



Latigo Biotherapeutics Granted FDA Fast Track Designation for LTG-001, Potential Best-in-Class Nav1.8 Inhibitor for the Non-Opioid Treatment of Acute Pain

March 3, 2025

LTG-001 demonstrated favorable safety and tolerability profile with predictable pharmacokinetics in Phase 1 trial

Fast Track designation will facilitate development and expedited regulatory review of LTG-001

THOUSAND OAKS, Calif., March 3, 2025 – Latigo Biotherapeutics (“Latigo”) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation (FTD) to LTG-001, the company’s oral, investigational selective Na_v1.8 inhibitor for the treatment of acute pain. LTG-001 works by blocking peripheral sensory neurons responsible for pain signals, thus preventing the transmission of these pain signals to the central nervous system. The FTD follows positive Phase 1 results which demonstrated a favorable safety, tolerability, and pharmacokinetic profile for LTG-001.

“We are pleased the FDA has granted Fast Track designation to LTG-001, recognizing its potential to transform the treatment landscape for acute pain by targeting pain at its source,” said Nima Farzan, chief executive officer of Latigo. “This marks an important milestone for Latigo and reinforces the promise of LTG-001 as a highly selective, well-tolerated non-opioid approach for treating pain. With this designation, we look forward to working closely with the FDA to accelerate development and bring this much-needed non-opioid medicine to patients rapidly.”

“Receiving Fast Track designation for LTG-001 underscores the serious unmet medical need in patients suffering from acute pain conditions,” said Neil Singla, M.D., chief medical officer of Latigo. “Given the significant need for safe and effective non-opioid treatments for acute pain, we look forward to advancing the clinical program for LTG-001.”

Fast Track designation is designed to help drugs reach patients faster by facilitating the development and expediting the review of drugs with the potential to fill an unmet medical need and treat serious or life-threatening conditions. Programs receiving FTD benefit from early and frequent interactions with the FDA during the clinical development process and, if relevant criteria are met, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application.

LTG-001 Phase 1 Clinical Trial Results

LTG-001 is an oral, investigational selective inhibitor of Na_v1.8, a key sodium channel involved in pain signaling. LTG-001 works by blocking peripheral sensory neurons responsible for pain signals, thus preventing the transmission of these pain signals to the central nervous system. As a result, LTG-001 may provide effective pain relief without the risks associated with opioids. The Phase 1 first-in-human clinical trial was designed to evaluate the safety and tolerability of single- and multiple-ascending oral doses, relative bioavailability, and food effect of LTG-001 versus placebo in healthy subjects. Results from the trial with 72 healthy subjects showed that LTG-001 was well tolerated and demonstrated rapid absorption with a T_{max} of about 1.5 hours and predictable pharmacokinetics. Exposure was proportional across the dose range. Rapid onset of pain relief is critical for both acute and chronic pain management and achieving a T_{max} in under two hours in this study indicates this may be possible.

About Latigo Biotherapeutics

Latigo Biotherapeutics is a private clinical-stage biotechnology company developing innovative non-opioid pain medicines with potential best-in-class profiles that directly target the source of pain. Latigo’s goal is to provide effective, rapid-acting pain relief without the risk of addiction. Latigo is supported by leading investors including Westlake Village BioPartners, 5AM Ventures, Foresite Capital, and Corner Ventures. For more information, please visit www.latigobio.com or follow us on [LinkedIn](#).

Media Contact:

Kathy Vincent
Greig Communications Inc.
kathy@greigcommunications.com