Scilex Holding Company Announces FDA Final Approval to Precision Dosing for GLOPERBA® Label

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- FDA Final Approval to Precision Dosing for GLOPERBA® Label.
- We believe 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.
- Gout is a painful arthritic disorder affecting an estimated 9.2 million people in the United States[1]. As gout cases increase every year, treatment requirements increase. According to data gathered by Evaluate Pharma, the gout treatment market is projected to reach $2.0 billion in the U.S. by 2028 with a well-defined area of unmet need.[2]
- Over 70% of gout patients have comorbid conditions that may require dose adjustments, and such patients are a potential target population for GLOPERBA®.[3]
- Over 17% of gout patients on colchicine experienced severe gastrointestinal side effects like diarrhea. These patients may benefit from flexible dosing offered by GLOPERBA®.[4]
- Unlike other colchicine formulations, GLOPERBA® allows reduction of daily dose in patients with severe renal impairment (0.3 mg/day).

PALO ALTO, Calif., Aug. 29, 2024 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or the “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, today announced FDA approval of a Supplemental New Drug Application for Label Updates to GLOPERBA®.

GLOPERBA® is the only FDA-approved liquid formulation of colchicine for the prophylaxis of acute gout flares. Over 70% of gout patients have chronic kidney disease and many suffer from gastrointestinal sensitivity, necessitating a lower dose of colchicine than the standard 0.6 mg tablet or capsule. GLOPERBA® is expected to be the first liquid colchicine formulation that allows healthcare providers to prescribe precision dosing in at-risk patient populations, and thereby help mitigate against severe toxicity in patients. Healthcare providers can now safely and effectively manage such patients at doses below 0.6 mg once or twice daily, which is the standard dose for prophylaxis. In patients who are treated at lower doses than 0.6 mg, the 150 ml bottle of GLOPERBA® is expected to last more than 30 days, delivering additional value to patients. Unlike other colchicine formulations, GLOPERBA® allows reduction of daily dose in patients with severe renal impairment (0.3 mg/day).

A recent market research study among rheumatologists conducted by Scilex revealed a high degree of interest in Gloperba® as a liquid colchicine formulation designed for precision dosing.[5] Specifically, clinicians using colchicine for prophylaxis of gout flares in adults indicated a strong likelihood to use GLOPERBA® instead of tablets/capsules in certain at-risk patient populations who have a clinical need for lowered precision dosing to mitigate the risk of colchicine toxicity. Notably, the American College of Rheumatology (ACR) guidelines also reflect this need.[6]

INDICATIONS AND USAGE

- GLOPERBA® (colchicine USP) Oral Solution is indicated for prophylaxis of gout flares in adults.
- Limitations of use: The safety and effectiveness of GLOPERBA® for acute treatment of gout flares during prophylaxis has not been studied. GLOPERBA® is not an analgesic medication and should not be used to treat pain from other causes.

DOSAGE AND ADMINISTRATION

- Gout Prophylaxis
    - The recommended dosage of GLOPERBA® (0.12 MG/ML OF COLCHICINE ORAL SOLUTION) for adults and adolescents older than 16 years of age is 0.6 mg once or twice daily. The maximum recommended dose is 1.2 mg/day.

Colchicine mg to Gloperba mL Conversion Table	
Colchicine (mg)	Gloperba (mL)
0.3 mg	2.5 mL
0.6 mg	5 mL
1.2 mg	10 mL

    - GLOPERBA® is administered orally, without regard to meals.
    - Prophylactic therapy may be beneficial for at least the first six months of uric acid-lowering therapy.

For more information on Scilex Holding Company, refer to www.scilexholding.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. 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 chronic neck pain and for which Scilex has recently completed a Phase 2 trial in 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.

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 estimates for the gout treatment market and affected patient population, estimates for potential demand for Gloperba, the belief that Scilex is well-positioned to market and distribute Gloperba, Scilex's expectations for Gloperba to be the first liquid colchicine formulation allowing providers to prescribe precision dosing and Scilex's expectations for Gloperba to last more than 30 days in patients who are treated with lower doses than 0.6 mg.

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: risks associated with the unpredictability of trading markets; general economic, political and business conditions; 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, 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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Reference

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2) Evaluate Pharma data
3) Comorbidities of Gout and Hyperuricemia in the US General Population: NHANES 2007-2008
4) Stewart et al. Arthritis Research & Therapy (2020) 22:28; https://doi.org/10.1186/s13075-020-2120-7
5) Scilex market research study of US rheumatologists, Nov-Dec 2023
6) Khanna D, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 2: Therapy and Anti-inflammatory Prophylaxis of Acute Gouty Arthritis. Arthritis Care & Research. Vol. 64, No. 10, October 2012, pp 1447–1461

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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