



**Innovative Leader in Non-Opioid  
Pain Therapeutics  
April 2024**

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# 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	<ul style="list-style-type: none"> <li>Launched in the U.S. in October 2018</li> </ul>
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	<ul style="list-style-type: none"> <li><b>2H 2022:</b> In-licensed U.S. rights</li> <li><b>2024:</b> U.S. launch</li> </ul>
ELYXYB® (celecoxib) oral solution (Acute Treatment of Migraine)	Approved for acute treatment of migraine					2036	<ul style="list-style-type: none"> <li><b>1Q 2023:</b> In-licensed U.S. / Canadian rights</li> <li><b>2Q 2023:</b> U.S. launch</li> <li><b>4Q 2023:</b> Canada filing</li> <li><b>Expected 1H 2024:</b> Acute pain filing</li> </ul>
	Expected to file acute pain indication with FDA in 1H 2024						
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Fast Track					2036	<ul style="list-style-type: none"> <li><b>1H 2022:</b> Phase III achieved endpoints</li> <li><b>2H 2023:</b> FDA agreed on NDA path</li> </ul>
SP-103 Lidocaine Topical System 5.4% (3X) (Chronic Neck Pain)	Plan to file Fast Track for neck pain in 1H 2024					2031	<ul style="list-style-type: none"> <li><b>2Q 2023:</b> Completed Phase II trial.</li> <li><b>1H 2024:</b> File Fast Track for neck pain</li> <li><b>3Q 2022:</b> Received Fast Track for low back pain</li> </ul>
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Prepare Phase II Trial					2041	<ul style="list-style-type: none"> <li><b>1H 2022:</b> Completed Phase I trial(s)</li> <li><b>2024:</b> Initiate Phase II trials</li> </ul>

# 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 patients who need precise dose adjustment



## **ZTlido**

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

# ZTlido Sales Performance Fiscal Year 2023 vs. 2022

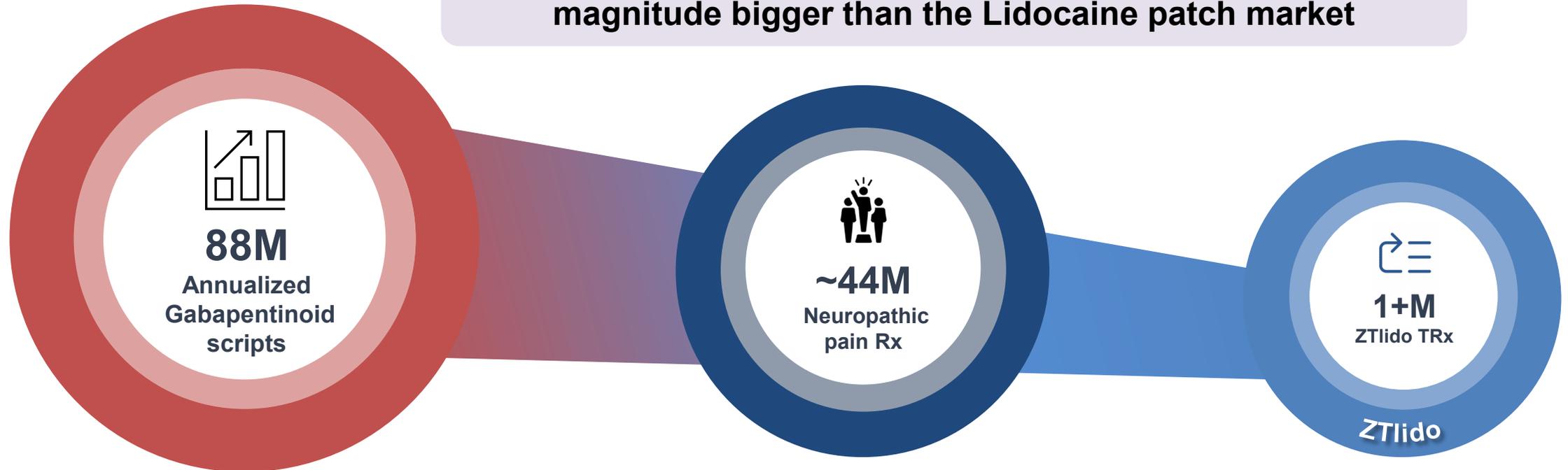


- Based on the independent market research conducted by Syneos Health Consulting (“Syneos”), with the new campaign, health care providers (HCPs) report increased awareness and substantial intent to utilize for ZTlido® with peak sales potential projected to reach over \$500 million in the next 6 years in the U.S.
- ZTlido® #1 prescribed branded non-opioid analgesic by pain specialist
- Scilex continues to grow gross sales with a goal of exceeding \$200 million in 2024
  - ZTlido gross sales for the fiscal year ended December 31, 2023 were 149.1 million, compared to \$96.0 million for the fiscal year ended December 31, 2022, representing growth of approximately 55%.
  - ZTlido net sales for the fiscal year ended December 31, 2023 were 46.3 million, compared to \$38.0 million for the fiscal year ended December 31, 2022, representing growth of 22%.

# 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



# 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 ENOUGH<sup>1</sup>**



**FIND THE PERFECT PARTNER in ZTlido<sup>®</sup>**

**ADDING ZTlido DOUBLES PAIN RELIEF<sup>1</sup> – WITHOUT THE BAGGAGE OF ORAL ANALGESICS<sup>2</sup>**

\*Chronic neuropathic pain of post-herpetic neuralgia.

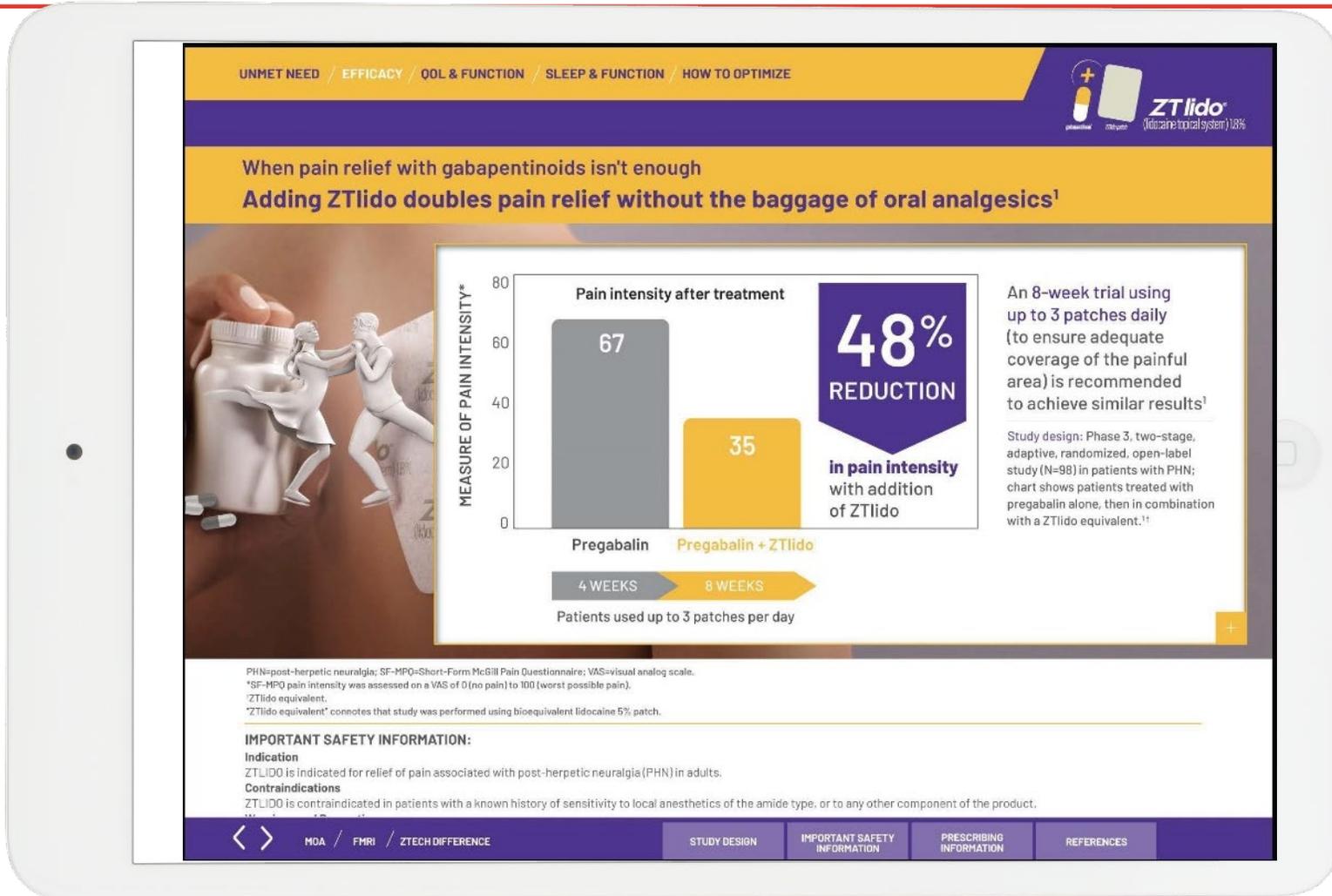
**IMPORTANT SAFETY INFORMATION:**  
**Indication**  
ZTLIDO is indicated for relief of pain associated with post-herpetic neuralgia (PHN) in adults.  
**Contraindications**  
ZTLIDO is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other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

# The ZTlido Solution to the Unmet Need with Gabapentinoids



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

**When pain relief with gabapentinoids isn't enough  
Adding ZTlido doubles pain relief without the baggage of oral analgesics<sup>1</sup>**

**48% REDUCTION**  
in pain intensity with addition of ZTlido

**Pain intensity after treatment**

Treatment	4 WEEKS	8 WEEKS
Pregabalin	67	35
Pregabalin + ZTlido	35	18

MEASURE OF PAIN INTENSITY\*

An 8-week trial using up to 3 patches daily (to ensure adequate coverage of the painful area) is recommended to achieve similar results<sup>1</sup>

Study design: Phase 3, two-stage, adaptive, randomized, open-label study (N=98) in patients with PHN; chart shows patients treated with pregabalin alone, then in combination with a ZTlido equivalent.<sup>1†</sup>

PHN=post-herpetic neuralgia; SF-MPQ=Short-Form McGill Pain Questionnaire; VAS=visual analog scale.  
\*SF-MPQ pain intensity was assessed on a VAS of 0 (no pain) to 100 (worst possible pain).  
†ZTlido equivalent.  
†ZTlido equivalent\* denotes that study was performed using bioequivalent lidocaine 5% patch.

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MOA / FMRI / ZTECH DIFFERENCE

STUDY DESIGN

IMPORTANT SAFETY INFORMATION

PRESCRIBING INFORMATION

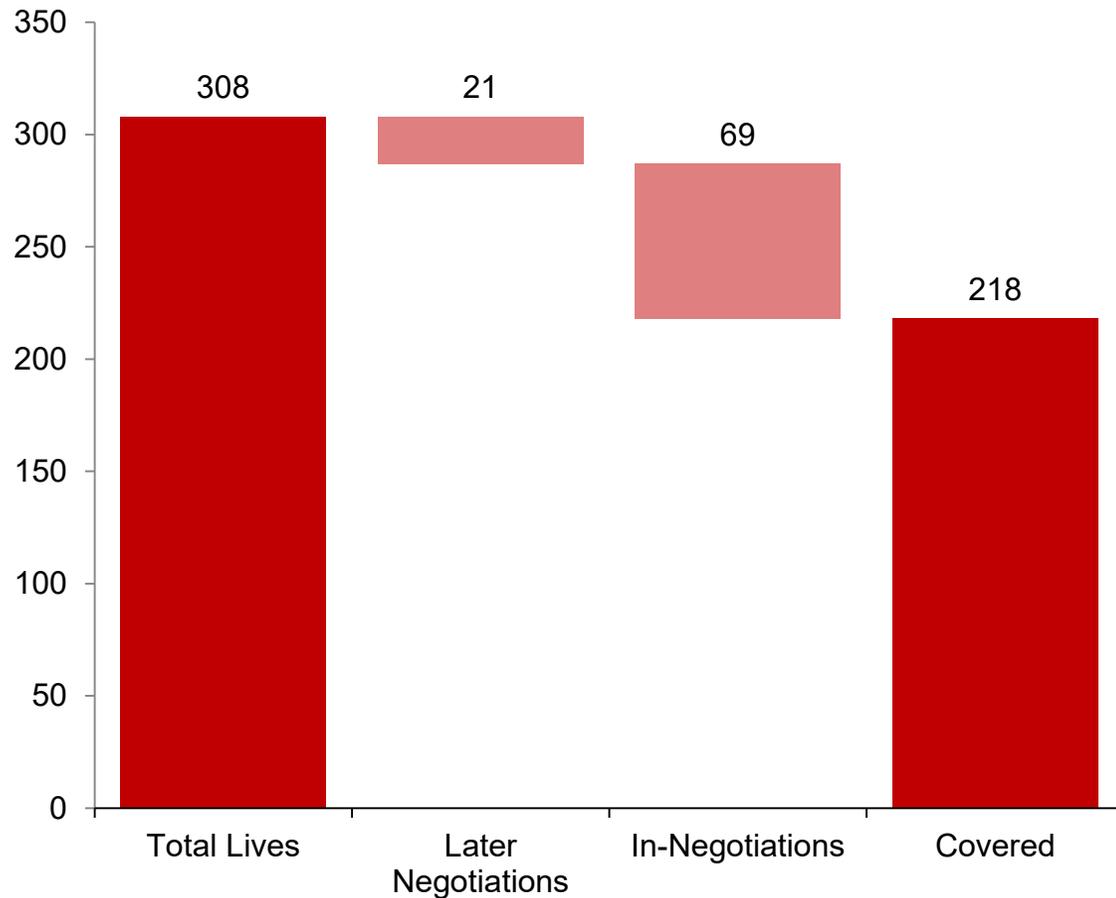
REFERENCES

- Improved patient QoL by 78% in 8-week trial of ZTlido with gabapentin
- In a real-world use trial, 88% patients claimed they could function better
- 89% patients claimed they were completely or mostly satisfied



# ZTlido Market Access Update

## ZTlido Covered Lives Overview



## Key Players - Preference



*ZTlido Preferred*

State of California (MediCal)

*Lidocaine Preferred*



*ZTlido Preferred*



*ZTlido Preferred*

## 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.

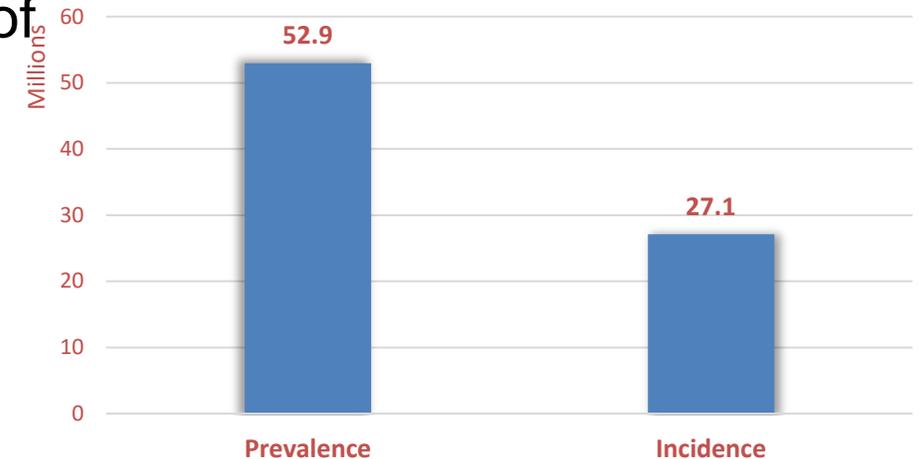
Prevalence of Neck Pain is estimated at >20% of adult population

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)



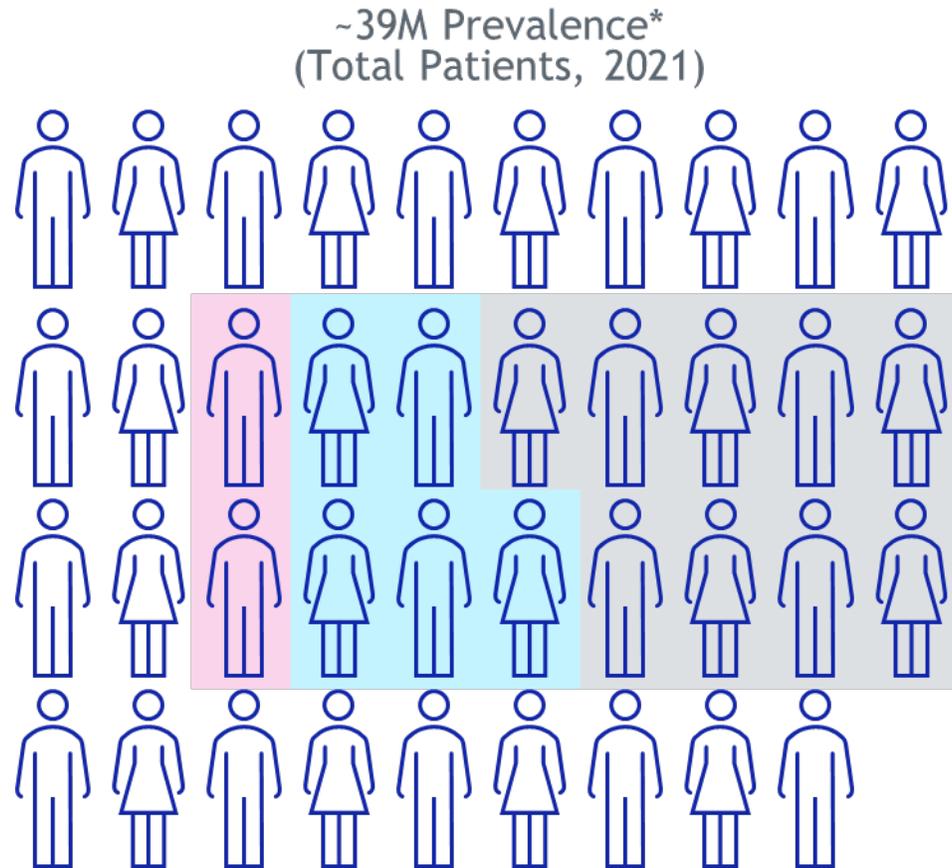
Neck Pain: U.S. Epidemiology





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

# 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*

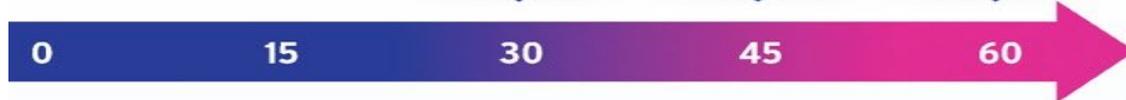
# Elyxyb Promotion Materials

## Fast-Acting Formulation

Works as quickly as 15 minutes<sup>4,6\*</sup>

Delivers significant pain relief in 45 minutes in nearly 50% of patients<sup>4</sup>

Symptom improvement (vs placebo) as early as<sup>4</sup>:



Proven pain relief in Phase III studies involving 1253 patients<sup>7,8</sup>

Pooled analysis of pain freedom in patients 2 hours post-dose with ELYXYB vs placebo<sup>9</sup>:



**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).<sup>1,7,8,9</sup>

\*Pain relief trended as early as 15 minutes for some patients in post-hoc analysis.<sup>6</sup>

### 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<sup>7,8</sup>



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<sup>™</sup>**  
(celecoxib)  
Oral Solution



**ELYXYB**

**(Celecoxib) Oral Solution  
Episodic Migraine Treatment**

***Elyxyb***<sup>®</sup>  
*(celecoxib) Oral Solution*<sup>16</sup>

# Unmet Needs for Migraine Patients – Elyxyb Well Positioned to Address

Up to 40% of 1<sup>st</sup> line and 2<sup>nd</sup> line prescriptions are for triptans<sup>1</sup>

Up to 60% of patients on triptans, have a suboptimal response<sup>2</sup>

Do not achieve pain freedom at 2 hours postdose

Have recurrence of headache 2-24 hours postdose

Discontinue or can't tolerate side effects

The greatest unmet needs for patients are:<sup>3</sup>

Speed to pain freedom

Durability of response

1. Data on file. ELYXYB Baseline ATU Study, Fielded April 2023.

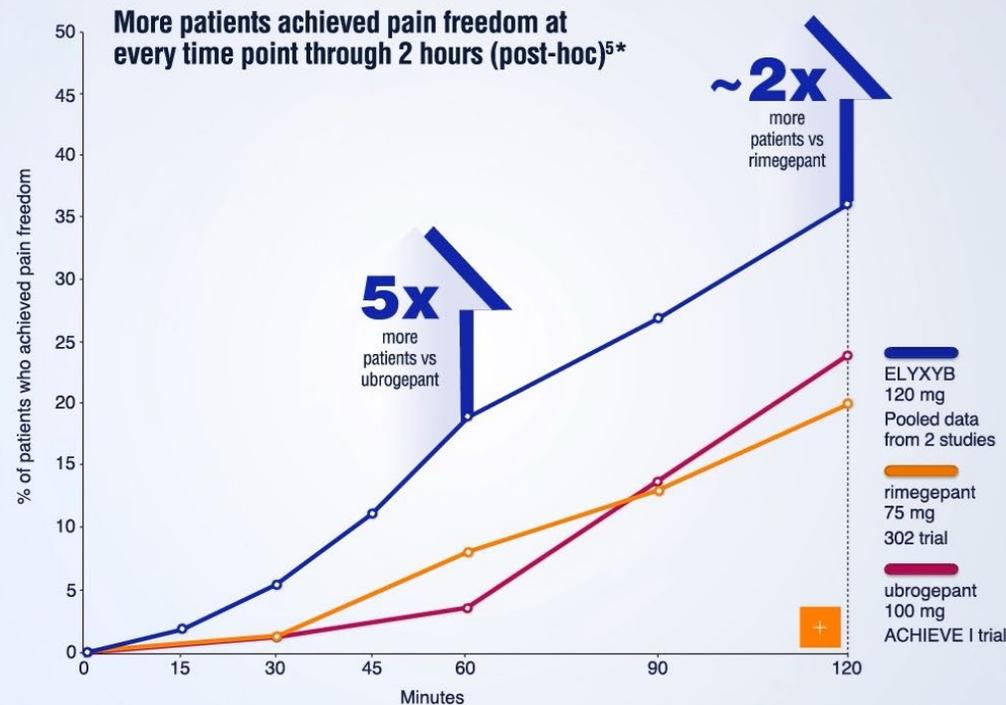
2. de Boer I, Verhagen IE, Souza MNP, Ashina M (2023) Place of next generation acute migraine specific treatments among triptans, non-responders and contraindications to triptans and possible combination therapies. Cephalalgia

3. Data on file. ELYXYB Patient Message Testing, fielded November 2023.

# Elyxyb Efficacy Comparison to CGRP Inhibitors

## Post-hoc Indirect Comparative Analysis

### Proven to deliver faster pain freedom<sup>5</sup>



- 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

# Acute Migraine Brand WAC Pricing



Brand	Generic	Launch	Route	Package Size	Unit WAC Price	Package WAC Price	WAC Per Migraine	Avg annual price Δ
Cambia (505b2)	Diclofenac	Oct'16	Oral powder for solution	9 Sachets	\$98.55	\$886.97	\$98.55	+10%
Elyxyb	Celecoxib	Feb'21*	Oral Solution	6 Bottles	\$135.00	\$810.00	\$135.00	N/A
Nurtec ODT	Rimegepant	Mar'20	Oral ODT	8 Tablets	\$118.93	\$951.45	\$118.93	~+4%
Ubrelvy	Ubrogapant	Jan'20	Oral	10 Tablets	\$98.40	\$984.00	\$137.76 (40% Redose)	+5%
Zavzpret	Zavegepant	May'23	Nasal	1 squeeze bottle	\$183.33	\$1,100	\$183.33	N/A

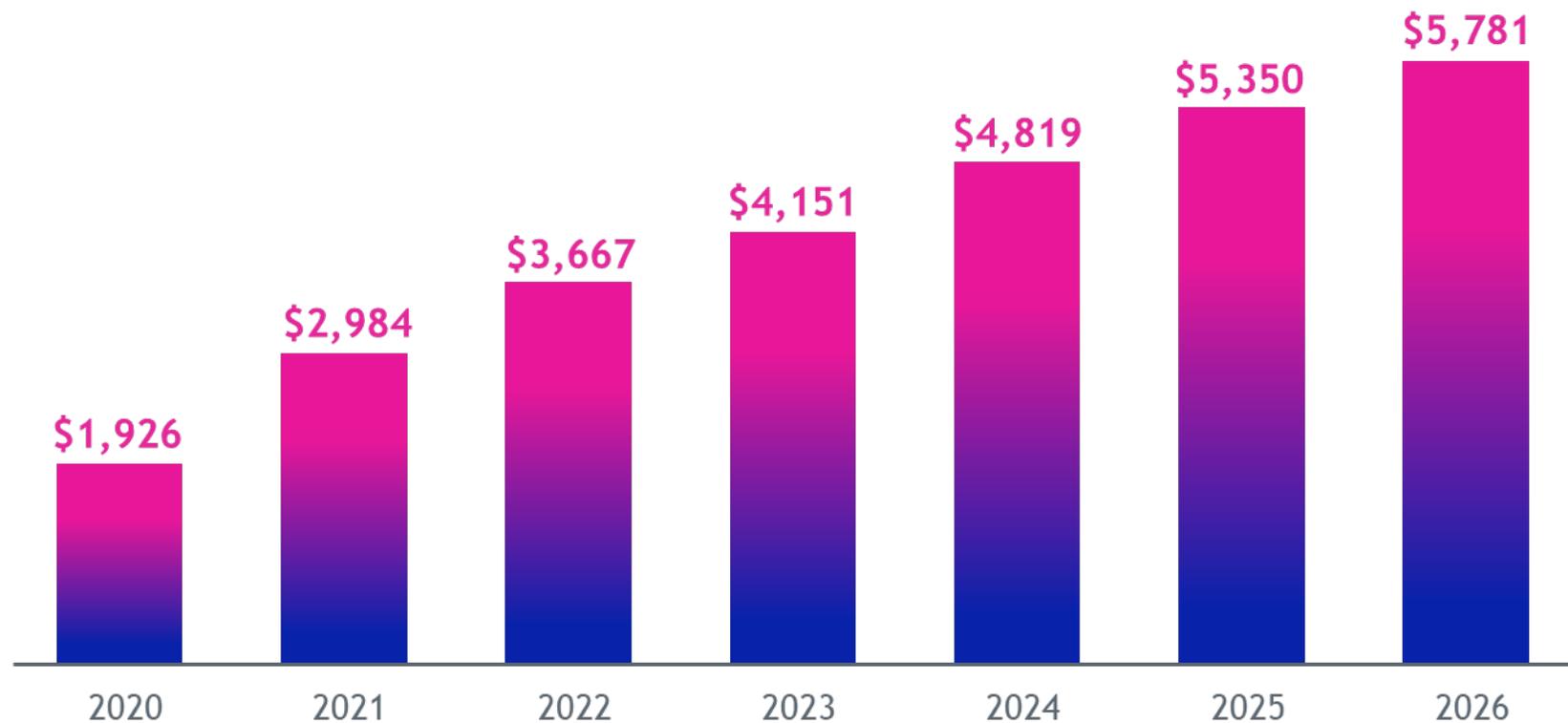
\* Last date of record  
Source: Analysource (First Data Bank)

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

## US Migraine Annual Sales

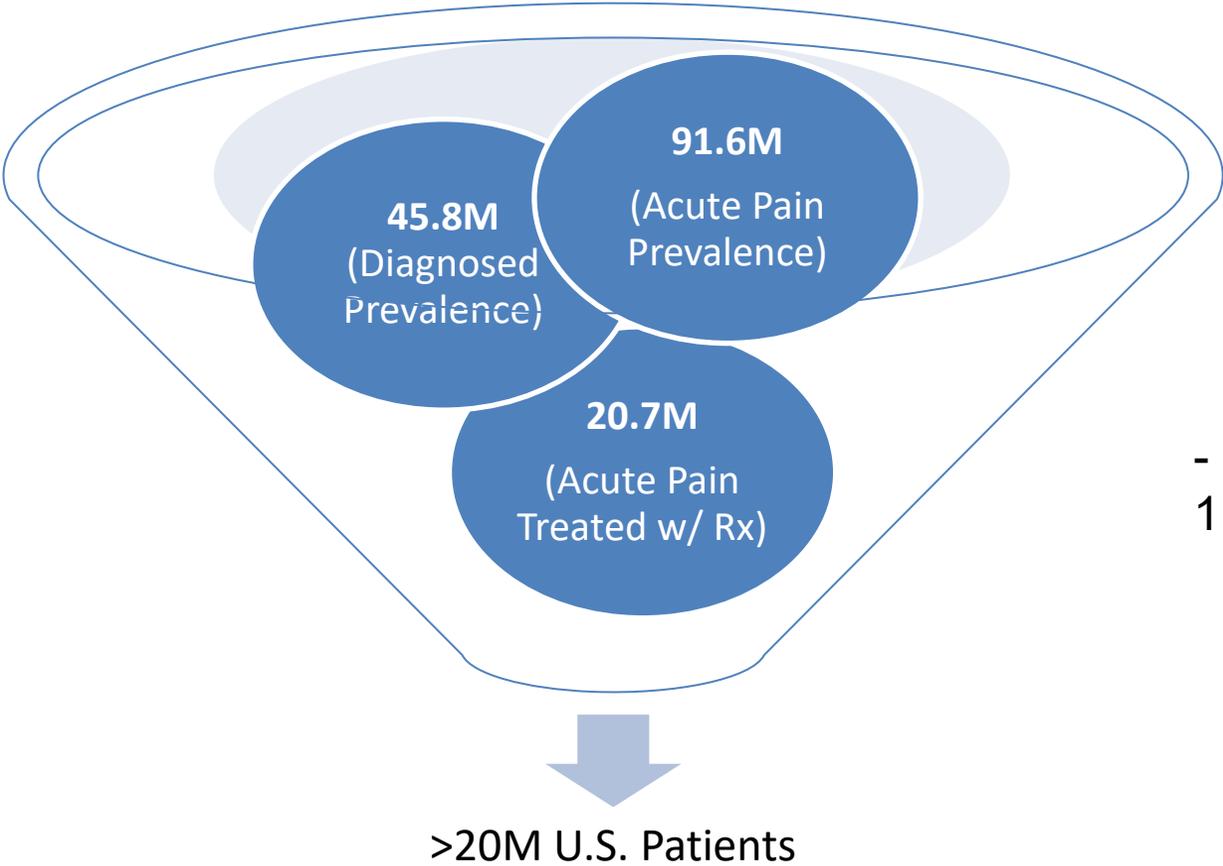
*(Refreshed based on 2022 data)*

Acute + Preventive Treatments



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

# Elyxyb Acute Pain Opportunity: Market Size



- sNDA filing planned in 1H 2024

***Large market opportunity for Elyxyb in Acute Pain***



## **Gloperba**

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

# Target Patients For Gloperba Today (excluding Cardiovascular)

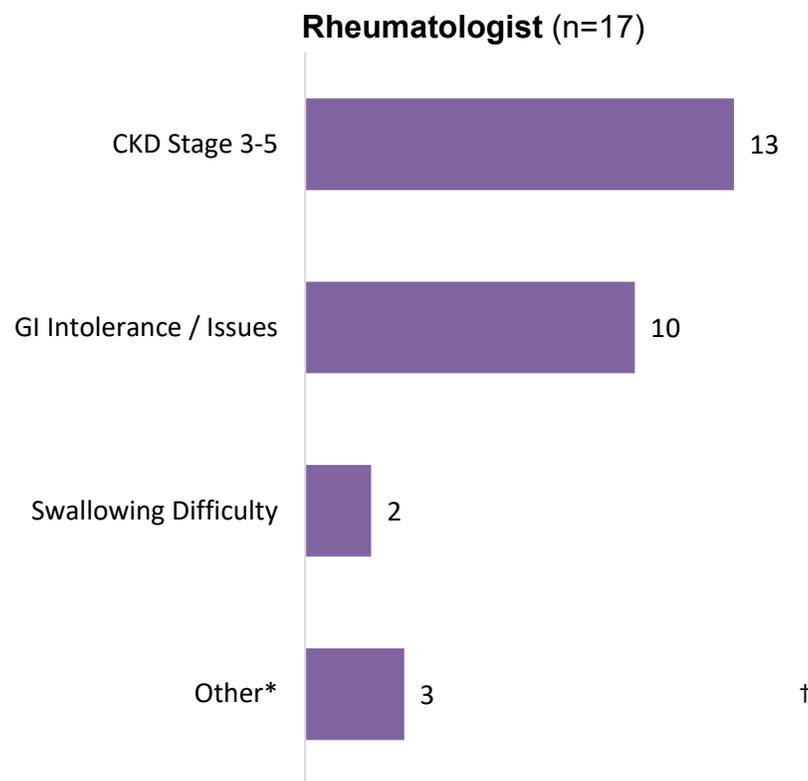
- Patients with CKD Stage 3/4/5: 6 million patients
- Patients with GI tolerability issues: 1 million patients
- Patients at risk of drug-to-drug interaction (DDI)
- Patients who have difficulty swallowing

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

# 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	
Severe Renal Impairment eGFR 15-29	0.3 mg	2.5 mL	
	0.36 mg	3.0 mL	
Moderate Renal Impairment eGFR 30-59	0.48 mg	4.0 mL	GI Sensitivity
	0.6 mg	5.0 mL	

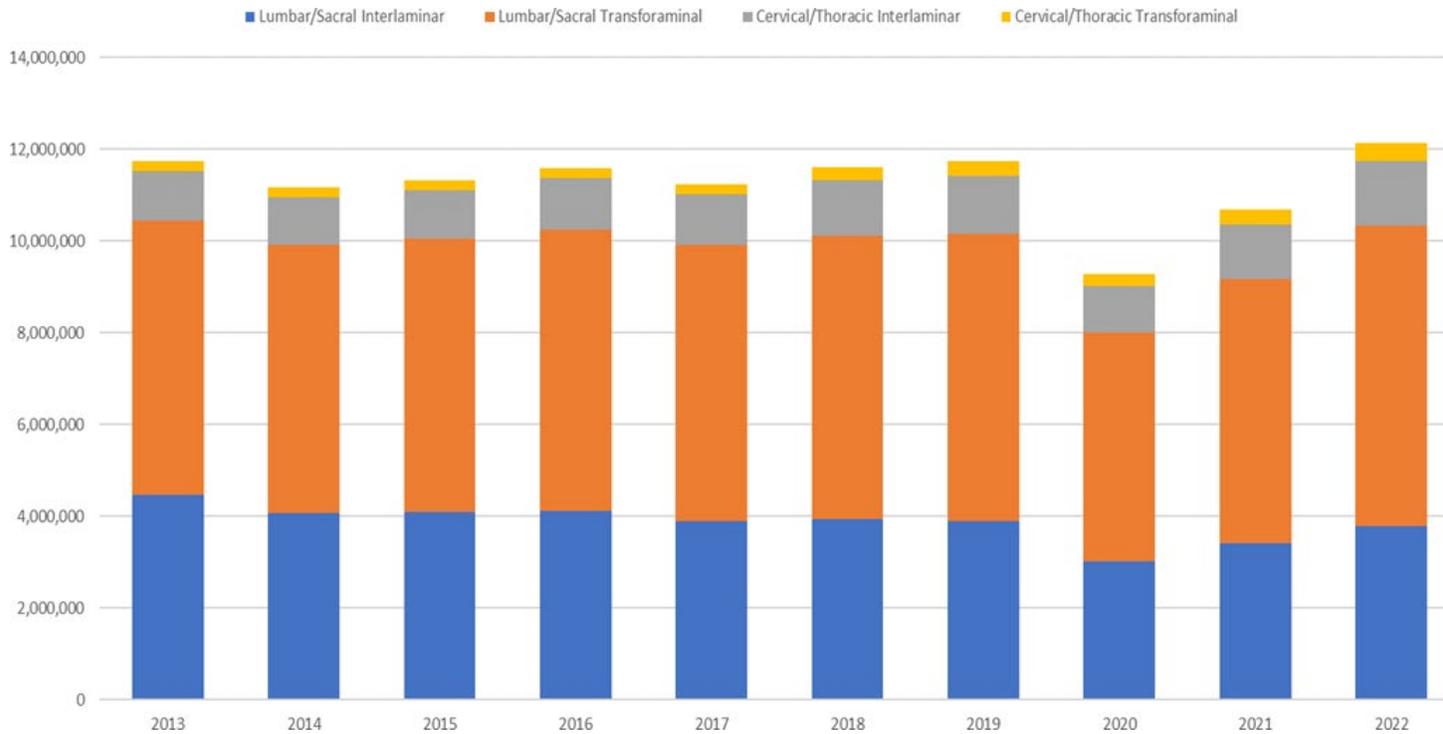


**SP-102 (SEMDEXA)  
Treatment of Chronic Low Back  
Pain/ Sciatica**

# Epidural Steroid Injections (ESI) for Chronic Back Pain

One of the Most Common Medical Procedures / Top Pain Procedures

## Strong Growth Rate, Evidenced by Medicare Procedure Volumes (MM)



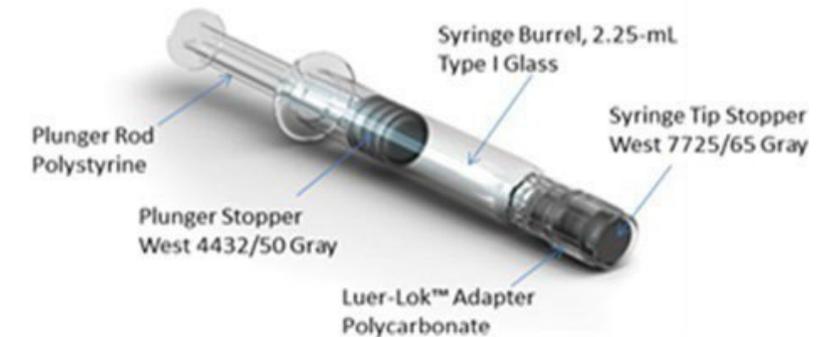
## Medicare Overall ESI Injection Volume<sup>1</sup>

- 1 ESIs widely reimbursed as procedure to delay or avoid back surgery
- 2 Transforaminal ESI route (used in C.L.E.A.R. trial) majority of Total ESI procedures
- 3 Over 12 million ESI pain procedures per year, greater than all Cardiovascular and GI procedures

1. Syneos Health Consulting/Campbell Alliance market research (Estimated)

# On-Track as First Epidural Steroid Injection with a Label to Treat Sciatica

- ❖ SP-102 (SEMDEXA) is a preservative free, surfactant free and particulate free viscous gel formulation of well known corticosteroid for sciatica (subacute 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.



# Phase III C.L.E.A.R. Trial Achieved Objectives



A total of 401 patients enrolled (202 SP-102 / 199 placebo) across 37 US sites

The primary endpoint - change in average daily pain in the affected leg over 4 weeks LS mean (SE) of -0.52 (0.163) compared to placebo,  $p=0.002$ . Supported by:

Disability Index, ODI -3.38 (1.388),  $p=0.015$ . 23% reduction from baseline (17% clinically meaningful<sup>1</sup>)

Global Change, PGIC and CGIC,  $p<0.001$

Worst daily pain in affected leg at Week 4 ( $p=0.004$ ) and over 4 weeks ( $p=0.001$ )

Average daily lower back pain,  $p=0.035$

Brief Pain Inventory for pain severity ( $p=0.003$ ) and pain interference ( $p=0.049$ )

Responders at 30%,  $p=0.002$

The time to repeat injection (95% CI): 84 (71, 100) days for SP-102 vs. 58 (50, 69) days for placebo,  $p=0.001$

Subjects received repeat injections, open-label SP-102: 134 (66%) SP-102 vs 152 (76%) placebo,  $p=0.026$

Favorable safety profile

No Adverse Events of special interest (paraplegia, hematoma, or infection)

No Serious AEs related to SP-102 or injection procedure

# SP-102 Regulatory Discussion(s) to Date

- 1 Toxicology program complete
- 2 Pharmacokinetic bridge established to Reference Listed Drug
- 3 Phase II, additional PK / PD / Safety of repeat injection trial completed
- 4 CLEAR Trial completed
- 5 NDA 505(b)(2) application confirmed
- 6 Agreement with FDA on next steps to NDA – Phase III Open Label Safety Study of 600 to 700 Patients

# Investment Highlights

1

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

2

***Worldwide Commercial Rights to Most Product Candidates***

3

***Blockbuster Pipeline With Limited Capital Required for Commercialization***

4

***Established Reimbursement Access***

5

***Strong Proprietary Platform with High Barriers to Entry***

# Nasdaq (November 11, 2022)

