

serina  
therapeutics



## **SER-252 (POZ-apomorphine) & Enable Injections enFuse**

**Patient-enabled Therapy for Advanced Parkinson's Disease:**

A Case Study with Serina Therapeutics' SER-252 +  
Enable Injections enFuse Wearable Drug Delivery Platform

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CCO, Enable Injections

October 2<sup>nd</sup> 2024  
14<sup>th</sup> Injectables Summit

# Forward Looking Statements

This presentation contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this presentation and our Serina investor webcast include, but are not limited to, statements about: the potential attributes and benefits of our product candidates; the format, timing and objectives of our product development activities and clinical trials; the timing and outcome of regulatory interactions, including whether activities meet the criteria to serve as registrational; the ability to compete with other companies currently marketing or engaged in the development of treatments for relevant indications; the size and growth potential of the markets for product candidates and ability to serve those markets; the rate and degree of market acceptance of product candidates, if approved; and the sufficiency of our cash resources. We cannot assure you that the forward-looking statements in this presentation will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including, among others: clinical trial results may not be favorable; uncertainties inherent in the product development process (including with respect to the timing of results and whether such results will be predictive of future results); our ability to recruit and enroll suitable patients in our clinical trials, including the effectiveness of mitigation measures; whether and when, if at all, our product candidates will receive approval from the FDA or other regulatory authorities, and for which, if any, indications; competition from other biotechnology companies; uncertainties regarding intellectual property protection; and other risks identified in our SEC filings, including those under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, our Current Report on Form 8-K that was filed with the SEC on April 1, 2024, and our subsequent SEC filings. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

NON CONFIDENTIAL

# POZ Platform<sup>®</sup>

## Enabling Technology



### Small Molecules

New / improved  
small molecule drugs  
Clinically validated



### RNA

Optimized targeting &  
reduced immunogenicity



### ADCs

Improved delivery of  
cancer-killing toxins

# ENABLE INJECTIONS

Redefining drug delivery for the benefit of patients, providers, payers, and partners



**400M+**  
INVESTED



**20,000**  
INJECTIONS



**50+**  
PATENTS



**2023**



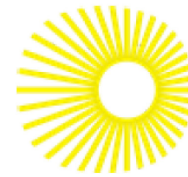
**7**  
ACTIVE  
PARTNERSHIPS



**2010**  
FOUNDED



\*Approved in the United States in combination with a specific drug, more information: <https://enableinjections.com/our-products>



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**Source:** *Enable Injections, Inc.*

*May 15, 2024 07:30 ET*

## **Enable Injections and Serina Therapeutics Announce Agreement to Develop SER-252 in Combination with enFuse® for Advanced Parkinson's Disease**

CINCINNATI and HUNTSVILLE, Alabama, May 15, 2024 (GLOBE NEWSWIRE) -- [Enable Injections, Inc.](#) ("Enable"), a healthcare innovation company developing and manufacturing the enFuse® wearable drug delivery platform and [Serina Therapeutics](#) ("Serina") (NYSE American: SER), a clinical-stage biotechnology company advancing its POZ Platform™ to develop and improve efficacy and safety across multiple modalities including small molecules, RNA-based therapeutics and antibody-based drug conjugates (ADCs), today announced a partnership to develop and commercialize SER-252 (POZ-apomorphine) in combination with enFuse for the treatment of Parkinson's disease.

## **SER-252 (POZ-Apomorphine)**

**Continuous Dopaminergic Stimulation (CDS) with Best-in-class Potential for Treatment of Advanced Parkinson's Disease**

**10M**

people in the world are currently living with Parkinson's disease

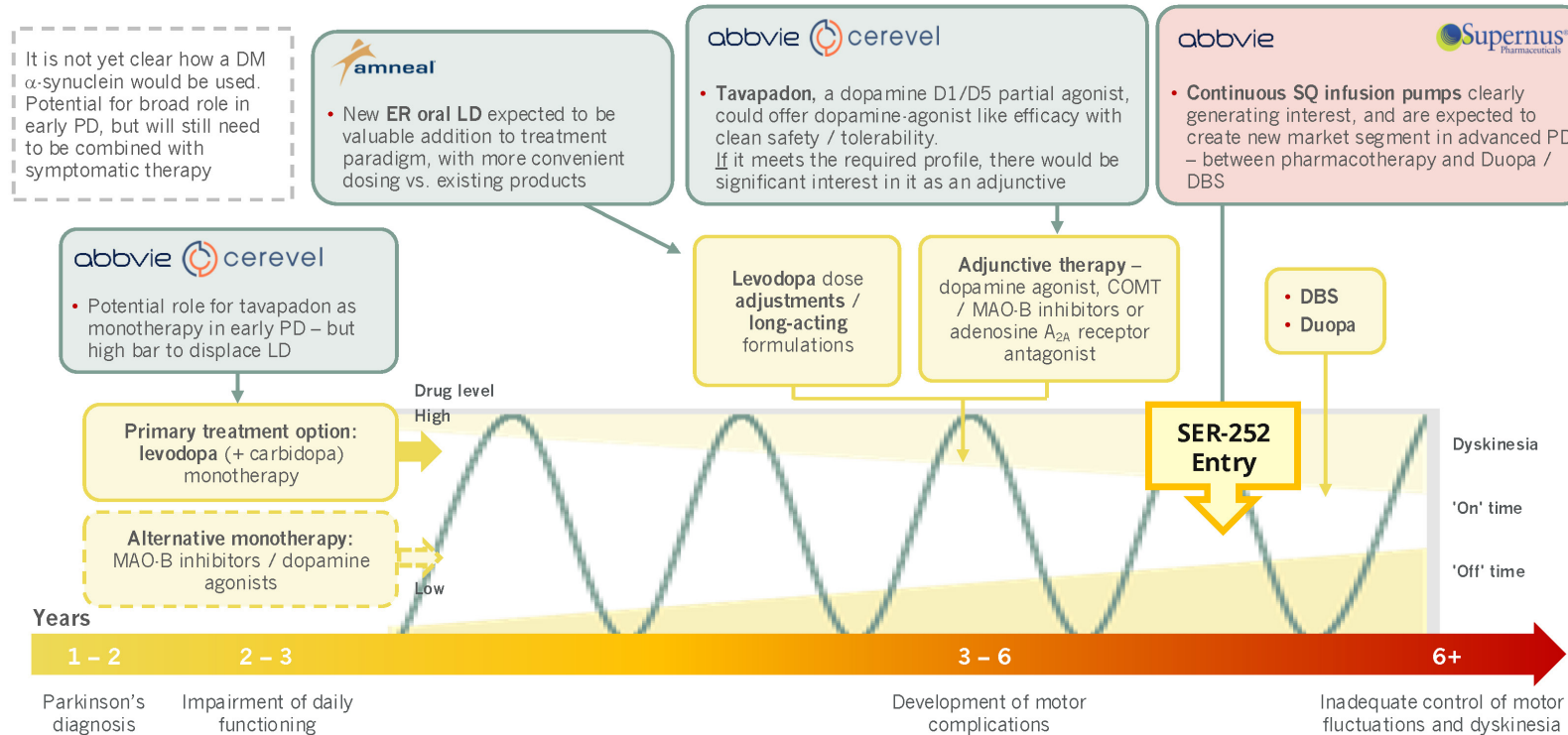
**Every 9 mins**

A person is diagnosed with Parkinson's disease in the US alone

**50+ years**

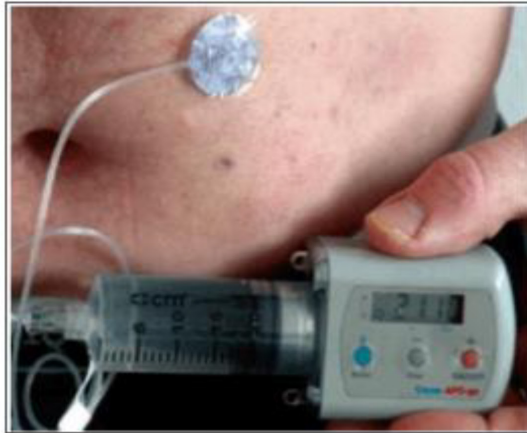
With no major clinical advances – Levodopa standard of care since 1967

# Current Landscape for Treatment of Parkinson's Disease



# Treatments Approved for the Advanced Stages of Parkinson's disease all Require Daily Electronic Devices and May Cause Significant Adverse Events

## APO-go & SPN-830



Apomorphine sub-q can cause skin necrosis and lead to permanent scarring

## Novel Infusion Products



Key direct future competition for SER-252 – which includes pump-based subcutaneous infusions of CD/LD (or prodrugs of CD/LD) and apomorphine

## Bypasses the stomach



Delivered in the intestine, where levodopa is mostly absorbed

## Duodopa

## Produodopa

**The Vyafuser pump**

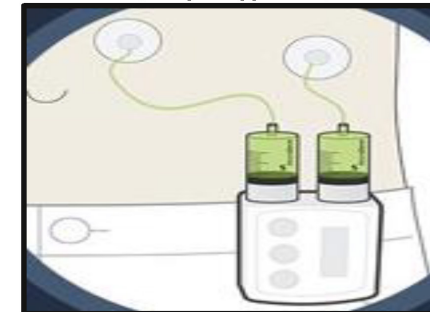
The Vyafuser pump connects to your patient's abdomen via a cannula.<sup>1,2</sup>



- 3 programmable flow rates (low, base, high and an extra-dose capability)<sup>1,2</sup>
- Display to show Pump status information and options for user actions<sup>2</sup>
- Arrow keys to scroll through menu options or increase and decrease a value<sup>3</sup>
- Lightweight, 284 grams<sup>2</sup> (vs Cadd legacy pump, 500 grams)

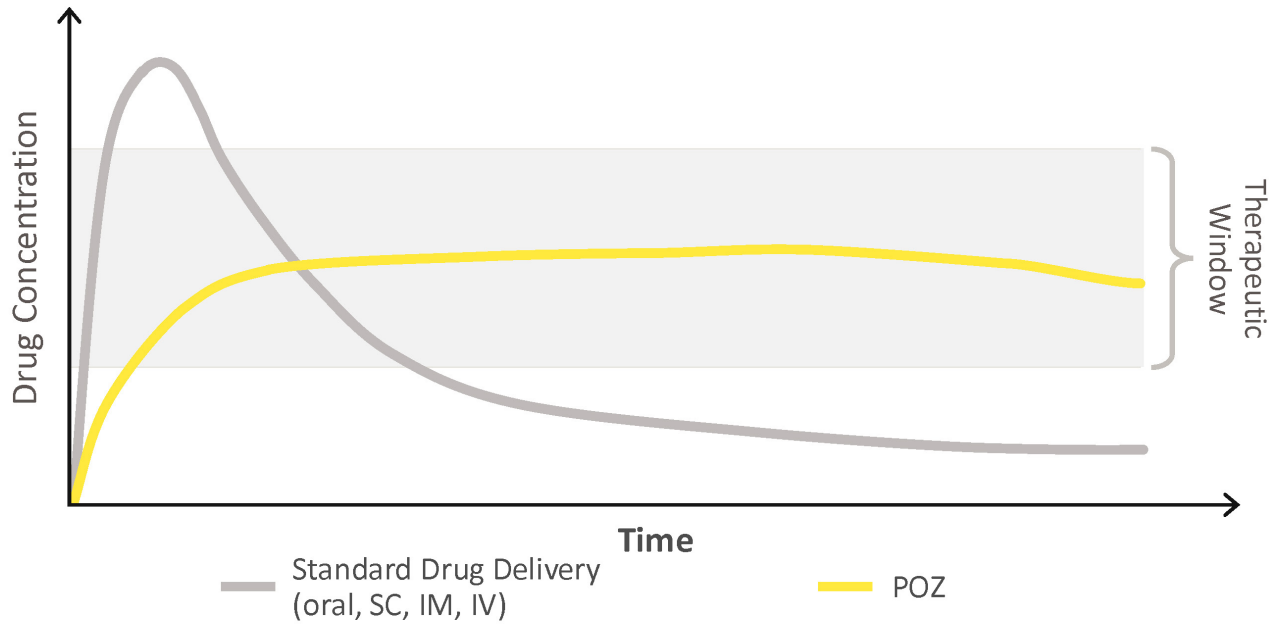
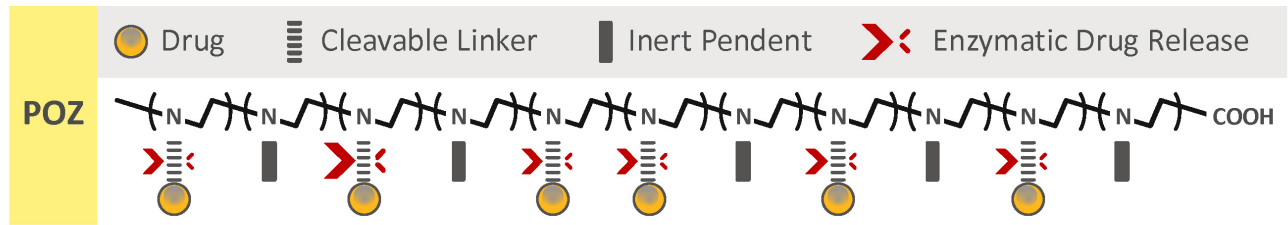
Source: Produodopa UK HCP Website, accessed Mar 2024

## ND-0612 (Not yet approved)





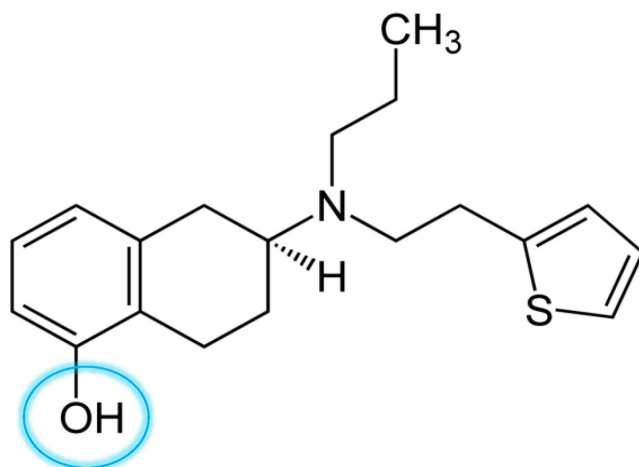
# How Does POZ Accomplish Continuous Drug Delivery ?



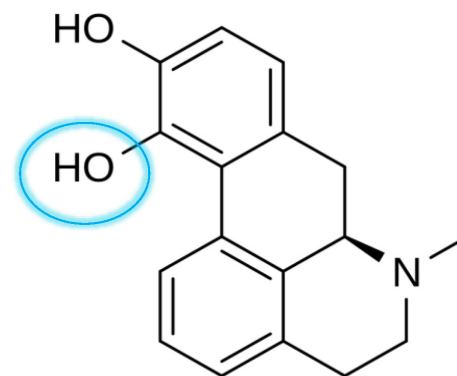
- Drug is attached to multiple pendent groups via a cleavable linker
  - A single plasma enzyme (butyrylcholinesterase) releases the active drug
- 
- **Extends** delivery and administration interval
  - **Optimizes** safety / efficacy profile
  - **Precision** tuning release profile of drug via linker and drug load
  - **POZ** - Designed for small molecules the way PEG was for biologics

# Chemical Structures of PD Compounds

Both have an accessible chemical handle ... but posed different challenges



Rotigotine



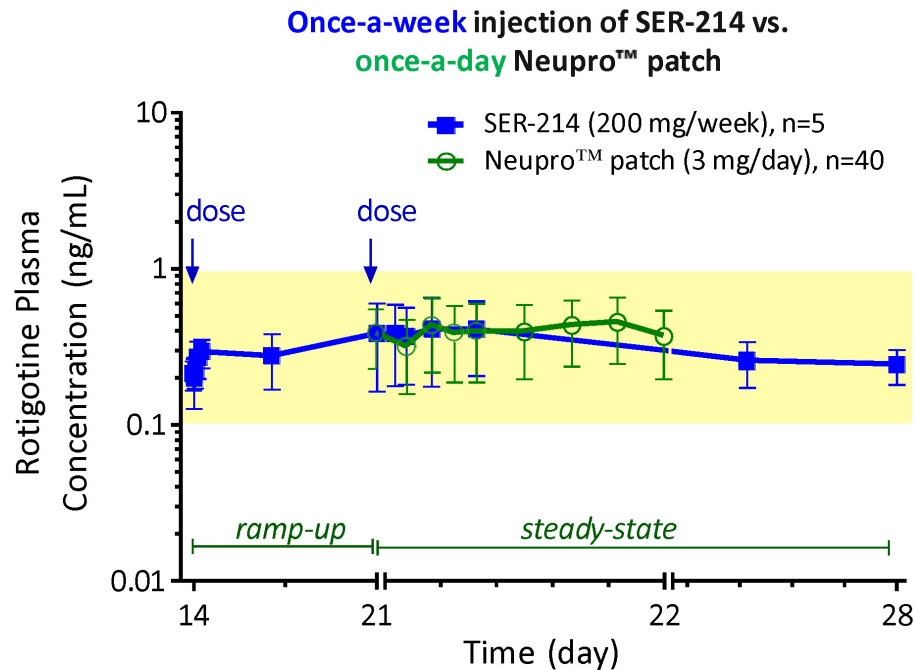
Apomorphine

- Candidate small molecules must have a “chemical handle”
- Linkers are attached to the -OH (creates a stable ester), an azide moiety on the end of the linker allows for permanent “click chemistry” attachment to the pendent alkyne of the polymer backbone
- Search known structures (AdisInsight) - ***thousands*** of candidate molecules (phenolic hydroxyl, alcohols)

# Clinical Validation of POZ – SER-214 (POZ-Rotigotine) Phase 1a Trial

## Continuous, Stable Plasma Levels of Rotigotine

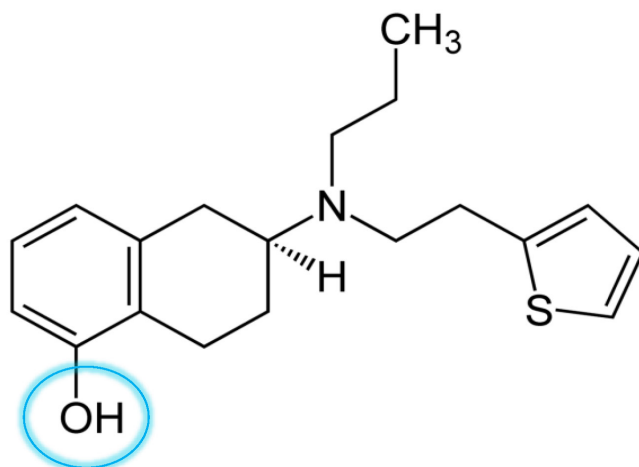
Safety, tolerability and PK was evaluated in 19 stably-treated Parkinson's disease patients



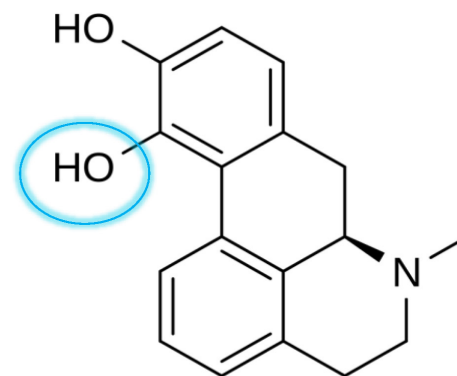
- SER-214 (1 mL injection) was safe & well tolerated: AE profile typical of a dopamine agonist and SC administration
- SER-214 provided continuous delivery of rotigotine at dose-dependent levels within the therapeutic window
- PK profile supports once weekly dosing (Once weekly injection of 200mg SER-214 matches daily 3mg Neupro™ patch)
- The volume of SER-214 to achieve the highest therapeutic dose of rotigotine would be ~ 5mL

# Chemical Structures of PD Compounds

Both have an accessible chemical handle ... but posed different challenges



Rotigotine

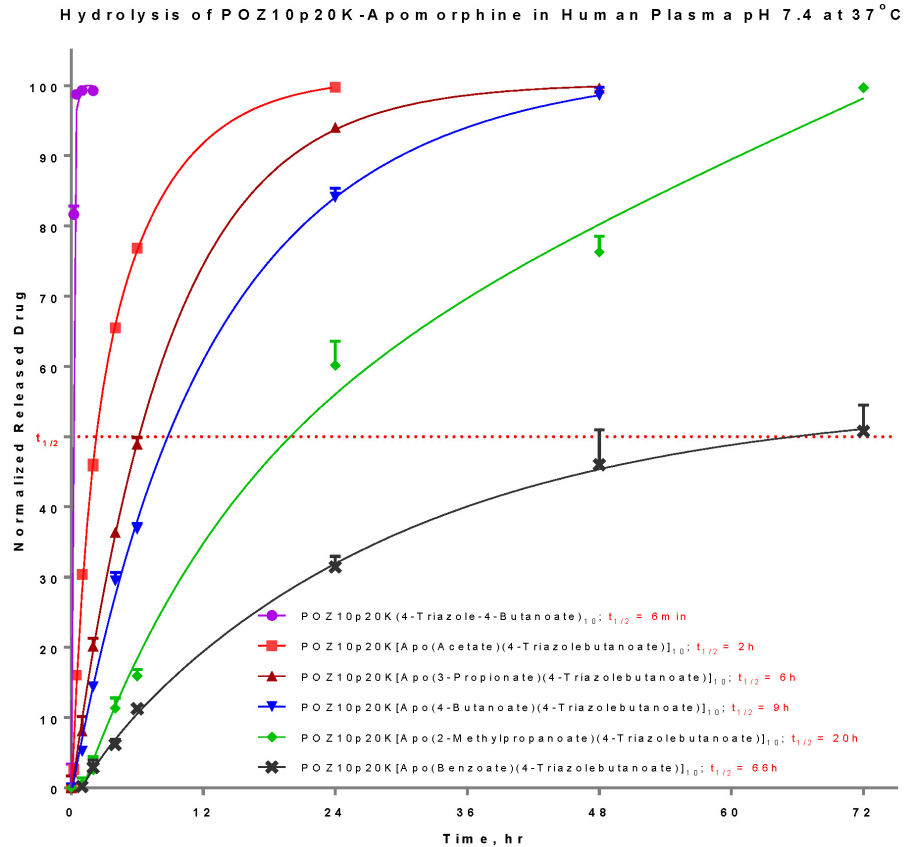


Apomorphine

- Candidate small molecules must have a “chemical handle”
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- Search known structures (AdisInsight) - ***thousands*** of candidate molecules (phenolic hydroxyl, alcohols, carboxylates)

# POZ-apomorphine

The release kinetics of apomorphine required chemistry at both hydroxyl groups



Mono-esterification of apomorphine to POZ showed complete release of apo within minutes

Apomorphine attachment requires both -OH groups be protected – a linking group that attaches to the POZ polymer, and a capping group that controls rate of hydrolysis

The rate of release of apomorphine is controlled by the nature of the “capping group”

Dozens of different combinations of “linking group” and “capping group” were investigated in single-dose & multi-dose PK in monkeys

Four years later ...

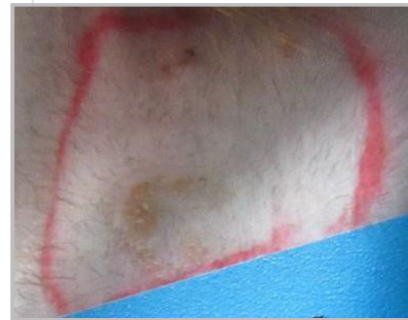
# SER-252 (POZ-Apomorphine) for Advanced Parkinson's Disease

Continuous delivery in the patient's home without skin ulcers

## How did POZ solve the skin issues ?

Attachment of apomorphine to POZ is stable in the SC compartment because there is no enzyme to release it (butyrylcholinesterase is found only in the vascular compartment)

APO-go Infusion (12 hr)



APO-go caused skin abscesses in all treated monkeys

VS

SER-252



No skin reactions and biopsy of injection site revealed no inflammation

# SER-252 (POZ-Apomorphine) for Advanced Parkinson's Disease

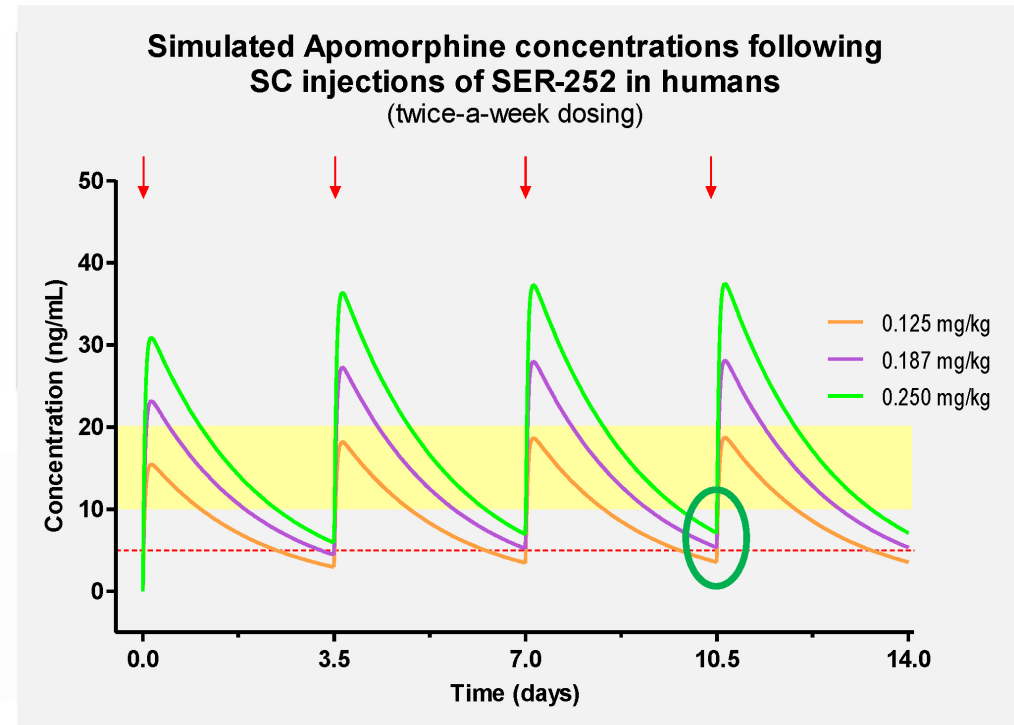
Continuous delivery – Patients may achieve “ON” state without going into “OFF” state between doses

## How will POZ achieve continuous levels of apomorphine ?

Predicted levels of apomorphine following an injection of SER-252 every three and a half days – achieves the known plasma levels to get patients in the “ON” state (addresses morning akinesia)

## Will patients go “OFF” ?

Modeling predicts we should be able to titrate the dose so that trough levels never go below the level of apomorphine that will keep patients “ON”



Note : The yellow hashed area brackets the apomorphine levels in TOLEDO

# ENABLE TECHNOLOGY PLATFORM



5 – 25 ML ENFUSE



SYRINGE TRANSFER SYSTEM



VIAL TRANSFER SYSTEM



**High Volume Delivery**  
No Drug Reformulation



**Original**  
Container Closure



**Hands-Free**  
Flexible Delivery,  
In Clinic or at Home



**Hidden Needle**  
Address Needle Phobia



**Connected HealthCare**  
Dose Verification

Approved in the United States in combination with a specific drug, more information: <https://enableinjections.com/our-products>



# Patient-enabled Delivery

The patient can deliver SER-252 with the 25 mL enFuse®\* in the comfort of their home



Vacuum pulls diluent into vial  
Gentle rotation to dissolve SER-252  
Self-assembly using needleless transfer



Attach resuspended SER-252  
to port on Vial Transfer enFuse  
Filters and loads 25 mL enFuse

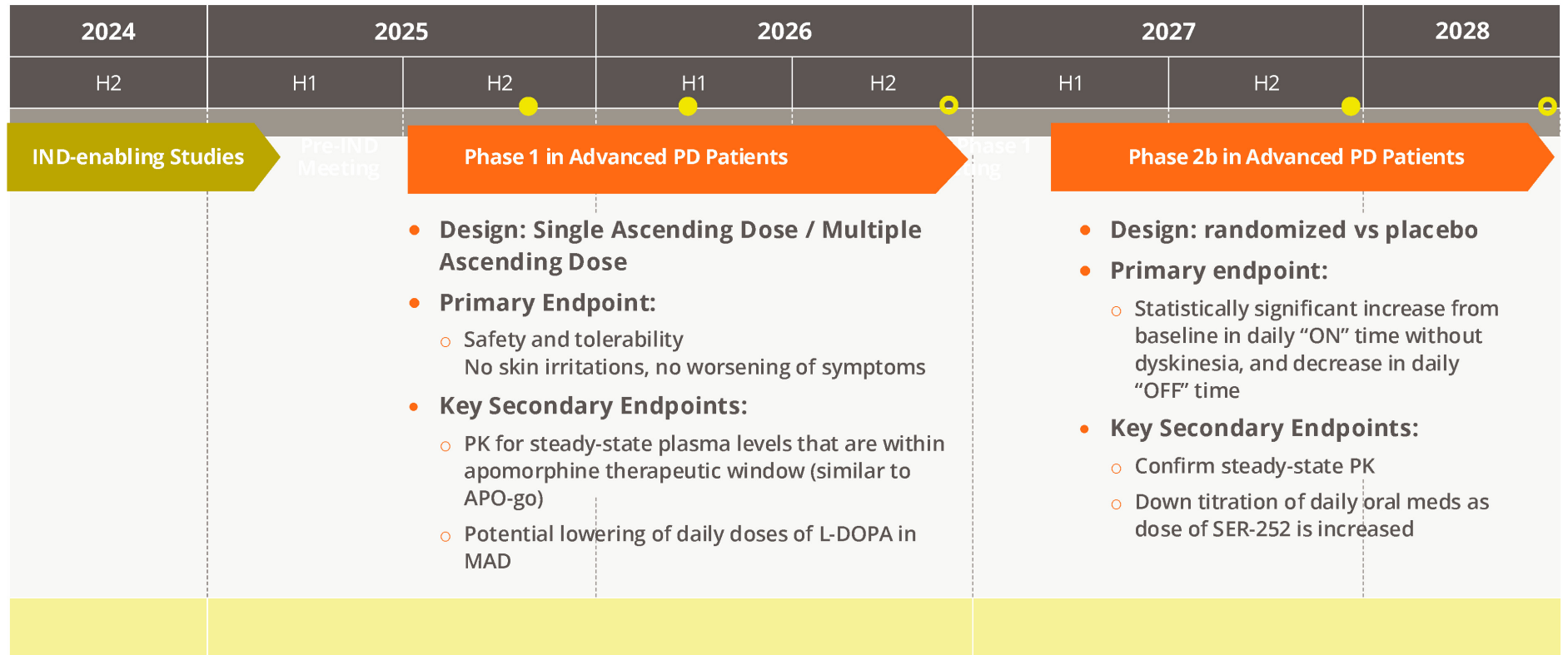


Once loaded the chin strap pops up  
Adhesive is exposed when removed  
Press onto abdomen, press button

**Highly Differentiated TPP: Wearable on-body 2x per week for 10 to 20 minutes - versus daily invasive, continuously worn electronic pump / tubing set that requires an infusion needle**

\*Approved in the United States in combination with a specific drug, for more information: <https://enableinjections.com/our-products>

# SER-252 Development Plan



- Interim Data
- Final Data

# Enable Injections – The enFuse® System



**How will patients receive SER-252 in the SAD Study?**  
Site staff will use the syringe transfer (ST) system  
Enable Injections



**How will patients deliver it in their home?**  
Patients will use the vial transfer (VT)  
Enable Injections

**The Phase I SAD/MAD study is designed to use Enable’s enFuse technology\***

\*Approved in the United States in combination with a specific drug, more information: <https://enableinjections.com/our-products>

# Market Opportunity for Advanced Parkinson's Therapies

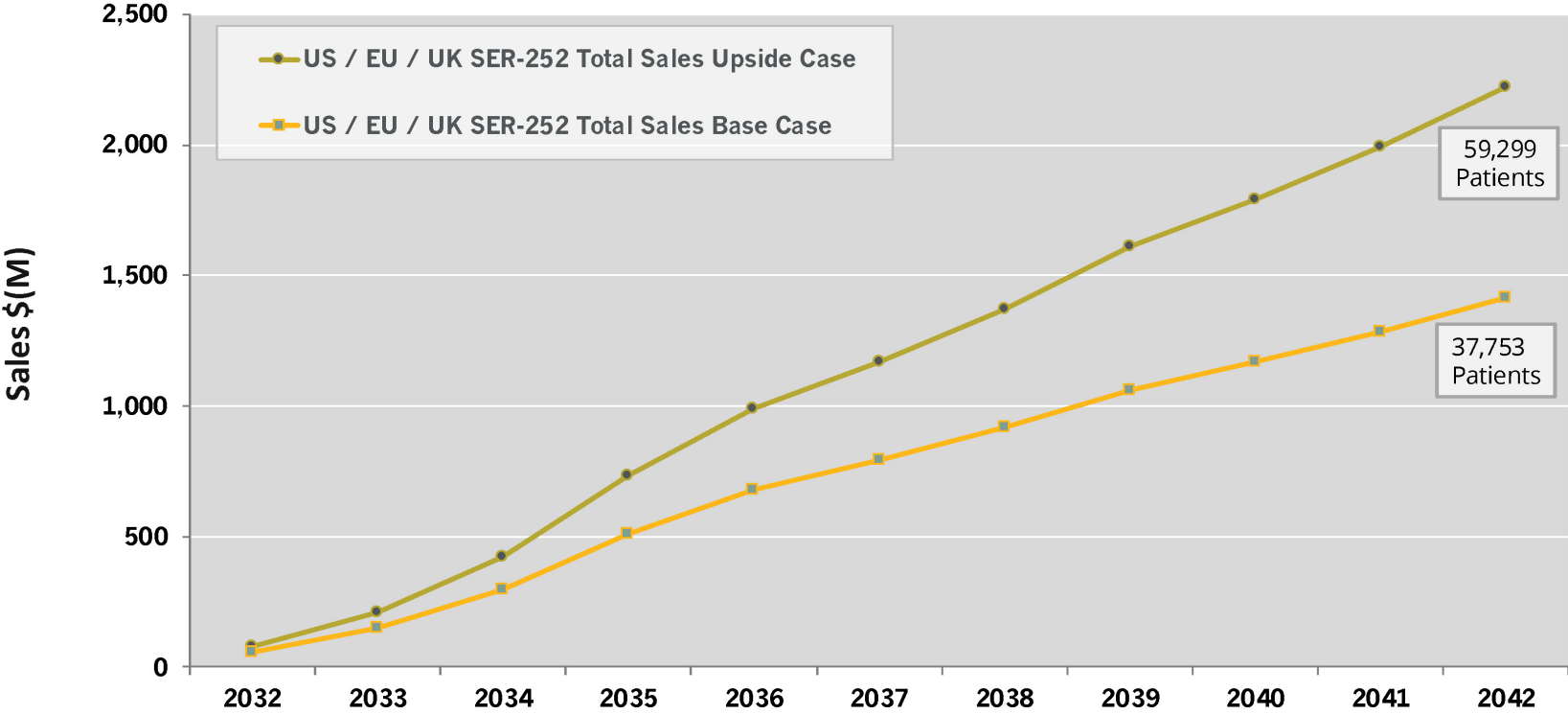


**Major Market Patients Inadequately Controlled With Current Electronic Device Therapies**

1. Parkinson's Foundation, accessed Mar 2024  
2. Roche Pharma Day Epidemiological Data 2022  
3. Various Analyst Reports from Oct 2019, Feb 2020, Dec 2023, Feb 2024  
4. Based on Globe Life Sciences Primary Research

# POZ Apomorphine has Blockbuster Potential

\$1.4B to \$2.2B Peak Sales Opportunity (US / EU / UK)



1. Globe Life Sciences Primary Research  
serina therapeutics

# Summary

SER-252 + enFuse represents a disruptive new treatment for advanced Parkinson's disease

- **POZ Technology**

- Non-immunogenic polymer that is safe, provides predictable pharmacokinetics in humans
- SER-252 is predicted to provide continuous dopaminergic stimulation (CDS) in advanced PD without skin reactions

- **Enable Injections' enFuse**

- The only purely mechanical large volume, on-body delivery system approved for subcutaneous delivery
- Utilization of a non-integrated, original container closure (vial) allows for flexible delivery, simplified drug development and speed to market



**Thank You**