



Scilex Holding Company announces completion of commercial manufacturing of Gloperba® with the brand marketed and distributed under Scilex Pharmaceuticals, Inc. and is expecting to Launch in the U.S. in the first quarter of 2024

November 27, 2023 2:00 PM EST

- 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 States¹. 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
- Scilex is well-positioned to market and distribute 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) 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., Nov. 27, 2023 (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 completed commercial manufacturing of Gloperba®, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. and is expecting to launch Gloperba® in the U.S. in the first quarter of 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.

For more information on Gloperba®, refer to the Exhibits hereto and visit <https://www.gloperba.com>.

Exhibit A-1

NDC 69557 222 01


GLOPERBA[®]
(colchicine) oral solution

0.6 mg/5 mL

Rx Only

Dispense with Medication Guide



Exhibit A-2

See package insert for
full prescribing information.

Each mL contains 0.12/mg colchicine USP.

Store at 20°-25°C (68° - 77°F); excursions
permitted to 15°-30°C (59°-86°F).

[See USP Controlled Room Temperature.]

Keep out of the reach of children.

 **SCILEX**[®]
PHARMACEUTICALS

Manufactured for:
SCILEX Pharmaceuticals, Inc.
Palo Alto, California 1-866-SCILEX3
GLO-00051 Rev 03/23



Exhibit B



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 is uncompromising in its focus to become the global pain management leader committed to social, environmental, economic, and ethical principles to responsibly develop pharmaceutical products to maximize quality of life. Results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. Scilex participated in the type C meeting for purposes of pre-NDA discussion with the FDA and reached agreement on a path forward to file an NDA for SP-102 (SEMDEXA™) in Lumbosacral Radicular Pain (Sciatica) with the FDA. Scilex targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with moderate to severe pain. Scilex launched its first commercial product ZTlido® in October 2018, in-licensed a commercial product Gloperba® in June 2022, and launched its third FDA-approved product Elyxyb® in April 2023. It is also developing its late-stage pipeline, which includes a pivotal Phase 3 candidate, and one Phase 2 and one Phase 1 candidate. Its commercial product, ZTlido® (lidocaine topical system) 1.8%, or ZTlido®, is a prescription lidocaine topical product approved by the U.S. Food and Drug Administration for the relief of pain associated with post-herpetic neuralgia, which is a form of post-shingles nerve pain. Scilex in-licensed the exclusive right to commercialize Gloperba® (colchicine USP) oral solution, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. Scilex in-licensed the exclusive rights to commercialize Elyxyb® (celecoxib oral solution) in the U.S. and Canada, the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults. Scilex launched Elyxyb® in April 2023, and is planning to commercialize Gloperba® by 2024, and is well-positioned to market and distribute those products. Scilex's three product candidates are SP-102 (injectable dexamethasone sodium phosphate viscous gel product containing 10 mg dexamethasone), or SEMDEXA™, a Phase 3, novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, with FDA Fast Track status; SP-103 (lidocaine topical system) 5.4%, a Phase 2 study, triple-strength formulation of ZTlido®,

for the treatment of chronic neck pain, with FDA Fast Track status. We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute low back pain associated with muscle spasms. SP-103 was safe and well-tolerated. Increase of lidocaine load in topical system by three times, compared with approved ZTlido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. We will continue to analyze the SP-103 Phase 2 trial data along with a recently completed investigator study of ZTlido in patients with chronic neck pain which also has showed promising top-line efficacy and safety results. Scilex is planning to initiate Phase 2/3 trial in chronic neck pain in 2024; and SP-104, 4.5 mg Delayed Burst Release Low Dose Naltrexone Hydrochloride (DBR-LDN) Capsule, for the treatment of chronic pain, fibromyalgia that has completed multiple Phase 1 trial programs and is expected to initiate Phase 2 trials 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 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

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

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 use the registered trademark by Scilex Holding Company.

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

All other trademarks are the property of their respective owners.

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Photos accompanying this announcement are available at:

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Source: Scilex Holding Company

Exhibit A-1

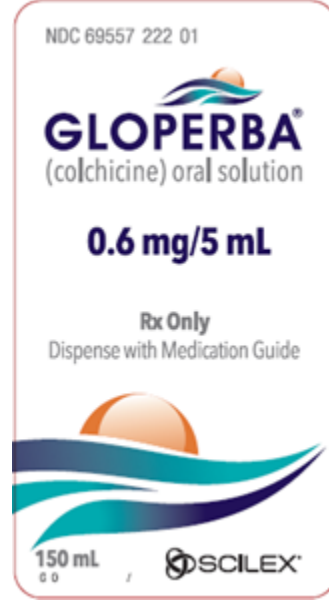


Exhibit A-1

Exhibit A-2



Exhibit A-2

Exhibit B



Exhibit B