NASAL NALOXONE

(PRODUCT UNDER DEVELOPMENT)

SEAMUS MULLIGAN

CHAIRMAN & CEO

About Adapt

Our Commitment

Sole focus development of an accessible option to treat opioid overdose

To serve as a responsible and innovative business focused on patients

What That Means

Development of an FDA approved easy to administer naloxone nasal spray

Price responsibly to support broad access

Collaborate with public/private stakeholders who are focused on Common Goal

Common Goal

Help reduce mortality and morbidity from opioid overdose

HHS Initiative in Response to Epidemic

Opioid overdose related death and hospital visits have reached alarming levels

Naloxone to play a role in HHS opioid overdose initiative[1]

- **Opioid Prescribing Practices** to reduce opioid use disorders and overdose
- Expanded use and distribution of **Naloxone**
- Expansion of **Medication-assisted Treatment (MAT)** to reduce opioid use disorders and overdose

(1) HHS ASPE Issue Brief March 26 2015

NALOXONE: OPIOID OVERDOSE TREATMENT

Naloxone has been FDA approved for over 44 years [1]

Naloxone is the standard treatment for opioid overdoses[2]

Naloxone is only FDA approved in injectable formulations[1]

(1) Accessdata.fda.gov: Narcan NDA 016636 approved April 1971 (2) FDA News Release April 3 2014 FDA approves new hand-held auto-injector to reverse opioid overdose; (3) Electronic Orange Book search "naloxone"

Many Voices Are Calling For Naloxone

ADAPT PHARMA

HHS[1]

"FDA has encouraged innovations in more user friendly naloxone delivery systems […] for lay use outside of health care settings."

Physicians[2]

"AMA encourages physicians to co-prescribe naloxone to their patients at-risk who are taking opioid analgesics."

Community Groups[3]

"It is essential that naloxone be available across all community sectors reaching all those potentially at risk."

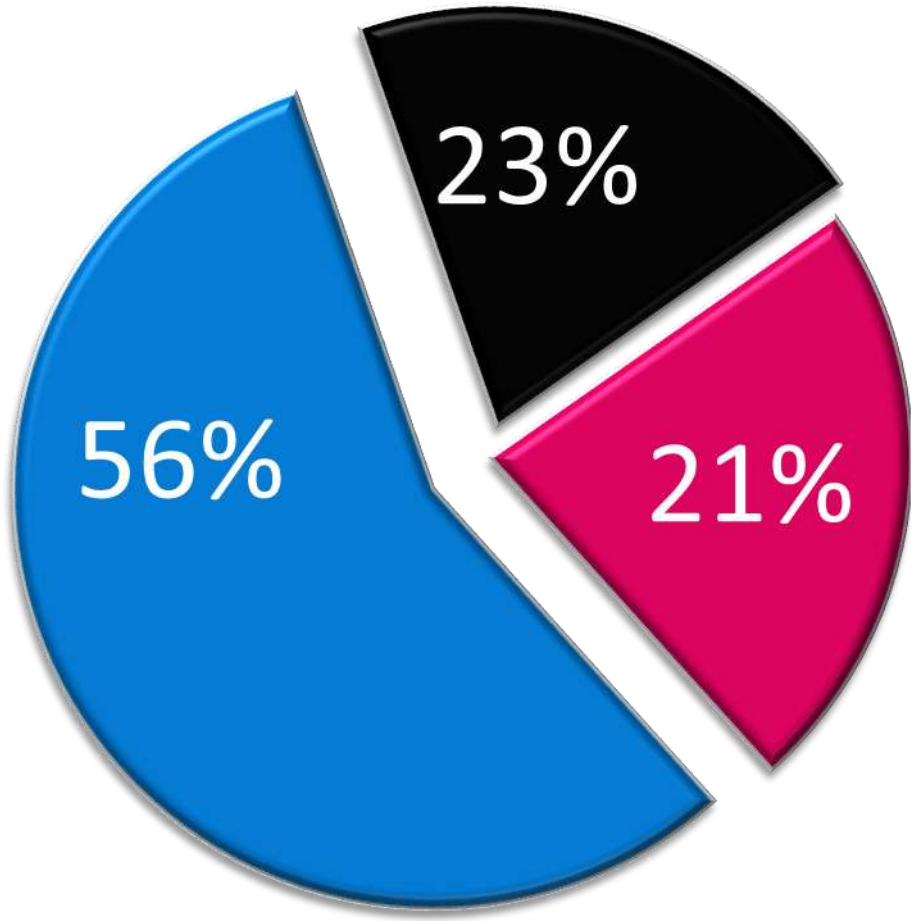
(1) HHS Richard Frank Testimony to Congress May 1 2015 (2) AMA Patrice Harris Testimony to Congress, April 23 2015; (3) Fred Wells Branson CEO Project Lazarus Testimony to Congress, March 25 2015

OVERDOSE SITE REQUIRES MORE OPTIONS

HOME

OTHER

MEDICAL SETTING



77% of Opioid Overdose Related Deaths Happen Outside Medical Setting[1]

56% of Opioid Overdose Related Deaths Happen at Home[1]

(1) CDC Wonder Database Multiple Cause of Death MCD - ICD-10 Codes: T40.1 (Heroin), T40.2 (Other opioids), T40.3 (Methadone), T40.4 (Other synthetic narcotics) 2013

WHAT ADAPT IS DOING

Adapt and NIDA Collaboration Goals

Development of Naloxone Nasal Spray to Effectively Treat Opioid Overdose

Accessible and easy to administer outside a healthcare setting

The following describes the Naloxone Nasal Spray product currently under development, including clinical trials, regulatory milestones and timeline to projected approval. Accordingly, at this time, all test data and product information are presented for informational purposes only, and must be considered experimental

Development Target Product Profile

Accessibility: Device Option

Single Spray Device

Supine Position Dosing

Low Volume Spray (0.1ml)

No Assembly, Priming Requirement

Portable Device

Effectiveness: Treatment

Appropriate Dose Selection

Time to Onset Compared to IM

Drug Exposure Compared to IM

Any New Adverse Events

All test data/product information presented must be considered experimental

The Proposed Name and The Device

NARCAN® (naloxone HCl)
NASAL SPRAY
(Product Under Development)

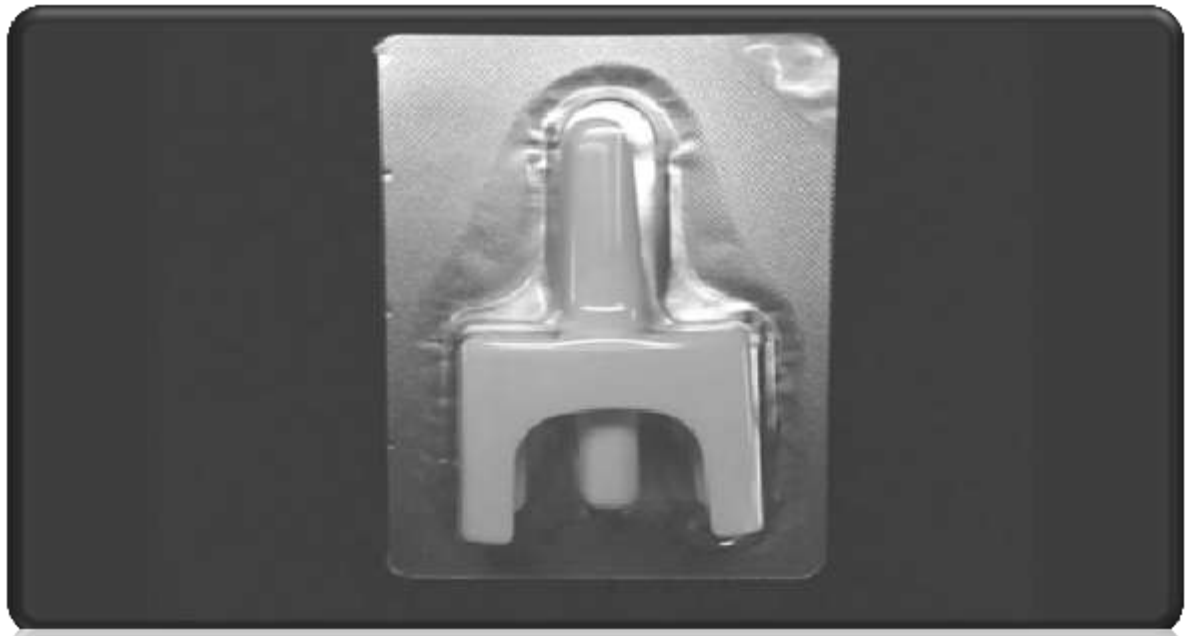
Licensed Narcan

High Brand Familiarity

Accelerate Awareness

Use Subject to FDA Approval

Device Spraying Water



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Working with FDA – Regulatory Status

Timeline	1Q15	2Q15	2H15
Regulatory Status	FDA Grants Fast Track Designation	Initiated Rolling NDA submission	Target Final NDA Seek Priority Review Possible FDA Approval

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Summary of Key Studies Conducted

- **Two Pharmacokinetic (PK) Studies Comparing doses from 2mg to 8mg Naloxone in 0.1ml Nasal Spray to FDA approved 0.4 mg IM Naloxone**
  - Healthy Patients in Both PK Studies Received Nasal Spray in Supine Position
- **Three Studies to Measure Comprehension and Ease of Administration**
  - Included cohorts of adults, juveniles and low literacy
  - No device training was provided
- **Other Supportive Studies Required to Characterize Product Included:**
  - Extractable, Stability, Spray geometry etc.

All test data/product information presented must be considered experimental

HUMAN USE STUDIES

Design Objective to Assess Ease of Administration

- 3 studies (1 qualitative 2 validation) with total of 175 subjects
- No device training was provided
- Included cohorts representing everyday Americans: Adults, Juveniles, low literacy
- Included Stress Simulations
- Primary (administration of placebo dose) and secondary endpoints (e.g. call 911, place in Recovery position) measured

Results

- Over 90% of participants successfully simulated administering Narcan Nasal Spray without training

All test data/product information presented must be considered experimental

PIVOTAL PK NASAL V 0.4MG IM

- Time to Maximum Plasma Concentration for Nasal Spray compared to IM
- Nasal Plasma Levels Exceeded 0.4mg IM Plasma Level at all time points
- Nasal Plasma Levels Exceeded 0.4mg IM Peak Plasma Level For Over 2 hours
- Data suggested Nasal comparable bioavailability was 50% relative to IM
- No Change to Adverse Event Profile
- Expect selected dose to be within recommended comparable initial dose range of i.m.

All test data/product information presented must be considered experimental

Note: Inpatient open-label, randomized, 5-period, 5-treatment, 5-sequence, crossover study involving 30 healthy volunteers for 18 days.

NEXT: COLLABORATION TO SUPPORT ACCESS

ADAPT is committed to:

- Launching Narcan Nasal Spray Rapidly Post FDA Approval with a focus on current naloxone distributors and users; high-risk opioid users, their friends and family; and others that may witness an overdose
- Collaborating with public/private stakeholders who address distribution, reimbursement and other challenges
- Pricing Responsibly to Support Broad Access

Help Reach Common Goal of Treating Opioid Overdoses with Effective, Accessible and Easy to Administer Naloxone Nasal Spray

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CONTACTS

Thank you

Questions

Seamus.Mulligan@adaptphama.com

Eunan.Maguire@adaptpharma.com

Matt.Ruth@adaptpharma.com

NARCAN® (naloxone HCl) NASAL SPRAY

(PRODUCT UNDER DEVELOPMENT)