Scilex Holding Company announces the U.S. FDA has approved the sNDA for commercial manufacturing of Gloperba® which will be launched in the US in the week of June 10th 2024

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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.
- 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. The gout treatment market is projected to be $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 could be 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]
- Scilex is well-positioned to market and distribute its third commercial non-opioid product, Gloperba®:
    - Scilex has a direct distribution network to national and regional wholesalers and pharmacies throughout the U.S.
    - Scilex has an experienced commercial and managed care team that has successfully launched and grown market access for ZTlido® (lidocaine topical system) 1.8% to more than 225 million covered lives in the U.S. as well as successfully launching Elyxyb® (celecoxib oral solution) in the U.S. in April 2023, the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults.

PALO ALTO, Calif., June 06, 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 that it has the FDA approval of commercial manufacturing of Gloperba®, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. and will launch in June 2024. Scilex will stock Gloperba® in all major wholesalers and pharmacies starting June 10, 2024.

Gloperba® is a highly complementary commercial asset that allows the Company to provide physicians with another tool in their non-opioid pain management armamentarium to treat gout earlier in the patient journey as the Company continues to work towards re-defining the role of opioids as a last resort rescue medication.

Gloperba® is a novel liquid colchicine formulation with a launch price of $595 per 150ml bottle. 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.

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]

For more information on Gloperba®, visit https://www.gloperba.com.

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 and will be launched on June 10, 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.

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 Gloperba®'s potential to further expand Scilex's non-opioid portfolio and its potential to address high unmet needs in treating gout, the potential size of the U.S. gout treatment market, Scilex's plans to launch Gloperba ®s in the U.S. in the first quarter of 2024, its plans to initiate a Phase 2/3 trial in chronic neck pain in 2024 and plans to initiate Phase 2 trials in 2024 for SP-104, Scilex's belief that it is well positioned to continue its growth over the next several years, Scilex's long-term objectives and commercialization plans, Scilex's potential to attract new capital, future opportunities for Scilex, Scilex's future business strategies, the expected cash resources of Scilex and the expected uses thereof; Scilex's current and prospective product candidates, planned clinical trials and preclinical activities and potential product approvals, as well as the potential for market acceptance of any approved products and the related market opportunity; statements regarding ZTlido®, Gloperba®, ELYXYB®, SP-102 (SEMDEXA™), SP-103 or SP-104, if approved by the FDA; Scilex's development and commercialization plans; and Scilex's products, technologies and prospects.

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 that Scilex may not achieve the results expected from the commercialization of Gloperba®; 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 for SP-102, SP-103 or SP-104 may not be successful; risks that the prior results of the clinical 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 set forth in Scilex's filings with the Securities and Exchange Commission. 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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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 Antiinflammatory Prophylaxis of Acute Gouty Arthritis. Arthritis Care & Research. Vol. 64, No. 10, October 2012, pp 1447–1461

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