Scilex Holding Company Enters into Master Distributor Agreement Among CH Trading Group and Devart Middle East for the Distribution of ZTlido® in Morocco, Tunisia, Libya, Jordan, Iraq, and South Africa

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PALO ALTO, Calif., Aug. 09, 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 a Master Distributor Agreement with Devart Middle East Food Supplements ("Devart Middle East"), as Master Distributor, and CH Trading Group LLC ("CH Trading Group"), as Territories Distributor, to expand the distribution of ZTlido® into the countries of Morocco, Tunisia, Libya, Jordan, Iraq, and South Africa ("Designated Territories").

The Master Distributor Agreement is an outgrowth Scilex's existing Product Distribution Agreement with CH Trading Group, under which CH Trading Group is continuing the process of expanding commercialization of ZTlido® in the Middle East and North/South Africa markets and has the opportunity to distribute across the broader Islamic world and further expand the relationship for other products in Scilex's non-opioid pain portfolio.

Under the Master Distributor Agreement, Devart Middle East assumes the responsibility, among other things, of promoting, marketing, selling and distributing ZTlido®, and potentially other Scilex products, through a network of business associates, into the above Designated Territories.

ZTlido® is a lidocaine topical system approved for the relief of neuropathic pain associated with post-herpetic neuralgia (PHN). ZTlido® was strategically designed to address the limitations of current prescription lidocaine patches by providing significantly improved adhesion and continuous pain relief throughout the 12-hour administration period.

- Over one million patients are estimated to have been treated with ZTlido® in the United States since its launch according to Symphony Health prescription data.
- ZTlido® is now the number one prescribed, non-opioid, branded, pain medication by pain specialists in the United States, based on Symphony Health prescription data gathered for 2023.
- In the U.S., patients report 89% satisfaction with ZTlido®, in a 2023 patient survey conducted by Scilex (n=100, rating as "completely" or "mostly" satisfied with ZTlido® treatment).

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 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.

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.

About CH Trading Group

CH Trading Group LLC is part of the CH Group family of companies. CH Group constitutes a diversified conglomerate targeting eight economic" Sectors": healthcare, pharmaceuticals, food, finance, cosmetics, tourism, fashion, media/entertainment. Spanning a variety of multi-national products, services and solutions, its world mission involves connecting, developing, and promoting, from Local to Global™ and throughout the world, all aspects of a wholesome, healthy, and productive lifestyle.

CH Trading Group focuses on international import/export and trade, prioritizing the countries of the Organization of Islamic Cooperation (OIC), as well as the Middle East and North Africa (MENA) and Gulf Cooperation Council (GCC) Regions. It has responded to worldwide demands for identifying and securing supply chains by introducing innovative products, including from the US, and developing a robust distribution network for goods.

For more information, please visit https://chgroupus.com/

About Devart Middle East

Devart Middle East Food Supplements is part of the DevartLab Group family, headquartered in Egypt. Devartlab Group consists of investors and enterprising visionaries focusing on three pivotal areas: pharmaceuticals, non-banking microfinance and cutting-edge digital solutions, across various Islamic Markets and beyond into the European and US markets. Its diverse expertise includes healthcare, technology, B2C finance, business innovation, manufacturing, promotion, marketing, sales and distribution.

For more information, please visit: https://devartlab.com/en

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 the Company's preliminary unaudited financial results for the month ended July 31, 2024, the Company's outlook, goals and expectations for 2024, and the Company's development and commercialization plans.

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, 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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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.

ELYXYB® is a registered trademark owned by Scilex Holding Company.

All other trademarks are the property of their respective owners.

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Source: Scilex Holding Company