Consano Bio Receives FDA Investigational New Drug Clearance to Expand the C-1101 Chronic Sciatica Clinical Development Program into the United States

C-1101 is a potential first-in-class, disease-modifying, non-opioid therapy designed to address the underlying biology of chronic sciatica

BURLINGTON, MA — July 20, 2026 — Consano Bio, Inc., a clinical-stage biotechnology company advancing novel therapeutics designed to address serious, painful orthopedic conditions, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for C-1101, its lead investigational therapy for chronic painful lumbosacral radiculopathy (LSR), commonly known as chronic sciatica.

The IND clearance authorizes expansion of Consano Bio's ongoing Phase 1 clinical trial to include U.S. clinical sites, complementing the study currently underway in Australia. The multi-center, randomized, controlled, double-blinded Phase 1 study (C-1101-101, NCT07264270) is evaluating C-1101 in patients with chronic sciatica. The study is enrolling symptomatic patients across three sequential, dose-escalation cohorts with each participant receiving a single epidural injection.

"IND clearance is a significant step forward for Consano and reflects the rigor of the program we have built," said Andrew Hall, Chief Executive Officer of Consano Bio. "From our founding in 2023, we have engaged the FDA continuously and constructively. IND clearance confirms that C-1101 meets the high scientific and manufacturing standards required to begin clinical development in the United States. C-1101 is a potential first-in-class, disease-modifying, non-opioid modality that targets the root biology of chronic sciatica, a condition affecting millions with no FDA-approved pharmaceutical treatment. We expect to begin dosing U.S. patients in the coming months and intend to build on our strong relationship with the agency as we move C-1101 through U.S. development toward registration and approval."

Unlike conventional therapies for chronic sciatica that primarily provide temporary pain relief or require invasive procedures, C-1101 is being developed to address the underlying biology of chronic LSR.

About Chronic Lumbosacral Radiculopathy (LSR)

Chronic, painful LSR, or chronic sciatica, is a chronic lower back pain condition caused by damage or irritation of spinal nerve roots in the lower back, leading to radiating pain, numbness, and weakness from the spine into the leg. There are no FDA-approved pharmaceutical treatments for chronic sciatica despite its prevalence and widespread societal and economic impact.

About C-1101

C-1101 is Consano Bio's lead investigational clinical candidate and the first pharmaceutical therapy of its kind in development: a novel, platelet-derived multi-protein biologic therapeutic. It is designed to treat LSR, or chronic sciatica, by modulating inflammation and stimulating and enhancing cellular repair at the site of injury. The product contains consistent concentrations of cytokines, growth factors, and matrix proteins designed to help trigger the body's natural healing response. Delivered via an epidural injection, C-1101 is intended to provide supraphysiologic concentrations of these proteins directly to the site of nerve injury.

About Consano Bio

Consano Bio is a clinical-stage biotechnology company dedicated to transforming the treatment of painful and debilitating orthopedic conditions through a new class of multi-protein biologic therapeutics. Founded in 2023, the company is headquartered in the Greater Boston area. For more information, visit www.consanobio.com.

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