

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 2, 2019

Heron Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

4242 Campus Point Court, Suite 200, San Diego, CA
(Address of principal executive offices)

001-33221
(Commission
File Number)

94-2875566
(I.R.S. Employer
Identification No.)

92121
(Zip Code)

Registrant's telephone number, including area code (858) 251-4400

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common Stock, par value \$0.01 per share

Trading Symbol(s)
HRTX

Name of each exchange on which registered
The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On October 2, 2019, Heron Therapeutics, Inc. (the “Company”) issued a press release announcing positive topline results from a multi-center postoperative pain management study in which patients undergoing total knee arthroplasty (TKA) surgery received the investigational agent, HTX-011, with a scheduled postoperative regimen of generic oral analgesics (acetaminophen and celecoxib), as described in the press release filed herewith as Exhibit 99.1.

Item 7.01 Regulation FD Disclosure.

A copy of presentation materials describing the business of the Company, all or a part of which may be used by the Company in investor or scientific presentations from time to time, is furnished herewith as Exhibit 99.2 (the “Corporate Presentation”). The Corporate Presentation has also been posted on the Company’s website at www.herontx.com. The Company does not undertake any obligation to update the Corporate Presentation.

This Item 7.01 and the Corporate Presentation are being furnished to the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 2, 2019
99.2	Corporate Presentation, dated October 2, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Heron Therapeutics, Inc.

Date: October 2, 2019

/s/ David Szekeres

David Szekeres

Senior Vice President, General Counsel,

Business Development and Corporate Secretary



Heron Announces Positive Topline Results from Phase 3b Clinical Study of HTX-011 in Total Knee Arthroplasty

*- Mean Pain Scores Remain in Mild Range for 72 Hours following Surgery -
- 75% of Patients Were Discharged without Opioids -*

SAN DIEGO, Calif.– (PR NEWSWIRE)—October 2, 2019-- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced positive topline results of a multi-center postoperative pain management study in which 51 patients undergoing total knee arthroplasty (TKA) surgery received the investigational agent, HTX-011, together with a scheduled postoperative regimen of generic, oral analgesics (acetaminophen and celecoxib). A follow-on study to the Phase 2b study of HTX-011 in TKA (Study 209) that was completed in 2018, this study was designed to evaluate the decrease in pain and opioid use with HTX-011 when used together with a regimen of generic oral analgesics. In Study 209, HTX-011 significantly reduced pain and opioid use compared to placebo through 72 hours and significantly reduced pain compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control, using a last observation carried forward (LOCF) analysis. The Phase 3b study included the same multimodal, oral analgesic regimen as a prior published study with liposomal bupivacaine in TKA (Mont doi: 10.1016/j.arth.2017.07.024).

Topline results of this Phase 3b study include the following:

- Mean pain scores remained in the mild range through 72 hours post-surgery.
- Median consumption of opioids was 4-to-5 pills of oxycodone (22.5 morphine milligram equivalents) through 72 hours.
- 75% of patients were discharged from the hospital without a prescription for opioids.
- HTX-011, together with the multimodal, oral analgesic regimen, was well tolerated in this study. There were no deaths, serious adverse events or premature discontinuations due to adverse events.

These Phase 3b study results in TKA complement the positive results of HTX-011 studies in hernia repair and bunionectomy. In January 2019, Heron reported that 90% of patients who received HTX-011 together with a regimen of over-the-counter (OTC) oral analgesics (acetaminophen and ibuprofen) did not require opioids through 72 hours post-hernia repair surgery. In March 2019, Heron reported that 77% of patients that received HTX-011 together with the OTC oral analgesic regimen did not require opioids through 72 hours post bunionectomy.

"Without appropriate multimodal analgesic postoperative pain management, TKA is usually a very painful procedure, especially for patients with end-stage arthritis," said Paul Lachiewicz,



M.D., Consulting Professor, Department of Orthopedic Surgery, Duke University. "This study provides strong evidence that HTX-011, together with a standard multimodal analgesic pain regimen, may play an essential role in not only providing superior pain relief with reduction of severe pain, but also reducing opioid consumption and the need for opioid discharge prescriptions for patients undergoing TKA. With the majority of patients only requiring 4-to-5 opioid pills and 75% being discharged without an opioid prescription, these results also demonstrate that new innovative non-opioid pain medications, like HTX-011, can substantially improve patient care, change current prescribing practices and help to stem the overreliance on opioids after major orthopedic surgery."

"In 2017, more than 47,000 individuals died due to an opioid overdose in the U.S. This dire statistic is fueled by the more than one-billion opioid pills prescribed to patients following surgery and the lack of effective alternative regimens," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "The results from recent studies in TKA, hernia repair and bunionectomy demonstrate that HTX-011 can effectively reduce pain and allow the majority of patients to be discharged without opioids."

About HTX-011 for Postoperative Pain

HTX-011, an investigational agent, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter (CRL) was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical efficacy or safety were noted. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019. A Marketing Authorisation Application (MAA) for HTX-011 was validated by the European Medicines Agency (EMA) in March 2019 for review under the Centralised Procedure.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from pain or cancer.

For more information, visit www.heronrx.com.

**Forward-looking Statements**

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Heron cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to, those associated with: whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011; the timing of the EMA Committee for Medicinal Products for Human Use (CHMP) review process for HTX-011; whether the European Commission authorizes the MAA for HTX-011; and other risks and uncertainties identified in the Company's filings with the U.S. Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and Heron takes no obligation to update or revise these statements except as may be required by law.

Investor Relations and Media Contact:

David Szekeres
Senior VP, General Counsel, Business Development and Corporate Secretary
Heron Therapeutics, Inc.
dszekeres@herontx.com
858-251-4447

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Corporate Update

October 2, 2019

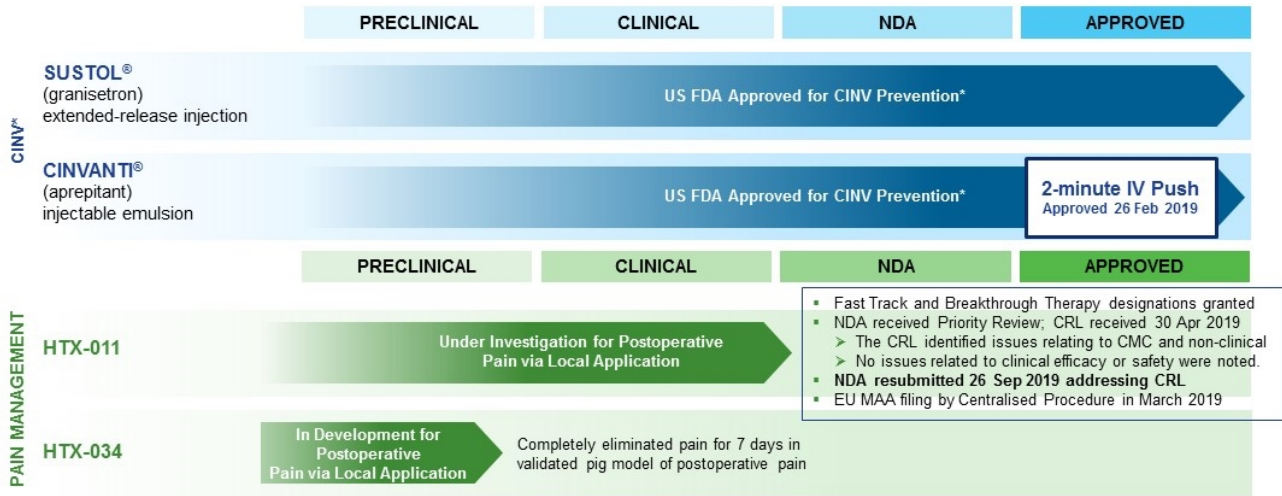


Forward-Looking Statements

This presentation contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. We caution investors that forward-looking statements are based on management's expectations and assumptions as of the date of this presentation, and involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, those associated with: the full-year 2019 net product sales guidance for the CINV franchise; whether the FDA approves the NDA for HTX-011; the timing of the FDA's review process for HTX-011; the timing of the commercial launch of HTX-011; the timing of the CHMP's review process for HTX-011; whether the European Commission authorizes the MAA for HTX-011; the potential market opportunity for SUSTOL, CINVANTI and HTX-011; the timing and results of the studies in the HTX-011 and HTX-034 development programs; the expected future balances of Heron's cash, cash equivalents and short-term investments; the expected duration over which Heron's cash, cash equivalents and short-term investments balances will fund its operations; and other risks and uncertainties identified in Heron's filings with the Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and we take no obligation to update or revise these statements except as may be required by law.

Heron Pipeline

We are currently developing and commercializing pharmaceutical products for patients suffering from cancer or postoperative pain:



*CINV, Chemotherapy-induced nausea and vomiting. SUSTOL® (granisetron) extended-release injection is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. CINVANTI® (aprepitant) injectable emulsion, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). CINVANTI has not been studied for treatment of established nausea and vomiting.

3 HTX-011 and HTX-034 are an investigational new drugs and are not approved by the FDA or other regulatory authority



HTX-011 Has Shown Favorable Results on Postoperative Pain in Several High-Value Procedures

Procedure	Annual Volume ('000s, US, 2015)						Overall % Local Anesthetic Use	
	Total Procedures	Inpatient	Outpatient (C-code)	ASC (C-Code)	Medicare	Non-Medicare**	Survey	
Ortho Surgery	Knee arthroplasty	1,043	977	41	25	41%	59%	86%
	Hip arthroplasty	599	579	8	12	42%	58%	80%
	Shoulder arthroplasty	161	149	9	3	47%	53%	85%
	Rotator cuff repair	319	6	193	120	27%	73%	81%
	Spine procedures	1,459*	928	456	75	34%	66%	76%
Bunionectomy & Phalangectomy	597	42	343	212	25%	75%	88%	
General Surgery	Hernia repair	1,064	212	731	121	26%	74%	82%
	Cholecystectomy	987	323	600	64	10%	90%	83%
	Colon and small bowel resection	476	457	18	1	33%	67%	75%
Plastic Surgery	Abdominoplasty	130	23	95	12	16%	84%	75%
	Mammoplasty	292	32	208	52	16%	84%	79%
OB/GYN	C-Section	1,168	1158	10	0	2%	98%	58%

Completed studies

On-going studies

4

* Includes Laminectomy, Foraminotomy, Discectomy, Fusion
 ** Non Medicare includes Commercial, Medicaid and Cash

Sources: DRG Claims Data 2017/ update 2018
 The Link Group ATU survey May 2019



**Phase 2b
Total Knee
Arthroplasty
(TKA)
(Study 209)**

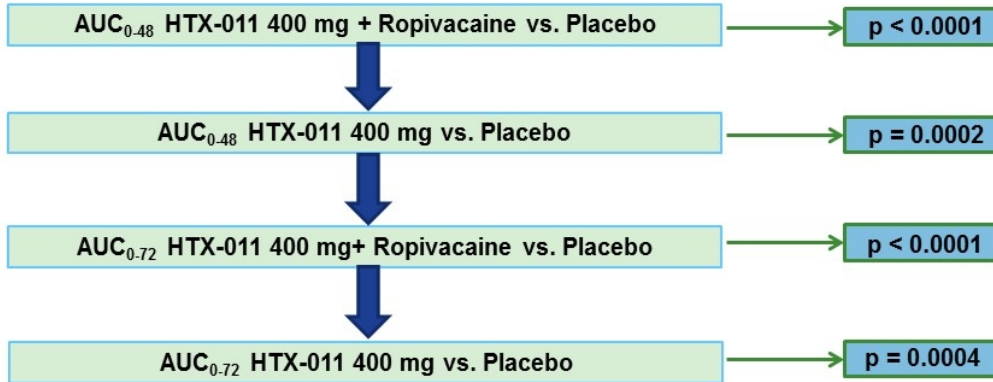
**Study 209 Follow-on:
HTX-011 + MMA in TKA*
(Study 306)**

*The multimodal analgesic (MMA) regimen used in this study was identical to the PILLAR Study of liposomal bupivacaine

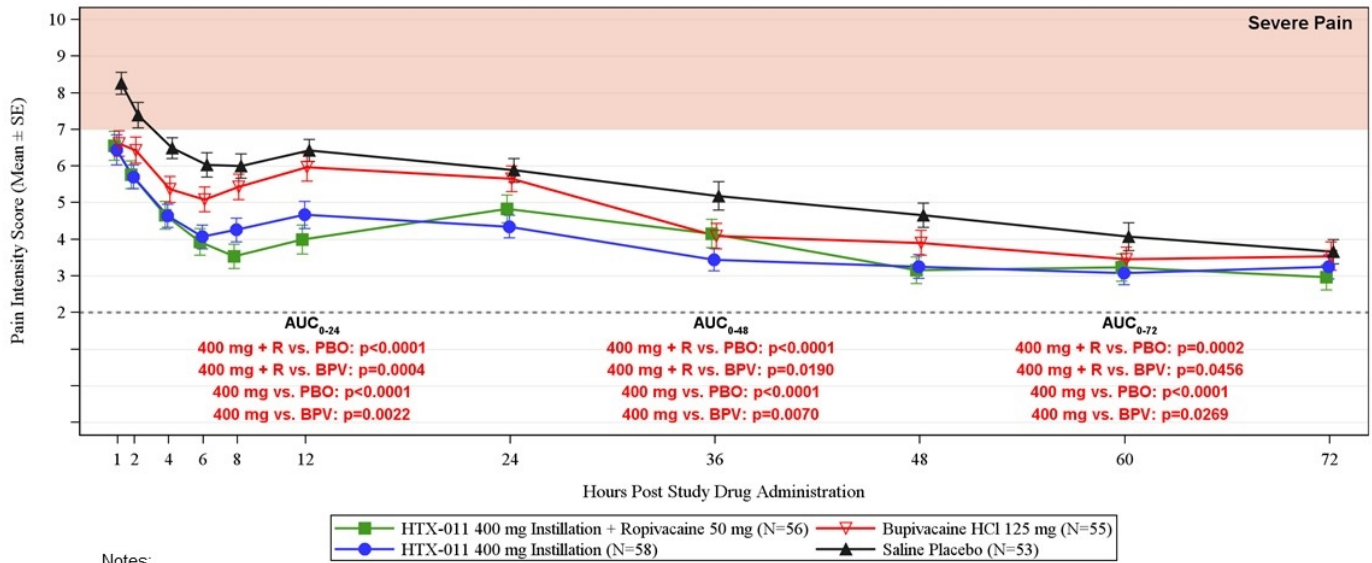


Study 209 TKA: Results Hierarchy

HTX-011 via instillation achieved primary and key secondary endpoints for reduction in pain intensity scores



Study 209 TKA: HTX-011 Significantly Superior to Both Placebo and Bupivacaine Through 72 Hours Without Adjusting for Opioid Use



Notes:

Pain intensity collected using Numeric Rating Scale (NRS)

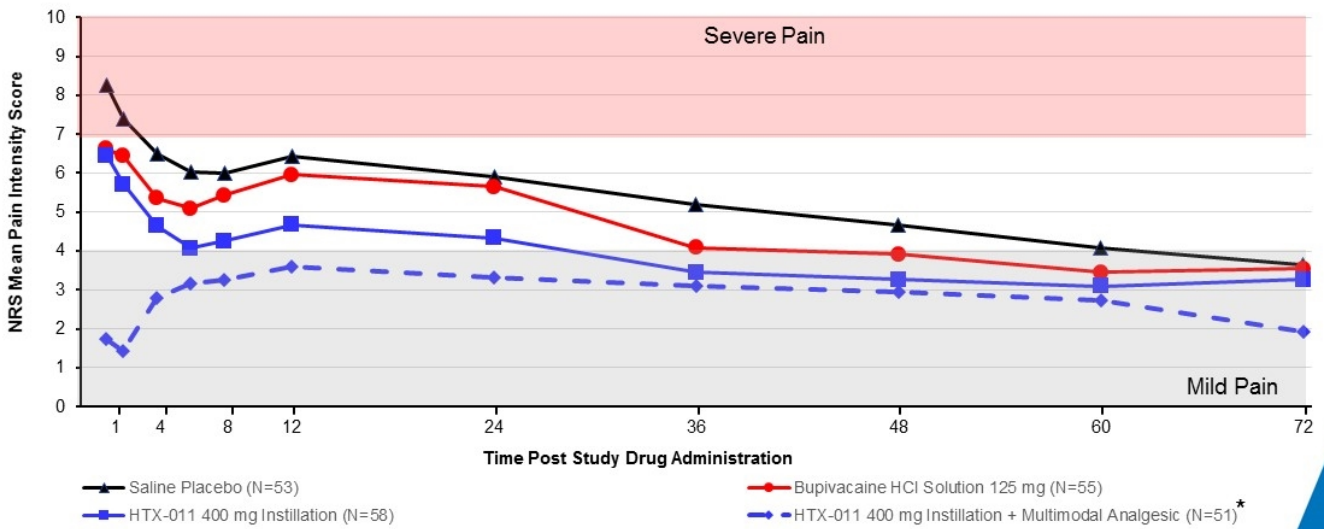
LOCF for missing data and no adjustment for use of opioid rescue medication

7

HTX-011 is an investigational new drug and not approved by the FDA



Study 209 Follow-on: HTX-011 + Generic Analgesics* Kept Pain in the Mild Range Through 72 Hours With 68% Less Opioid Than Bupivacaine



* Multimodal analgesic (MMA) regimen for postoperative pain in Study 306 included oral acetaminophen 1000 mg every 8 hours (maximum 3000 mg/d) and oral celecoxib 200 mg every 12 hours until discharge, as described in Mont doi: 10.1016/j.arth.2017.07.024. Patients in Study 209 received no scheduled MMA and only received opioids for rescue

LOCF for missing pain data

HTX-011 is an investigational new drug and not approved by the FDA



Cross-Study Comparison of Day 1 in Study 306 and Exparel PILLAR Study (Dysart 2019)

Cross-Study Comparison of 0 – 24 Hour Results in TKA Using Pillar-Based MMA and the Same Analysis ¹	Study 306 HTX-011 (N=51)	PILLAR Study	
		Exparel + Bupivacaine ¹ (N = 70)	Bupivacaine ¹ (N = 69)
AUC0-24 VAS Pain ²	59.5	98.5	121.6
Opioid-Free	21.6%	17.1%	1.4%
Mean Opioid Consumption MME(SD)	10.6 (9.2)	45.5 (35.01)	56.8 (38.26)
Log-transformed Geometric Mean Opioid Consumption MME	0.54	3.5	38.5
Discharge Ready in 12 hours Based MPADSS \geq 9	60.8%	42.9%	27.5%

1. <https://doi.org/10.1016/j.arth.2018.12.026>.
 2. Assumes LOCF as publication does not describe any correction for opioid use

Disclaimer

- This is a cross-study comparison of Study 306 to the PILLAR Study of Exparel plus bupivacaine; these comparisons are not based on head-to-head clinical studies. The results from these two studies are not directly comparable and do not imply a clinical benefit of HTX-011 over Exparel.

HTX-011 is an investigational new drug and not approved by the FDA



Cross-Study Comparison of 48 Hour Results From Study 306 (Preliminary Results) and Exparel Pillar Study (Mont 2017)

Comparison of 48 Hr Results in TKA Using Pillar-Based MMA and the Same Analysis ¹	Study 306 HTX-011 (N=51)	PILLAR Study	
		Exparel + Bupivacaine ¹ (N = 70)	Bupivacaine ¹ (N = 69)
Mean AUC12-48 VAS Pain	143.2	180.8	209.3
Opioid-Free	11.8%	10%	0%
Mean Opioid Consumption (MME)	19.6 (Median=16.7)	Not Shown	Not Shown
Log-transformed Geometric Mean Opioid Consumption MME	3.0	18.7	84.9
≤ 20 MME @ 48 hr	56.9%	18.6%	4.4%
> 20 and ≤ 220 MME @ 48hr	43.1%	78.6%	87%
> 220 MME @ 48 hr	0	2.9%	8.7%
DID NOT Receive a Discharge Prescription for Opioids	74.5%	Not Shown	Not Shown

1. Mont doi: 10.1016/j.arth.2017.07.024

Disclaimer

- This is a cross-study comparison of Study 306 to the PILLAR Study of Exparel plus bupivacaine; these comparisons are not based on head-to-head clinical studies. The results from these two studies are not directly comparable and do not imply a clinical benefit of HTX-011 over Exparel.

HTX-011 is an investigational new drug and not approved by the FDA



Potential Reduction of Discharge Opioids Based on Study 306

- Currently, following TKA an average of 90 opioid pills are prescribed per patient at the time of discharge, with an additional 4 refills over the next year¹

Potential Impact on Discharge Opioids of Study 306 Extrapolated to the 1,043,000 TKA Surgeries Annually²	
	Pills Prescribed
Current Practice Estimates With Initial Rx	93,870,000
Study 306 Results (25.5% only)	23,936,850
Potential Reduction with HTX-011 + MMA	69,933,150↓

1. Truven Database – Commercial patients
 2. Decisions Resources Group claims data 2018;



**EPOCH 1:
Bunionectomy
Results
(Study 301)**



**EPOCH 1 Follow-on:
Opioid Elimination
Study in
Bunionectomy**



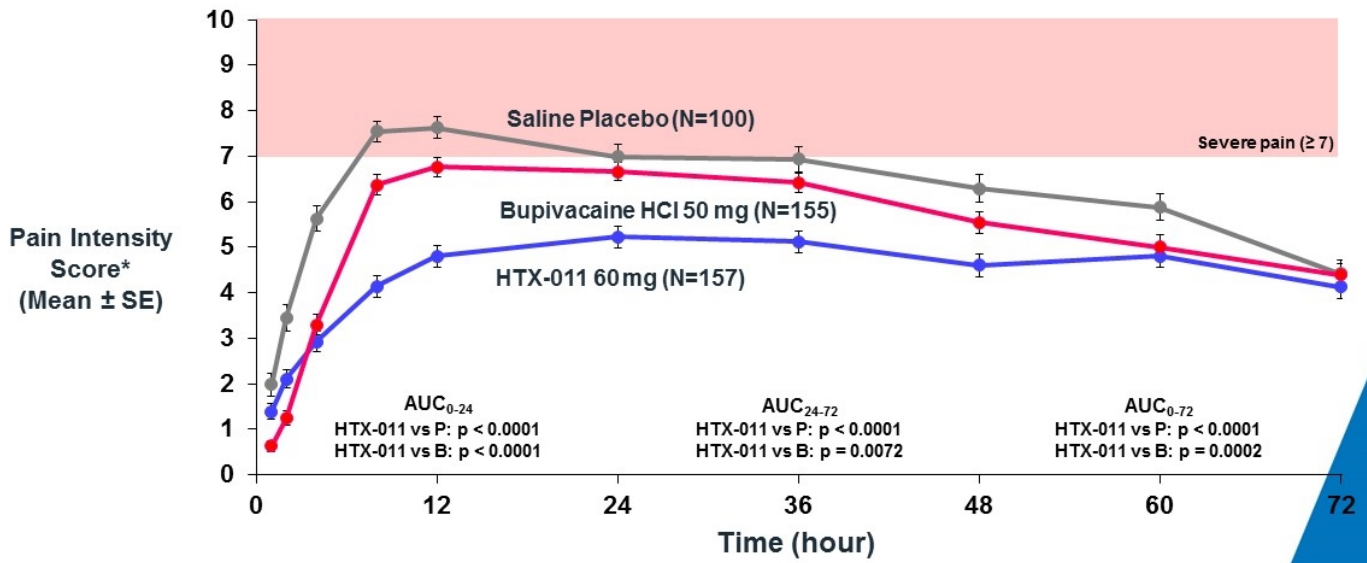
EPOCH 1 Bunionectomy: All Key Endpoints Favor HTX-011

Hierarchical hypothesis testing ($P \leq .05$)

Primary	NRS Pain Intensity (AUC₀₋₇₂) vs placebo	p < 0.0001
1st Key Secondary	NRS Pain Intensity (AUC₀₋₇₂) vs bupivacaine HCl	p = 0.0002
2nd Key Secondary	Opioid Use (0-72 hours) vs placebo	p < 0.0001
3rd Key Secondary	Opioid Free (0-72 hours) vs bupivacaine HCl	p = 0.0001
4th Key Secondary	Opioid Use (0-72 hours) vs bupivacaine HCl	p = 0.0022

NRS: numeric rating scale AUC: area under the curve; placebo: saline placebo

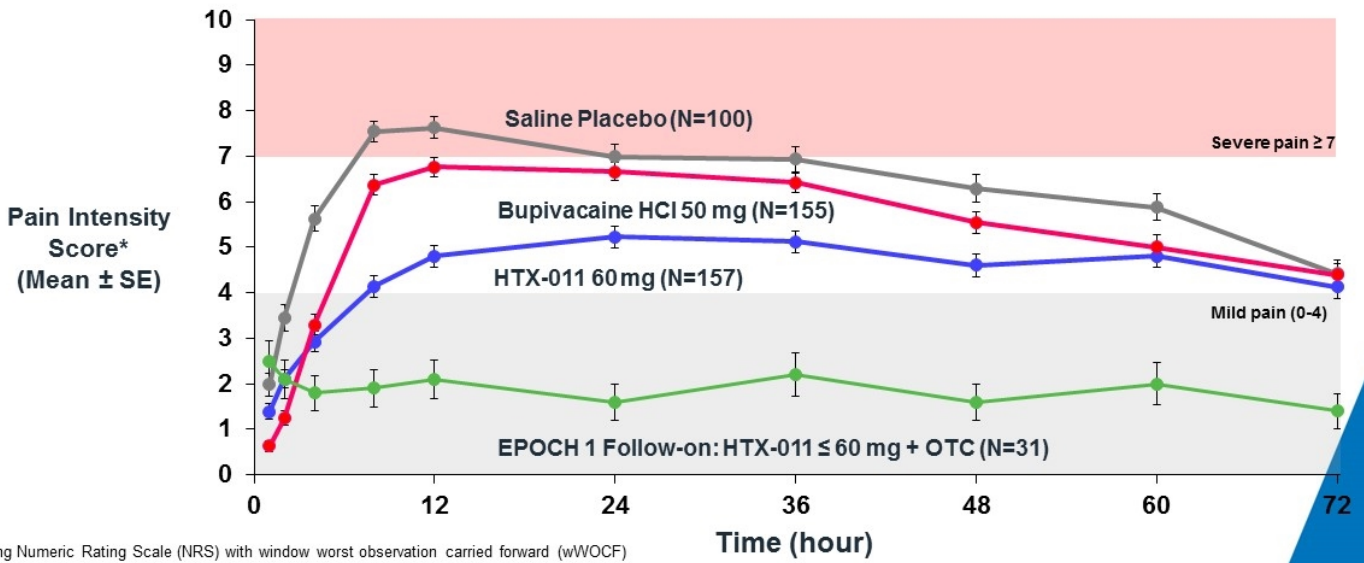
EPOCH 1 Bunionectomy: HTX-011 Significantly Reduced Pain Through 72-hours as Compared to Bupivacaine and Placebo



* Using Numeric Rating Scale (NRS) with window worst observation carried forward (wWOCF)

HTX-011 is an investigational new drug and not approved by the FDA

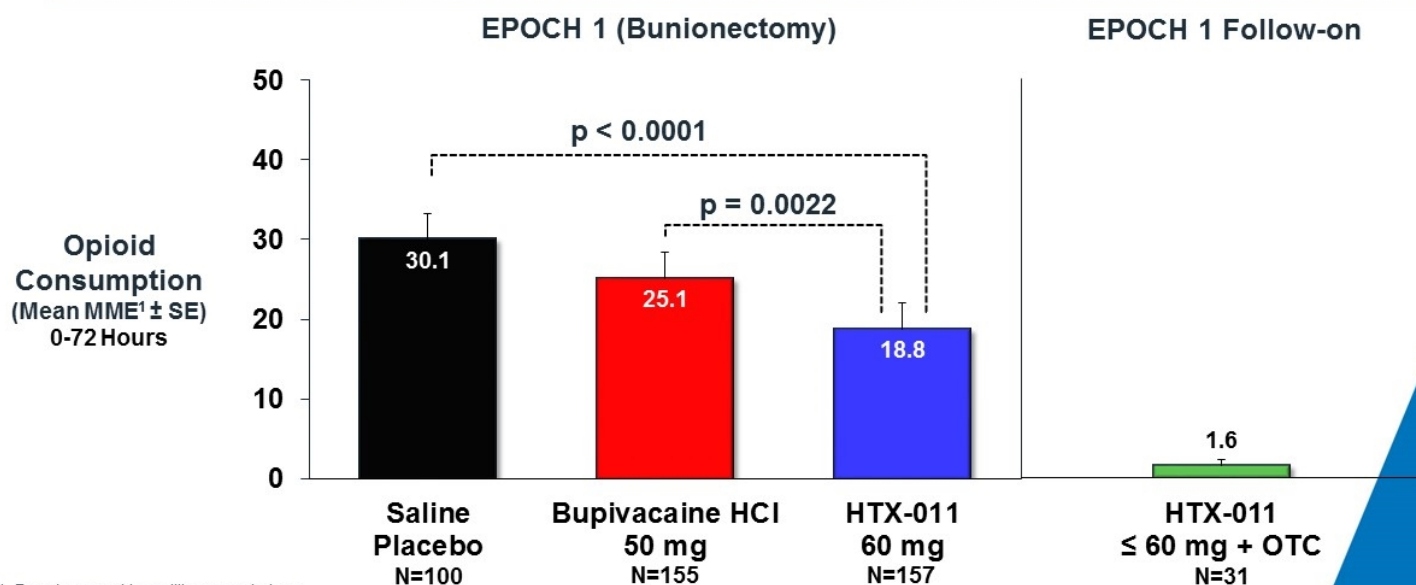
Epoch 1 Follow-on: HTX-011 + OTC Acetaminophen and Ibuprofen Kept Pain in the Mild Range Through 72 Hours



* Using Numeric Rating Scale (NRS) with window worst observation carried forward (wWOCF)

OTC = Over the counter analgesic regimen of ibuprofen 600 mg q6h alternating 3 hours later with acetaminophen 1000 mg q6h

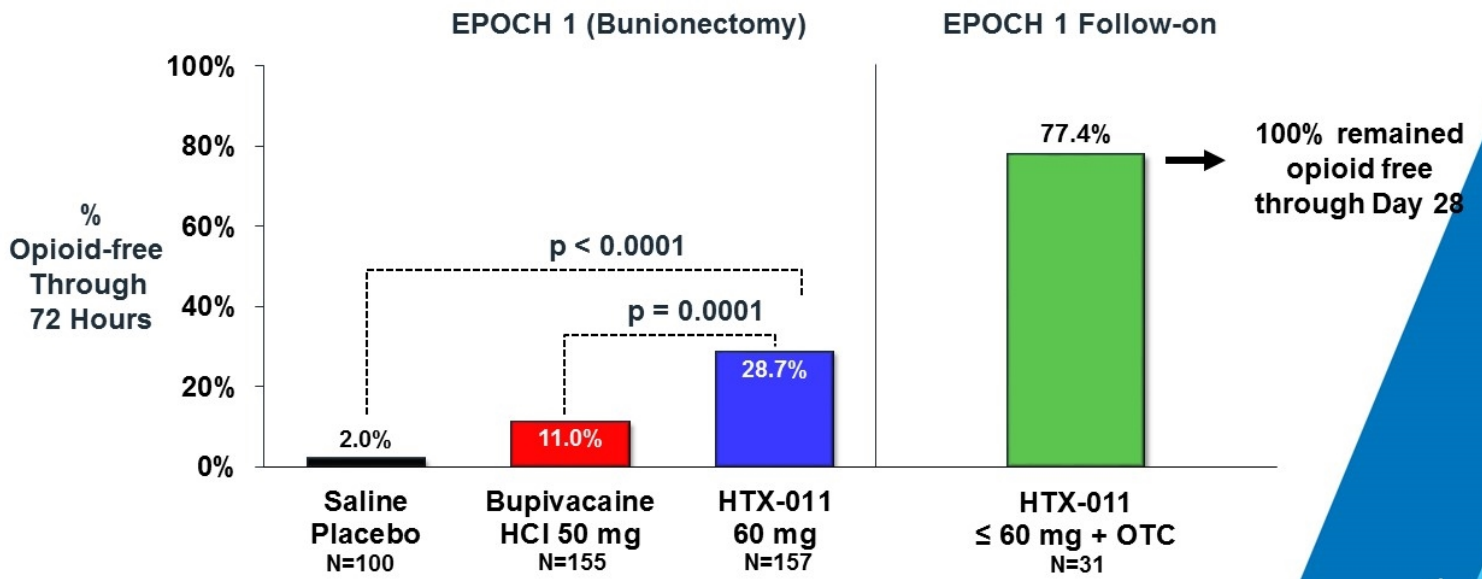
HTX-011 Significantly Reduced Total Opioid Consumption Through 72-hours as Compared to Bupivacaine and Placebo



1. Based on morphine milligram equivalents

OTC = Over the counter analgesic regimen of ibuprofen 600 mg q6h alternating 3 hours later with acetaminophen 1000 mg q6h

HTX-011 Significantly Increased Proportion of Opioid-Free Patients Through 72-hours as Compared to Bupivacaine and Placebo



OTC = Over the counter analgesic regimen of ibuprofen 600 mg q6h alternating 3 hours later with acetaminophen 1000 mg q6h

**EPOCH 2:
Herniorrhaphy
Results
(Study 302)**

**EPOCH 2 Follow-on:
Opioid Elimination
Study in
Herniorrhaphy**



EPOCH 2 Herniorrhaphy: All Key Endpoints Favor HTX-011

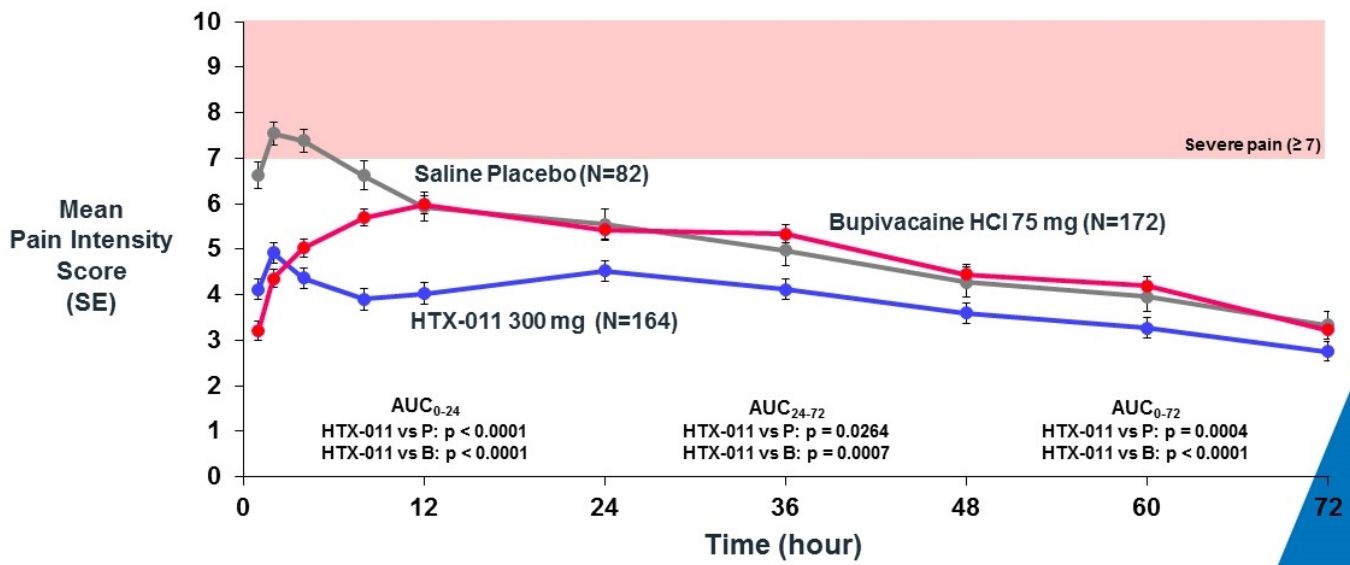
Hierarchical hypothesis testing ($P \leq .05$)



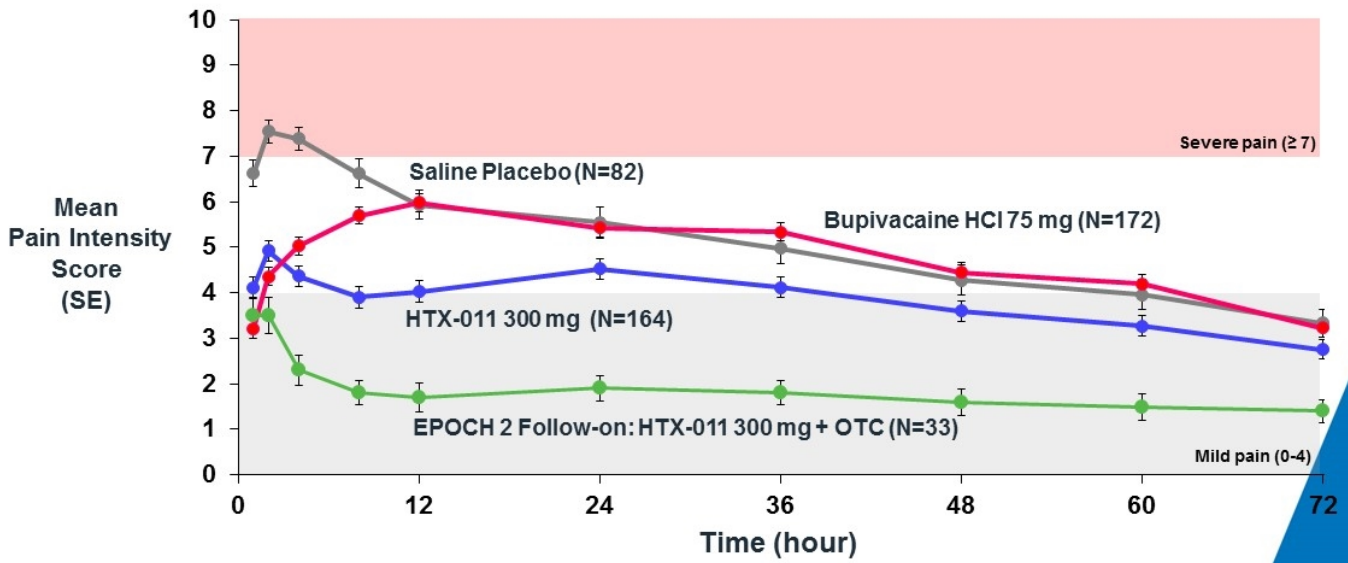
Primary	NRS Pain Intensity (AUC₀₋₇₂) vs placebo	p = 0.0004
1st Key Secondary	NRS Pain Intensity (AUC₀₋₇₂) vs bupivacaine HCl	p < 0.0001
2nd Key Secondary	Opioid Use (0-72 hours) vs placebo	p = 0.0001
3rd Key Secondary	Opioid Free (0-72 hours) vs bupivacaine HCl	p = 0.0486
4th Key Secondary	Opioid Use (0-72 hours) vs bupivacaine HCl	p = 0.0240

AUC: area under the curve; placebo: saline placebo

EPOCH 2 Herniorrhaphy: HTX-011 Significantly Reduced Pain Through 72-hours as Compared to Bupivacaine and Placebo



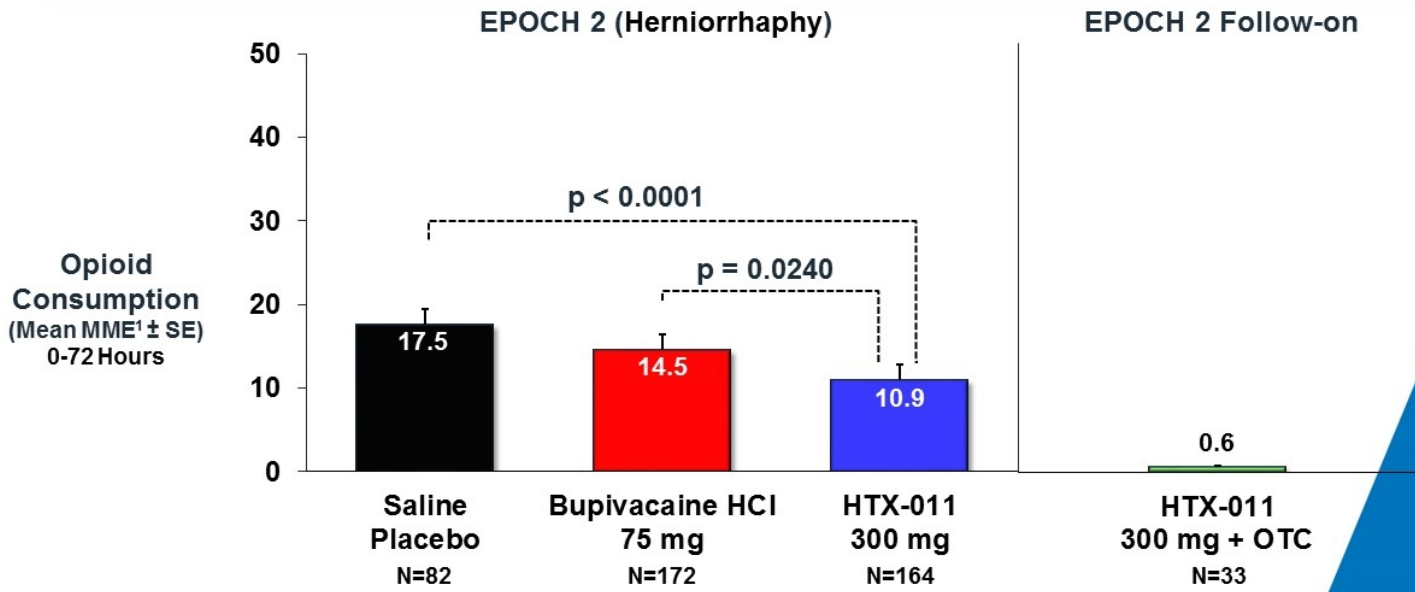
Epoch 2 Follow-on: HTX-011 + OTC Acetaminophen and Ibuprofen Kept Pain in the Mild Range Through 72 Hours



OTC = Over the counter analgesic regimen of ibuprofen 600 mg q6h alternating 3 hours later with acetaminophen 1000 mg q6h

Source: Figure 14.3

HTX-011 Significantly Reduced Total Opioid Consumption Through 72-hours as Compared to Bupivacaine and Placebo



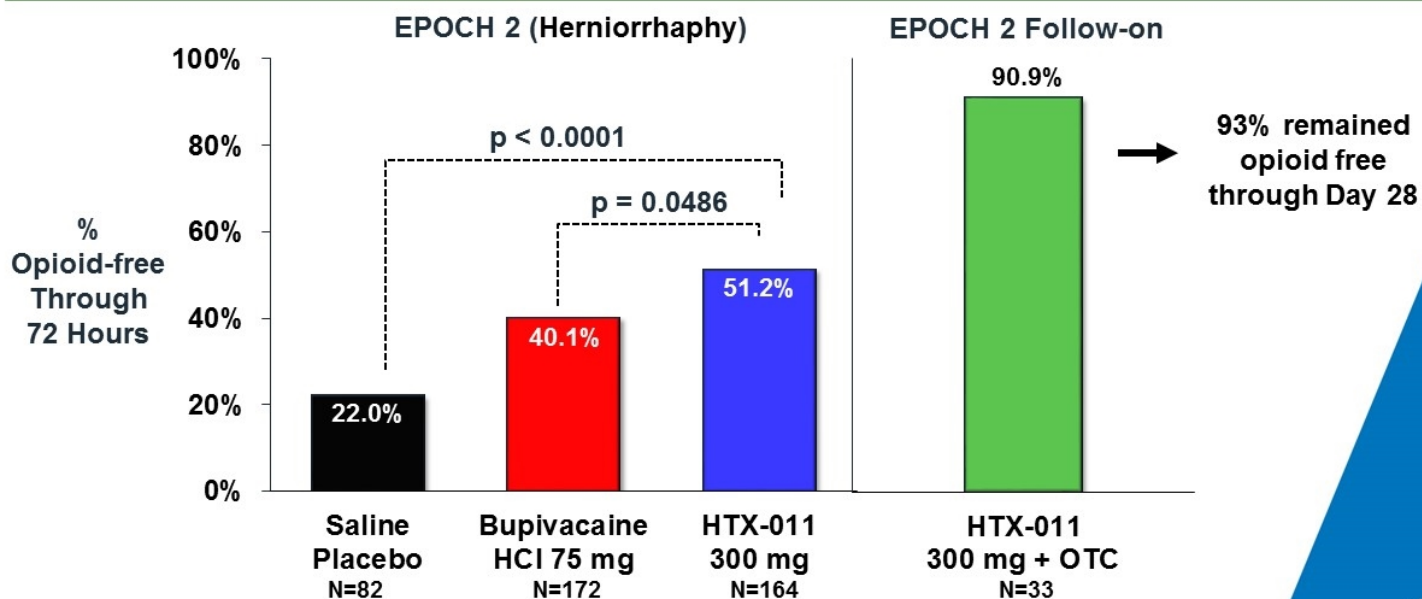
1. Based on morphine milligram equivalents

OTC = Over the counter analgesic regimen of ibuprofen 600 mg q6h alternating 3 hours later with acetaminophen 1000 mg q6h

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HTX-011 is an investigational new drug and not approved by the FDA

HTX-011 Significantly Increased Proportion of Opioid-Free Patients Through 72-hours as Compared to Bupivacaine and Placebo

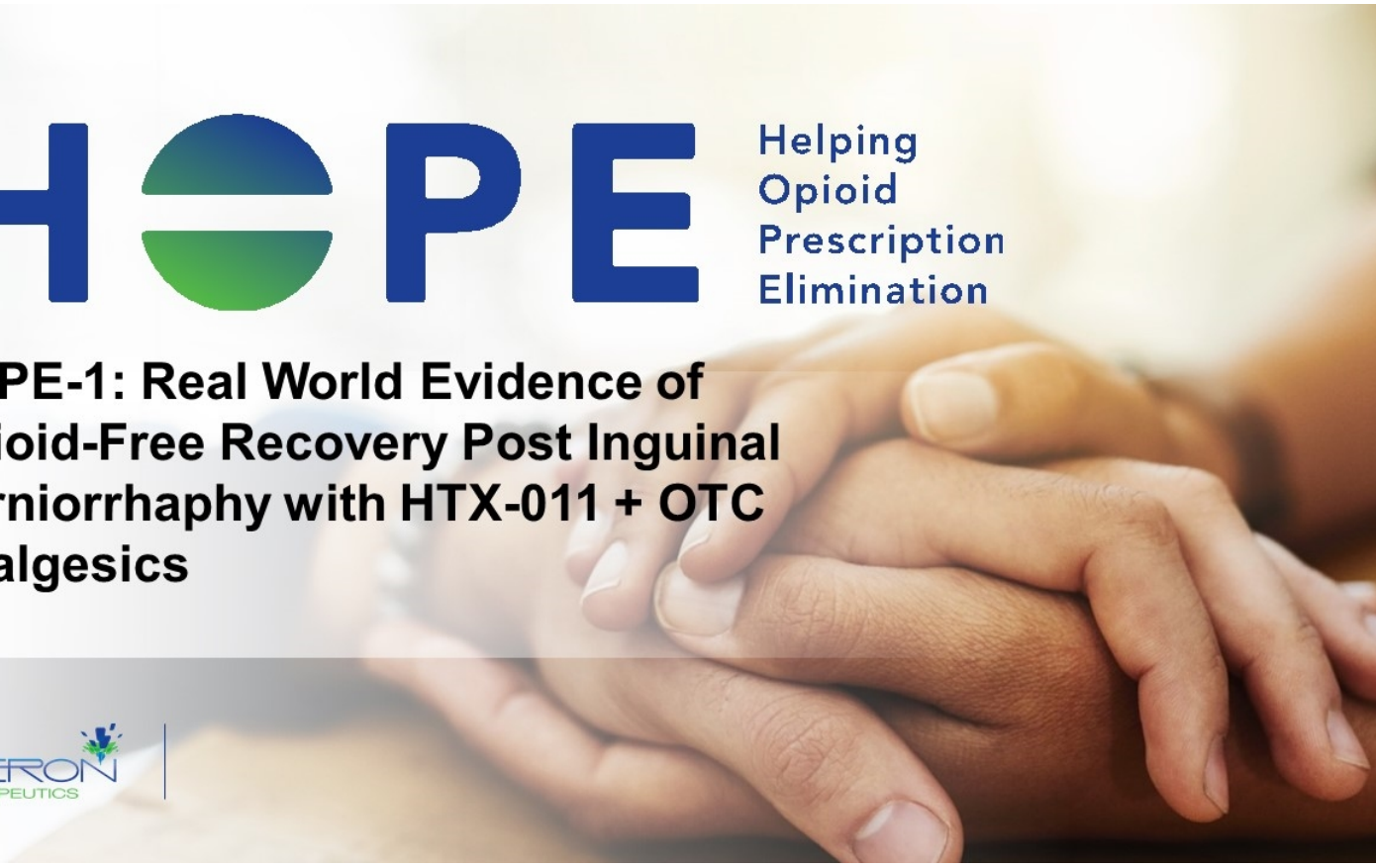


OTC = Over the counter analgesic regimen of ibuprofen 600 mg q6h alternating 3 hours later with acetaminophen 1000 mg q6h

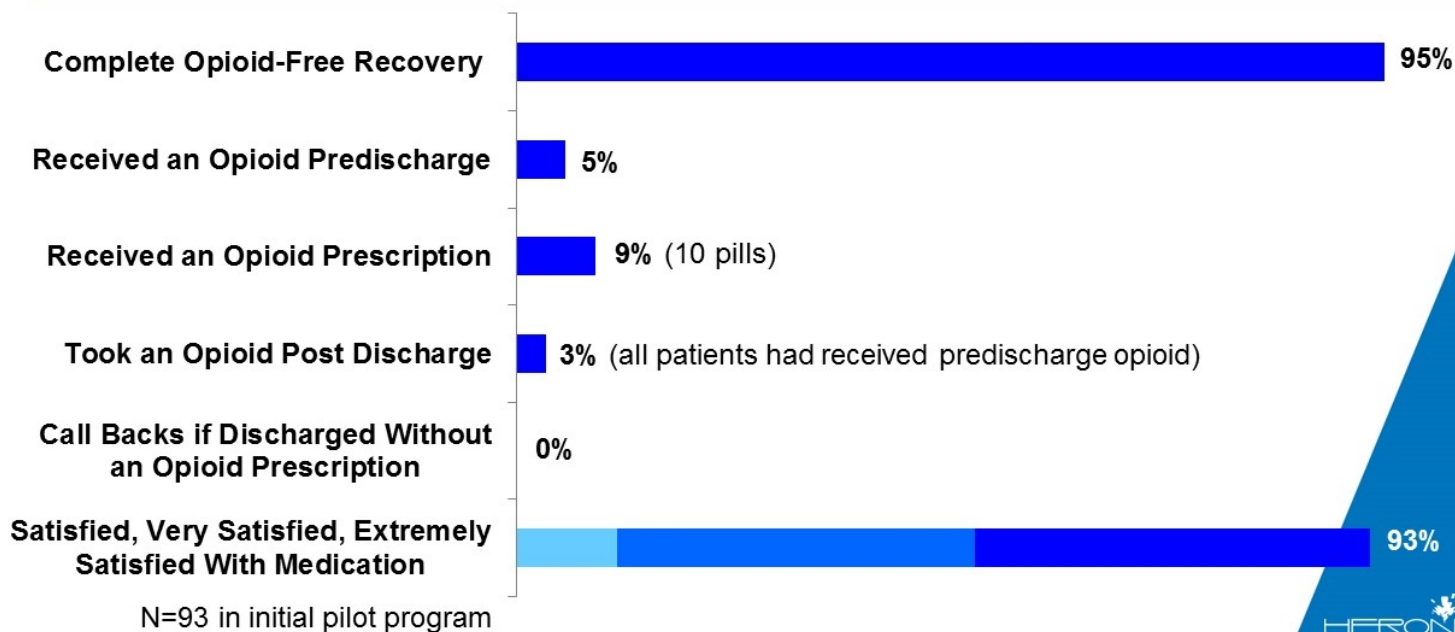
HOPE

Helping
Opioid
Prescription
Elimination

HOPE-1: Real World Evidence of Opioid-Free Recovery Post Inguinal Herniorrhaphy with HTX-011 + OTC Analgesics



HOPE-1: Opioid-Free Recovery in 95% of Inguinal Herniorrhaphy Patients with HTX-011 + OTC Analgesics



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Potential Reduction of Discharge Opioids Based on HOPE-1

- Currently, following inguinal hernia repair an average of 30 opioid pills are prescribed per patient of which an average of 9 pills are consumed¹

Potential Impact if HOPE-1 Extrapolated to the ~800,000² Inguinal Hernia Surgeries Annually

	Pills Prescribed	Pills Consumed	Pills Leftover
Current Practice Estimates	24,000,000	7,200,000	16,800,000
HOPE-1 Estimates	774,194	283,871	490,323
Potential Reduction with HTX-011 + OTC	23,225,806 ↓	6,916,129 ↓	16,309,677 ↓

1. Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) November 15, 2018

2. Decisions Resources Group claims data 2017 ;



Safety Summary

HTX-011 was generally well tolerated across all Phase 2 and Phase 3 studies with no clinically meaningful differences from placebo and bupivacaine in:

- Overall adverse events
- The incidence of serious adverse events
- Premature discontinuations due to adverse events
- Potential local anesthetic systemic toxicity (LAST) adverse events
- Potential wound healing related adverse events
- Deaths (none on HTX-011; one on bupivacaine)

The Commercialization of HTX-011

Advancing Pain Management



HTX-011 is an investigational new drug and not approved by the FDA

Confidential

Established Platform With Experienced Teams in Place

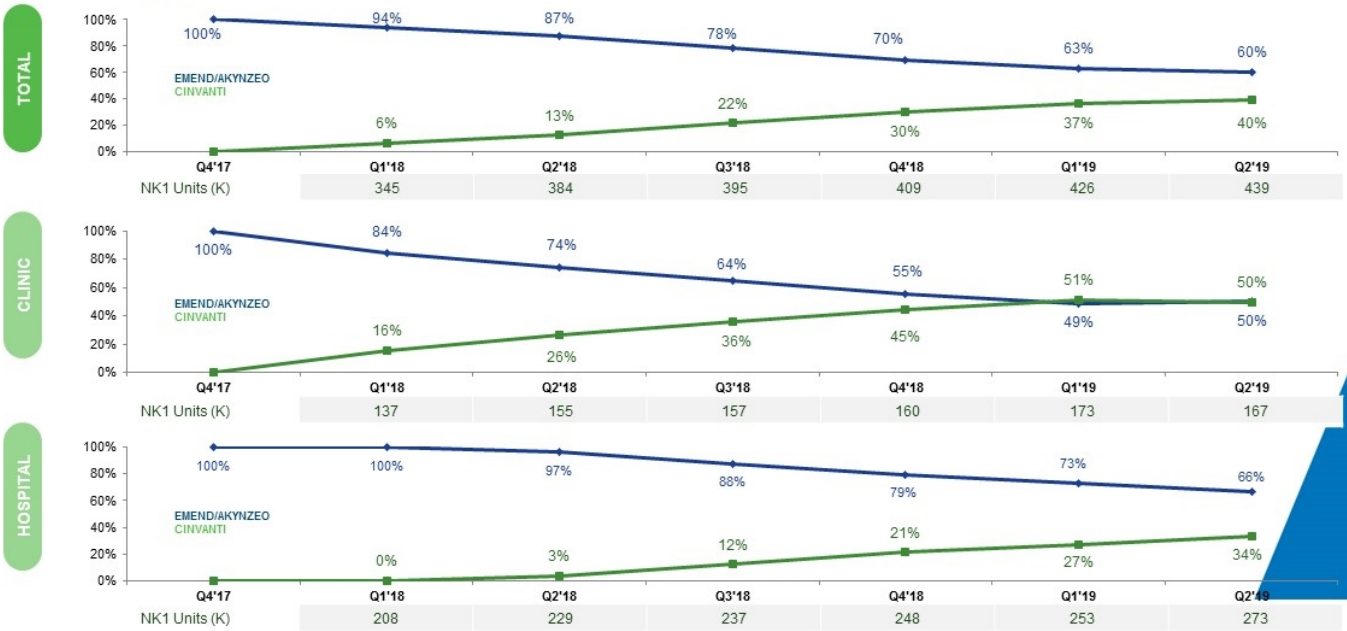
We are prepared for the launch of HTX-011. Our critical teams are already in place, with extensive experience in successful hospital launches.



EXISTING PLATFORM ADVANTAGES

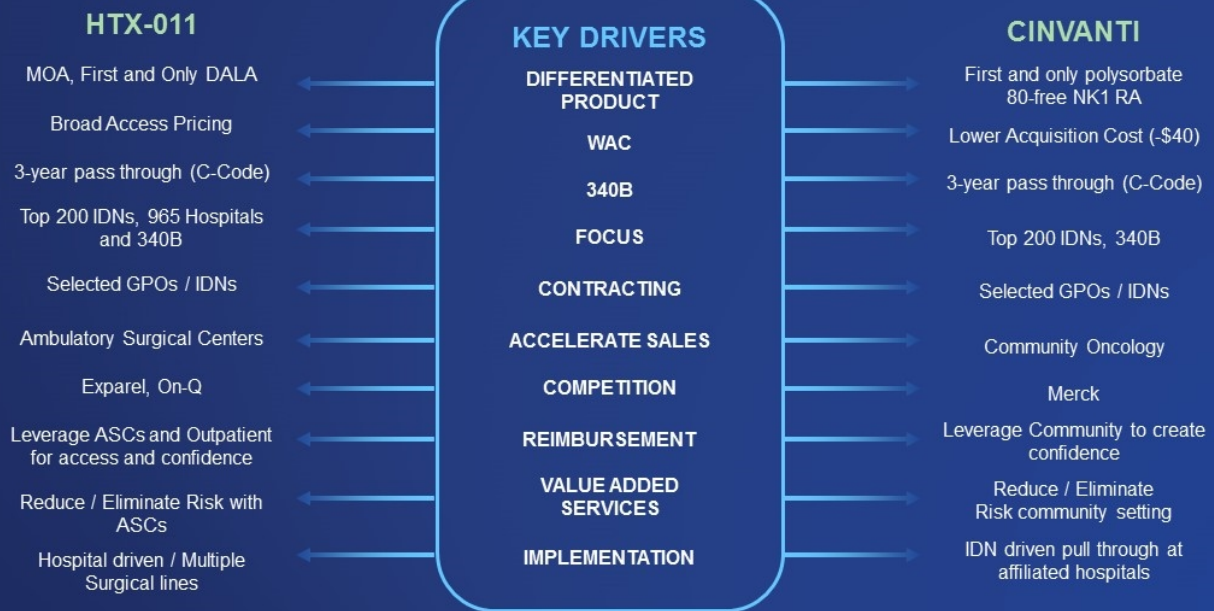
- ✓ Strong KOL relationships
- ✓ Successful hospital and pain management launch experience
- ✓ IDN/hospital/ASC expertise and relationships
- ✓ Reimbursement infrastructure in place
- ✓ GPO contracts in place
- ✓ Full Line Wholesaler agreements and 3PL in place
- ✓ Safety monitoring structure in place
- ✓ Proven compliant execution
- ✓ Robust systems in place and pressure tested for blockbuster launch

CINVANTI Market Share is Climbing Steadily Across All Segments



Data Source(s): 867 through 7/6/19, DDD through 6/21/19, Chargeback Report 7/3/19

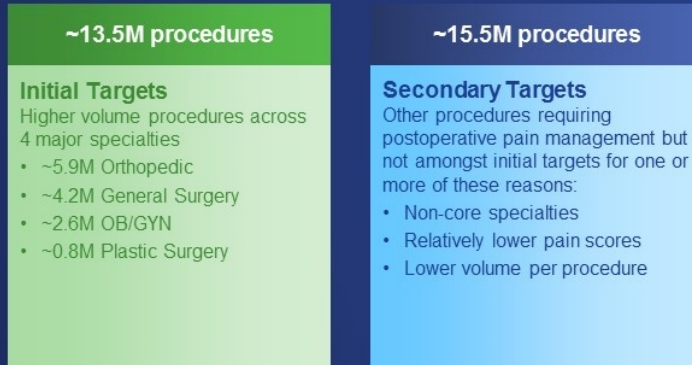
Key CINVANTI Learnings to Support HTX-011 Launch



The Market is Large and Waiting for an Effective Non-opioid Solution

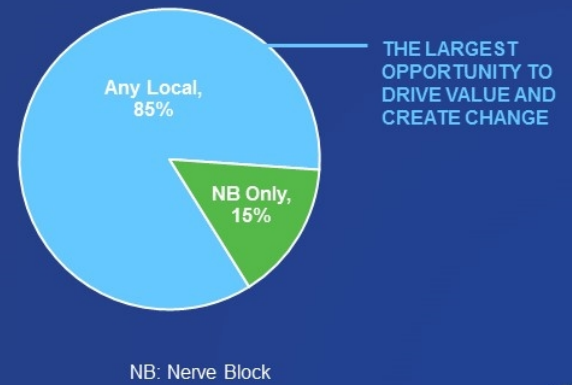
Theoretical and Target Market

~29M Annual US Surgical Procedures Requiring Postoperative Pain Management



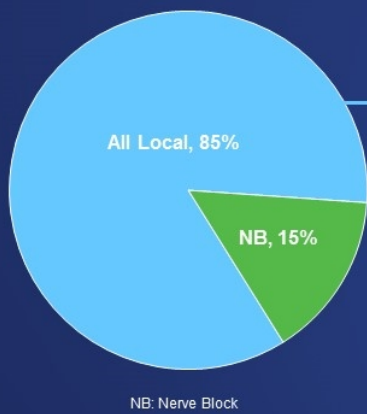
* Local Anesthetics are used in ~70% of procedures

Local Anesthetic Route of Delivery *



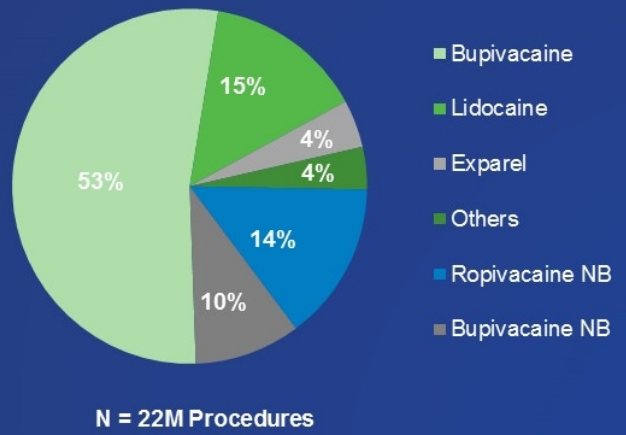
HTX-011 is Focused on the Largest Market Opportunity

Local Anesthetic Route of Delivery



THE LARGEST OPPORTUNITY TO DRIVE VALUE AND CREATE CHANGE

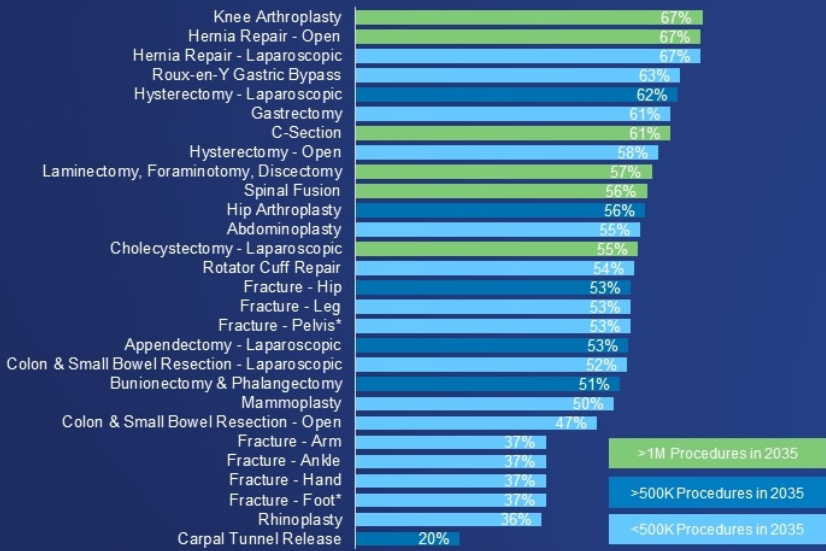
Local Anesthetic Volume Share



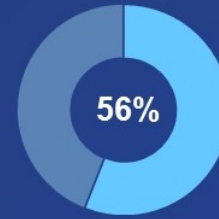
DRG Foundational Insights Research Dec. 2016

Physicians Indicated a Raw Preference Share of 56% for a Drug with HTX-011's Potential Attributes Across the Covered Procedures

Preference Share (% , Raw)



Overall Wt. Average Preference Share



- Raw preference share for a drug with HTX-011's potential attributes from physicians: 56%
- The top procedures where physicians expected to use such a drug were knee arthroplasty and hernia repair
- Several procedures saw higher raw preference shares than prior market research, notably knee & hip arthroplasty, C-section, laparoscopic hysterectomy and spine procedures

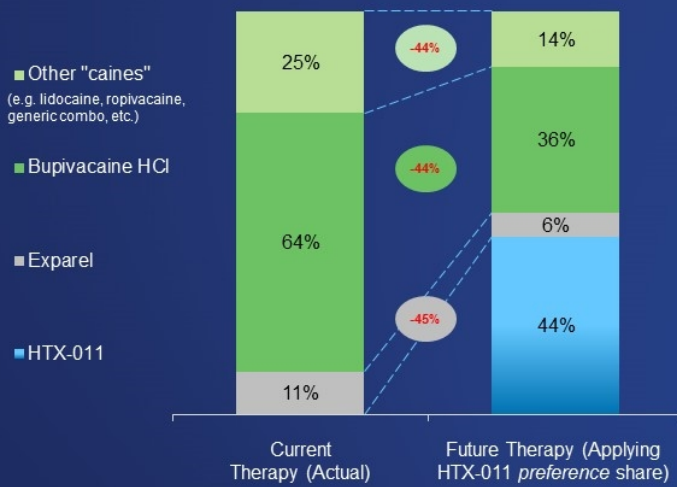
Reference: DRG Postoperative Pain Quantitative Research (Nov 2018) - n = 290 physicians; *Less than 100K procedures at peak

HTX-011 is an investigational new drug and not approved by the FDA



A Drug with HTX-011's Potential Attributes Enjoyed a Physician Preference Share of 44%

Adjusted Physician Preference Share Distribution



- If approved, we believe HTX-011 is likely to initially convert share from Exparel, as well as the rest of the local anesthetics (bupivacaine & other "caines")
- There is an additional opportunity to convert physicians not using local anesthetics; physicians indicated a willingness to use such drug with characteristics similar to HTX-011 in ~30% of procedures where they are currently not using local anesthetics

Current therapy based on Claims data from 2017 for Exparel, other agents are based on 2018 Physician Survey

Data from analysis of physician static survey & conjoint - Sample includes n = 330 physicians

HTX-011 has Potential Strategic Advantages Across Each Setting of Care

Clearly differentiated strategy supported by building advocacy with pharmacy, surgeons, and anesthesiologists

**13.5
MILLION**
INITIAL TARGET
PROCEDURES

Hospitals account for 91%, including top 200 IDNs (12.3M procedures)

52%
Hospital
Inpatient
(7M procedures)

- Part of DRG payment
- Multiple SKUs - lower average cost
- ~50% connected 340B hospitals

39%
Hospital
Outpatient
(5.3M procedures)

- 3-year pass through (C-Code)
- 340B opportunity
- High value IDN and procedure focus

Ambulatory surgical centers account for 8% (1.1M procedures)

8%
Ambulatory Surgical
Centers (ASCs)
(1.1M procedures)

- ASP +6%
- Lower access barriers
- Targeted facilities
- Connected to top IDNs
- Targeted high value procedures

47% of the opportunity lends itself to favorable reimbursement and access

The remaining 1% of procedures are performed at private physician practices

340B Hospital Summary

- ~2258 hospitals (excluding children's & psych)
 - 8.4M outpatient surgeries/year
 - 4.4M inpatient surgeries/year
- Manufacturers required to provide 23.1% discount off ASP/WAC
- Discount does not impact ASP or best price calculations
- Products used in the OR that are considered part of the surgical package are not reimbursed, unless they have pass-through status
- **Approximately 3 months after approval, HTX-011 will receive a C-Code providing pass-through status**

340B Drug Reimbursement for Postoperative Pain

With C-Code	Without C-Code
ASP + 6%	Bundled Payment – No Direct Reimbursement

Heron is Well Positioned to Execute a Blockbuster Launch for HTX-011

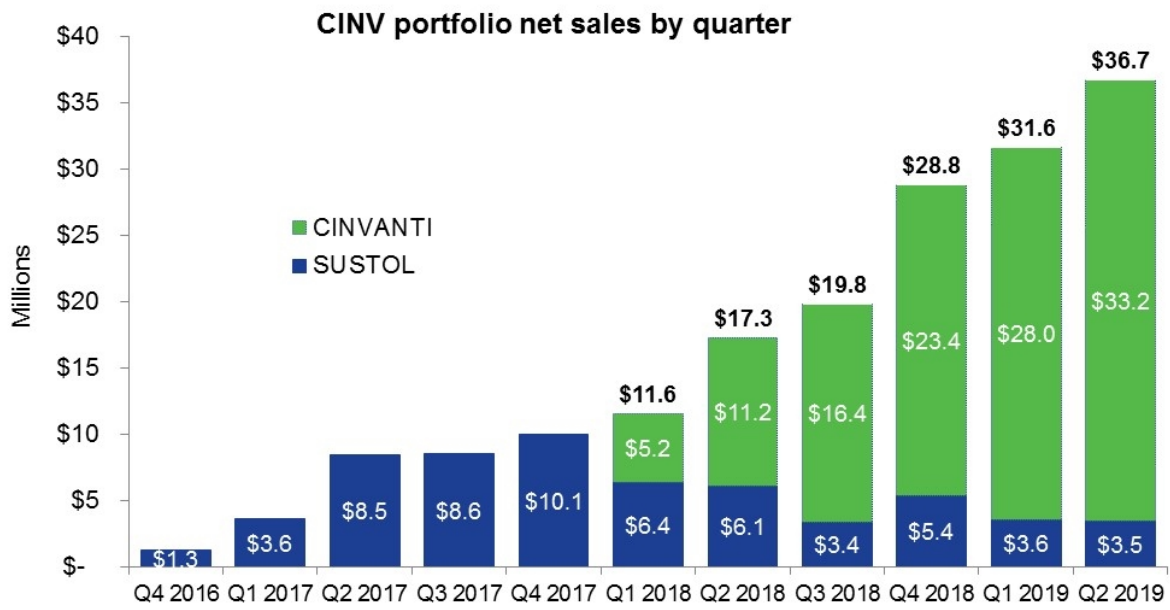
- ✓ Proven track record with hospital launch success
- ✓ Existing robust platform and structure to support launch
- ✓ Significant unmet need and market opportunity
- ✓ Highly focused launch strategy to accelerate sales
- ✓ Unprecedented value proposition

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CINV Commercial Products

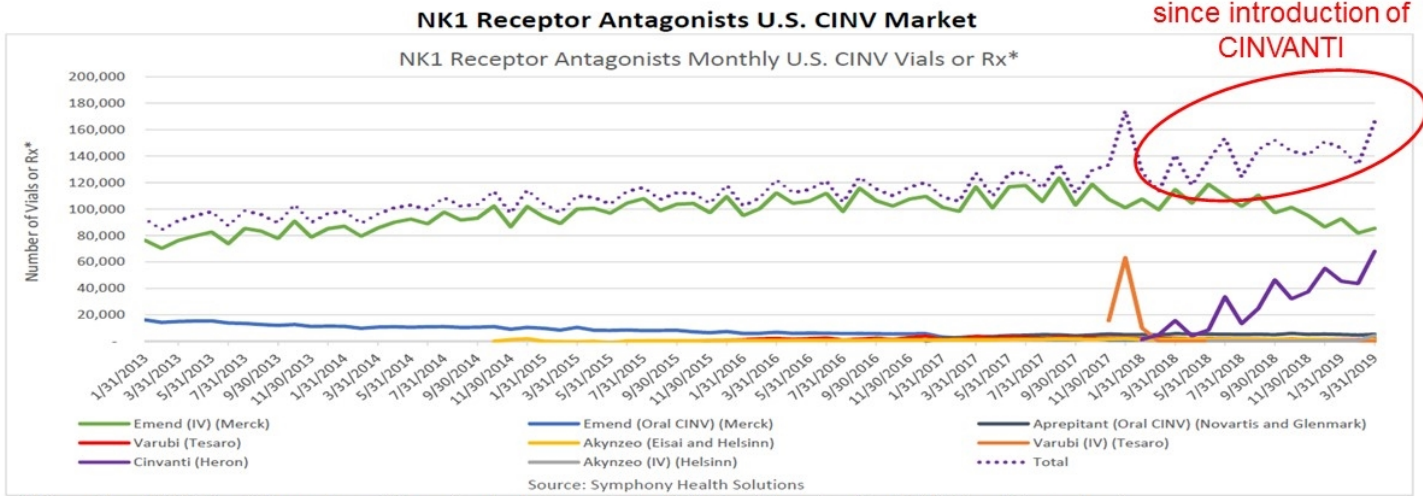


CINV Portfolio Continues to Grow With Over \$177M Since Inception



CINVANTI is Both Taking Share From Emend and Growing the NK1 Market

NK1 market has grown since introduction of CINVANTI



*1 Emend (oral CINV) Rx = 3.7 capsules or 125mg of oral solution, excludes PONV Rx; 1 Aprepitant (oral CINV) Rx = 3.6 capsules; 1 Varubi Rx = 2.4 tablets; 1 Akynzeo Rx = 1.3 capsules

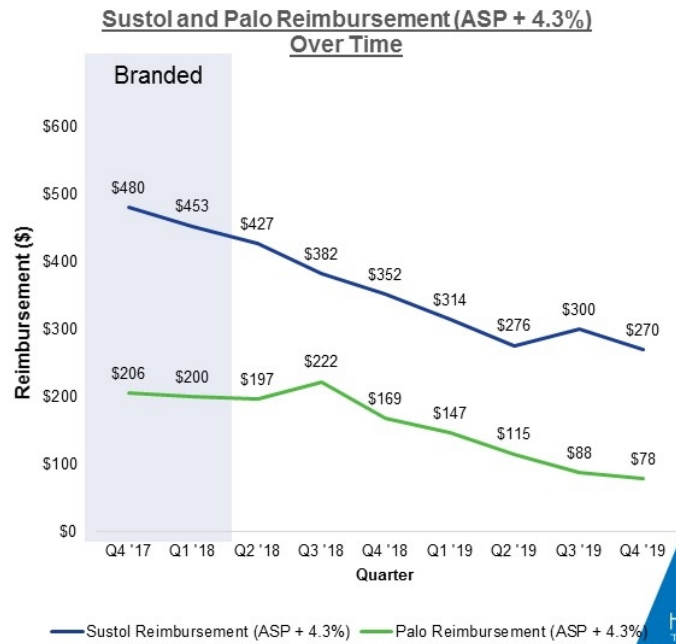


Strategy to Preserve CINVANTI Through Generic Arbitrage

- Leverage favorable 340B pass through status, ASP+ 6% through 2020
- IV push sNDA approved further differentiating CINVANTI from Emend and generics
- Long-term contracting
- CINVANTI has become an established brand across both clinics and hospital capturing 40% of the market in Q2 2019

ALOXI/Palonosetron Arbitrage Lasted Much Longer Than Projected, Resulting in an Accelerated Decline in Sustol ASP

- Even with multiple generics on the market, the price of palonosetron did not drop as quickly as in past arbitrage periods
- Slow decline in prices resulted in a very long arbitrage, which also **resulted in an accelerated decline in the Sustol ASP**
- The only way to rebuild value in the brand is to implement an innovative strategy:
 - Starting October 1, all discounting of Sustol was discontinued, which will result in lower sales
 - In approximately 5 quarters the ASP of Sustol will reset to approximately the WAC
 - Sustol will be re-launched with enhanced value for practices and Heron



2019 CINV Franchise Outlook



SUSTOL®: To recover from the protracted palonosetron arbitrage, Heron has implemented an innovative strategy to refresh the ASP

- This will result in greatly reduced sales for approximately 5 quarters, followed by a significant rebound in units and revenue



CINVANTI®

- Cinvanti continues to have the best overall profile compared to the other available NK₁ antagonists and is completely differentiated from generic fosaprepitant with the 2-min IV Push administration
- CINVANTI (aprepitant) injectable emulsion received unique J-Code J0185 effective January 1, 2019, so generic pricing does not effect Cinvanti reimbursement
- Generic fosaprepitant IV entered the market in September 2019
 - Due to significant sales in 340b hospitals, IV push label and other factors, we do not expect this arbitrage to have the same magnitude as the Aloxi arbitrage
 - Based on early price reductions within weeks of the first generic entry, the duration of the arbitrage should also be shorter than with Aloxi



CINV Franchise

- **2019 guidance: \$115M - \$120M**

Financial Summary

Heron expects to end 2019 with more than \$190 million in cash, cash equivalents and short-term investments.

Summary Statement of Operations and Net Cash Used in Operations (In thousands, except per share data)	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Net product sales	\$ 36,659	\$ 68,261
Operating expenses ¹	88,438	184,740
Other income, net	1,557	3,245
Net loss ¹	\$ (50,222)	\$ (113,234)
Net loss per share ²	\$ (0.63)	\$ (1.43)
Net cash used in operations	\$ (23,108)	\$ (72,132)

Condensed Balance Sheet Data (In thousands)	June 30, 2019
Cash, cash equivalents and short-term investments	\$ 276,005
Accounts receivable, net	\$ 66,821
Total assets	\$ 411,666
Total stockholders' equity	\$ 305,359

Common shares outstanding at June 30, 2019 totaled 79.8 million.

¹ Includes \$12.7 million and \$30.6 million of non-cash, stock-based compensation expense for the three and six months ended June 30, 2019, respectively.

² Based on 79.5 million and 79.0 million weighted-average common shares outstanding for the three and six months ended June 30, 2019, respectively.

Key Catalysts in Pain Management & CINV Franchises

HTX-011 & HTX-034 for Postoperative Pain	CINVANTI [®] and SUSTOL [®] for CINV
<ul style="list-style-type: none"> CRL received 30 April 2019 identified issues relating to CMC and non-clinical <ul style="list-style-type: none"> ➢ No issues related to clinical efficacy or safety were noted ➢ NDA resubmitted 26 September 2019 addressing all the issues raised in the CRL – expect 6 month review 	<ul style="list-style-type: none"> 2019 net sales guidance for CINV franchise: \$115M - \$120M
<ul style="list-style-type: none"> HOPE Project launched across the US 	
<ul style="list-style-type: none"> Publication of Phase 3 and Phase 2b studies <ul style="list-style-type: none"> ✓ Phase 3 studies published in peer-reviewed journals <ul style="list-style-type: none"> ➢ EPOCH 1: Reg Anesth Pain Med. 2019;0:1–7. doi:10.1136/rapm-2019-100531 ➢ EPOCH 2: Hernia. doi: 10.1007/s10029-019-02023-6 	
<ul style="list-style-type: none"> Phase 2 with HTX-034 initiated in late 2019 	

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