Scilex Holding Company Announces Collaboration to Leverage ACEA Therapeutics' R&D Expertise and Local Market Connections to Support the Expansion of ZTlido® Program in ex-US and Potentially Provide Additional Access to Patients in Certain Key Markets in Far East Region

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- ACEA Therapeutics ("ACEA") will serve as exclusive territories distributor in Greater China, including mainland China, Taiwan, Hong Kong and Macau, with potential minimum purchase commitment for ZTlido once approved locally in the region.

- ACEA to immediately start the process to explore potential commercialization of ZTlido®, with the opportunity to distribute with partners across Greater China and further expand the relationship to include other products in Scilex's non-opioid pain portfolio.

PALO ALTO, Calif., July 17, 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 that that it has entered into a Memorandum of Understanding (MOU) for collaboration agreement with ACEA, a China-based company focused on the development of innovative treatments for high unmet needs. Under the terms of the MOU, ACEA may receive exclusive rights to develop and commercialize of ZTlido® in mainland China, Taiwan, Hong Kong, Macau, including the current formulation and a right of first negotiation for a future next generation formulation of a 3X version of ZTlido, SP-103. The MOU provides Scilex with the opportunity to expand collaboration with ACEA across other products in Scilex's non-opioid pain management portfolio in the Greater China region.

ZTlido® is a lidocaine topical system approved for the relief of neuropathic pain associated with post-herpetic neuralgia or 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. According to the most recent analysis by Precedence Research March 2022 Pain Management Therapeutics Market Size, the pain management market size is estimated to reach US$101.27 billion by 2029 and growing at a CAGR of 4.3% from 2022 to 2030.[1] In mainland China, the pain management market size in 2022 was US$17.5 billion with annual growth of 5.64%. [2]

"Based on current market demand for Scilex's innovative non-opioid pain management products, we believe there is a significant commercial opportunity for ZTlido® across Greater China markets. We are excited to be in a position with our potential partners to expand access to ZTlido® and other important pain solutions with Scilex in the future," said Xiao Xu, CEO of ACEA.

"This joint collaboration effort with ACEA reflects on our mission to bring our innovative non-opioid medicines to acute and chronic pain patients in greater China region. This agreement is an important step toward our shared goal of bringing safe and effective pain management to people worldwide, to ensure more patients are able to benefit from these innovative medicines," said Jaisim Shah, Chief Executive Officer and President of Scilex.

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

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.

About ACEA Therapeutics

ACEA Therapeutics is a clinical stage pharmaceutical company with a diverse product portfolio to address unmet medical needs. Alongside a robust R&D and clinical organization, ACEA has established drug manufacturing and commercial capabilities in China to support its long-term growth. This infrastructure provides ACEA with greater control over our supply chain for timely delivery of highest quality products to patients.

Its lead compound, Ovydso® (olgotrelvir), a small molecule dual inhibitor of SARS-CoV-2 main protease (Mpro) and human cathepsin L, has been developed as a stand-alone oral medication for the treatment of COVID-19. A pivotal Phase III clinical trial COVID-19 patients treated with Ovydso® or placebo has been successfully recently completed and has been in the process of regulatory approval by National Medical Products Administration (NMPA) in China. Fujovee® (abivertinib), a small molecule kinase inhibitor, has completed Phase II EGFR T790M+ NSCLC study in China with positive results published in Clinical Cancer Research. Recently FDA granted IND clearance for Phase II study of Fujovee® to treat patients resistant to the NSCLC drug Tagrisso (Osimertinib). STI-8591, a second-generation small molecule inhibitor of FMS-like tyrosine kinase 3 (FLT3), is in Phase I development in China for the treatment of acute myeloid leukemia (AML).

Multiple other investigational drug candidates including small molecule, large molecule and cell therapy programs are currently in development. With the diverse portfolio and drug development milestones, ACEA is well-positioned to fulfill the promise to deliver innovative treatments to patients, while creating value for shareholders, employees, and society.

ACEA Therapeutics is headquartered in San Diego, California with wholly owned subsidiaries in China.

For more information on ACEA Therapeutics, refer to www.aceatherapeutics.com.

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 Scilex'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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Reference

1. Precedence Research March 2022 Pain Management Therapeutics Market Size to Reach US$ 101.27 BN by 2029. https://www.precedenceresearch.com/sample/1224
2. Research Report - Analysis of the Development Status, Market Size and Investment Prospects of China Pain Management Drug Industry in 2023. **https://xueqiu.com /8666823409/259817440**

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc., a wholly-owned subsidiary of Scilex Holding Company.

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