

scPharmaceuticals

**Wedbush PacGrow Healthcare Conference
August 14, 2019**

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About scPharmaceuticals

Advancing patient care and reducing healthcare costs through innovative subcutaneous delivery

- Leveraging approved drugs with well-known efficacy and safety profiles through subcutaneous delivery of hospital-based/in-patient IV drugs
- Two late-stage programs in large markets utilizing 505(b)(2) pathway
 - Heart failure (HF)
 - FUROSCIX® NDA expected 2020
 - Broad spectrum antibiotics
 - Ceftriaxone NDA expected 2021
- High barriers to competitive entry
 - Patent coverage of drug formulation and methods of treatment until 2034
- Ended 2Q19 with cash of \$79.6; 2019 quarterly burn of \$8-10M

Large unmet need in heart failure

Lead program targets heart failure – a large global market opportunity with a clear value proposition

- Prevalence of HF is 6.5 million adults in the US¹
 - 10.5 million adults in the G7²
- In the US ~3.7 million HF events occur annually^{1,3}
 - Congestion is the most common reason for hospitalization and patients seeking medical care⁴
- \$8B total addressable market opportunity in the US
- HF patients represent 33% (\$123B) of annual Medicare Part A and B spending⁵
- Potential for significant cost reductions for payers and hospitals by reducing patient hospital admission/readmission rates

1. Circulation 2018, Benjamin 2. Decision Resources 2014 Cardium report, note: G7=US, Germany, France, UK, Italy, Spain, Japan 3. Data on file; calculation from market research 4. Mullens W, et al. [Eur J Heart Fail.](#) 2019 Feb;21(2):137-155. 5. Cost Burden of Worsening Heart Failure in the Medicare fee for service population, Milliman, 2017

Cycle of decompensation and hospitalization is the primary burden for patients suffering from HF



1. HCUP National Inpatient Sample (NIS), 2014, Agency for Healthcare Research and Quality (AHRQ) based on ICD-9 codes
2. scPharmaceuticals data on file: Decision Resources HF landscape and Forecast December 2016

Segmenting HF patients

Target HF patient population

Stable

Patient is not symptomatic - i.e. little to no edema, able to breathe normally and weight is in line with the patient's dry or ideal weight on usual diuretic dose

Pre-Acute

Patient has worsening symptoms-gained 2-4lbs over a short period of time, has mild to moderate dyspnea and edema, is in need of an increase in diuretic therapy

Acute

Patient is acutely decompensated, needs immediate IV diuretic therapy

Post-Acute

Patient has had a recent decompensation, but is no longer acutely decompensated. The patient may not be back to their dry weight yet. This patient may be being discharged from the hospital or may be seen in the clinic in a follow-up visit to a IV treatment

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A New Model of Treating Heart Failure – FUROSCIX®

FUROSCIX – a drug-device combination product

- Drug: scFurosemide
 - Proprietary formulation of furosemide
 - Furosemide is the most widely used oral and parenteral diuretic in treatment of edema associated with congestive heart failure
 - Physiologic pH formulation
 - Pre-filled, Crystal Zenith® cartridge
- Device: On-Body Infusor
 - SmartDose® Gen II 10 mL on-body delivery system
 - Developed to deliver fixed dose of 80mg of scFurosemide subcutaneously through a pre-programmed, biphasic delivery profile with 30 mg administered over the first hour, followed by 12.5 mg/hour for the subsequent 4 hours
- Completed preliminary feasibility studies with SmartDose drug delivery system

FUROSCIX delivery system incorporates an easy-to-use On-Body Infusor

Incorporates West Pharmaceutical Services, Inc.'s ("West") SmartDose platform technology

This platform technology has been previously approved by FDA and EMEA as part of a combination product

- Single-use, pre-filled cartridge
- Visual, tactile, and audible feedback
- Electromechanical drive
 - Delivery volume up to 10mL
- Pre-programmable injection time
- Patient-centric design
- Wireless connectivity



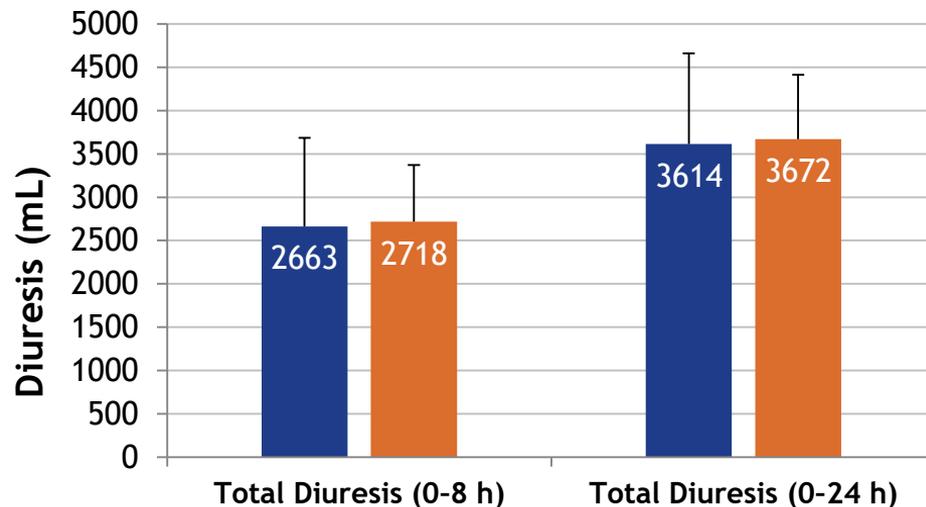
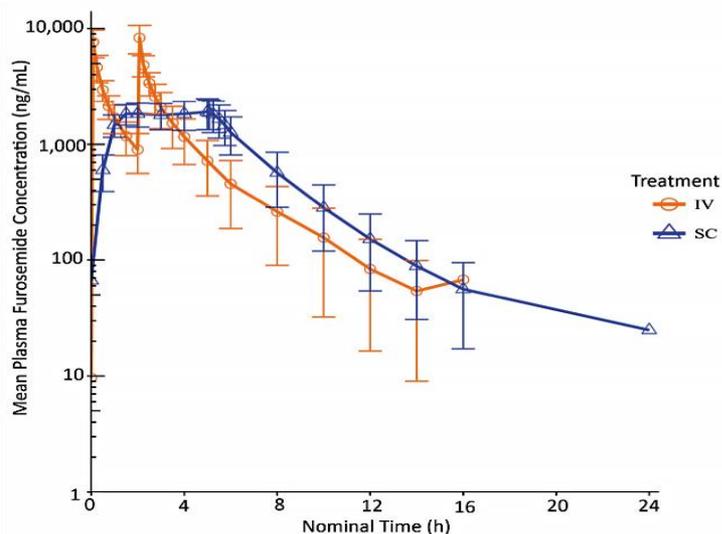
FUROSCIX – Path forward for resubmission

Anticipate the resubmission of FUROSCIX NDA with the U.S. Food and Drug Administration (FDA) by mid-year 2020

- Type C Meeting with the FDA held on June 18, 2019
 - FDA does not believe additional clinical safety, efficacy, or pharmacology studies will be required to support NDA resubmission and review
 - NDA resubmission under the current NDA
- Completed first of two human factor studies supporting the new FUROSCIX Infusor
 - Studies designed to assess and optimize user interaction with the FUROSCIX Infusor

Pivotal study demonstrated drug exposures and diuresis comparable to IV furosemide

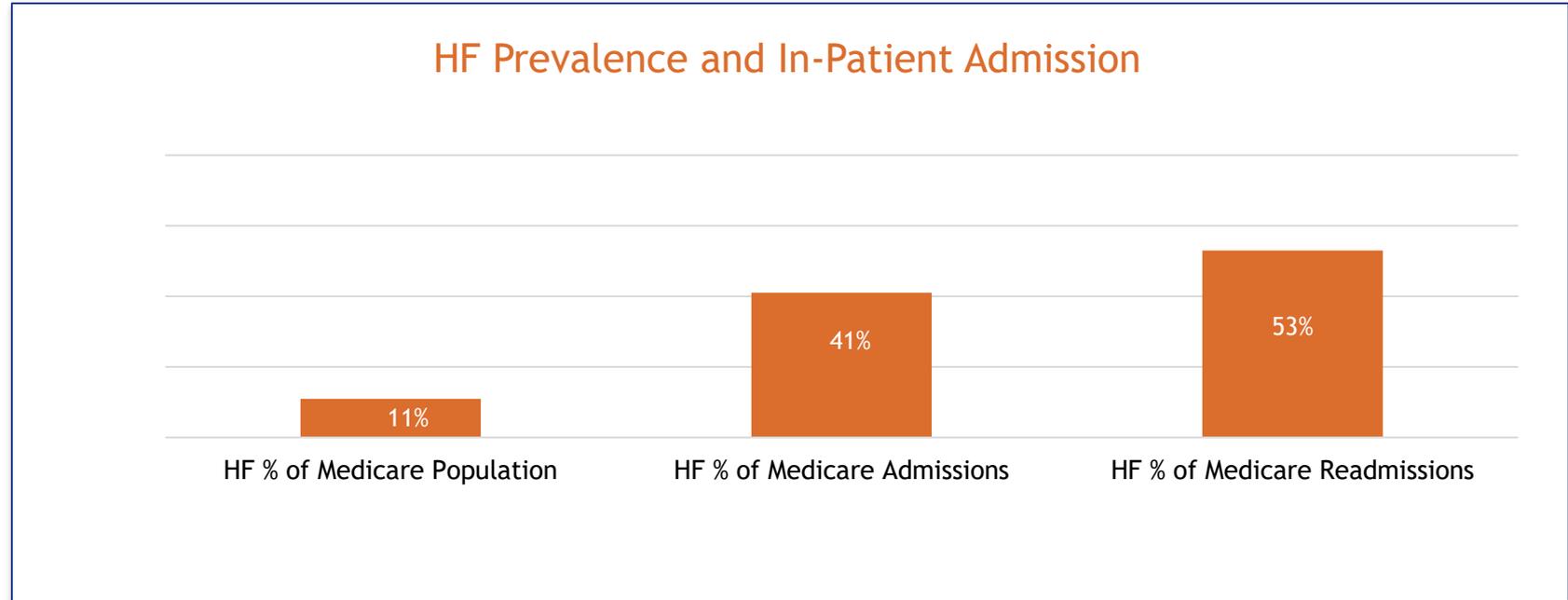
- Administered via B-Braun pump
- Subcutaneous: 80 mg over 5 hours
- Intravenous: 40 mg x 2 doses over 2 hours



Sica, D. A., de Boer, R. A., & Pitt, B. (2018). Subcutaneous Furosemide in Heart Failure: Pharmacokinetic Characteristics of a Newly Buffered Solution. *JACC Basic Transl Sci.* doi:10.1016/j.jacbt.2017.10.001

FUROSCIX Value Proposition

Heart failure patients present a significant burden to Medicare



59% of admissions directly attributed to volume overload¹

1. Bennett S, et al. American Journal of Crit Care. 1998;7(3):168-174*

Stakeholders are aligned on the need to reduce the number of HF hospitalizations and treatment costs



Payer

- Average cost to Medicare for a HF admission is \$11,840¹
- HF is top condition targeted by CMS readmission reduction initiative²
- HF will be moving to Medicare Quality Payment Program in 2019³



Hospital and HCP

- Average length of stay is 5.2⁴ days with DRG only reimbursing 3.9 days⁵
- Increased financial exposure for providers based on readmission penalty risk
- HF in-patient care represents multi-million dollar loss for targeted hospitals

1. Fitch K, et al (2017) The cost burden of worsening heart failure in the Medicare fee for service population: an actuarial analysis [white paper]

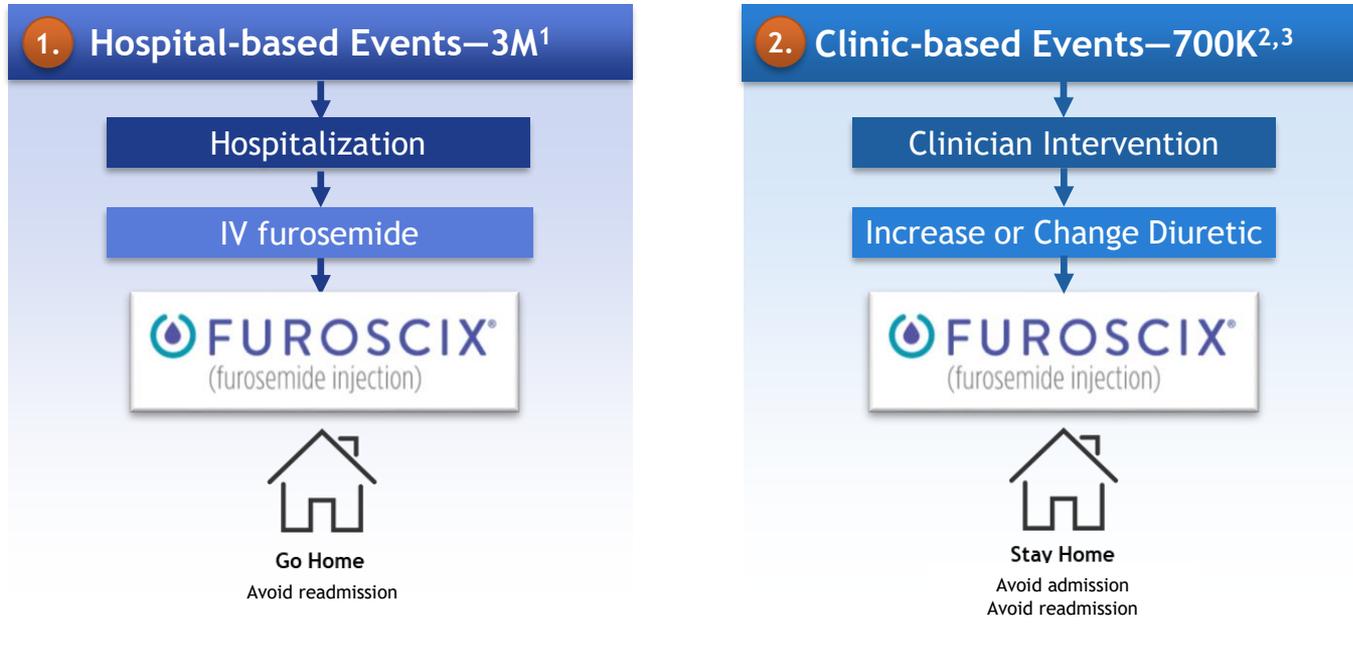
2. Readmission Reduction Program (HRRP) (updated 2018, April 27) Retrieved from <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html>

3. Quality Payment Program from CMS <https://qpp.cms.gov/>

4. Agency for Healthcare Research and Quality (AHRQ). HCUP National Inpatient Sample (NIS), 2014

5. scPharmaceuticals. Data on File. CMS. 2014 data based on DRGs, Table 5: List of MS-DRGs, relative weighting factors and geometric and arithmetic mean length of stay

Target patient is well identified and represents a large outpatient opportunity

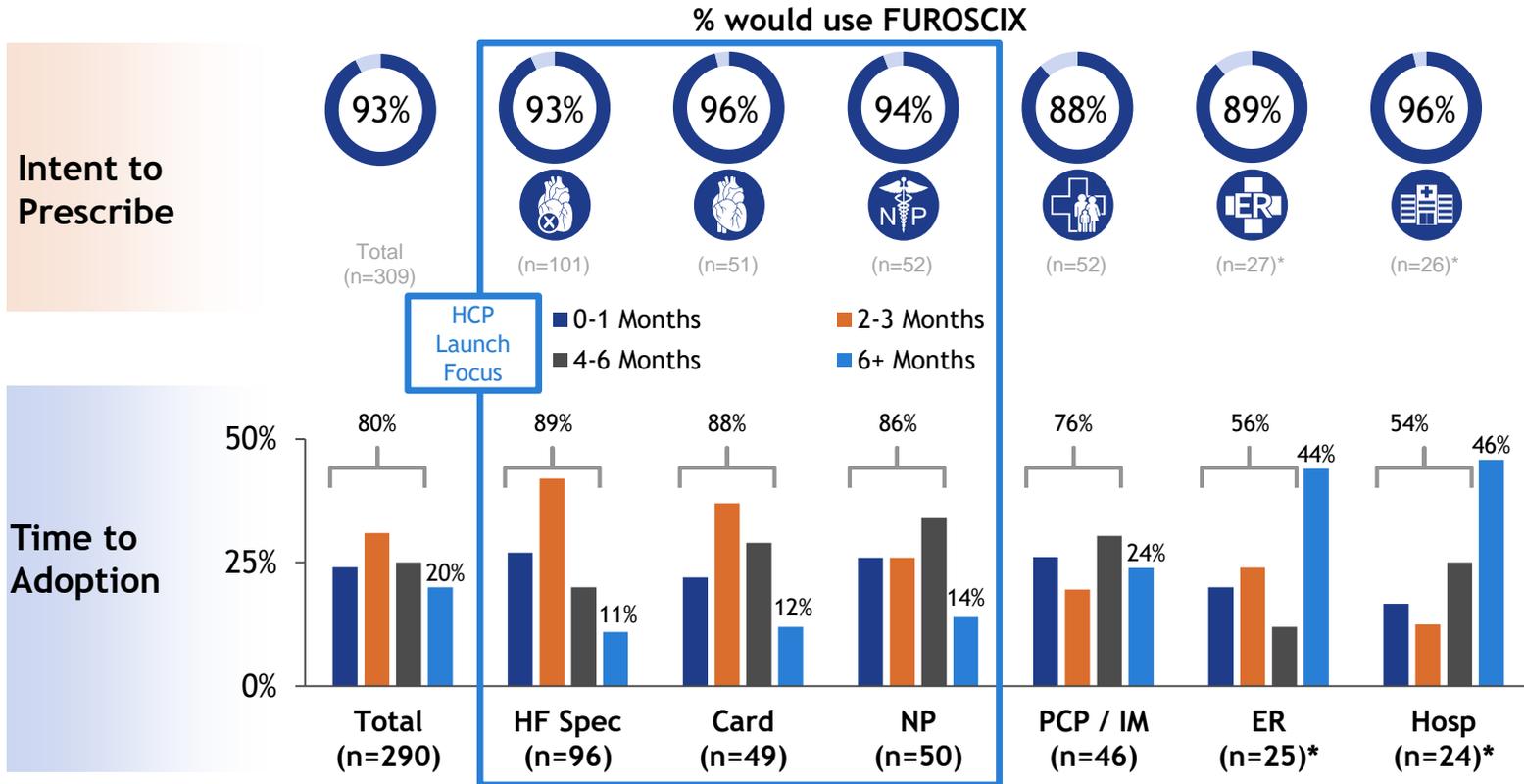


1. Decision Resources HF landscape and Forecast Dec 2016 adjusted HCUP all listed 2014 number down based on chart abstraction, KOL interviews, and ARIC study

2. Benjamin E, et al. Circulation. 2017;135:e146-e603

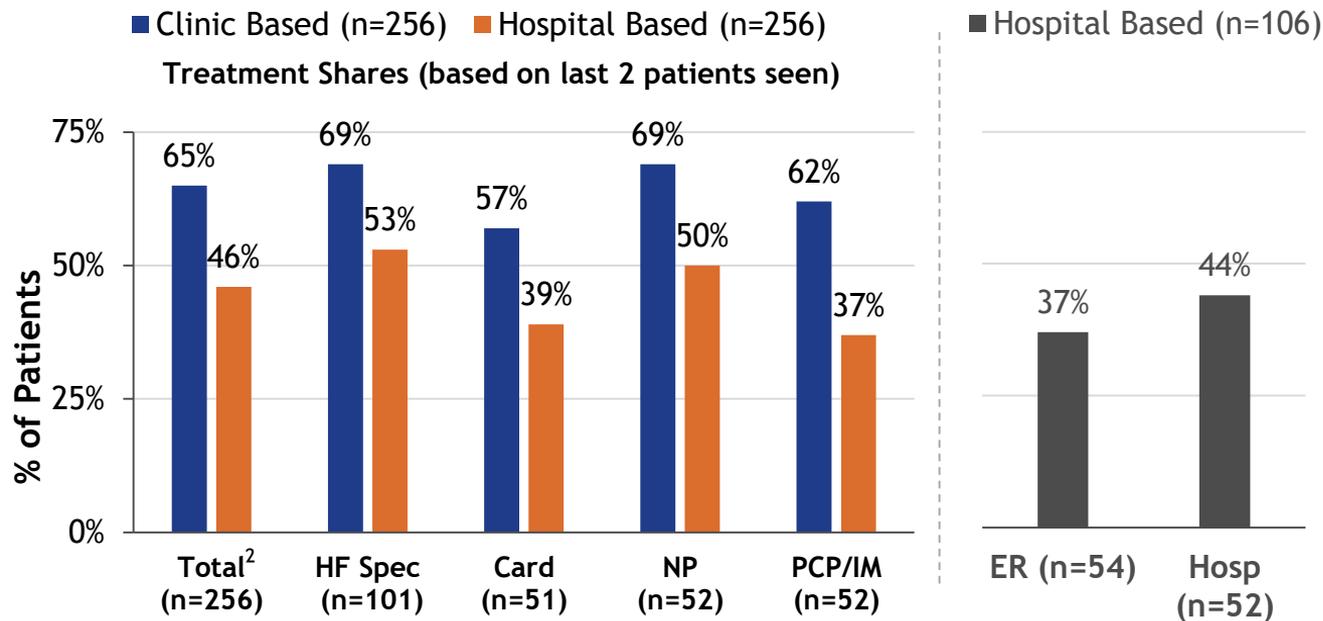
3. Data on file; calculation from market research

HCPs have a high willingness to prescribe FUROSCIX and a rapid time to adoption



1. scPharmaceuticals data on file: Reason Research quantitative study (n=309 HCPs)

FUROSCIX HCP research—treatment share¹

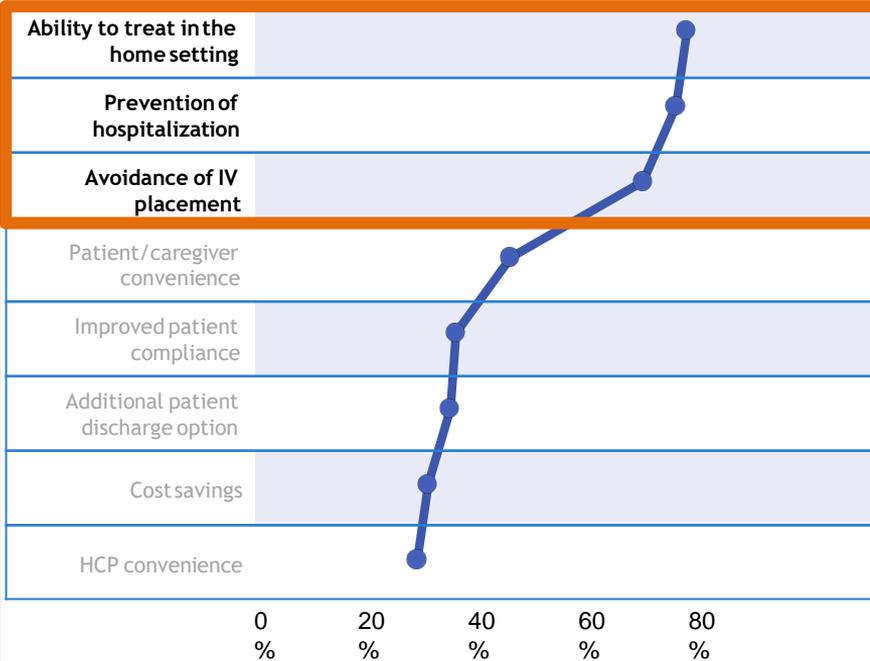


1. scPharmaceuticals data on file: Reason Research quantitative study (n=309 HCPs)

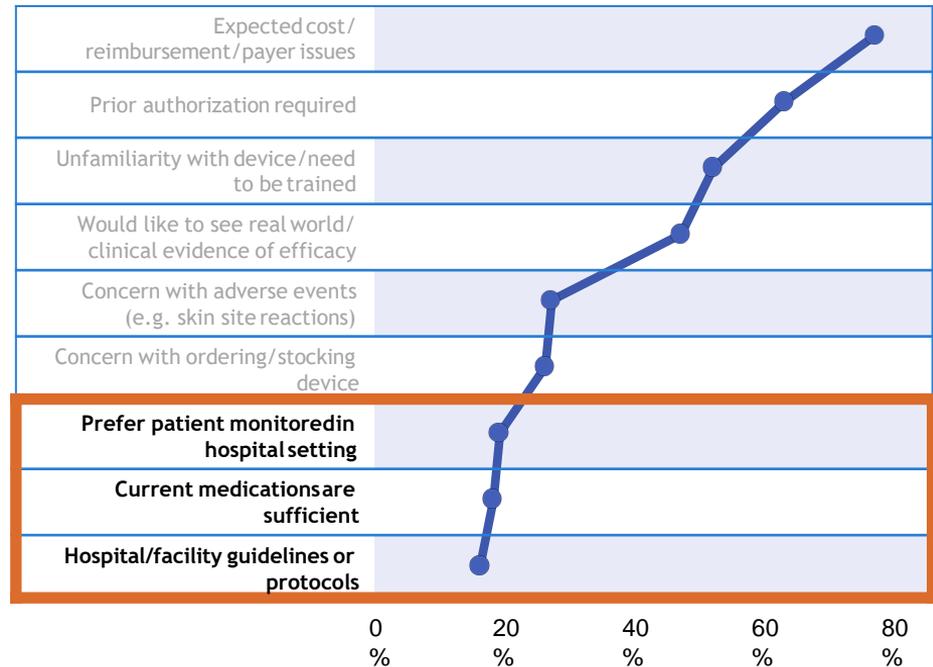
2. Total = HF Spec, Card, NP and PCP/IM patients; No ER or Hospitalist/ER and Hospitalists were only asked about their last 2 patients, while HF Spec, Cards, NPs, and PCP/IM were asked for their last pre-acute and last post-acute patient/Q71. Assume Product X were available (without insurance coverage issues) for long enough for you to begin prescribing. If you were to treat adult patients with fluid overload with the same characteristics as your last Pre-Acute Patient and your last Post-Acute Patient/Patient 1 and Patient 2, would you change your previous treatment choice to Product X?

HCPs clearly identify advantages of FUROSCIX and believe it has the ability to improve HF treatment

What are the advantages of FUROSCIX®?



What are the barriers to adopting FUROSCIX® ?



Reason Research Quantitative study (n=309 HCPs)

Highly concentrated hospital targets

Hospital Account Universe

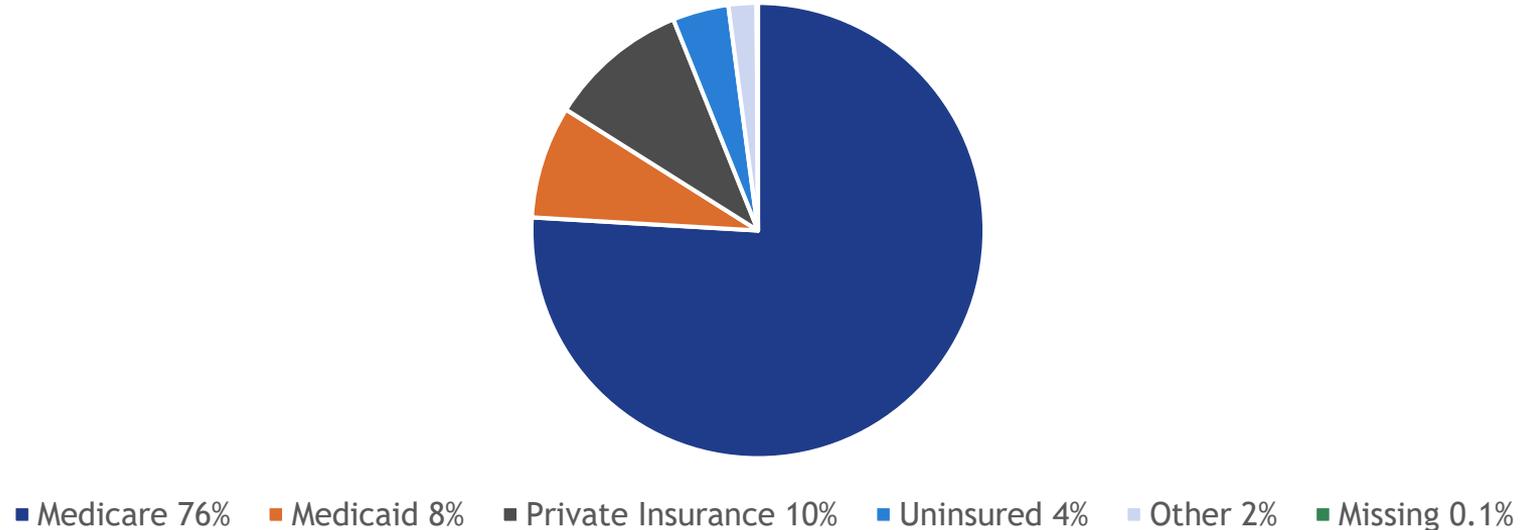
IV Furosemide Segment	Number of Accounts*	Total IV Doses
High / Very High	349	7,041,506
Medium	473	3,515,214
Low / Very Low	22,565	7,032,129
Total	23,387	17,588,849

Launch Target

Coverage of 349 hospital accounts, representing 40% of the annual IV doses, will require a specialty sales force of approximately 40 representatives

FUROSCIX provides a clear value proposition to payers

Payer Mix for Heart Failure Patients (2013)¹



FUROSCIX Value: Reduction in PMPM costs when FUROSCIX is utilized

1. HCUP National Inpatient Sample (NIS), 2013, Agency for Healthcare Research and Quality (AHRQ)

FUROSCIX life cycle management and development planning

- Enhancing FUROSCIX to continually improve the patient experience
 - Prefilled cartridge with West
 - Potential with device and drug development to shorten infusion time
 - Potential with higher concentration to create future dose flexibility
- Increasing barriers to entry
 - Patent application for concentrated furosemide formulation could extend protection through 2040

80 mg
10 mL
5-hour Infusion

80 mg
10 mL
Shortened (≤ 2 hrs) Infusion

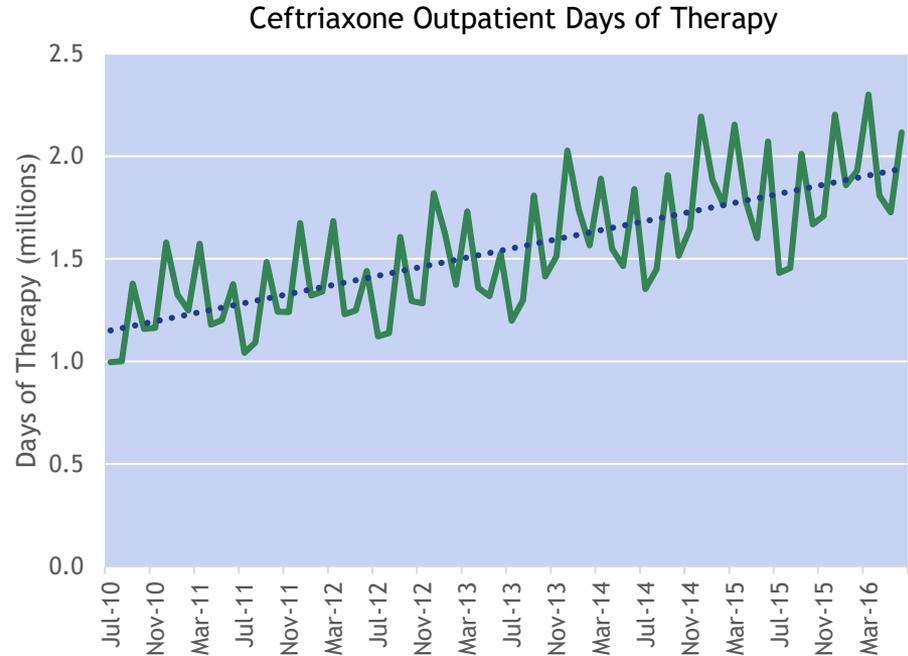
Higher Concentration
80 - 160 mg
Fixed Dose

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Anti-infective Program

Subcutaneous delivery of ceftriaxone has the potential to transform the outpatient antibiotic market

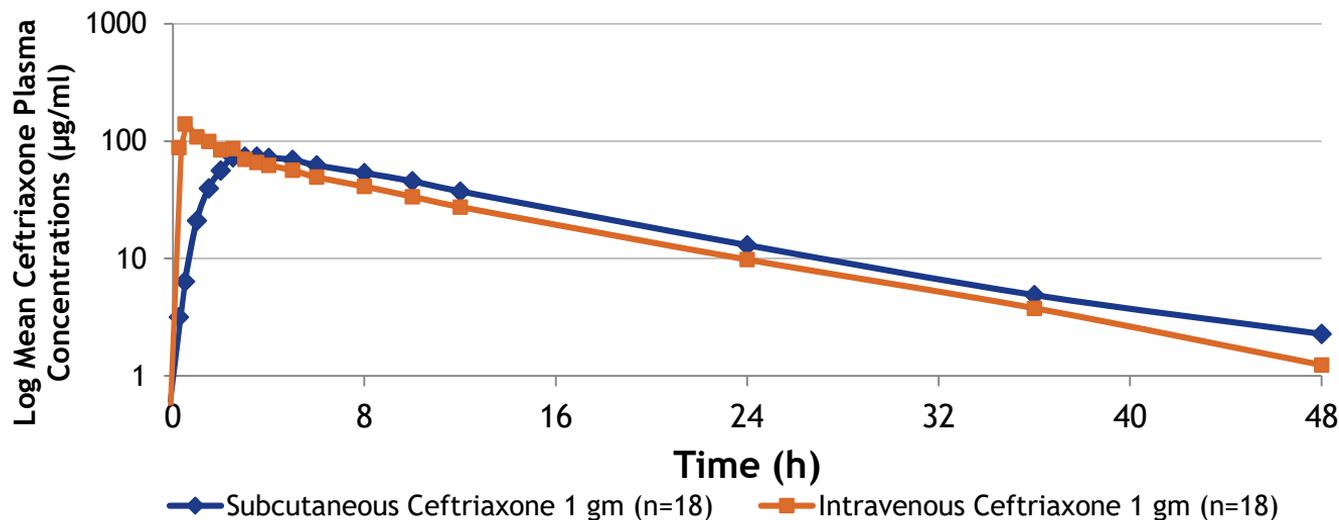
- ~15 million US ceftriaxone doses^{1,2} in outpatient setting projected for 2021
- \$4.5B total addressable market opportunity in the US projected for 2021
- Clear clinical and economic value proposition
 - Eliminate the reliance on intravenous catheters/PICC lines
 - Avoid the need for coordination of home infusion services which often delays discharge
 - Provide patients an alternative to hospitalization or driving to an infusion center daily
 - Alternative to suboptimal oral agents (fluoroquinolones)
- Subcutaneous option benefits multiple stakeholders: patients, hospitals, physicians, payers



1. IMS Health data (July 2015-June 2016); 2. Decision Resources AMR data 2016

Pivotal study confirms scCeftriaxone comparable to IV

- Similar drug exposures (AUC 0-∞) between IV ceftriaxone and scCeftriaxone
- Complete bioavailability (107.7%) with subcutaneous administration
- Pharmacodynamic profile (%T>MIC24) of scCeftriaxone is non-inferior to IV infusion



US NDA submission expected 2021

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Corporate Summary

Opportunity summary

- Pipeline includes products with large global market opportunity
 - FUROSCIX represents \$8B addressable US opportunity
 - scCeftriaxone represents \$4.5B addressable US opportunity in 2021
- Clear value proposition
- Established reimbursement model
- 505(b)(2) regulatory pathway
- High barriers to entry
 - Provisional patent of FUROSCIX filed that would extend protection through 2040

Alignment of patients/caregivers, HCPs and payers in a life science innovation that can transform and reduce cost of care

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CEO, scPharmaceuticals

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Thank you