Scilex Holding Company Announces Seeking Approval from the FDA for Modification of the Gloperba® Label to Provide Specific Dosing Guidance for Patients with Renal Impairment and Other Circumstances Where Dose Adjustment is Needed

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- Seek approval from the FDA for the modification of the Gloperba® label to include its ability to utilize dosing flexibility of liquid formulation to address unmet medical needs and provide specific dosing guidance to patients with renal impairment as set out below:
  - Patients with mild or moderate renal or hepatic impairment should be considered for dose adjustment.
  - For patients with severe renal impairment, the starting dose should be 0.3 mg/day.
  - For patients undergoing dialysis, the total recommended dose should be 0.3 mg and be given twice a week.
- 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 United States 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 could be potential target population for Gloperba®[3]
- Over 17% of gout patients on colchicine have experienced severe gastrointestinal side effects like diarrhea. These patients may benefit from flexible dosing offered by Gloperba®[4]

PALO ALTO, Calif., March 20, 2024 (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, today announced it will seek approval from the FDA for the modification of the Gloperba® label to include its ability to utilize dosing flexibility of liquid formulation to address unmet medical needs and provide specific dosing guidance to patients with renal impairment as set out below:

- Patients with mild or moderate renal or hepatic impairment should be considered for dose adjustment.
- For patients with severe renal impairment, the starting dose should be 0.3 mg/day.
- For patients undergoing dialysis, the total recommended dose should be 0.3 mg and be given twice a week.

A recent market research study among rheumatologists 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]

Scilex expects to launch Gloperba® in the first half of 2024. 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. Approximately 70% of gout patients have chronic kidney disease stage 2 and many suffer from gastrointestinal sensitivity, necessitating a lower dose of colchicine than the standard 0.6 mg tablet or capsule[3]. Gloperba® is the first and only liquid colchicine formulation that allows healthcare providers to prescribe precision dosing in these at-risk patient populations, and thereby help mitigate against severe toxicity in patients. Healthcare providers can now safely and effectively manage these patients at doses below 0.6 mg once or twice daily, which is the standard dose for prophylaxis. For patients who are treated at doses lower than 0.6 mg, the 150 ml bottle of Gloperba® is expected to last longer than 30 days, delivering additional value to patients.

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

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

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

For more information on ZTlido® including Full Prescribing Information, refer to www.ztlido.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 are 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, expected to launch in the first half of 2024.

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 has 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 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 and a Phase 2 clinical trial is expected to commence in 2024.

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®, estimates for the launch pricing of Gloperba®, the belief that Scilex is well-positioned to market and distribute Gloperba®, Scilex's expectations for Gloperba ® to be the first liquid oral version of colchicine formulation allowing providers to prescribe precision dosing, Scilex's expectations for Gloperba ® to last more than 30 days in patients who are treated with doses lower than 0.6 mg, Scilex's expectation to launch Gloperba® in the first half of 2024 , each parties' releases of claims arising from the captioned patent infringement lawsuit, the granting of the non-exclusive license and FDA's approval for the modification of the Gloperba ® label and plans to initiate a Phase 2 clinical trial in 2024 for SP-104.

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 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, 2022 and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, 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:

1) https://jamanetwork.com/journals/jama/fullarticle/2787544#:~:text=How%20Common%20Is%20Gout%3F,%25%20of%20the%20adult%20population

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

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