



**Innovative Leader in
Non-Opioid Pain Therapeutics/Obesity/
Neurodegenerative/Cardiometabolic Disease**

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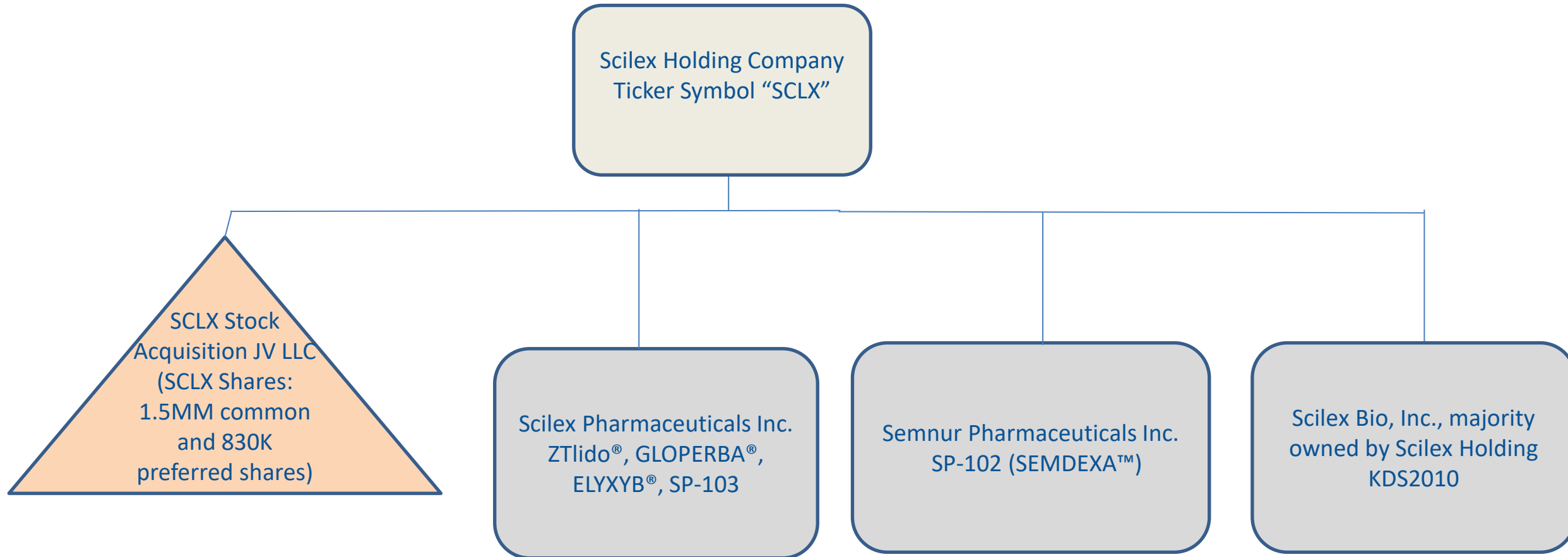
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Scilex Holding Company Structure





Scilex Bio
**Obesity/ Neurodegenerative/
Cardiometabolic Disease**

- Familiar old drug class – Inhibitor of Monoamine Oxidase (B)
- New generation
 - Highly selective, highly potent, BBB permeable, and reversible inhibitor
 - New anti-obesity mechanism discovered
 - Suppresses aberrant GABA (gamma-aminobutyric acid) production in reactive astrocytes
 - Eliminates neuronal inhibition in Lateral Hypothalamic Area, stimulating metabolism and energy expenditure without affecting appetite
 - Weight loss effect in Diet Induced Obesity model
 - Improvement of memory and cognitive function in Alzheimer's model
 - Anti-allodynic effect in chemotherapy induced neuropathy model
- Potential indications
 - Weight management, Alzheimer's Disease, Neuropathic pain (Diabetic Polyneuropathy), Nociceptive pain (Fibromyalgia), Parkinson's Disease, Spinal Cord Injury, Memory and Cognitive improvement in Schizophrenia, Depression.

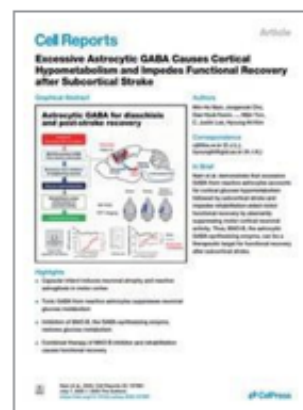
Publications



• Nature Medicine

GABA from reactive astrocytes impairs memory in mouse models of Alzheimer's disease

2014. 6. 29.



• Cell Reports

Excessive Astrocytic GABA Causes Cortical Hypometabolism and Impedes Functional Recovery after Subcortical Stroke

2020. 7. 7.



• Nature Neuroscience

Excessive Production of Astrocytic H₂O₂ Causes Neurodegeneration and Memory Loss in MAOB-dependent way

2020. 12. 23.



• Science Advances

Newly developed reversible MAO-B inhibitor circumvents the shortcomings of irreversible inhibitors in Alzheimer's

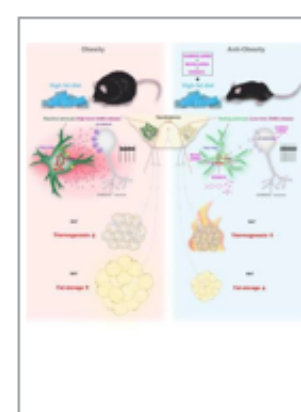
2019. 3. 20.



• Neurotherapeutics

KDS2010, a Newly Developed Reversible MAO-B Inhibitor, as an Effective Therapeutic Candidate for Parkinson's Disease

2021. 10. 5.



• Nature Metabolism

Reactive astrocytes in Lateral Hypothalamic Area causes MAOB-dependent GABA production and obesity

2023. 08.31

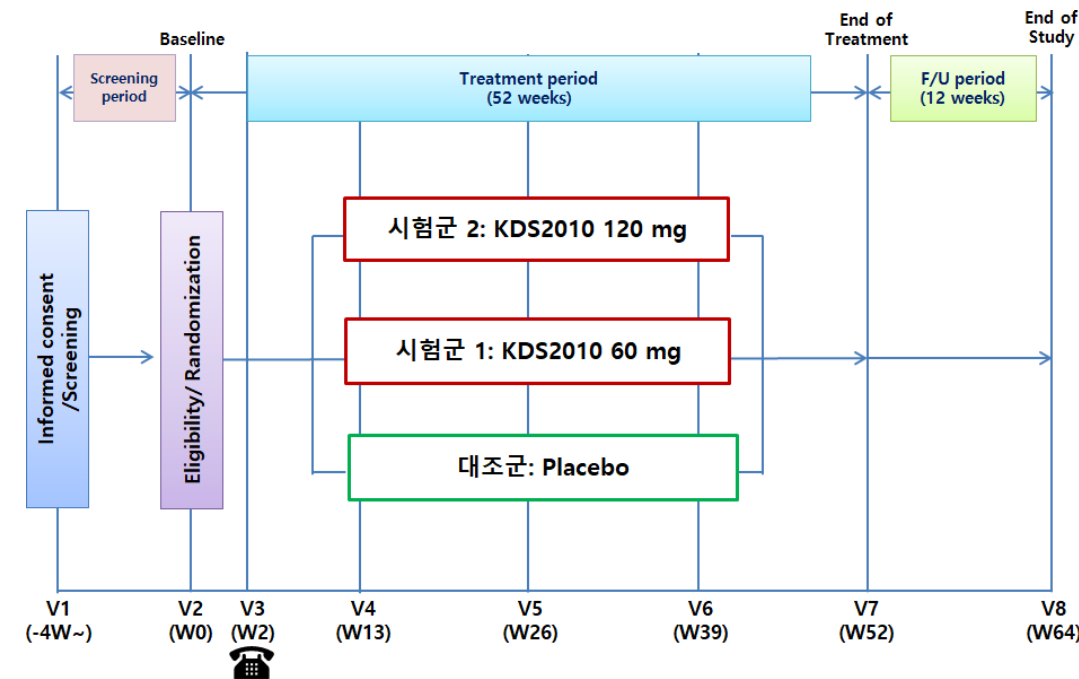
KDS2010 Phase 1 Clinical Program Completed



- KDS2010 well tolerated and safe for single dose (30 to 960 mg) and repeated dosing over 7 days (60 to 480 mg).
- Adequate pharmacokinetics for once-daily dosing in the range of 60 to 480 mg for repeat dosing.
- No food effect on pharmacokinetics, allowing for meal-independent dosing in future clinical trials.
- No significant differences in safety/tolerability and pharmacokinetics in healthy adults and the elderly.
- Similar safety/tolerability and pharmacokinetics between Korean and Western populations.

Phase 2 Clinical study design of KDS2010-AD (U.S. IND 1H 2025)

Title	A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding, Phase 2a Clinical Trial to Evaluate the Efficacy and Safety of KDS2010 in Patients with Alzheimer's Disease with Mild Cognitive Impairment and Mild Dementia due to Alzheimer's Disease
Indication	Alzheimer's disease with mild cognitive impairment(MCI) Mild dementia due to Alzheimer's disease (Mild AD)
Drug	KDS2010 Mesylate Tablets 60 mg Placebo to Match KDS2010 Mesylate Tablets 60 mg
Design	Randomized, double-blind, placebo-controlled, dose finding, , population PK, phase2a study
Duration by subjects	Total 64 Weeks (treatment 52 Weeks, F/U 12 weeks)
Sample size	Total 114 subjects including partial US cohort
Inclusion criteria	Age: between 50 and 85 years male and females MCI group: Stage 2 or 3 (NIA-AA 2018), CDR-SB 0.5~2.0 Mild AD group: Stage 4 (NIA-AA 2018), CDR-SB 2.5~4.0 MMSE: 18~30 Amyloid PET confirmed
Primary end-point	CDR-SB(26W, 64W), MMSE(26W, 52W, 64W), ADAS-Cog13(26W, 52W, 64W)

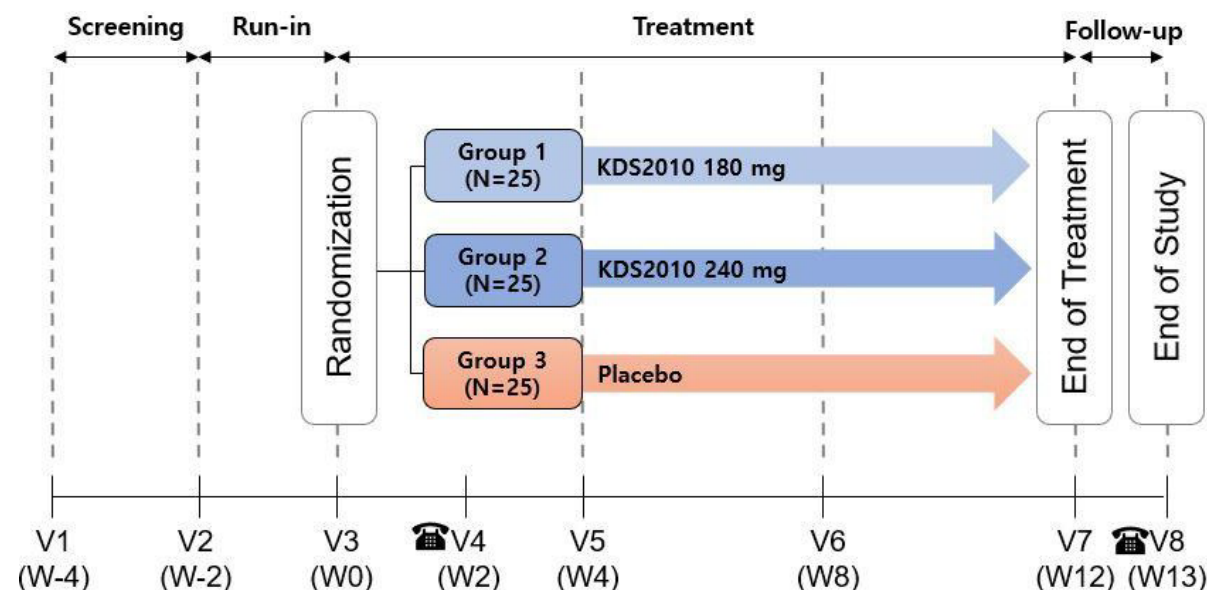


F/U= Follow up, N= Number of subject

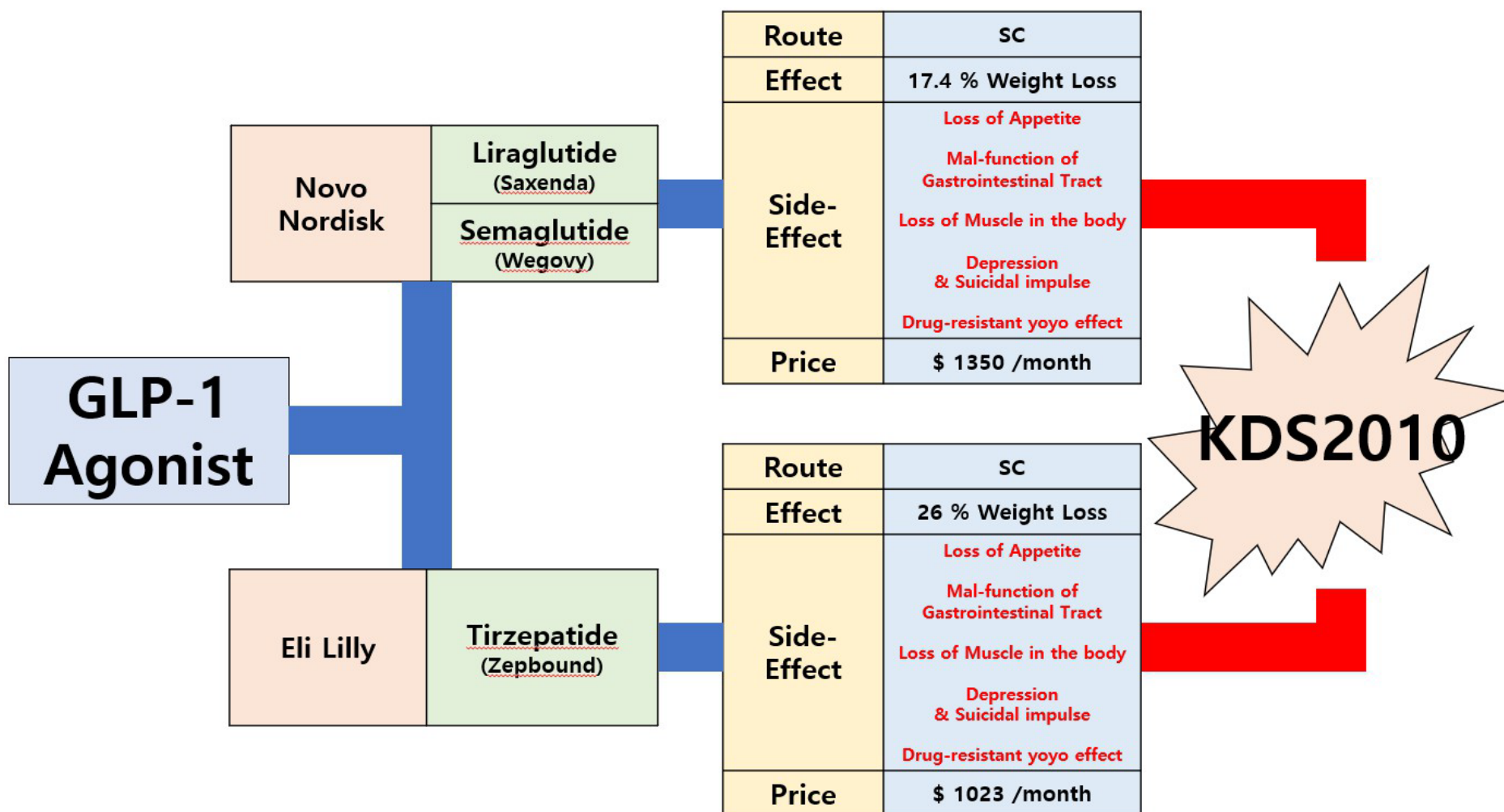
Biomarker analysis (% of change, 26W, 52W, 64W)
MAO-B specific activity, GFAP, P-tau181, P-tau217, A β -40, A β -42, NfL, BDNF, IL-1 β , TNF- α

Phase 2 Clinical study design of KDS2010-Obesity (U.S. IND 1H 2025)

Title	A Randomized, Double-blind, Placebo-controlled, Dose Finding, Phase 2a Clinical Trial to Evaluate the Efficacy and Safety of KDS2010 in Overweight or Obese Patients
Indication	Overweight or Obesity
Drug	KDS2010 Mesylate Tablets 60 mg Placebo to Match KDS2010 Mesylate Tablets 60 mg
Design	Randomized, Double-blind, Placebo-controlled, population PK, Phase 2a
Duration by subjects	Total 15 Weeks (run-in TLC 2W, treatment 12W, F/U 1W)
Sample size	Total 75 subjects including partial US cohort
Inclusion criteria	Age: ≥ 19 years males and females BMI: ≥ 30 kg/m ² or ≥ 27 kg/m ² with at least one of the following weight-related comorbidities (treated or untreated): hypertension, dyslipidaemia, or cardiovascular disease
Primary end-point	% of $\geq 5\%$ Body weight reduction % Body weight change from baseline



KDS2010 Competitive Edge vs. GLP1





Scilex Pharmaceuticals

960 San Antonio Rd, Palo Alto CA 94303

Wholly Owned Subsidiary of Scilex Holding Company
(NASDAQ: SCLX)

Key Achievements

- Fifth year company anniversary
- ZTlido - #1 prescribed branded non-opioid analgesic by the pain specialist
- Over 1MM patients treated with ZTlido since launched
- ~90% of patients are satisfied with ZTlido treatment
- 88% patients felt they could do more when on ZTlido treatment
- Consecutive years with a product launch
 - Elyxyb - The best in class for acute Migraine treatment
 - Gloperba – Only solution for gout prophylaxis patients who need precise dose adjustment

Scilex Business Opportunity Highlights

- In US 50m patients live with chronic pain – A billion adults suffer from acute or chronic pain globally
- With opioid pandemic, medical community and regulatory agency seeking non-opioid pain options
- Scilex has three commercial products on the market and offers broad, diverse non-opioid pain pipeline addressing large markets with few or no competition

Commercial Products:

- ZTlido® (1.8% lidocaine topical system equivalent to 5% lidocaine) for the treatment of Postherpetic Neuralgia-PHN related pain.
- ELYXYB® (celecoxib) oral solution for acute treatment of migraine
- GLOPERBA® (colchicine USP) oral solution for the prevention of painful gout flares in adults

Product Candidates:

- **SP-102 (SEMDEXA - Lumbar Radicular / Sciatica Pain)**
 - Over 12MM ESI procedures performed yearly in US, about 80% are for LRP/sciatica
 - No product, including currently used ESI are approved for epidural use to treat sciatica
 - Safety warnings in the labels of current steroid formulation restrict use for epidural injections
 - SP-102 will be the first and only product approved for epidural injection for sciatica
- **SP-103 (Lidocaine Topical System 5.4% (3X) - Low Back Pain)**
 - Over 30MM people suffer from low back pain in US
 - No product is indicated for treating chronic neck pain
- **SP-104 (Delayed Burst Low Dose Naltrexone - Fibromyalgia)**
 - Current 3 approved treatments for fibromyalgia are not effective – High unmet need exists
 - Fibromyalgia prevalence - over 8MM patients in US
 - Average patients take an average 2.6 medications
 - Low dose naltrexone currently used off label for fibromyalgia
- **KDS2010**
 - 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, neurodegenerative, and cardiometabolic diseases including Alzheimer's Disease

Innovative Non-Opioid Pain Therapeutics

KEY PROGRAMS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	APPROVED	IP	MILESTONES / KEY COMMENTARY
ZTlido® (1.8% lidocaine topical system equivalent to 5% lidocaine)	Approved for the treatment of Postherpetic Neuralgia-PHN related pain					▪ 2031	▪ Launched in the U.S. in October 2018
GLOPERBA® (colchicine USP) oral solution (For the prevention of painful gout flares in adults)	Approved for the prevention of painful gout flares in adults					▪ 2036	▪ 2H 2022: In-licensed U.S. rights ▪ June 2024: U.S. launch ▪ January 2025: In-licensed Ex-US rights
ELYXYB® (celecoxib) oral solution (Acute Treatment of Migraine)	Approved for acute treatment of migraine					▪ 2036	▪ 1Q 2023: In-licensed U.S. / Canadian rights ▪ 2Q 2023: U.S. launch
	Filed acute pain indication with FDA in January 2025						▪ 2Q 2025: Canada migraine approved ▪ 2Q 2025: Acute pain filed
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Fast Track					▪ 2036	▪ Scilex Pharmaceuticals has global promotional rights to SP-102 (SEMDEXA) ▪ 2H 2023: FDA agreed on NDA path ▪ 2024: Finalizing Ph 3 open label safety trial
SP-103 Lidocaine Topical System 5.4% (3X) (Acute Pain)	Fast Track for Low Back Pain					▪ 2031	▪ 2Q 2023: Completed Two Positive Phase II trials ▪ 2025: Initiate pivotal trial for acute pain ▪ 3Q 2022: Received Fast Track for low back pain
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Prepare Phase II Trial					▪ 2041	▪ 1H 2022: Completed Phase I trial(s)
KDS2010, Joint Venture Between Scilex Bio and IPMC for treatments for obesity, neurodegenerative, cardiometabolic disease	Global License Rights					▪ 2040	▪ 2025: US IND

Investment Highlights



3 FDA approved Non-Opioid Acute and Chronic Pain Management Products



Worldwide Commercial Rights to Most Product Candidates



Strong Proprietary Platform with High Barriers to Entry



Established Reimbursement Access



Blockbuster Pipeline With Limited Capital Required for Commercialization



ZTlido

(1.8% lidocaine topical system equivalent to 5% lidocaine for the treatment of Postherpetic Neuralgia-PHN related pain)

ZTlido Commercialization Success

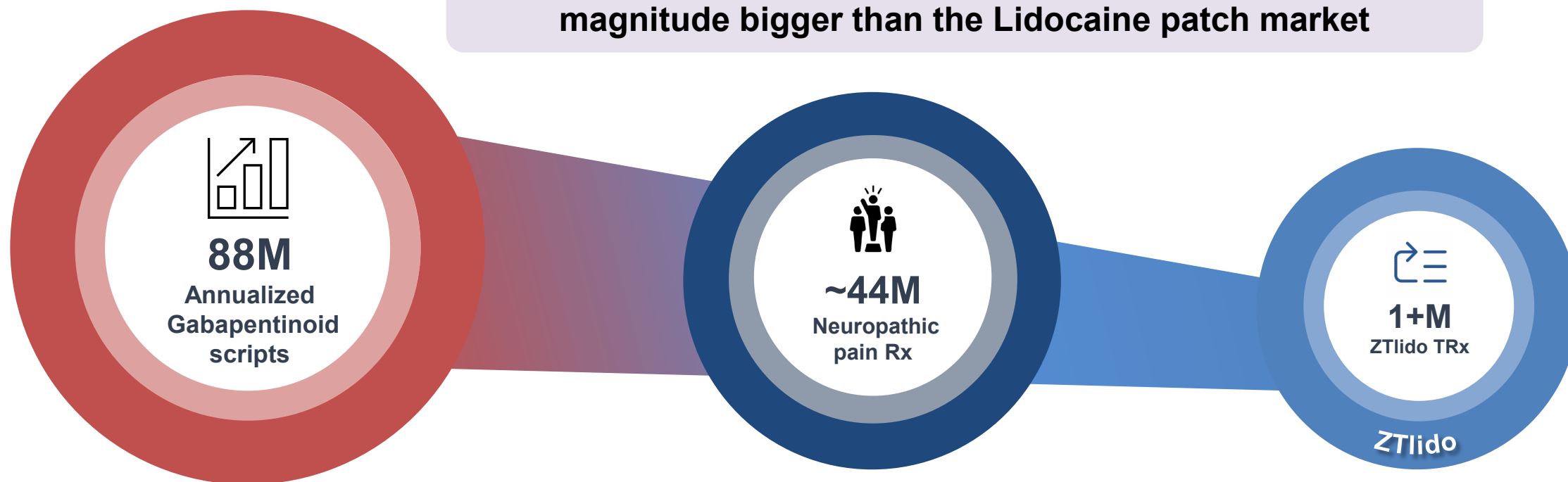
Aiming to Improve the World of Non-Opioid Management



The Gabapentinoid Market Is Massive

Gross sales of \$370M would equate to ~1M ZTlido TRx

The Neuropathic Pain Gabapentinoid market is an order of magnitude bigger than the Lidocaine patch market



ZTlido® 1.8% (FDA approved for relief of PHN pain)

1 Lidocaine Patch Market Overview

- +4.6mm prescriptions in 2022
- +169mm prescription lidocaine patches sold in the U.S. in 2022¹

2 Benefits versus Other Lidocaine Patches

- Superior adhesion compared to other lidocaine patches head-to-head studies
- Only lidocaine patch proven in moderate exercise

3 How does it compare to Lidoderm (5%)

Properties	ZTlido (1.8%)	Lidoderm (5%)
Bioavailability	~45%	~3 ± 2%
Weight	2 grams	14 grams
Thickness	0.8 millimeters	1.6 millimeters
Lidocaine Content	36 milligrams	700 milligrams
Adhesion	Non-aqueous	Water-based



- Only ZTlido delivers a 12-hour adhesion in a non-opioid therapy
- Superior adhesion versus other lidocaine patches in various head-to-head studies
- Only lidocaine patch proven in moderate exercise
- Savings & support system makes it easy to receive inexpensive monthly prescription

The ZTlido New Campaign as the ideal add-on to Gabapentinoids

UNMET NEED / EFFICACY / QOL & FUNCTION / SLEEP & FUNCTION / HOW TO OPTIMIZE

WHEN PAIN* RELIEF WITH GABAPENTINOIDS ISN'T ENOUGH¹

FIND THE PERFECT PARTNER in ZTlido[®]

ADDING ZTlido DOUBLES PAIN RELIEF¹ – WITHOUT THE BAGGAGE OF ORAL ANALGESICS²

*Chronic neuropathic pain of post-herpetic neuralgia.

IMPORTANT SAFETY INFORMATION:
Indication
ZTLIDO is indicated for relief of pain associated with post-herpetic neuralgia (PHN) in adults.
Contraindications
ZTLIDO is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.
Warnings and Precautions

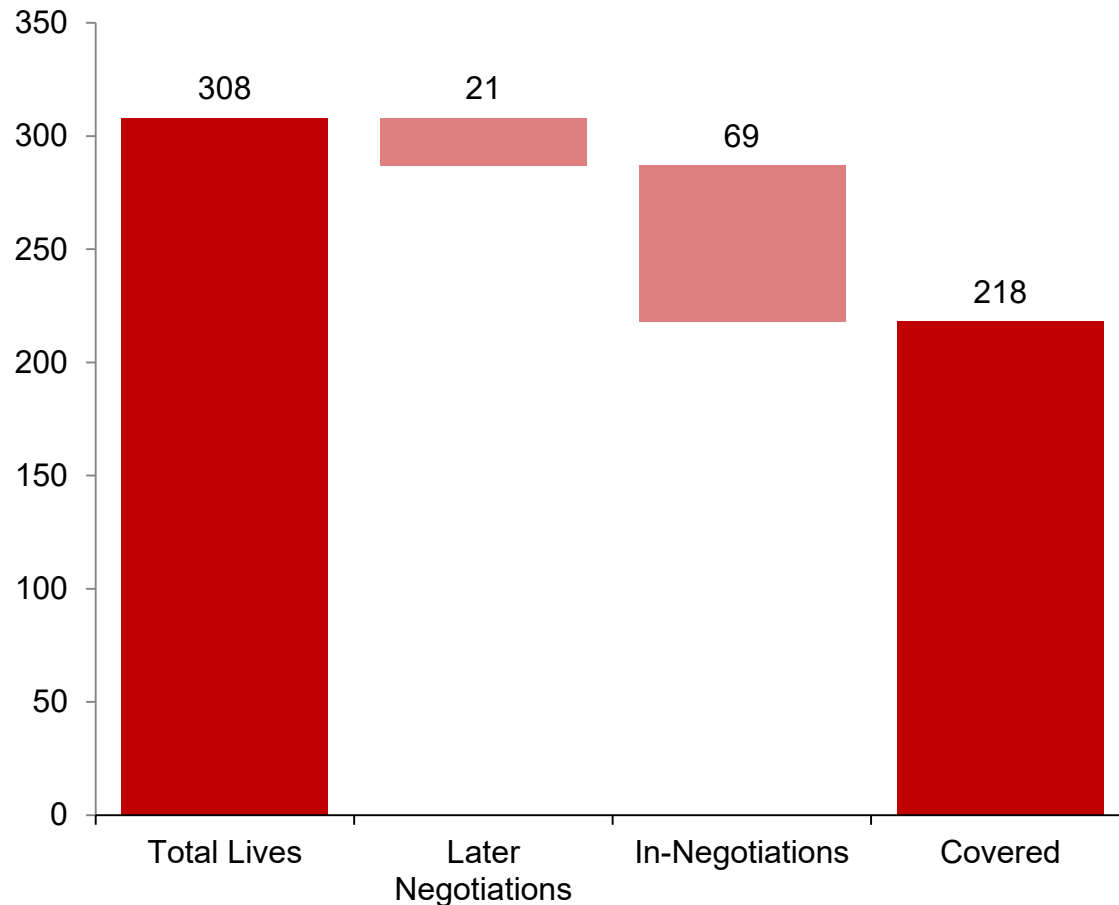
MOA / FMRI / ZTECH DIFFERENCE

IMPORTANT SAFETY INFORMATION | PRESCRIBING INFORMATION | REFERENCES

- ⊗ Designed to allow the brand to achieve its true potential by repositioning from Adhesion to Efficacy
- ⊗ ZTlido is uniquely capable of optimizing gabapentinoids – doubling efficacy without the baggage/side effects of other analgesic options (opioids, TCAs, SNRIs, NSAIDs, Acetaminophen).
- ⊗ This combination efficacy data is “new” as HCPs are unaware of it – we can own the data as we believe we the only lidocaine patch being actively promoted.
- ⊗ Aligns with managed care thinking (step edit ZTlido through gabapentinoids)
- ⊗ Establish us in a 10X bigger market of gabapentinoids.

ZTlido Market Access Update

ZTlido Covered Lives Overview



Key Players - Preference



ZTlido Preferred

State of California (MediCal)

Lidocaine Preferred



ZTlido Preferred



ZTlido Preferred

The “New ZTlido” Opportunity: Summary

- Relaunching ZTlido in a 10X market potential
- The Unmet Need in the neuropathic pain market/PHN – efficacy without side effects – is high.
- HCP satisfaction with Gabapentinoids (gabapentin and pregabalin) is low.
- ZTlido is uniquely capable of optimizing Gabapentinoids – doubling efficacy without the baggage/side effects
- This improves the key QoL metrics of Function and Sleep.
- No other lidocaine patch can deliver these efficacy results, because they do not adhere.
- Early signs (scripts and customer feedback on the new campaign) are very positive.
- The confluence of these factors puts the “New ZTlido” on track to achieve \$200M gross sales



**ZTlido® (lidocaine topical system)
1.8%**

LTC Opportunity

Non-Opioid Pain Opportunity in LTC

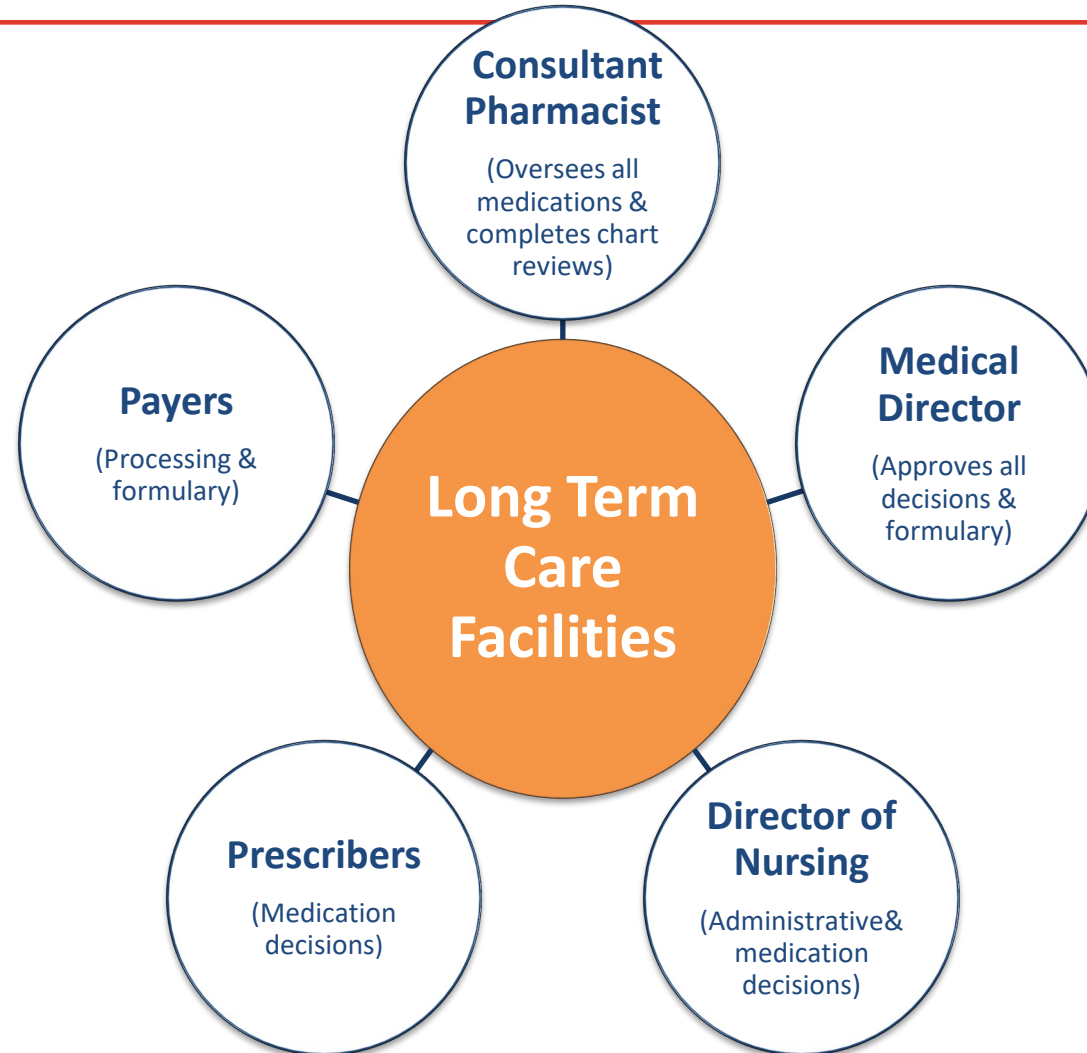
- Long Term Care Skilled Nursing Facilities are an untapped opportunity for Scilex, CMS estimates there are 1.5 million residents in certified facilities across the US¹
85.1% of Skilled Nursing patients are aged 65 and over, with 67.7% being women²
Chronic pain present in large % (estimate over 50%) of patients within the nursing home setting.
- Skilled Nursing Facilities (SNF's) - 16,700 facilities across the US
- Assisted Living Facilities (ALF's) – 30K across the US or roughly 1.2 Million Beds and growing.
- Correctional Facilities (non-Federal) – roughly 1500 State and private facilities, and 3116 local jails.

1. Trends in Nursing Facility Statistics. American Health Care Association Web site.

http://www.ahcancal.org/research_data/trends_statistics/Documents/Trend_PVNF_FINALRPT_March2015.pdf Published March 2015. Accessed February 8, 2016.

2. Harris-Kojetin L, Sengupta M, Park- Lee E, Valverde R. Long-Term Care Services in the United States: 2013 Overview. National Center for Health Statistics. Vital Health Stat 3(37). 2013.

Key Players In Skilled Nursing Facilities



Long Term Care Key Players

Government (CMS)

- Medicare
- Medicare Advantage Programs (through Commercial Payers)
- Medicaid
- Dual eligible patients (Medicaid & Medicare eligible)

Commercial Payers

- United Healthcare and Humana represent two large Medicare Advantage plans

Pharmacy Distribution Organizations

- Omnicare and Pharmerica

Group Purchasing Organizations

- MHA, GeriMed, Broadlane & Innovatix
- New contract opportunities

LTC Key Influencers - GPO's and Pharmacy Providers

GPO's

MHA (Managed Healthcare Associates), *GeriMed*, *Innovatix/Premier*, *Asembia* (more in Specialty space) and *Vizient* (Works thru GeriMed contract – Pull Thru main target once GeriMed contracted).

Pharmacy Providers

Omnicare – (Owned by CVS) diminishing vastly in size but still a small player with about 100 (and shrinking) pharmacies and *Pharmerica* (part of BrightSpring Health who is owned by Black Rock and Walgreens) growing with the recent contract with Genesis Health at about 120 LTC Pharmacies. Additional 2000 closed door LTC pharmacies approachable with few LTC distributors.

LTC Associations – Influence Pain Management

Associations

- *ASCP* (American Society of Consultant Pharmacist),
- *GAPNA* (Gerontological Advanced Practice Nurses Association),
- *PALTC* (Post- Acute LTC Medical Directors),
- *AAPA* (American Association of Physician Assistants),
- *AAPACN* (American Association of Post-Acute Care Nursing),
- *NADONA* (National Association of Directors of Nursing Administration in LTC),
- *AHCA/NCAL* (American Healthcare Association/National Center for Assisted Living) and well as *Argentum* (Trade Association for companies that own and operate in Senior Living).

Next-Generation, Triple Strength Formulation of ZTlido 1.8%

ZTlido[™]
(lidocaine topical system) 1.8%

- ✓ Superior adhesion and drug formulation efficiency with only 36mg of lidocaine
- ✓ Safe, convenient, functional pain treatment, label allows for light exercise and under water stress conditions
- ✓ Indicated for relief of pain associated with post-herpetic neuralgia (shingles pain)

SP-103 Phase 2

Next-Generation, 5.4%
Lidocaine Topical System

- ✓ 3x drug load (108 mg vs 36 mg lidocaine)
- ✓ Triple strength localized dose of lidocaine
- ✓ Expected same superior adhesion and efficient formulation
- ✓ Initiated Phase 2 trial in Q2-2022 with Results Q3-2023. Phase 3 Chronic Neck Pain trial in planning
- ✓ Large market opportunities for neck pain and acute low back pain
- ✓ Fast Track designation granted in low back pain by FDA in August 2022

Neck Pain Market Overview

Neck pain, or cervicalgia, is one of the most common pain presentations in U.S. and the 4th leading cause of disability

52.9M adults suffer from Neck Pain in the U.S.

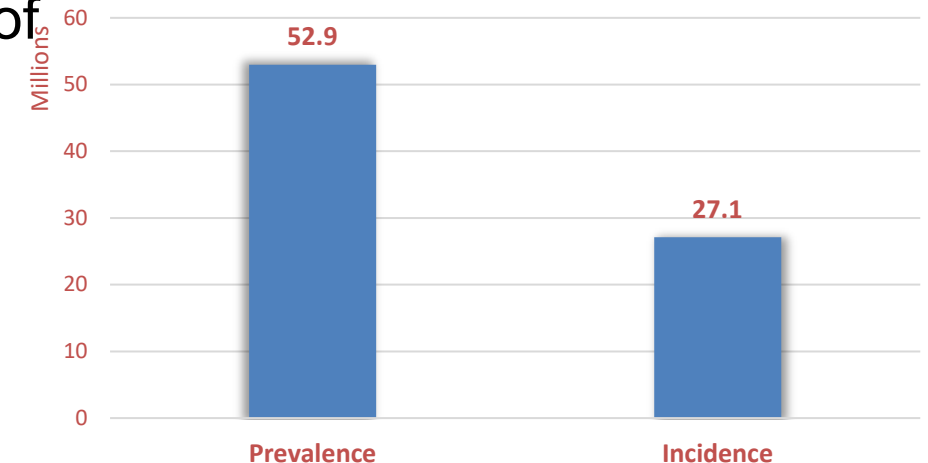
Prevalence of Neck Pain is estimated at >20% of adult population

Neck pain was responsible for job absences among 25.5 million Americans, who missed an average of 11.4 days of work

\$134.5B U.S. *low back and neck pain market*, which according to a 2020 JAMA (Journal of the American Medical Association)



Neck Pain: U.S. Epidemiology

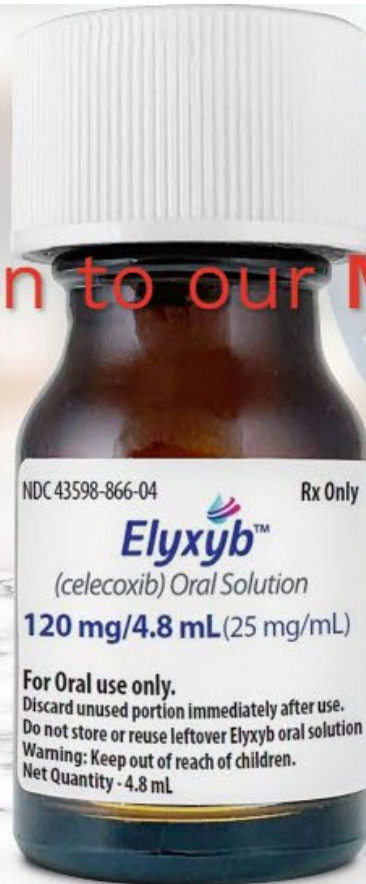




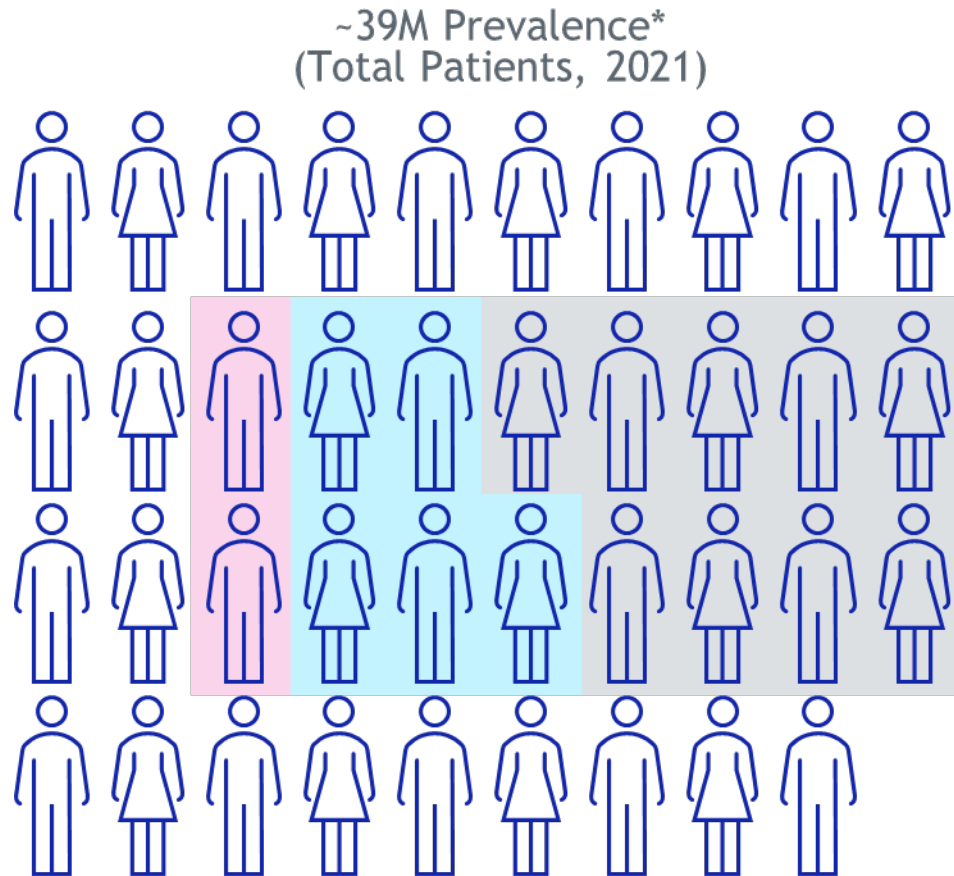
**Elyxyb
(celecoxib) oral solution (Acute
Treatment of Migraine)**

Elyxyb Launched in USA in 2023

Newest Addition to our Market Leading Non-Opioid Portfolio



Approximately 39M People with Migraine in the US



~43%
~16.8M Patients
Diagnosed with Migraine

~36%
~14.0M Patients
receiving treatment

~23%
~9.0M Patients
treated acutely
(Target patient pool)

*Some patients may receive
both acute as well as
preventive treatment*

Elyxyb Promotion Materials

Fast-Acting Formulation

Works as quickly as 15 minutes^{4,6*}

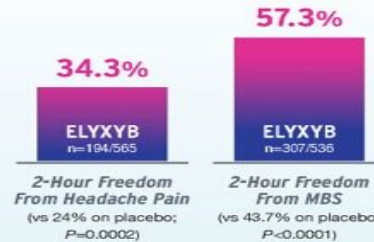
Delivers significant pain relief in 45 minutes in nearly 50% of patients⁴

Symptom improvement (vs placebo) as early as⁴:



Proven pain relief in Phase III studies involving 1253 patients^{7,8}

Pooled analysis of pain freedom in patients 2 hours post-dose with ELYXYB vs placebo⁹:



Phase III Trials Design:
1253 patients were enrolled across 2 identical, multicenter, randomized, double-blind trials. Participants were screened and then randomized 1:1 to receive celecoxib oral solution (120 mg) or placebo to administer within 1 hour of onset of a moderate to severe migraine attack. The coprimary endpoints were 2-hour pain freedom and 2-hour freedom from most bothersome symptom (MBS).^{7,7,8,9}

*Pain relief trended as early as 15 minutes for some patients in post-hoc analysis.⁶

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ELYXYB is contraindicated in the following patients:

- Known hypersensitivity to celecoxib or any components of the drug product or sulfonamides.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.

Please see Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.

Long-Lasting Relief

Relief up to 24 hours for most patients^{7,8}



Works whenever patients need it regardless of ...



IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Post-MI Patients: Avoid the use of ELYXYB in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

Elyxyb™
(celecoxib)
Oral Solution



ELYXYB

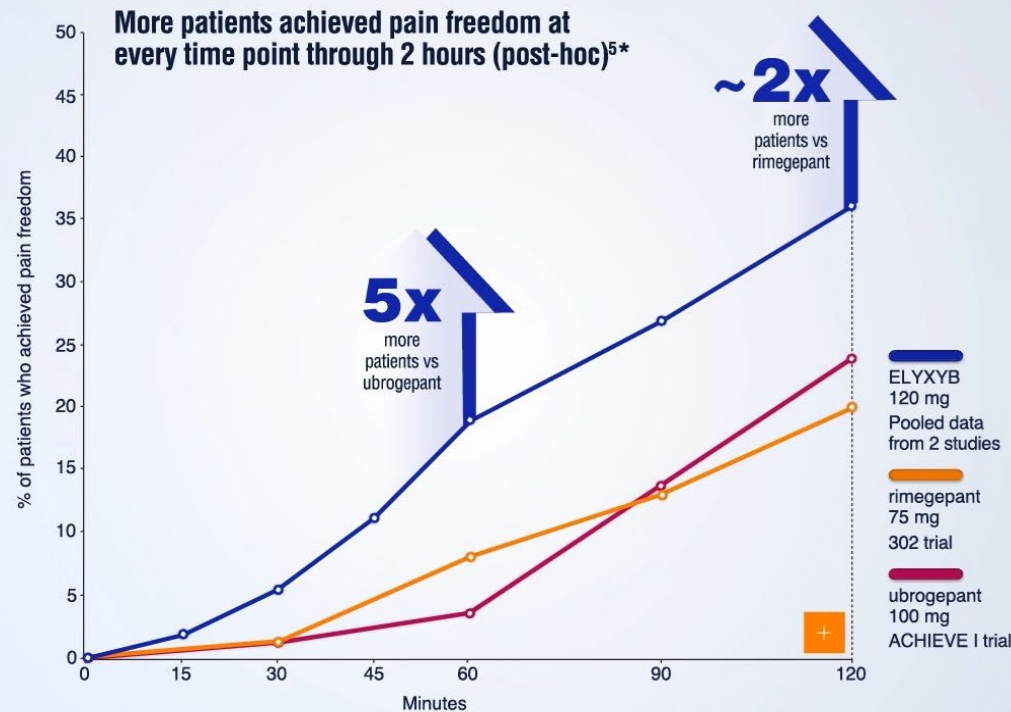
(Celecoxib) Oral Solution
Episodic Migraine Treatment

Elyxyb[®]
*(celecoxib) Oral Solution*³⁵

Elyxyb Efficacy Comparison to CGRP Inhibitors

Post-hoc Indirect Comparative Analysis

Proven to deliver faster pain freedom⁵



- Gepants are known to have a slow onset of action
- At 1 hour, 5x more patients on ELYXYB will be pain free vs Ubrelvy®
- At 2 hours postdose, about 2x as many patients on ELYXYB will be pain free vs. Nurtec®
- ELYXYB's pain freedom of 34% and pain relief of 71% at 2 hours is higher than that of the Ubrelvy and Nurtec, approximately, 21% and 61%, respectively

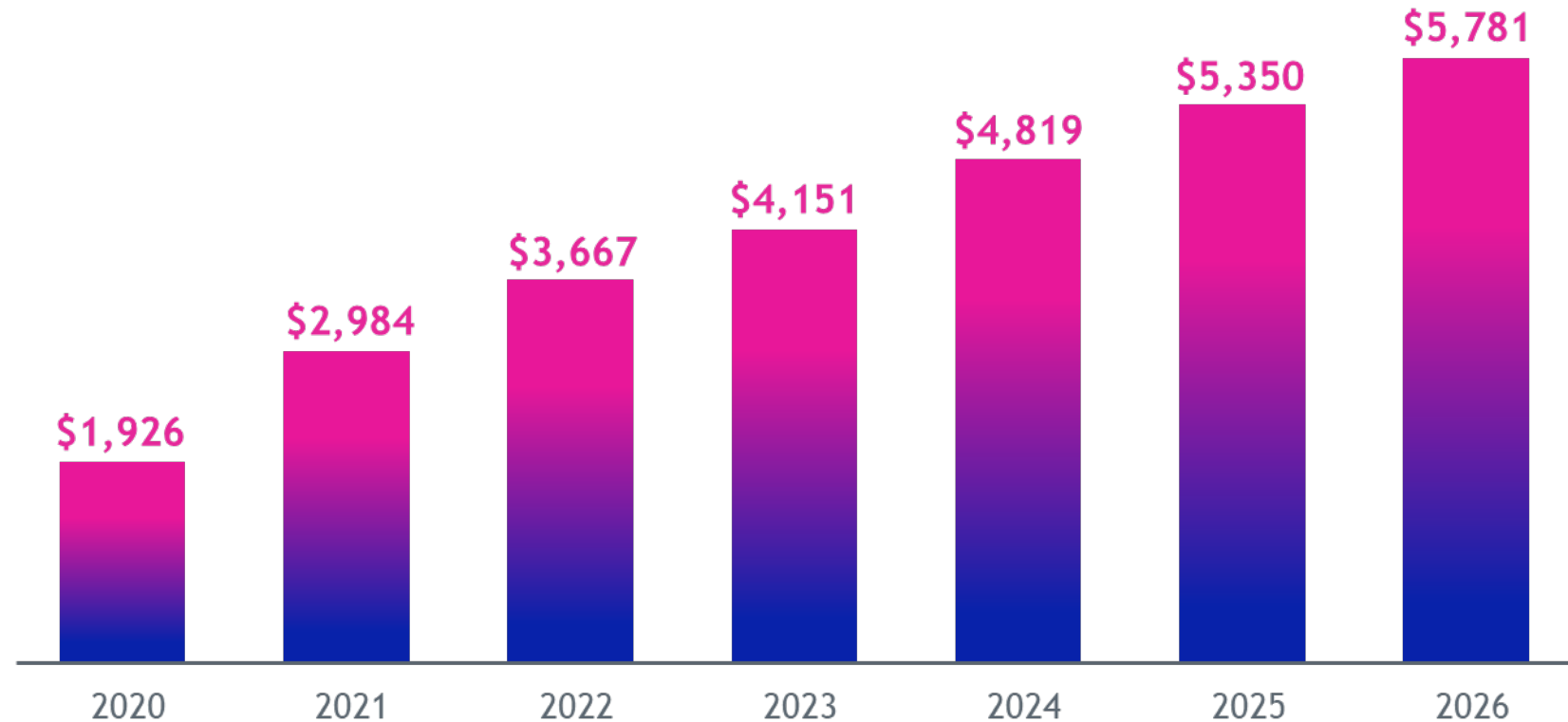
The US Migraine Market Is Projected To Grow By 195% Between 2021 to 2026



US Migraine Annual Sales

(Refreshed based on 2022 data)

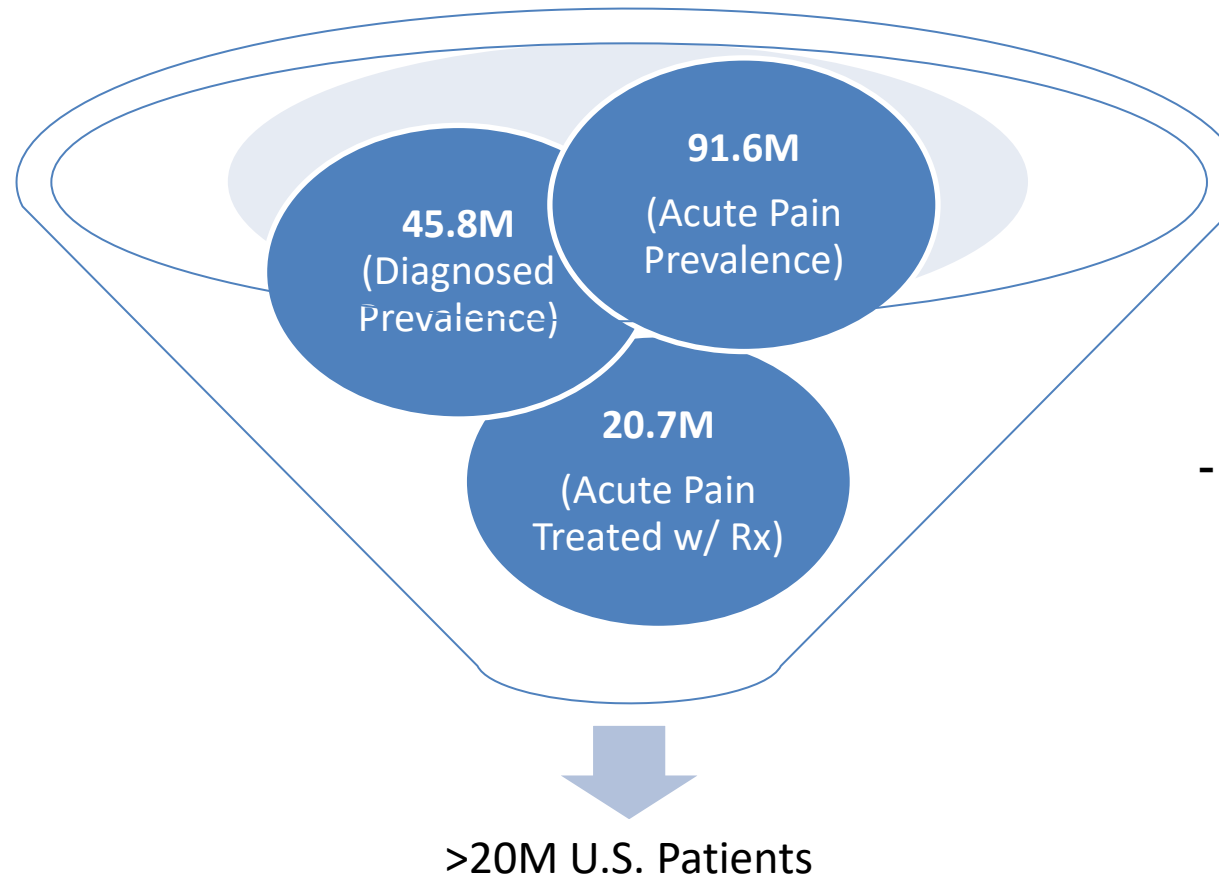
Acute + Preventive Treatments



- Scilex current forecast growth of more than 3X in 2024 compared to 2023.

Source: Evaluate; Above data includes both acute and preventative therapies; Data refreshed in January 2022

Elyxyb Acute Pain Opportunity: Market Size



- sNDA filed in January 2025

Large market opportunity for Elyxyb in Acute Pain

Elyxyb Acute Pain Opportunity: Unmet Needs

Key Unmet Needs in Acute Pain:

- Fast onset

- Need for safer and more effective treatments

- Non-Opioid alternatives



Elyxyb

Regulatory Filings

SP-105 US sNDA (Acute Pain)



- Supplement to add acute pain indication to Elyxyb[®] currently approved for acute treatment of migraine
- Primary efficacy and safety data are PK modeling between Elyxyb[®] and Celebrex[®]
 - Celebrex[®] is approved for treatment of acute pain
 - PK modeling was used to (1) determine dose and dosing regimen (200 mg initially followed by 100 mg Q6h) and (2) provide 505(b)(2) pharmaceutical bridge between Elyxyb[®] and RLD Celebrex[®] (i.e., no need to perform additional clinical or nonclinical studies)
 - Modeling based on Elyxyb[®] and Celebrex[®] PK data in Studies DFN-15-CD-003, DFN-15-CD-008, and DFN-15-CD-010, and efficacy data in Study DFN-15-CD-010
- No additional nonclinical studies (i.e., relying on nonclinical pharmacology and safety established for Celebrex[®])
- No CMC changes (i.e., same drug substance and drug product formulation/manufacturing)
- sNDA needs to include initial Pediatric Study Plan (iPSP) agreed to by FDA
 - Requesting waiver of pediatric studies (lack of prevalence in these populations and other available therapies)
 - iPSP has been submitted and responded to all Information Requests
 - Fall-back position is post-approval studies (PK) in age groups 6 to <17 years
- Status
 - sNDA has been prepared and being published
 - Filed January 2025

SP-105 Canadian NDS (Acute Treatment of Migraine)



- Primarily a conversion of NDA to NDS with preparation of regionally-specific documents and modules (Premier)
- Efficacy
 - Same clinical studies conducted by DRL to support US approval
- Safety
 - DRL clinical studies
 - Reliance on safety established for Celebrex® supported by comparative PK study between Elyxyb and Celebrex (i.e., PK of Elyxyb® at labeled dose is lower than the highest labeled dose for Celebrex®)
- Nonclinical
 - Reliance on Celebrex®: while Canada does not have a formal equivalent to US 505(b)(2) regulations, there are regulatory mechanisms to allow reliance on approved products (i.e., no need to perform additional nonclinical safety studies)
- CMC
 - Same drug substance and drug product formulation/manufacturing approved for the US
- Status
 - Filed submission in January 2024

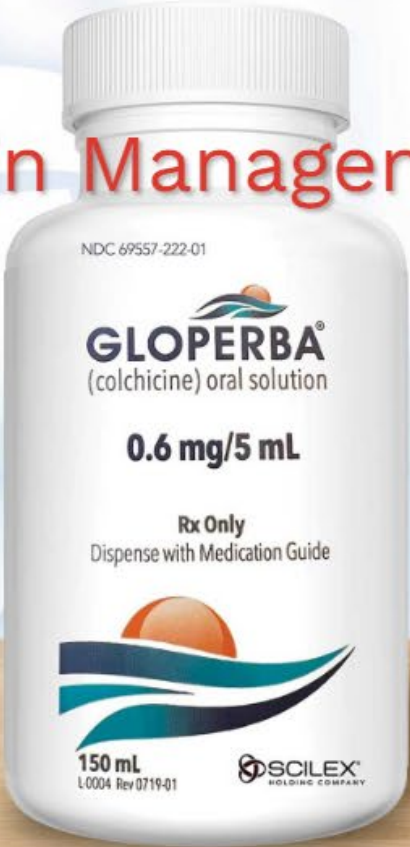


Gloperba

**(colchicine USP) oral solution (For the
prevention of painful gout flares in adults)**

Gloperba Launched in USA in June 2024

Expanding our Non-Opioid Pain Management Portfolio



Gloperba Launched in June 2024



Scilex Holding Company announces the U.S. FDA has approved the sNDA for commercial manufacturing of Gloperba® which was launched in the US in the week of June 10th 2024.

- Gloperba® is the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults.
- Gout is a painful arthritic disorder affecting an estimated 9.2 million people in the United States¹. As gout cases increase every year, treatment requirements increase. The gout treatment market is projected to be \$2.0 billion in the U.S. by 2028 with a well-defined area of unmet need.²
- Over 70% of gout patients have comorbid conditions like CKD that may require dose adjustments, and such patients could be a potential target population for Gloperba®³
- Over 17% of gout patients on colchicine experienced severe gastrointestinal side effects like diarrhea. These patients may benefit from flexible dosing offered by Gloperba®⁴
- Scilex is well-positioned to market and distribute its third commercial non-opioid product, Gloperba®:
- Scilex has a direct distribution network to national and regional wholesalers and pharmacies throughout the U.S.
- Scilex has an experienced commercial and managed care team that has successfully launched and grown market access for ZTlido® (lidocaine topical system) 1.8% to more than 225 million covered lives in the U.S. as well as successfully launching Elyxyb® (celecoxib oral solution) in the U.S. in April 2023, the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults.

1) <https://jamanetwork.com/journals/jama/fullarticle/2787544#:~:text=How%20Common%20Is%20Gout%3F,%25%20of%20the%20adult%20population>

2) Evaluate Pharma data

3) Comorbidities of Gout and Hyperuricemia in the US General Population: NHANES 2007-2008

4) Stewart et al. Arthritis Research & Therapy (2020) 22:28; <https://doi.org/10.1186/s13075-020-2120-7>

Target Patients For Gloperba Today (excluding Cardiovascular)

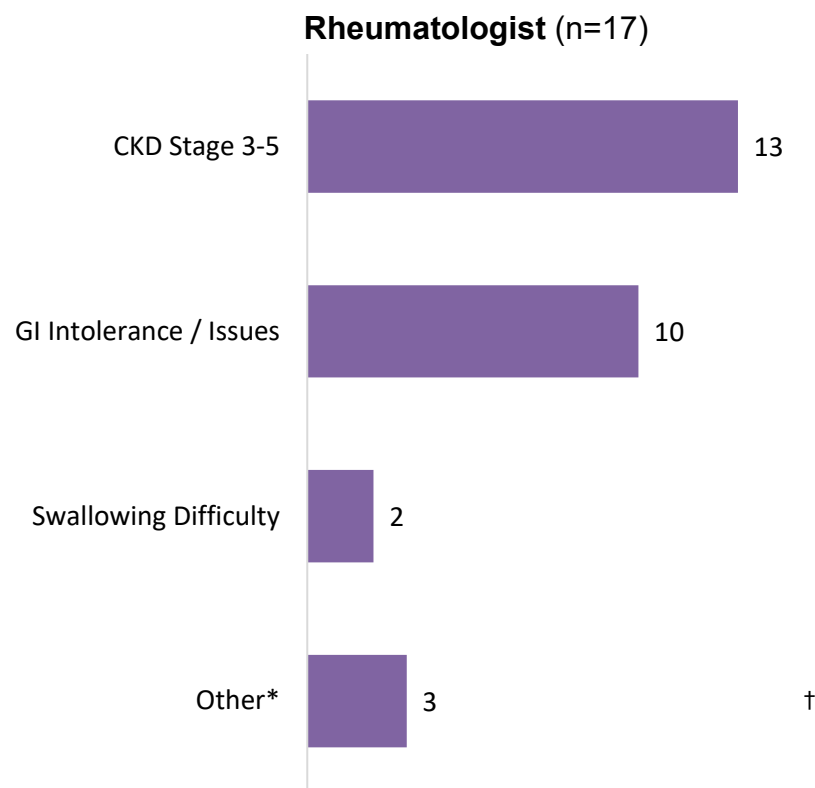
- Patients with CKD Stage 3/4/5: 6 million patients
- Patients with GI tolerability issues: 1 million patients
- Patients at risk of drug-to-drug interaction (DDI)
- Patients who have difficulty swallowing
- Cardiovascular up to 6.5 million patients

Rheumatologists indicated that they would use Gloperba in patients with CKD 3-5 and GI Sensitivity





Over 70% of gout patients suffer from CKD

Number of Physicians who Expect to Prescribe GLOPERBA in Different Types of Patients



Rheumatologists showed high willingness to prescribe Gloperba, and even do Prior Authorization

	Motivation to Prescribe Gloperba	Likelihood to do a PA for Gloperba
Current Level	<p>HIGH: 6.1/7 (Ave.)</p> 	<p>MODERATE: 5.4/7 (Ave.)</p> 
Reason for Current Level	<ul style="list-style-type: none"> Offers precise dosing of a trusted product– HCPs feel they have no reason not to prescribe it in this formulation They mention they could prescribe more colchicine because precision dosing mitigates current toxicity concerns HCPs are motivated to improve safety while also providing needed efficacy—they want to reduce the high patient burden of gout flares 	<ul style="list-style-type: none"> PAs are a hassle that rheumatologists prefer not to do. But insurance hurdles are anticipated for Gloperba, so HCPs will prioritize time and other resources in the PA process for patients at high risk for colchicine toxicity (e.g., severe CKD patients)

Gloperba reduced dosing offers value for money



The WAC price of Gloperba is \$595 for a 150mL bottle.

-Value for \$: Will last for 60 days for patients with Severe renal impairment (CKD 4) - 0.3 mg , and 37 days for patients with Moderate renal impairment (CKD 3) and GI Sensitivity - 0.5 mg dose

-Effective gout control allows ULT (Urate Lowering Therapy) to continue, prevents progression of gout and related comorbid conditions – saving healthcare \$

Colchicine TABLET (mg) to GLOPERBA Liquid (mL) Conversion Table	
Colchicine (mg)	GLOPERBA (mL)
0.12 mg	1.0 mL
0.24 mg	2.0 mL
0.3 mg	2.5 mL
0.36 mg	3.0 mL
0.48 mg	4.0 mL
0.6 mg	5.0 mL

Severe Renal Impairment
eGFR 15-29

Moderate Renal Impairment
eGFR 30-59

GI Sensitivity

Gloperba solves for the Unmet Need HCPs have stated

GLOPERBA[®]
(colchicine) oral solution
Precision Dosing

When gout patients are at risk for colchicine toxicity



Go low **with GLO**

GLOPERBA[®] is the first and only liquid oral colchicine—designed for precision dosing below 0.6 mg for patients with renal impairment or GI sensitivity.¹⁻³





Semnur Pharmaceuticals

960 San Antonio Rd, Palo Alto CA 94303

Wholly Owned Subsidiary of Scilex Holding Company
(NASDAQ: SCLX)

SP-102 Market Opportunity



Developing SP-102 as a non-opioid injectable therapeutic for low back pain

Novel viscous gel formulation, optimized for epidural injection
Novel biocompatible excipient enables extended local effect



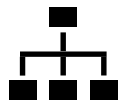
On track to be the first and only FDA-approved epidural steroid product

Currently used products are off-label and contain potentially neurotoxic preservatives, particulates, surfactants or solvents. Compounded epidural steroids led to >70 deaths in 2012 due to fungal contamination



Large market over 12 million epidural steroid injections per year in U.S.

Bigger opportunity than knee intra-articular OA injections, with no direct competition
Established reimbursement route for the most frequently performed pain procedure
Scilex Pharmaceuticals has global promotional rights to SP-102 (SEMDEXA)



Phase 3 CLEAR trial completed

Fast Track status granted by FDA



Significant barriers to entry for competitors or generics

Method of use patent granted (2036 expiry) and formulation patent approved (2036 expiry)
Complex manufacturing process and know-how for excipient and sterile viscous gel products

SEMDEXA (SP-102) On-Track to be the First Product Approved to Treat Sciatica

- SP-102 is a preservative free, surfactant free and particulate free viscous gel formulation of dexamethasone for sciatica (lumbosacral radicular pain).
- Extended local effect provides durable pain relief and significant improvement in functioning from a single injection with rapid onset.
- Improvement against placebo over 4 weeks and continued effect over 12 weeks with reduced use of rescue therapy.
- Good safety profile for single and repeat injections.
- Common epidural delivery by minimally invasive procedure conducted in outpatient pain clinics.
- Stable at refrigerated temperature in a prefilled syringe.



SP-102 Differentiated Product Profile & Positioning

Important Treatment Attributes	SP-102	Kenalog (triamcinolone)	Depo-Medrol (methylprednisolone)	Dexamethasone	Celestone (betamethasone)
FDA-approved for lumbosacral radicular pain	✓	—	—	—	—
Robust clinical data demonstrating safety and efficacy	✓	—	—	—	—
Fast onset of effect in LR with low spread	✓	—	—	—	—
Confirmed duration of efficacy	✓	—	—	—	—
Reduction in disability in LR	✓	—	—	—	—
Safe to administer repeat injections	✓				
Novel formulation with prolonged residency time at injection site	✓	—	—	—	—
No Surfactants	✓	—	—	—	—
No Preservatives	✓	—	—	—	—
No Particulates	✓	—	—	✓	—
Prefilled Syringe	✓	—	—	—	—

SEMDEXA – Broad Potential for Life Cycle Management

Physicians indicated there is potential opportunity for spontaneous use of SEMDEXA outside of lumbar radiculopathy which could represent an additional upside of ~50-200%* over LR

Additional Uses

- Carpel Tunnel
- Trigger Point Injections
- Injections for Knee, Shoulders, Wrists, Ankles, Joints
- Cervical Radiculopathy
- Knee Arthritis
- Hip and Knee Replacements
- Complex Regional Pain Syndromes (CRPS)
- Lumbar Spinal Stenosis
- Acute Spinal Injury
- Discogenic Pain

*Assumes similar degree of utilization for additional indications

Nasdaq (November 11, 2022)

