Consano Bio Initiates Phase 1 Clinical Trial of C-1101, a Potential First-in-Class, Non-Opioid Therapy for Chronic Sciatica

- *First patient successfully dosed in a randomized, controlled Phase 1 trial evaluating C-1101 in patients with chronic sciatica*
- *C-1101 is a novel biologic designed as a disease-modifying treatment targeting the underlying cause of chronic, painful lumbosacral radiculopathy (chronic sciatica), for which no FDA-approved therapies exist*
- *Founded in 2023, Consano Bio is advancing a new therapeutic approach for painful, debilitating orthopedic conditions*

BURLINGTON, MA — May 26, 2026 — Consano Bio, Inc., a clinical-stage biotechnology company advancing novel therapeutics designed to address serious painful orthopedic conditions, today announced that the first patient has been successfully dosed in its first Phase 1 clinical trial (C-1101-101, NCT07264270) evaluating C-1101 in patients with chronic, painful lumbosacral radiculopathy (LSR), also known as chronic sciatica.

C-1101-101 is a multi-center randomized, controlled, blinded, dose-escalation study designed to evaluate the safety and tolerability of C-1101. The study is designed to enroll 24 patients across three sequential cohorts with each participant receiving a single epidural injection. Additional assessments include measures of change in pain, physical function, and sleep quality, all key indicators of clinical improvement in chronic, painful LSR.

Chronic sciatica is a painful condition caused by damage and/or irritation of the nerve roots in the lower spine. The pain typically radiates from the lower back down the leg and can be accompanied by numbness, tingling, or weakness. For many patients, these symptoms are disabling, limiting mobility and quality of life.

“People living with chronic lumbosacral radiculopathy have limited treatment options and often struggle to find lasting relief,” said Paul Verrills, MD, lead investigator in Australia for the C-1101-101 study and founder of MetroPain in Melbourne, Australia. “We are eager to evaluate C-1101 in a clinical setting to better understand its safety profile and therapeutic potential. This trial represents an important step toward identifying new approaches for a condition that has been underserved for far too long.”

Lower back pain including LSR is the number one cause of disability in the U.S.[1] and has been for the past three years, with the cost to the U.S. healthcare system estimated at $135 billion annually. It is also the number one reason for opiate initiation[2]. Despite its prevalence, there are currently no FDA-approved pharmaceutical treatments for chronic sciatica. Common management options include pain medications, physical therapy, epidural steroid injections, or implantable devices that require invasive surgical intervention, such as the placement of spinal cord stimulators. Far too

often, these approaches provide only temporary relief and fail to address the underlying nerve injury or inflammation that drives the condition.

“Dosing the first patient marks a historic milestone for Consano Bio and the C-1101 program,” said Andrew Hall, Chief Executive Officer. “This achievement moves C-1101 from development into the clinic and reflects the focused, disciplined effort of our team to advance a potentially first-in- class therapeutic approach for patients with chronic lumbosacral radiculopathy. For patients who often cycle through temporary or invasive treatment options, C-1101 is designed to address the underlying drivers of the condition, rather than simply managing symptoms.”

C-1101 Mechanism of Action: Presentation at ORS 2026 Annual Meeting

Consano Bio presented preclinical data at the Orthopaedic Research Society Annual Meeting in March 2026 highlighting C-1101’s inflammation modulation and reparative activities across translational models, with findings showing anti-inflammatory effects in activated human immune cells, modulation of inflammatory pathways, activation of growth-related pathways, and reduced pain sensitivity in a rodent model of peripheral neuropathy.

“The data presented at ORS reinforce our belief that C-1101 has the potential to address the underlying drivers of chronic nerve-related pain,” said Mr. Hall. “We believe these data provide important scientific support as we advance C-1101 through clinical development toward potentially becoming the first FDA-approved, disease-modifying therapy for 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: 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 and headquartered in the Greater Boston area. For more information, visit www.consanobio.com.

Contacts:

Consano Bio
Rahul Bansal
VP, Finance & Investor Relations

rbansal@consanobio.com
(908) 230-6689

Investor Relations
Tiberend Strategic Advisors, Inc.
David Irish
(231) 632-0002
dirish@tiberend.com

Media Relations
Tiberend Strategic Advisors, Inc.
Casey McDonald
(646) 577-8520
cmcdonald@tiberend.com

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[1] *JAMA*. 2018;319(14):1444-1472. doi:10.1001/jama.2018.015
[2] *IQVIA market analytics 2024*