Scilex Holding Company Amends its License Agreement with Romeg Therapeutics, LLC, For the Worldwide Rights to Commercialize Gloperba®, an FDA-Approved Prophylactic Treatment for Painful Gout Flares in Adults

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- Gloperba® is the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults.
- Over 70% of gout patients have comorbid conditions that may require dose adjustments, and such patients could be a potential target population for Gloperba®[1]
- Over 17% of gout patients on colchicine experienced severe gastrointestinal side effects like diarrhea. These patients may benefit from flexible dosing offered by Gloperba®[2]
- Unlike other colchicine formulations, GLOPERBA® liquid oral solution allows for precision dosing and reduction of daily dose in patients with severe renal impairment (0.3 mg/day).
- The worldwide incidence of gout flares is estimated to be around 0.1 to 0.3% of the population, with a significantly higher prevalence in males compared to females, and a rising trend due to factors like increasing obesity rates and aging populations; however, exact figures can vary depending on the study and region analyzed.[3]
- The global population of individuals with gout increased in the past 30 years from 22 million (95% UI 17.52-27.37) to 53 million (95% UI 43.38-66.34).[4]

PALO ALTO, Calif., Jan. 16, 2025 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or “Company”), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain and, following the formation of its proposed joint venture with IPMC Company, in neurodegenerative and cardiometabolic disease, today announced that it has entered into an amendment (the “Amendment”) to its existing license agreement with Romeg Therapeutics, LLC (“Romeg”), entered into in June 2022, for ex-US rights to Gloperba®. Romeg had previously granted Scilex an exclusive license to commercialize Gloperba® only in the U.S.

Gloperba® is taken orally like cough syrup. The dosage of 0.6mg per 5ml (teaspoon) can fill that important void in treatment where patients may have difficulty swallowing pills. It can also provide more adjustable dosing, titration and dose-reduction options in specific populations, especially for gout patients with renal or hepatic impairment and reduce side effects with the goal to improve patient convenience and disease management.

According to Nature Reviews Rheumatology, gout is a common chronic crystal deposition disorder that affects between <1% and 6.8% of the population, depending on the population studied. Both prevalence and incidence of gout seem to be rising across the globe. Management of gout continues to be poor, with fewer than one-half of patients receiving definitive ‘curative’ urate-lowering therapy. Adherence to urate-lowering therapy is often poor and rates of non-persistence are high. Obesity and comorbidities are important risk factors for gout and are important drivers of its rising prevalence and incidence (https://www.nature.com/articles/s41584-020-0441-1).

For more information on Scilex Holding Company, refer to www.scilexholding.com.

For more information on Semnur Pharmaceuticals, Inc., refer to www.semnurpharma.com.

For more information on Scilex Holding Company Sustainability Report, refer to www.scilexholding.com/investors/sustainability.

For more information on ZTlido® including Full Prescribing Information, refer to www.ztlido.com.

For more information on ELYXYB®, including Full Prescribing Information, refer to www.elyxyb.com.

For more information on Gloperba®, including Full Prescribing Information, refer to www.gloperba.com.

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About Scilex Holding Company

Scilex Holding Company is an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain and, following the formation of its proposed joint venture with IPMC Company, neurodegenerative and cardiometabolic disease. Scilex targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with acute and chronic pain and is dedicated to advancing and improving patient outcomes. Scilex's commercial products include: (i) ZTlido® (lidocaine topical system) 1.8%, a prescription lidocaine topical product approved by the U.S. Food and Drug Administration (the "FDA") for the relief of neuropathic pain associated with postherpetic neuralgia, which is a form of post-shingles nerve pain; (ii) ELYXYB®, a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults; and (iii) Gloperba®, the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults.

In addition, Scilex has three product candidates: (i) SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) ("SEMDEXA" or "SP-102"), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, for which Scilex has completed a Phase 3 study and was granted Fast Track status from the FDA in 2017; (ii) SP-103 (lidocaine topical system) 5.4%, ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of acute pain and for which Scilex has recently completed a Phase 2 trial in acute low back pain. SP-103 has been granted Fast Track status from the FDA in low back pain; and (iii) SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) ("SP-104"), a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia, for which Phase 1 trials were completed in the second quarter of 2022.

Scilex Holding Company is headquartered in Palo Alto, California.

About Semnur Pharmaceuticals, Inc.

Semnur Pharmaceuticals, Inc. ("Semnur") is a clinical-late stage specialty pharmaceutical company focused on the development and commercialization of novel non-opioid pain therapies. Semnur's product candidate, SP-102 (SEMDEXA™), is the first non-opioid novel gel formulation administered epidurally in development for patients with moderate to severe chronic radicular pain/sciatica.

Semnur Pharmaceuticals, Inc. is headquartered in Palo Alto, California

About ROMEG Therapeutics, LLC

ROMEG Therapeutics, LLC, is a privately held, revenue-generating, specialty pharmaceutical company based in Woburn, Mass. The company's mission is to develop new FDA-approved therapies by formulating novel dosage forms, improving the design and function of existing approved drugs, and expanding clinical indications for use of those drugs, thereby bringing greater value to earlier scientific discovery. The company's first FDA-approved drug, Gloperba® (colchicine oral solution) was launched by commercial partner Scilex in the US in 2024. The company has two active pipeline programs targeting Sjogren's syndrome, and continues to focus on developing a broad intellectual property portfolio to offer novel therapies to provide patients and physicians better treatment options. For more information, visit www.romegrx.com.

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 Scilex and its subsidiaries 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 Gloperba being the first and only liquid oral version of the anti-gout medicine, Scilex's plans to commercialize Gloperba and the potential for the amended license agreement to accelerate Scilex's commercialization plans, Scilex's proposed joint venture with IPMC Company and the potential development and commercialization of treatments for obesity, neurodegenerative, cardiometabolic disease.

Risks and uncertainties that could cause Scilex's actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: Scilex's ability to commercialize GLOPERBA outside of the US, Scilex's ability to consummate a joint venture or any other transaction with IPMC Company and develop and commercialize treatments for obesity, neurodegenerative, cardiometabolic disease; risks associated with the unpredictability of trading markets and whether a market will be established for Scilex's common stock; general economic, political and business conditions; risks related to COVID-19 (and other similar disruptions); the risk that the potential product candidates that Scilex develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; risks relating to uncertainty regarding the regulatory pathway for Scilex's product candidates; the risk that Scilex will be unable to successfully market or gain market acceptance of its product candidates; the risk that Scilex's product candidates may not be beneficial to patients or successfully commercialized; the risk that Scilex has overestimated the size of the target patient population, their willingness to try new therapies and the willingness of physicians to prescribe these therapies; risks that the outcome of the trials and studies for SP-102, SP-103 or SP-104 may not be successful or reflect positive outcomes; risks that the prior results of the clinical and investigator-initiated trials of SP-102 (SEMDEXA™), SP-103 or SP-104 may not be replicated; regulatory and intellectual property risks; and other risks and uncertainties indicated from time to time and other risks described in Scilex's most recent periodic reports filed with the Securities and Exchange Commission, including Scilex's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q that the Company has filed or may file with the SEC, including the risk factors set forth in those filings. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Scilex undertakes no obligation to update any forward-looking statement in this press release except as may be required by law.

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3. https://www.sciencedirect.com/science/article/pii/S0049017220301220
4. https://pmc.ncbi.nlm.nih.gov/articles/PMC10285625/

SEMDEXA™ (SP-102) is a trademark owned by Semnur Pharmaceuticals, Inc., a wholly-owned subsidiary of Scilex Holding Company. A proprietary name review by the FDA is planned.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc., a wholly-owned subsidiary of Scilex Holding Company.

Gloperba® is the subject of an exclusive, transferable license to Scilex Holding Company to use the registered trademark.

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