PROOF-OF-CONCEPT CLINICAL TRIAL SUCCESSFULLY COMPLETED WITH LAT8881

Lateral Pharma has successfully completed its LAT8881 Phase 1b clinical trial in patients with chronic lumbar radicular pain (a condition commonly referred to as "sciatica").[1,2] The results from this study have demonstrated clinical "proof-of-concept" of LAT8881 as a novel first-in-class therapeutic for the treatment of neuropathic pain, a condition where a safe and effective treatment continues to represent a significant medical challenge.[3]

The clinical trial, conducted at PARC Clinical Research in Adelaide, South Australia, with Professor Guy Ludbrook, Principal Investigator was exploratory in design, seeking to: (i) demonstrate human proof-of-concept and safety, and (ii) identify the optimal endpoint for a future pivotal trial. The results from the trial demonstrated:

- LAT8881 dosed intravenously at 1.8 mg/kg achieved greater reductions than placebo in straight-leg raise-provoked pain from pre-dose levels during the 6 hours post-dose, particularly during the 1-2 hours post-dose, which was pre-defined in the protocol as an exploratory endpoint.
- No impact on resting levels of pain (our primary endpoint), however, having patients stay overnight at the clinical trial site for the two study days reduced baseline resting pain considerably, making it difficult to demonstrate any drug or placebo effects
- The pharmacokinetic profile of LAT8881 in humans, with the peptide and its active metabolite detected in the blood of subjects administered LAT8881
- LAT8881 was safe and well tolerated, with no serious adverse events and no dose-limiting safety events – this is particularly notable given the 1.8 mg/kg dose used was considerably higher than the 0.4 mg/kg tested in prior clinical trials.

Lateral Pharma's rigorous review of the trial results has included consultations with Professor Ludbrook, as well as with leading international pain experts (including Professors Ralf Baron, Tony Pickering, John Markman, and Patrick Dougherty).

Last month, at the International Association for the Study of Pain Neuropathic Pain Special Interest Group (NeuPSIG) Congress in Lisbon, Portugal, Lateral Pharma presented the results and the following conclusions from the trial:

- "Proof-of-concept" of LAT8881 as a novel first-in-class therapeutic for neuropathic pain.
- The results are particularly notable given only one dose of LAT8881 was tested and subjects were not required to stop existing pain management prior to the study.
- These results support further work to investigate:
    - The optimal formulation, dose form, and dosing
    - Whether LAT8881 has both analgesic and disease-modifying activity in chronic lumbar radicular pain and other neuropathic pain indications.

With this very positive clinical trial outcome, and encouraged by the response received at the NeuPSIG Congress, Lateral Pharma is currently undertaking a strategic review, the key objective of which is to confirm the next stage in the clinical development of the LAT peptides and opportunities to enable a significant capital raise and/or partnership opportunities.

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[1] CALHN HREC 2021/HRE00351
[2] ClinicalTrials.gov Identifier: NCT05298306
[3] Schmid et al. PAIN 164(8): p 1693-1704, August 2023