EP-104, A NOVEL MICROPARTICLE FORMULATION ACHIEVING EXTENDED-RELEASE OF FLUTICASONE PROPIONATE

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CONTROLLED RELEASE SOCIETY
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INTEGRATING
Delivery Science
ACROSS DISCIPLINES

Forward Looking Statements

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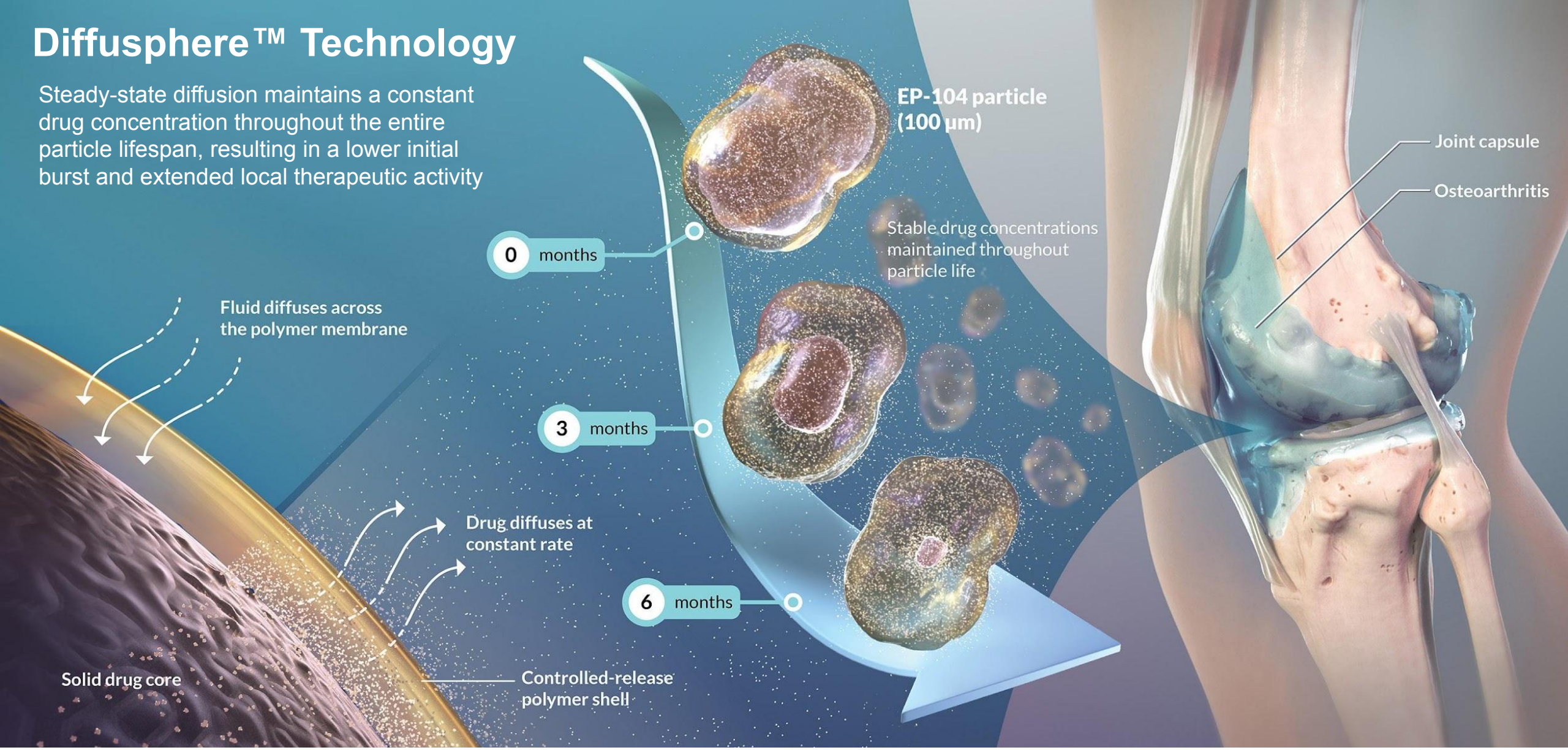
Disclosure Statement

- Paid executive and shareholder of Eupraxia Pharmaceuticals

Diffusphere™ Technology

Steady-state diffusion maintains a constant drug concentration throughout the entire particle lifespan, resulting in a lower initial burst and extended local therapeutic activity



Combined Effects of Diffusphere Technology *in vitro* and *in vivo*

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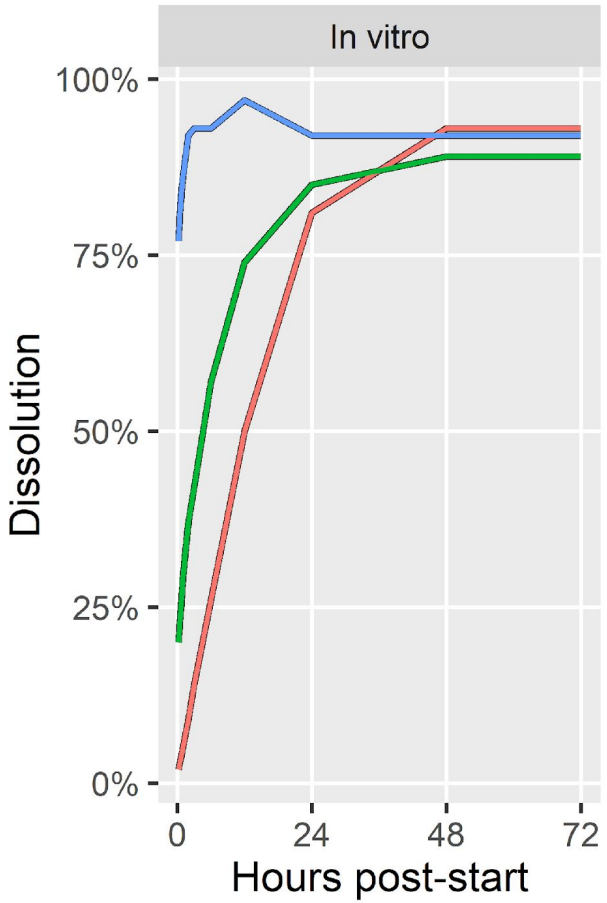

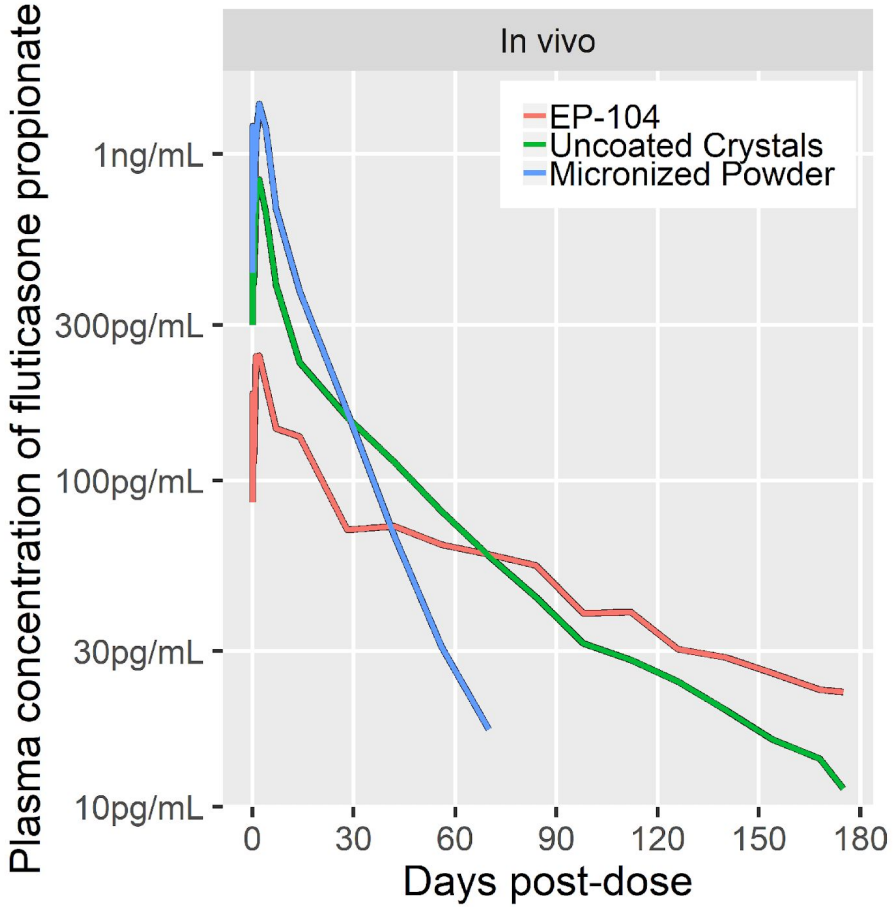

Phase 2b Study in Osteoarthritis
EP-104IAR

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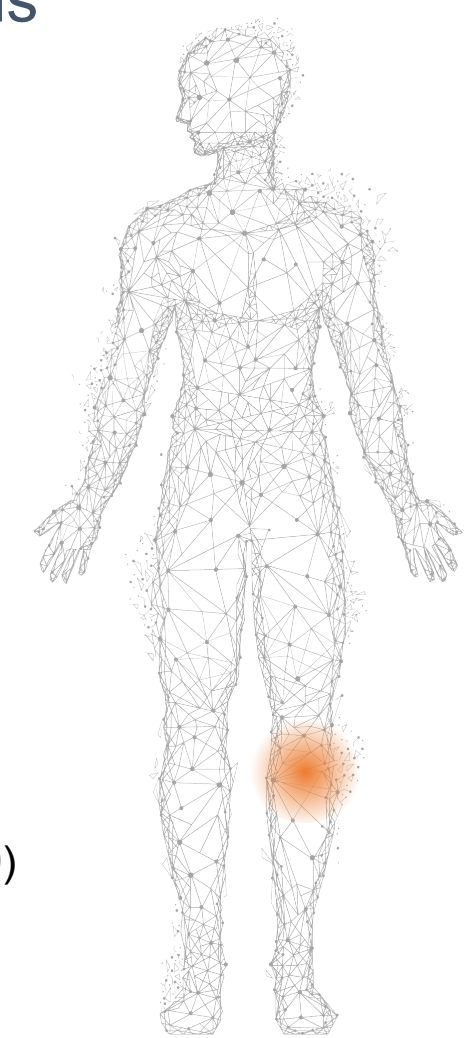
Study Design

- Double-blind, placebo-controlled
- Target 300 patients, 1:1 randomization
  - 80% power to detect 0.8-point change
  - Assumed 20% withdrawal rate
- 25 mg vs placebo (vehicle)
- 6-month follow-up
- Moderate OA (K-L Grade 2-3)
- Moderate to severe pain (WOMAC Pain 4-9)



Endpoints

Primary:

- Change in WOMAC Pain at Week 12

Key Secondary:

- Change in WOMAC Function at Week 12
- WOMAC Pain Area under the Curve (AUC) at Week 12
- Composite pain/function score (OMERACT-OARSI strict responders) at Week 12
- Change in WOMAC Pain at Week 24

Flat and Stable Pharmacokinetic Profile
EP-104IAR

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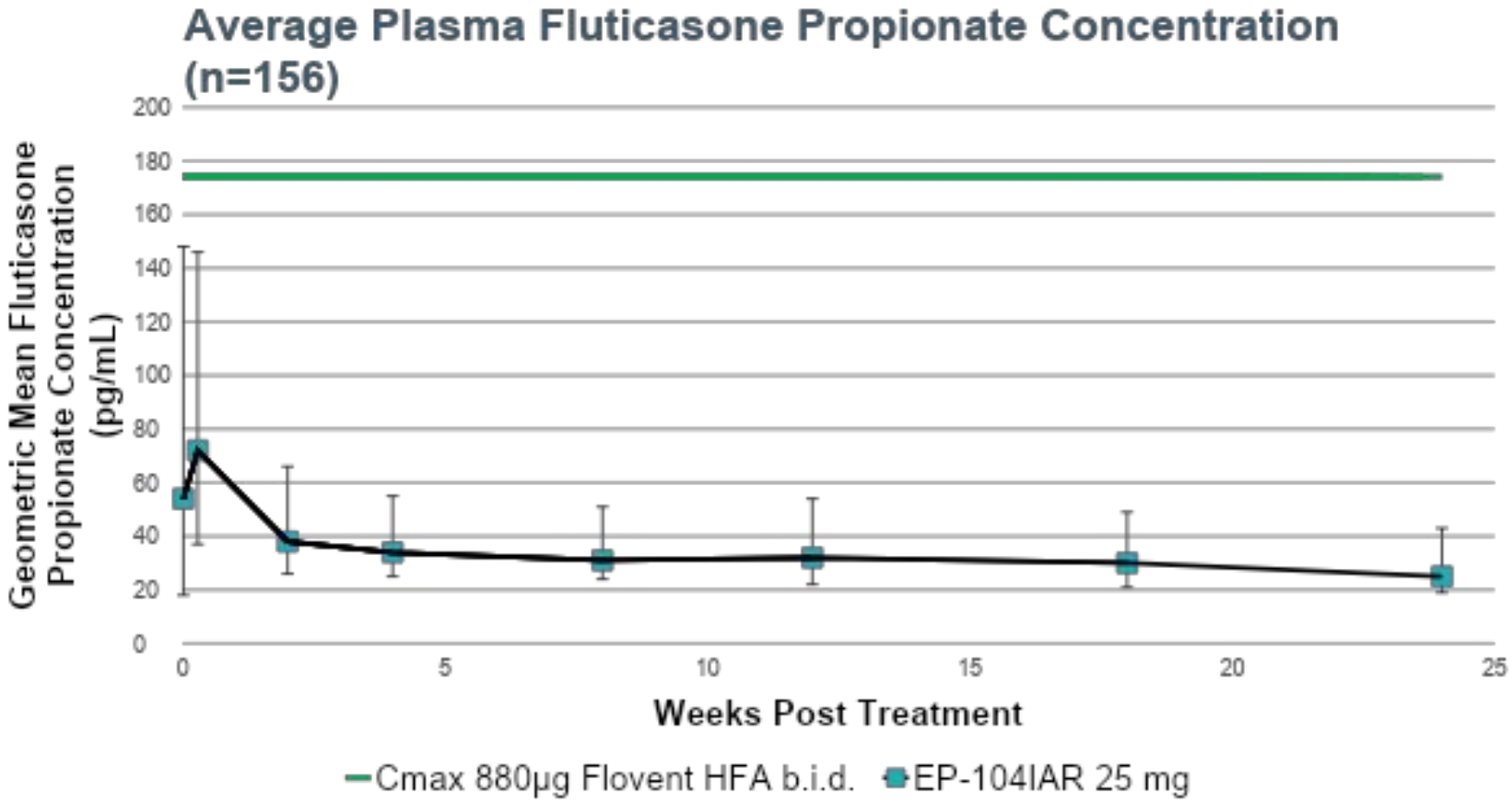

*Bars show inter-quartile range

Pharmacokinetics Facilitates Potential Prolonged Efficacy EP-104IAR

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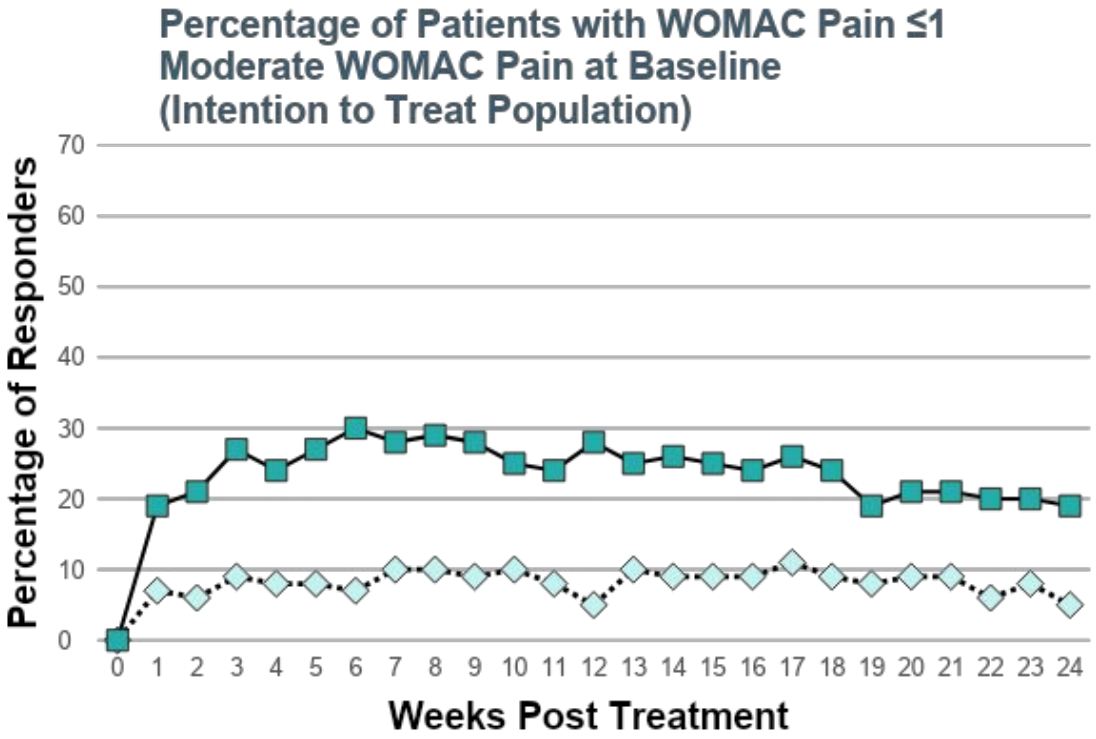
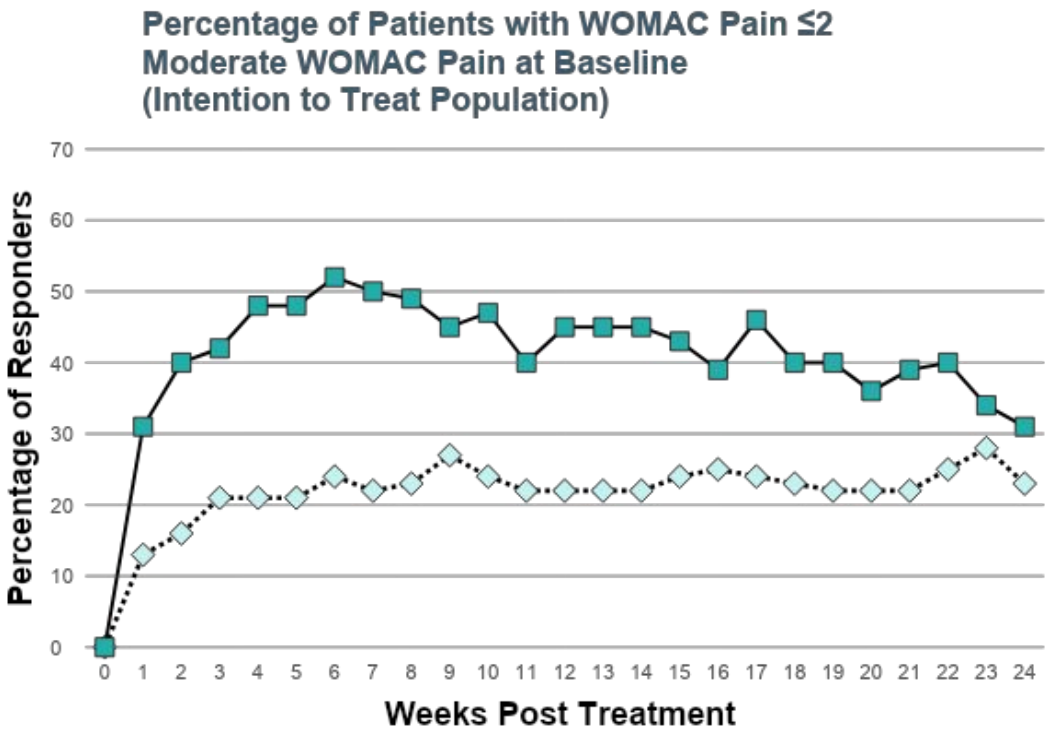
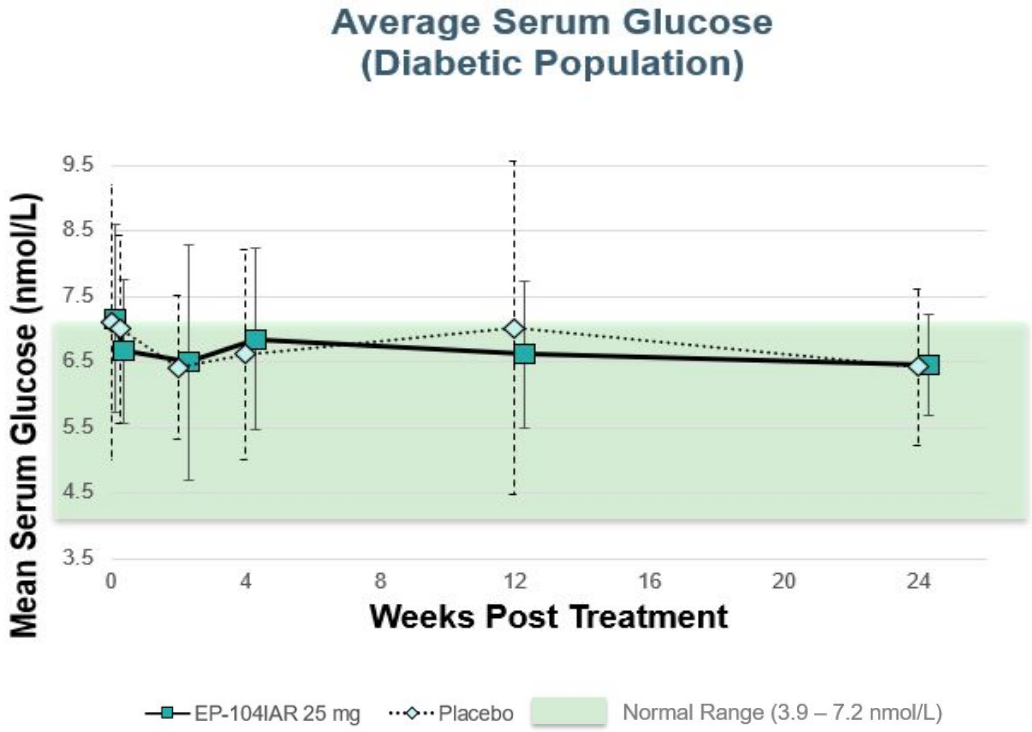




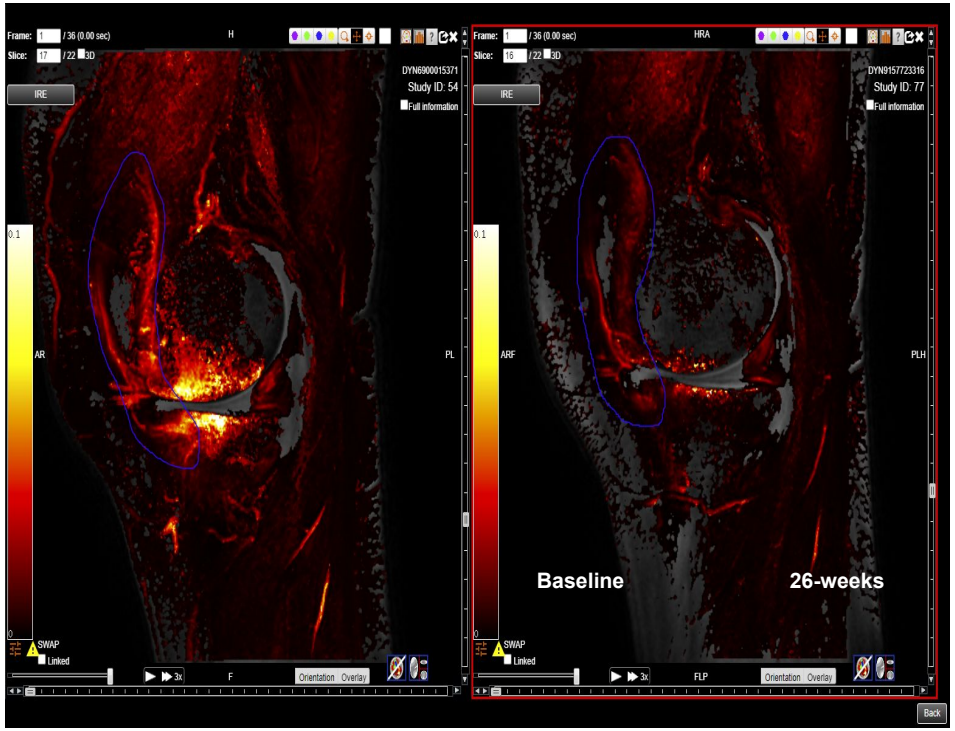
EP-104IAR 25 mg (p≤0.05) Placebo

Pharmacokinetics Facilitates Potential Enhanced Tolerability EP-104IAR

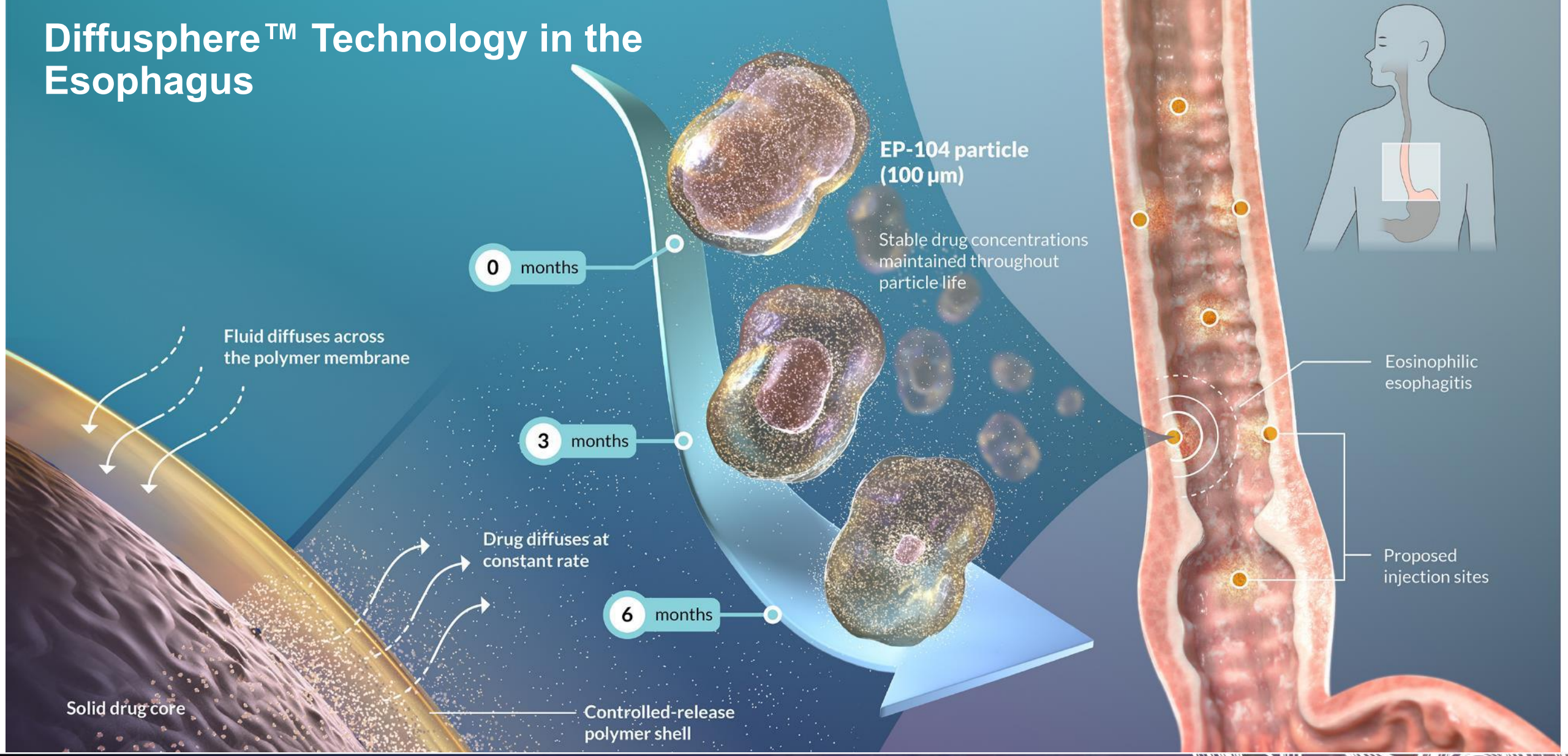


- 30% of OA patients are diabetics

Phase 2 MRI Data – reduced inflammation at 6 months

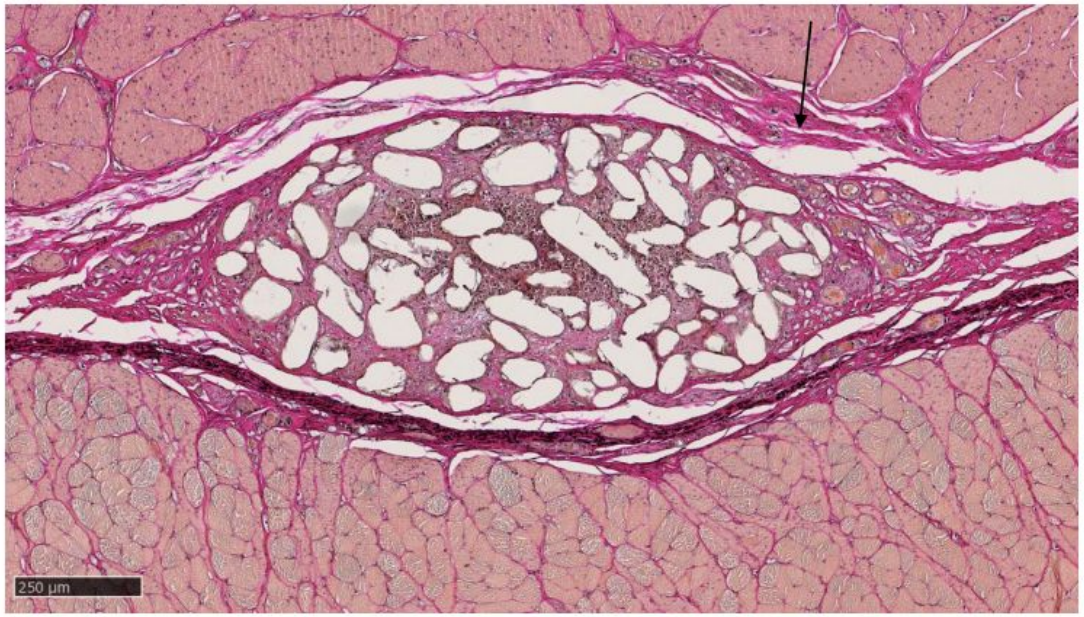


Diffusphere™ Technology in the Esophagus

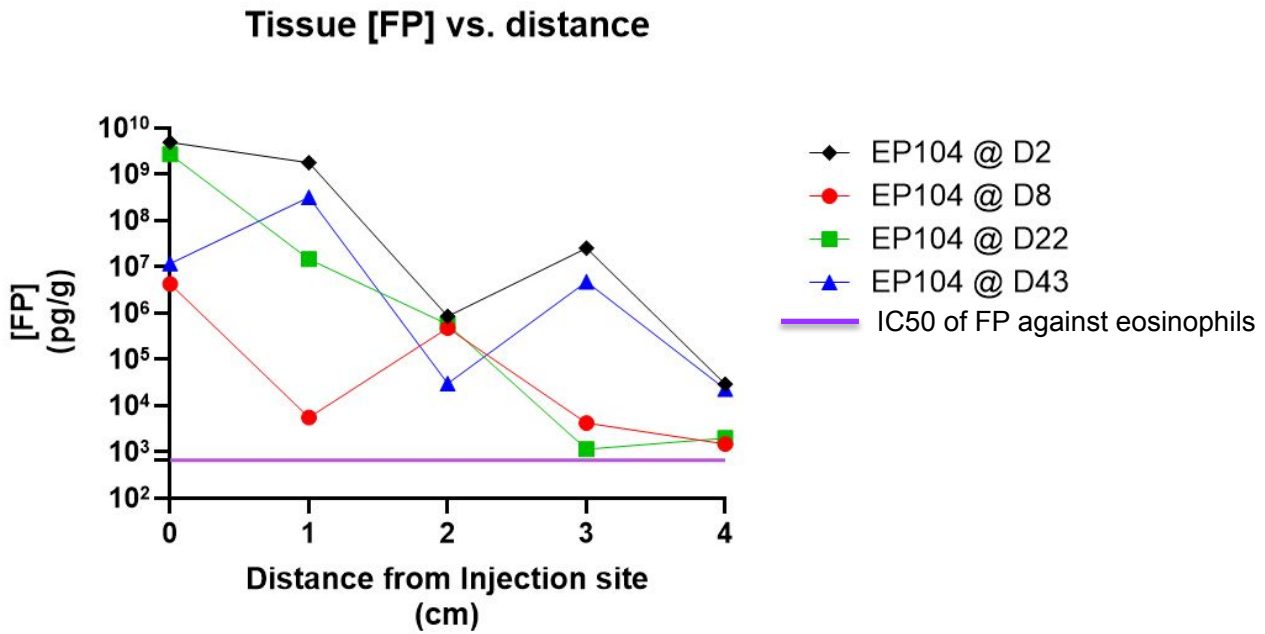


Pilot Swine PK and Tolerability Study
EP-104GI

Creation of an EP-104GI drug-releasing depot at each injection site



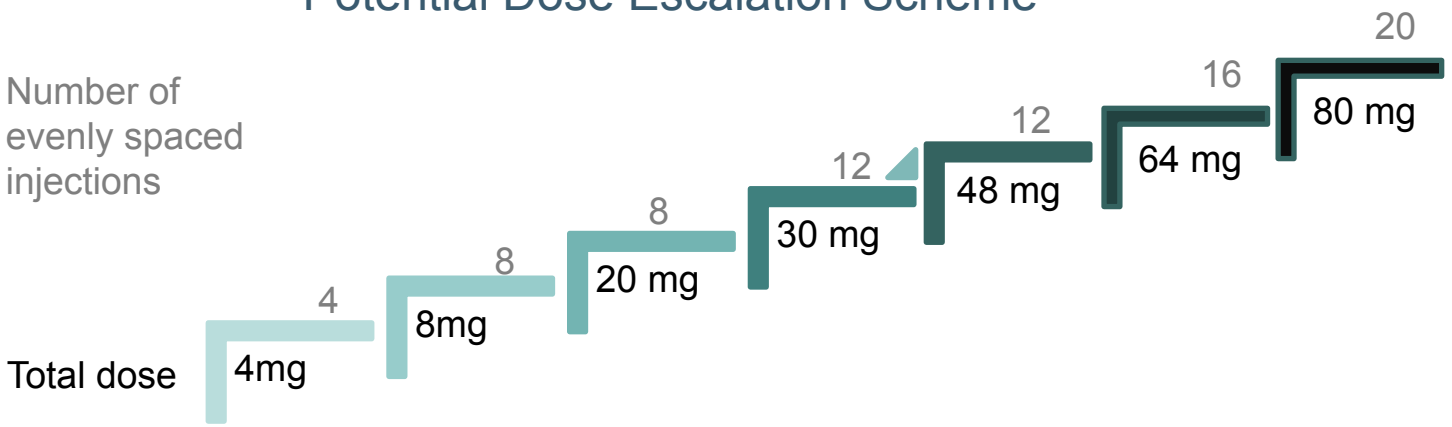
EP-104GI particles remaining at the injection site 6 weeks after injection

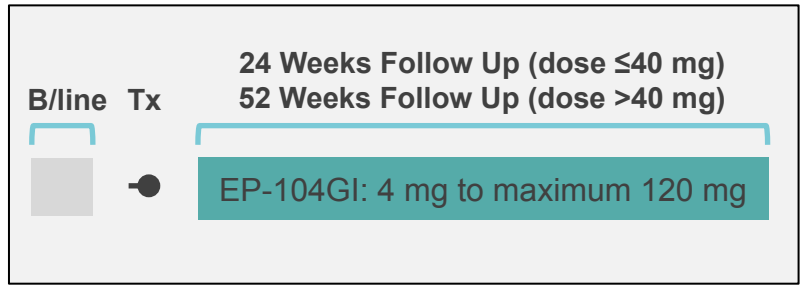


Resolve Phase 1b/2a Eosinophilic Esophagitis Trial: EP-104GI

Study evaluating reduction in eosinophils and improvement in function

Potential Dose Escalation Scheme





Key Features

- Un-blinded, open label
- Dose escalating either dose per injection site or number of injection sites
- Designed to provide favorable safety profile, efficacy and pharmacokinetics
- Sites in the Netherlands, Canada & Australia

Study Endpoints: Safety, PK and Efficacy

Primary Endpoints:

- Safety and tolerability of EP-104GI
- Pharmacokinetic profile of EP-104GI

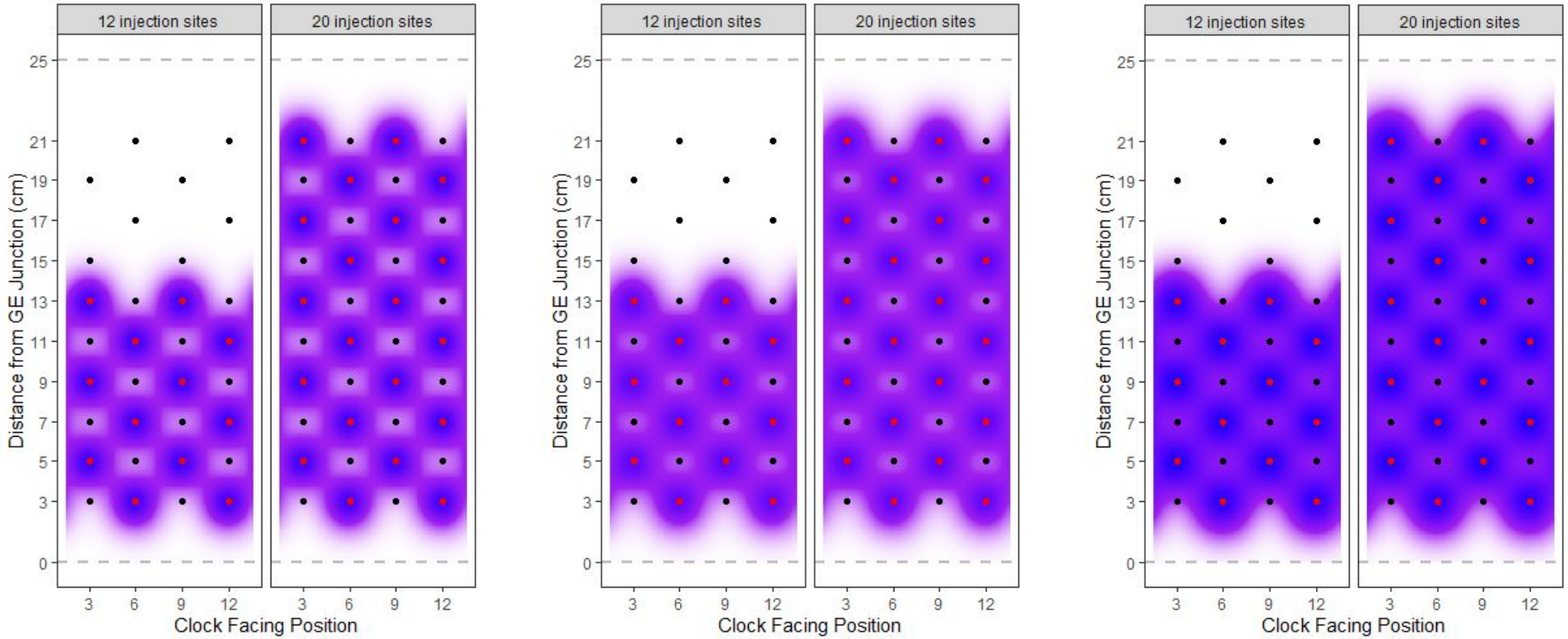
Secondary Endpoints: Disease Activity

- Histological response (eosinophil counts)
- Dysphagia (difficulty swallowing)
- Odynophagia (pain when swallowing)

Additional Endpoints:

- EoE endoscopic references scores (EREFS)
- EoE histology scores (EoEHSS)

Modeled Tissue Diffusion of Fluticasone EP-104GI

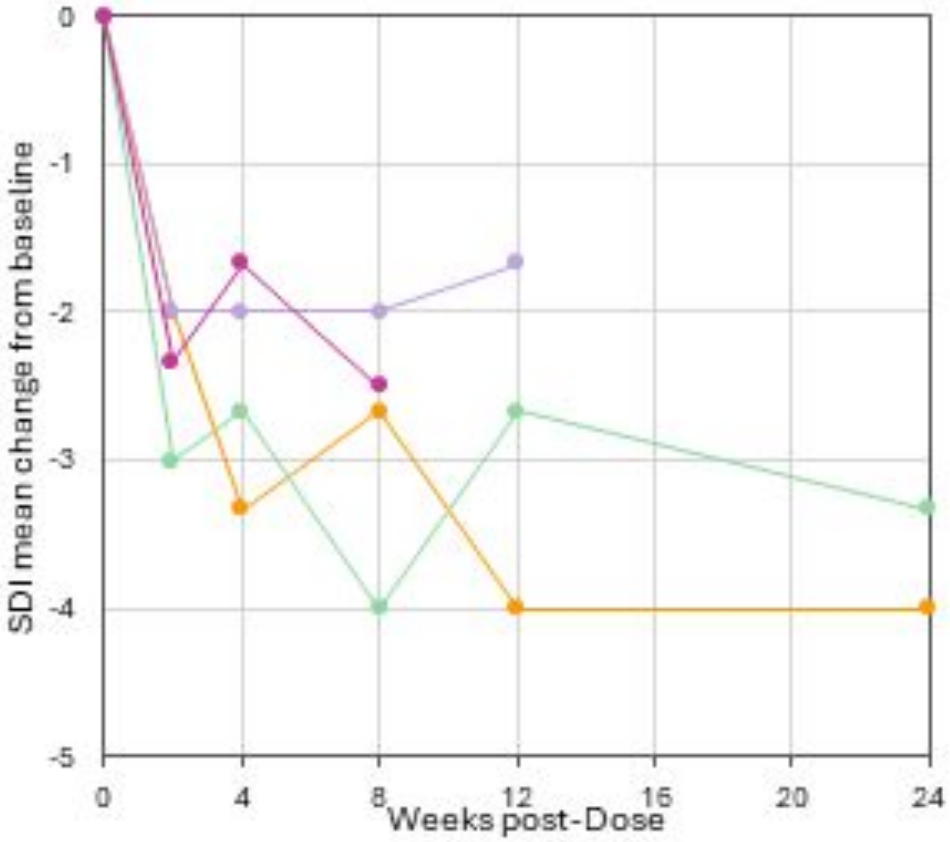


- Injection sites
- Biopsy sites

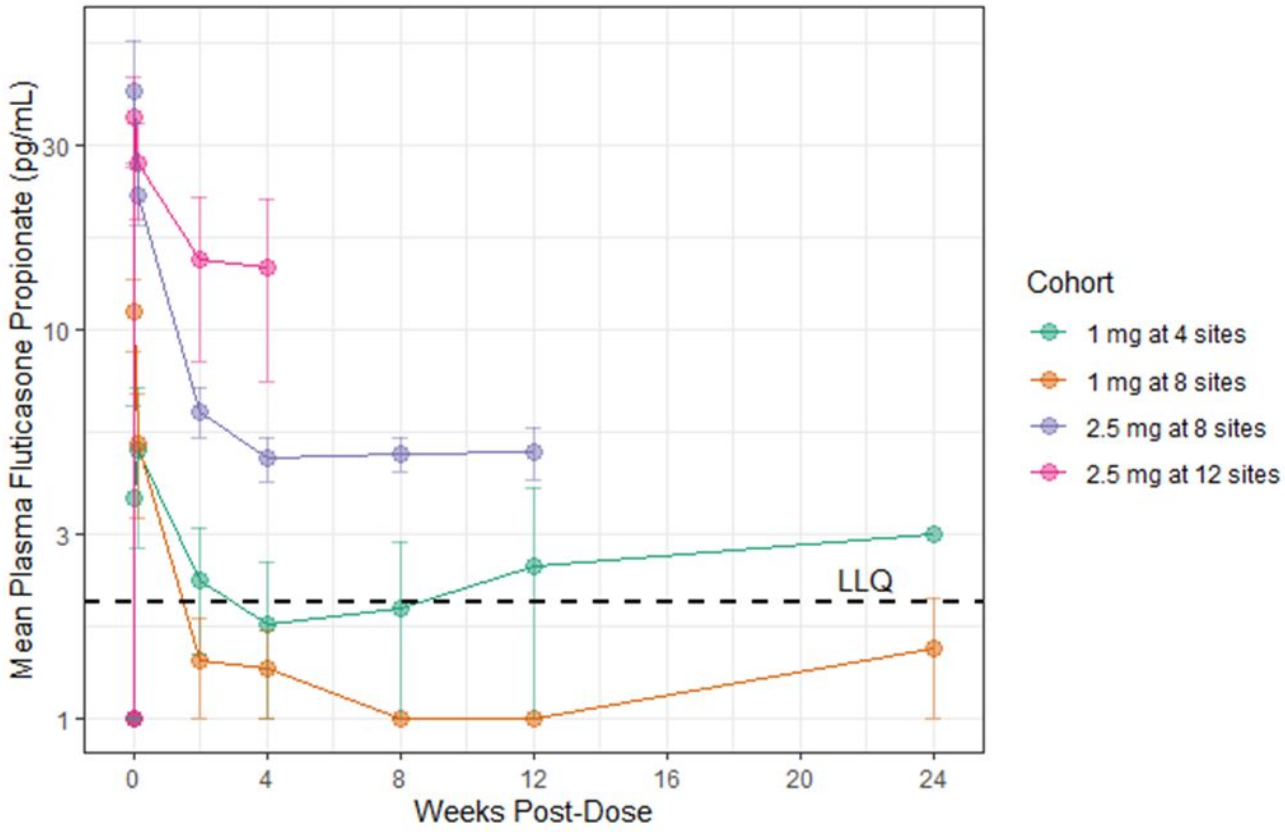
Increasing Dose

Efficacy and Pharmacokinetics
EP-104GI

Pain and difficulty swallowing scores



Plasma Pharmacokinetic Levels



Conclusions

- Diffusion-based microspheres showed pseudo-zero-order kinetic release in two different injection locations

- Observed PK correlated with potential for prolonged efficacy, local and systemic tolerability

- Potential for development of microspheres with new APIs to support other indications

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Thank you!