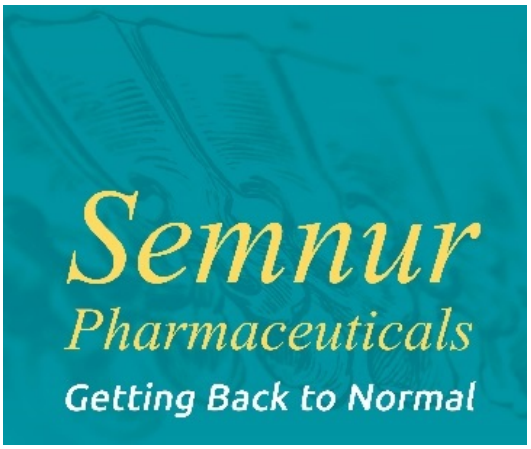
Semnur Pharmaceuticals Begins Pivotal Phase 3 Trial For SP-102 In Patients With Lumbar Radicular Pain/Sciatica

SP-102 Granted Fast Track Designation From The FDA

Semnur Pharmaceuticals Announces The Launch Of The New Clinical Trial Website At www.clearbackpainstudy.com.

Mountain View, Calif., Jan 7, 2018 /PRNewswire/ – Semnur Pharmaceuticals, Inc., a clinical stage specialty pharmaceutical company focused on developing and commercializing novel therapeutics for pain, announced the start of a pivotal Phase 3 clinical trial in the U.S. to evaluate its lead product SP-102 in patients with lumbar radicular pain/sciatica. In addition, the U.S. Food and Drug Administration (FDA) has granted SP-102 Fast Track Designation for the treatment of lumbar radicular pain/sciatica.



SP-102 is the first non-opioid corticosteroid formulated as a viscous gel injection in development for the treatment of lumbar radicular pain/sciatica, containing no neurotoxic preservatives, surfactants, solvents or particulates. The CLEAR ("Corticosteroid Lumbar Epidural Analgesia for Radiculopathy") Clinical Study is a randomized, double-blind, placebo-controlled Phase 3 trial that will enroll 400 patients with lumbar radicular pain at up to 35 sites across the U.S.. The primary endpoint of the study is mean change in the Numerical Pain Rating Scale for leg pain compared to intramuscular injection of placebo over four weeks. The secondary endpoints include other measures of pain at 4 and 12 weeks as well as time to repeat injection of SP-102, safety and disability. The study includes an open-label extension to build the safety database of patients treated with SP-102.

The FDA's Fast Track program was implemented to expedite the development and regulatory review of therapeutic programs that seek to address significant unmet medical needs. As Semnur develops SP-102 for lumbar radicular pain, the company is eligible for more frequent communication with the FDA related to the drug development plan and data necessary to expedite the development of this novel non-opioid pain treatment.

"On the heels of our successful Phase 1 / 2 bridging study results, we are excited to be starting our pivotal Phase 3 CLEAR trial to evaluate how a single epidural injection of SP-102 relieves sciatica pain. We've received significant interest from physicians to participate in this trial, looking for treatment alternatives for their patients without the burden of opioids," said Jaisim Shah, Chief Executive Officer, Semnur Pharmaceuticals.

"Patients with lumbosacral spinal conditions return frequently to their doctors looking for pain relief. We are eager to investigate what may be the first FDA-approved epidural injection that the interventional pain physicians could offer their patients for persistent relief of their pain, caused by nerve root compression usually by herniated intervertebral discs. We designed SP-102 to address expectations of medical community for a safer and longer-lasting injectable medication to reduce inflammation and pain," said Dr. Dmitri Lissin MD, Chief Medical Officer, Semnur Pharmaceuticals, Inc.

CLEAR Study Information for Patients

A website is now available for patients interested in the Phase 3 CLEAR Clinical Study. It includes information about SP-102 sciatica-related back and leg pain, the treatment protocol and resources to help patients determine if they may qualify for the clinical study to evaluate a new therapy for the treatment of lumbar radicular pain, commonly known as sciatica. If a patient is chosen to participate in the CLEAR trial, all study-related care is provided at no cost to the patient. Visit www.clearbackpainstudy.com.

About SP-102

SP-102 is a non-opioid corticosteroid formulated as a viscous gel injection, designed to prolong its analgesic effect at the site of the epidural injection, as demonstrated in clinical and preclinical studies. SP-102 does not contain neurotoxic preservatives, surfactants, solvents or particulates, which is expected to result in a better safety profile than commonly used off-label injected corticosteroids. Semnur's successful Phase 1/2 bridging study in patients with lumbar radicular pain achieved its primary pharmacokinetic endpoint of an extended product residency time at the site of injection, as well as demonstrated that a single injection of SP-102 led to over 30% improvement in leg and back pain over 30 days. Semnur's pivotal Phase 3 CLEAR trial is designed to satisfy regulatory requirements for a 505(b)(2) new drug application with the FDA.

About Lumbar Radicular Pain

In the U.S., more than 30 million people live with low back and radicular pain, with this population expected to grow in the low-single digit percentages annually.[1] Pain is one of the most common reasons

people seek medical treatment. Low back pain is the second most common cause of disability for adults in the U.S.. Approximately 149 million work days are lost every year because of low back pain, with total costs estimated to be $100 to 200 billion a year (of which two-thirds is due to lost wages and lower productivity).[2] There is a great need for highly effective analgesic medications to provide relief without the toxicity and tolerability challenges of NSAIDs and opioids. Opioid prescriptions account for about 60 percent of the chronic pain market and carry a well-known risk of abuse and misuse, underscoring the need for alternative pain therapies without the medical and societal challenges.[3]

About Semnur Pharmaceuticals, Inc.

Semnur Pharmaceuticals, Inc. is a clinical-stage specialty pharmaceutical company based in Mountain View, CA, focused on the development and commercialization of best in class novel non-opioid pain therapies. Semnur's lead program, SP-102, is a non-opioid novel gel formulation administered epidurally in development for patients with moderate to severe chronic radicular pain/sciatica. For more information, visit www.semnurpharma.com or www.clearbackpainstudy.com. Follow us on LinkedIn, Facebook, Twitter, and Clear Back Pain Study.

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting concerning the matters discussed in this press release contain forward-looking statements related to Semnur Pharmaceuticals, Inc. under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the outcome of the data from a clinical trial for SP-102, Semnur's prospects, future clinical trials and the results thereof, market and patient population trends, M&A strategy, and ability to accelerate the development of its lead program in the clinic. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to that SP-102 may not meet all endpoints of the clinical study and that the data may not support an NDA submission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release and we undertake no obligation to update any forward-looking statement in this press release except as may be required by law.

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References

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(2) World Health Organization: Priority Medicines for Europe and the World Update Report, 2013; Background Paper 6.24, Low Back Pain
(3) National Institutes of Health 2011: Opioids for Back Pain Patients – Primary Care Prescribing Patterns and Use of Services

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