



Levicept Announces Positive Results of Phase II Trial of novel Neurotrophin-3 Inhibitor, LEVI-04, for the Treatment of Patients with Moderate to Severe Osteoarthritis

- All primary and secondary efficacy endpoints met – significant analgesia across all measures for all doses
- Well tolerated with no increase in incidence of rapid joint deterioration compared to placebo
- First in class novel biologic under development as non-addictive pain treatment

Sandwich, UK – 6 August 2024 – Levicept Ltd, a biotechnology company focused on the development of LEVI-04, a first-in-class treatment for osteoarthritis and other pain indications, today announces positive results from its Phase II trial of LEVI-04 a novel and first in class neurotrophin-3 (NT-3) inhibitor, showing that LEVI-04 was highly effective and well tolerated.

The multiple arm, multicentre, randomized, double-blind, placebo-controlled, Phase II study enrolled more than 510 participants with pain and disability due to osteoarthritis of the knee ([ClinicalTrials.gov ID: NCT05618782](https://clinicaltrials.gov/ct2/show/study/NCT05618782)). The trial was conducted at sites across Europe and in Hong Kong, led by Professor Philip Conaghan MD from the University of Leeds and Leeds Teaching Hospitals NHS Trust, UK.

LEVI-04 demonstrated significant differences to placebo at Week 17 for all primary and secondary endpoints for all doses evaluated:

- The primary endpoint was WOMACⁱ pain assessment (change from baseline at Week 17). The mean reduction in WOMAC pain score from baseline was greater than 50% for all three doses of LEVI-04 and all statistically different to placebo.
- Secondary endpoints were WOMAC subscales of function and joint stiffness, patient global assessment and daily pain scores and all statistically different to placebo.

Standard safety monitoring plus peripheral nervous system assessments showed LEVI-04 to be well tolerated. There was no increase in incidence of rapidly progressive osteoarthritis (RPOA) as measured via detailed, closely examined, radiographic analysis.

Levicept intends to submit full results for publication in a peer-reviewed journal.

Professor Philip Conaghan MD, Director NIHR Leeds Biomedical Research Centre and **Principal Investigator** said, “These results are truly exceptional and clinically meaningful in their extent. Safe and effective pain management is of critical importance in arthritis with existing treatments limited by adverse effects, addiction liabilities and poor efficacy. In this trial, LEVI-04 has demonstrated the potential to safely harness the analgesic properties of neurotrophin-3 inhibition and offer a vital new treatment option to millions of patients in huge need. If Phase III trials replicate these results, LEVI-04 would represent a major break-through for osteoarthritis treatment, and with substantial potential in other pain indications.”

Globally, 595 million people had osteoarthritis (OA) in 2020, affecting 7.6% of the population and making it the most common form of arthritisⁱⁱ. It is estimated that the market opportunity for drugs that treat OA is worth in excess of \$10 billionⁱⁱⁱ.



Simon Westbrook, founder and CSO of Levicept, “The discovery of LEVI-04 harnessed the power of evolution to design a molecule that supplements the endogenous NT regulator, soluble p75NTR. LEVI-04 provides analgesia via inhibition of neurotrophin-3, while avoiding the use-limiting side effects of anti-NGF antibodies, including rapidly progressive of osteoarthritis. LEVI-04 retains the important trophic effects of the neurotrophins, including joint re-modelling. We want to thank all the clinicians and trial participants and hope that the results bring the prospect of a new treatment for them and many others.”

Kevin Johnson, Chairman of Levicept and Partner at founding investor Medicxi said, “The results from this robust and large-scale Phase II fully validate the belief of Levicept’s founders and investors that LEVI-04 could be a genuine breakthrough in the treatment of osteoarthritis. They also leave Levicept exceptionally well-positioned to consider the next strategic options to advance LEVI-04’s development.”

LEVI-04 is a proprietary p75 neurotrophin receptor fusion protein (p75NTR-Fc) that provides analgesia via inhibition of NT-3 activity and returns neurotrophin homeostasis by supplementing the endogenous p75NTR binding protein to scavenge excess neurotrophins present in chronic pain states.

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About Levicept – www.levicept.com

Levicept Ltd is a UK-based biotechnology company developing the first in a new class of novel, safe and efficacious biological therapies, LEVI-04 [p75NTR-Fc], for the treatment of osteoarthritis and chronic pain. LEVI-04 inhibits NT-3, one of the neurotrophin family of proteins. LEVI-04 has completed a Phase II clinical trial in more than 500 patients with osteoarthritis. It is estimated that the market opportunity for drugs that treat osteoarthritis is worth in excess of \$10 billion. LEVI-04 was discovered by Levicept’s founder, Simon Westbrook. Levicept’s investors include Medicxi, Advent Life Sciences, Gilde Healthcare and Pfizer Ventures.

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ⁱ The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) pain scale – a recognised standard pain scale

ⁱⁱ [https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913\(23\)00163-7/fulltext](https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(23)00163-7/fulltext)

ⁱⁱⁱ [Global Neurotrophins Market- Analysis, Size, Forecast 2033 \(futuremarketinsights.com\)](https://www.futuremarketinsights.com/reports/global-neurotrophins-market-analysis-size-forecast-2033)