Scilex Holding Company Enters into a Binding Term Sheet for a Joint Venture with IPMC and Bio Open Innovation Consortium to Develop and Commercialize a Phase 2 Clinical Stage, Potential Best-In-Class Novel Oral Tablet for the Treatment of Obesity and Neurodegenerative Diseases Including Alzheimer's Disease

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- The joint venture, Scilex Bio ("Scilex Bio JV"), will have global development and commercialization rights for a Phase 2 clinical stage, potential best-in-class novel oral tablet, KDS2010, for the treatment of obesity and neurodegenerative diseases including Alzheimer's disease.
- KDS2010 has shown promising preclinical results with a novel mechanism (controls GABA levels in astrocytes) that acts reversibly and selectively inhibits MAO-B enzymes and presents a potential innovative new treatment addressing several cardiometabolic and neurodegenerative disorders.
- KDS2010 pharmacokinetics, lack of food effect, safety and dose selection have been characterized in Single Ascending Dose and Multiple Ascending Dose Phase 1 clinical trials with 88 healthy young adults and elderly subjects, demonstrating favorable safety and tolerability profile in adults and elderly and adequate pharmacokinetics for once-daily dosing.
- Selective inhibition of astrocytic GABA is a molecular target for treating obesity. KDS2010 is being evaluated in a Phase 2 clinical trial as an obesity treatment, which inhibits astrocytic GABA in lateral hypothalamic area (LHA), a brain nucleus which regulates food intake and energy balance. KDS2010 facilitates fat thermogenesis and reduces weight gain without affecting food intake in mice. This new treatment may be a more effective and safer alternative to existing obesity treatments, which are known to cause vomiting, potential muscle loss, nausea, and inducing resistance to GLP-1 treatment after stopping medication.
- Scilex will plan to announce scientific data on the novel mechanism of actions of KDS2010 published in prestigious scientific journals.
- Pursuant to the terms of the binding term sheet, Scilex will own controlling interest of Scilex Bio JV upon contribution of $50 million of Semnur Pharmaceuticals, Inc. ("Semnur") common stock owned by Scilex, which is expected to be publicly traded on Nasdaq during Q1-2025 and IPMC will own 40% of the JV upon contribution of the exclusive, perpetual and worldwide rights to the KDS2010 compound for all indications.
- As millions seek access to weight loss drugs, IQVIA experts at Institute for Data Science see a vast opportunity in weight loss drugs with annual global sales forecasts for the emerging obesity drug treatments to about $150 billion by the early 2030s. Global spending on obesity medication totaled $24 billion last year, IQVIA estimated in a 5-year outlook that sales could reach $131 billion by 2028.[1]
- Per Health Care analyst reports 2023[2], Alzheimer's global drug market size is expected to rise above $15 billion by 2030 in the eight major markets, as new drugs show promise and are

being launched with FDA approval to slow cognitive decline.

PALO ALTO, Calif., Dec. 10, 2024 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or “Company”) and IPMC Company, a representative company of the Bio Innovation Consortium (“BOIC”), which holds the exclusive rights to NeuroBiogen Company’s (“NB”) KDS2010 global license, today announced a binding term sheet to create a commercial joint venture, Scilex Bio, to develop and commercialize a next-generation reversible MAO-B Inhibitor, a novel inhibitor of aberrant GABA production in reactive astrocytes for the treatment of obesity and neurodegenerative diseases including Alzheimer’s disease.

IPMC, a private biopharmaceutical company, represents the BOIC, an innovative consortium committed to establishing 'Open Innovation' as a transformative paradigm in biohealth research, development, and commercialization.

“The partnership between IPMC and Scilex spans almost a decade. At the 2017 IPMC International Conference in Seoul, leaders from both companies pledged to undertake a bold challenge for the next century, dedicated to upholding the dignity of human life. Since then, we have been deeply impressed by Scilex's efforts in advancing multiple non-opioid pain management programs, addressing areas of significant unmet medical needs in the U.S. and beyond. We believe Scilex is uniquely positioned to unlock the potential of KDS2010, offering hope to individuals suffering from neurodegenerative and cardiometabolic diseases. This potential milestone represents a significant advancement in fulfilling the vision of our bold challenge,” said Youngwoo Jang, President of IPMC.

“We are thrilled to partner with IPMC and BOIC to advance KDS2010, a promising oral therapy targeting some of the most pressing global health challenges, including obesity and neurodegenerative diseases, which affect over a billion people globally. By leveraging IPMC’s groundbreaking work on KDS2010 and Scilex’s strengths in development and commercialization, we believe this novel oral therapy may redefine treatment standards, offering a safer and more convenient solution for patients with obesity and other CNS diseases,” said Jaisim Shah, President and Chief Executive Officer of Scilex.

“KDS2010 has the potential to significantly advance treatment options for obesity and neurodegenerative diseases, areas where current therapies often fall short. With its innovative mechanism and favorable safety profile, this small molecule offers a unique opportunity to deliver better outcomes for patients. We are eager to bring this groundbreaking therapy to market,” said Dr. Jay Chun, M.D., Ph.D., board member of Scilex.

The formation and organizational structure of Scilex Bio JV is subject to negotiation of definitive agreements between Scilex and IPMC, with operations of Scilex Bio JV expected to commence during Q1-2025.

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

For more information on Semnur Pharmaceuticals, 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 the treatment for neurodegenerative and cardiometabolic diseases, and 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 acute pain and for which Scilex has recently completed a Phase 2 trial in acute 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.

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

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.

For more information on Semnur Pharmaceuticals, refer to www.semnurpharma.com

About IPMC

IPMC is a private biopharmaceutical company, represents the BOIC, an innovative consortium committed to establishing 'Open Innovation' as a transformative paradigm in biohealth research, development, and commercialization.

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 are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements Scilex and its subsidiaries, including but not limited to Semnur, statements regarding the terms of the potential joint venture transaction, statements regarding KDS2010 and the potential efficacy and preclinical results, the potential for KDS2010 to be an innovative new treatment for obesity and Alzheimer's disease benefitting people living with neurodegenerative and cardiometabolic diseases, the potential market size and growth opportunity for the weight loss and Alzheimer's global drug market, the timing of formation and operations of Scilex Bio JV , the expectation that Semnur common stock will be publicly traded on Nasdaq during Q1-2025, statements regarding the Company's outlook, goals and expectations for 2024, and the Company's development and commercialization plans. Although Scilex and its subsidiaries believe that they have a reasonable basis for each forward-looking statement contained in this press release 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.

Risks and uncertainties that could cause actual results of Scilex 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 complete the joint venture transaction, changes in timing of the proposed joint venture transaction and the ability of the parties to achieve the benefits of the proposed joint venture transaction 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 most recent periodic reports filed with the SEC, including the 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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2. www.ihealthcareanalyst.com/global-alzheimers-disease-market/
3. https://idf.org/news/one-billion-people-globally-estimated-to-be-living-with-obesity-by-2030/

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.

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