



Scilex Holding Announces Issuance of Halal Certification for its ZTlido® product by Circle H International, Inc.

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- The certification has the potential to open access to Islamic markets globally, expanding potential markets for Scilex's innovative FDA approved non-opioid therapies and pipeline candidate products.
- The certification is an important prerequisite for health care and covers health and wellness as well as non-addictive pain management products.
- Announcement advances the global expansion strategy for Scilex with plans for growing its presence in the Middle East and North Africa region with an initial focus on the UAE and Saudi Arabia.

PALO ALTO, Calif., March 15, 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 received Halal Certification of its commercial product ZTlido, indicating that ZTlido has undergone rigorous assessment to determine that it is permissible or acceptable in accordance with Islamic standards. The Halal certification was issued under the authority of Circle H International, Inc. ("Circle H") and offers the Company the opportunity to provide ZTlido to Islamic markets globally. This announcement supports the global expansion strategy for Scilex, which Scilex anticipates will include a presence in the Middle East and North Africa (MENA) region with an initial priority focus on the UAE and Saudi Arabia.

"Obtaining the broadly inclusive Halal Certification is a critical and important milestone in Scilex's plan to expand to potential Islamic markets for our innovative non-opioid non-addictive pain management therapeutic pipeline candidates and FDA approved products. With the global Muslim population representing over 25% of the world's population, according to Statista, this certification facilitates our ability to grow and expand in international markets," said Jaisim Shah, Chief Executive Officer and President of Scilex.

Circle H issued the Halal Certification based on the global standards promulgated by its esteemed Circle H Sharia Advisory Council (the "Council"). Circle H and the Council are recognized and supported by prominent governmental and non-governmental organizations and Islamic universities. Religious leaders drawn from these prominent institutions sit on or advise Circle H and the Council, for the development and support of its Halal standards.

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, 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 the potential for the Halal Certification to expand access to Islamic markets globally and the impact it has on Scilex's global expansion strategy, Scilex's plans to focus on expanding in the UAE and Saudi Arabia, Scilex's expectation to launch Gloperba® in the first half of 2024 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, 2023, 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 use the registered trademark by Scilex Holding Company.

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

All other trademarks are the property of their respective owners.

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