Scilex Holding Company Announces the U.S. Patent and Trademark Office Will Be Issuing New ELYXYB® Patent Related to the Treatment of Acute Pain

August 21, 2024 1:00 PM EDT

- Scilex today announced that the U.S. Patent and Trademark Office has allowed numerous claims from U.S. patent application no. 17/562,229 and will issue a new patent containing those claims related to the treatment of acute pain (the "Patent"), to Scilex in late 2024, further strengthening the Company's intellectual property position and coverage for its acute migraine treatment drug product, ELYXYB®, a liquid, micro-encapsulation formulation of celecoxib.
- ELYXYB™ is a 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.[1] The U.S. oral migraine drug market size is estimated to be $1.8 billion in 2022.[2]
- ELYXYB®, a rapid onset and ready to use formulation of Celecoxib, delivers a first line non-opioid therapeutic alternative to habit-forming opioids and acetaminophen, the leading cause of acute liver failure in the U.S.[3]
- DelveInsight estimates there were approximately 100 million cases of acute pain in the U.S. and that the total acute pain market in the U.S. was approximately $3 billion in 2021.[4]
- There is strong evidence for the use of non-steroidal anti-inflammatory drugs (NSAIDs) as a first-line treatment for migraine. ELYXYB® (celecoxib oral solution) is in the same class of agents, is fast acting, and has the potential to have the lowest gastrointestinal (GI) side effects of all NSAIDs.[5]

PALO ALTO, Calif., Aug. 21, 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 the U.S. Patent and Trademark Office has allowed numerous claims from U.S. patent application no. 17/562,229 and will issue a new patent containing those claims related to the treatment of acute pain (the "Patent"), to Scilex in late 2024, further strengthening the Company's intellectual property position and coverage for its acute migraine treatment drug product, ELYXYB®, a liquid, micro-encapsulation formulation of celecoxib. The Patent, titled "Methods of Treating Pain," covers methods of treating acute pain.

Clinicians in a recent market research study expressed their desire for fast and safe alternatives for two large pools of acute migraine patients – those who have an insufficient response to triptan therapy and those who have contraindications to triptan use. ELYXYB®'s product profile mapped with a high degree of certainty to these stated unmet needs. In clinical studies, patients treated with ELYXYB® demonstrated pain relief in as little as 15 minutes, and significant pain relief compared to placebo within 45 minutes in approximately 50% of patients.[6,7]

"We are very excited about the potential of ELYXYB® since launching the product in the U.S. in April 2023. This is a highly complementary commercial asset that allows us to provide physicians with another tool in their pain management armamentarium to treat migraines earlier in the patient's journey. These new patents will provide the ability to file application in the future for acute pain," 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 Semnur Pharmaceuticals, Inc., refer to www.semnurpharma.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 Semnur Pharmaceuticals, Inc.

Semnur Pharmaceuticals, Inc. ("Semnur") is a clinical-late stage specialty pharmaceutical company focused on the development and commercialization of novel non-opioid pain therapies. Semnur's lead program, SP-102 (SEMDEXA™), is the first non-opioid novel gel formulation administered epidurally in development for patients with moderate to severe chronic radicular pain/sciatica.

Semnur Pharmaceuticals, Inc. is headquartered in Palo Alto, California.

About Denali Capital Acquisition Corp.

Denali Capital Acquisition Corp. ("SPAC") is a blank check company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities.

Important Information and Where to Find It

This press release relates to a proposed transaction between Semnur and the SPAC and does not contain all the information that should be considered concerning the potential business combination and is not intended to form the basis of any investment decision or any other decision in respect of the potential business combination. This press release does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the transaction described herein, the SPAC will file relevant materials with the SEC, including a registration statement on Form S-4, which will include a proxy statement/prospectus. **Investors and security holders of the SPAC are urged to read these materials (including any amendments or supplements thereto) and any other relevant documents in connection with the transaction that the SPAC files with the SEC when, and if, they become available because they will contain important information about the SPAC, Semnur and the proposed transaction.** The preliminary proxy statement/prospectus, the definitive proxy statement/prospectus and other relevant materials in connection with the transaction (when and if they become available), and any other documents filed by the SPAC with the SEC, may be obtained free of charge at the SEC's website (www.sec.gov). The documents filed by the SPAC with the SEC also may be obtained free of charge upon written request to:

Denali Capital Acquisition Corp.
437 Madison Avenue, 27th Floor
New York, NY 10022

Participants in the Solicitation

The SPAC and its directors and executive officers may be deemed participants in the solicitation of proxies from the SPAC's shareholders with respect to the proposed business combination. Information about the SPAC's directors and executive officers and a description of their interests in the SPAC will be included in the proxy statement/prospectus for the proposed transaction and will be available at the SEC's website (www.sec.gov). Additional information regarding the interests of such participants will be contained in the proxy statement/prospectus for the proposed transaction when available.

Semnur and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of the SPAC in connection with the proposed business combination. Information about Semnur's directors and executive officers and information regarding their interests in the proposed transaction will be included in the proxy statement/prospectus for the proposed transaction.

Non-Solicitation

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of the SPAC, the combined company or Semnur, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

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 and the SPAC 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 SPAC, Scilex and its subsidiaries, including but not limited to Semnur, statements regarding the proposed business combination between Semnur and the SPAC, including the potential listing of the combined company's common stock and warrants on Nasdaq, obtaining the approval from the SPAC's shareholders, the expectation that the SPAC will file a registration statement on Form S-4 with the SEC, which would include a proxy statement/prospectus, the estimated or anticipated future results and benefits of the combined company following the proposed business combination, including the ability of the parties to successfully consummate the proposed business combination, the timing of the closing of the proposed business combination, future opportunities for the combined company, Semnur and the combined company's proposed business strategies, the estimated pre-transaction equity valuation of Semnur,

the estimated sales for SP-102, the Company's outlook, goals and expectations for 2024, and the Company's development and commercialization plans. Although each of the SPAC and Scilex and its subsidiaries believes that it has a reasonable basis for each forward-looking statement contained in this press release, each of the SPAC and Scilex and its subsidiaries caution you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain. In addition, there will be risks and uncertainties described in the proxy statement/prospectus included in the registration statement on Form S-4 relating to the proposed transaction, which is expected to be filed by the SPAC with the SEC, and described in other documents filed by the SPAC or Scilex from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Neither the SPAC nor Scilex and its subsidiaries can assure you that the forward-looking statements in this communication will prove to be accurate.

Risks and uncertainties that could cause actual results of Scilex and the SPAC to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: the inability of the parties to consummate any proposed business combination transaction for any reason, including any failure to meet applicable closing conditions; changes in the structure, timing and completion of the proposed transaction between the SPAC and Semnur; the SPAC's ability to continue its listing on the Nasdaq Capital Market until closing of the proposed transaction; the combined company's ability to list its securities on Nasdaq after closing of the proposed transaction; the ability of the parties to achieve the benefits of the proposed transaction, including future financial and operating results of the combined company; the ability of the parties to realize the expected synergies from the proposed transaction; risks related to the outcome of any legal proceedings that may be instituted against the parties following the announcement of the proposed business combination; risks associated with the unpredictability of trading markets; general economic, political and business conditions; 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 and the SPAC's most recent periodic reports filed with the SEC, including their Annual Reports on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q that the Company and the SPAC have respectively 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 and the SPAC 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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5) Source: Acute Migraine Headache: Treatment Strategies. https://www.aafp.org/pubs/afp/issues/2018/0215/p243.html
6) Data on file. Scilex Holding Company
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Source: Scilex Holding Company