placebo in participants with radiographic and symptomatic knee osteoarthritis. The trial is being conducted at sites across Europe and in Hong Kong, led by Dr Philip Conaghan at The School of Medicine, University of Leeds, UK.

LEVI-04 modulates the neurotrophin pathway that is clinically proven to provide effective analgesia in a range of indications and is designed to minimise use-limiting side effects of anti-NGF antibodies, including rapid progression of osteoarthritis. It is a proprietary p75 neurotrophin receptor fusion protein (p75NTR-Fc).

LEVI-04 is designed to deliver neurotrophin homeostasis by providing a reversible binding protein which scavenges excess neurotrophins present in chronic pain states. It operates across four receptor pathways in the neurotrophin system and is designed to supplement the existing endogenous p75NTR binding protein and returning normal neurotrophin function. Importantly, unlike anti-NGF antibodies which ablate NGF signalling as they bind irreversibly to NGF, LEVI-04 provides analgesia while maintaining the neurotrophin function required for cartilage and bone repair.

Phase I data on LEVI-04 demonstrated a favourable safety, tolerability and pharmacokinetic profile. Analysis of biomarkers indicated target engagement and provided early supporting evidence of efficacy / proof-of-concept.

Dr Philip Conaghan, Principal Investigator said, “Safe and effective pain management is a critical need in arthritis with existing treatments limited by addiction-liabilities, adverse effects and poor efficacy. While the potential of the neurotrophin pathway to provide effective pain relief is recognised, safety issues have significantly hampered development. LEVI-04 offers a highly promising new approach to safely harness the analgesic potential of neurotrophin modulation and we look forward to the trial results next year.”

Simon Westbrook, founder and CSO of Levicept, and study director said, “The fact we completed recruitment in this large-scale Phase II in under a year is testament to physicians’ interest in our programme and patients’ pressing need for new treatment options for their chronic pain.”

LEVI-04 was originally discovered at Pfizer UK by Levicept’s founder, Simon Westbrook who subsequently acquired the asset. Levicept recently announced the appointment of experienced biotech executive Eliot Forster as CEO to help steer the best path for the further development of LEVI-04 and its ultimate commercialisation.



ENDS

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About Levicept – www.levicept.com

Levicept Ltd is a UK-based biotechnology company developing a novel, safe and efficacious biological therapy (LEVI-04 [p75NTR-Fc]) for the treatment of chronic pain. LEVI-04 is currently in phase II in patients with osteoarthritis of the knee. LEVI-04 modulates the neurotrophin pathway, clinically proven to provide effective analgesia in a range of indications and is designed to minimise use-limiting side effects of anti-NGF antibodies, including rapid progression of osteoarthritis. It is estimated that the market opportunity for drugs that modulate neurotrophins, developed to a high safety standard, is worth in excess of \$10 billion. LEVI-04 was originally discovered at Pfizer by Levicept's founder, Simon Westbrook who subsequently acquired the asset. Levicept's investors include Medicxi, Advent Life Sciences, Gilde Healthcare and Pfizer Ventures.

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