

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): May 20, 2013

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-33609	30-0520478
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
4520 East-West Highway, 3 rd Floor Bethesda, Maryland		20814
(Address of Principal Executive Offices)		(Zip Code)

Registrant's telephone number, including area code: (301) 961-3400

(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))
-

Item 7.01. Regulation FD Disclosure.

On May 20, 2013, Sucampo Pharmaceuticals, Inc. (“the Company”) will meet with analysts, investors and investment bankers and make a corporate update presentation and webcast at the Company’s meeting discussing the FDA’s approval of the opioid-induced constipation indication for AMITIZA® (lubiprostone) in Orlando, Florida, that will include written communication comprised of slides. The slides from the presentation are being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 to this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 The corporate update presentation slides dated May 20, 2013.

SIGNATURE

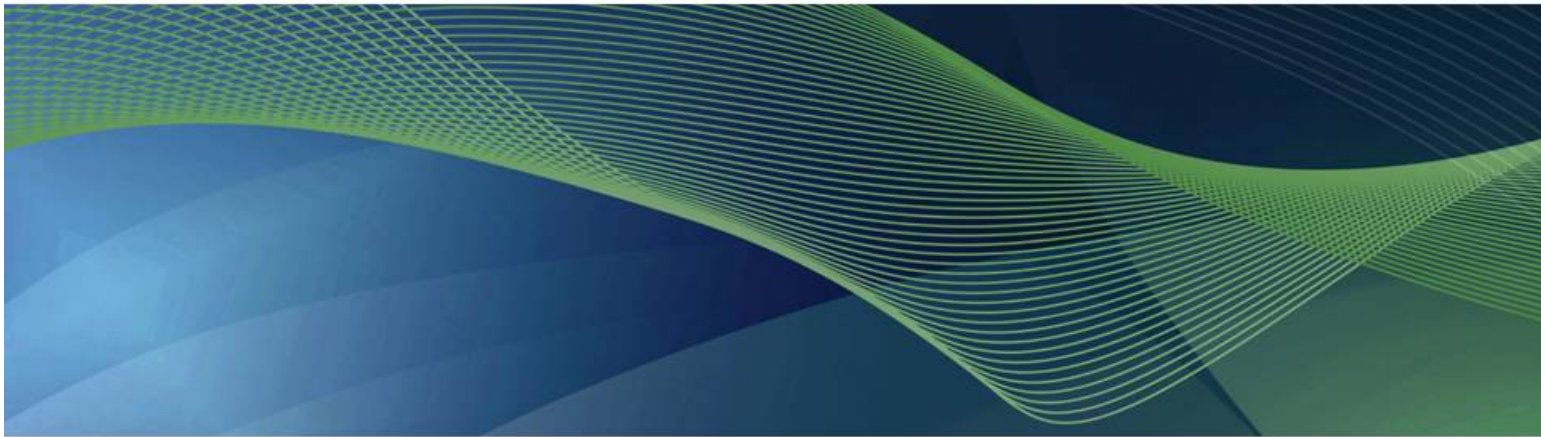
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SUCAMPO PHARMACEUTICALS, INC.

Date: May 20, 2013

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp
Title: Executive Vice President, Chief Legal
Officer & Corporate Secretary



AMITIZA[®] (lubiprostone)

Opioid-Induced Constipation Indication Update

Hard Rock Hotel, Orlando, Florida

May 20, 2013



Introductions and Forward-Looking Statements



Stanley G. Miele

*President, Sucampo Pharma Americas
and SVP, Sales and Marketing*

Agenda

Introduction and Forward-Looking Statements	Stanley G. Miele
Company Update	Stanley G. Miele
Mechanism of Action Review	Jack D. Wood, PhD
Clinical Data Overview	Taryn R. Joswick
Clinical Practice Overview	Brooks D. Cash, MD
Marketing Overview	Greg A. Deener
Closing Remarks	Stanley G. Miele

Forward-Looking Statements

This presentation contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, future financial and operating results, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the US and internationally and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 8-K and 10-K, which Sucampo incorporates by reference.

Company Update



Stanley G. Miele

*President, Sucampo Pharma Americas
and SVP, Sales and Marketing*

- **Market is still growing and addition of opioid-induced constipation (OIC) provides tangible benefit:**
 - Q1 2013 Net Sales up 7% YoY
 - First sale of OIC triggers \$10M milestone payment from partner Takeda
- **Building on legacy of more than 7M prescriptions over 7 years**
 - Growth trajectory expected to continue
 - Minimal losses from competitive launch; due in part to physicians' hesitance to prescribe unproven drug

“After practicing for 30 years I have learned not to adopt a new drug too soon, lest you find yourself calling patients several months later telling them to stop the drug because of some previously undiscovered but significant side effect. The long term safety and efficacy are unknown.” (PCP)

Priority Review

- A *Priority Review* designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists

What does this mean for Sucampo?

- **We have succeeded where others have failed**
 - Safety concerns impeded other companies' attempts to break into OIC market; mu-opioid-receptor agonist compounds under development may have cardiac issues
 - Ideally placed to meet the unmet need
 - OIC is most common reason for discontinuation of opioid therapy
 - Currently, no other oral branded competitors
 - Few options and patients are dissatisfied

Review of Mechanism of Action



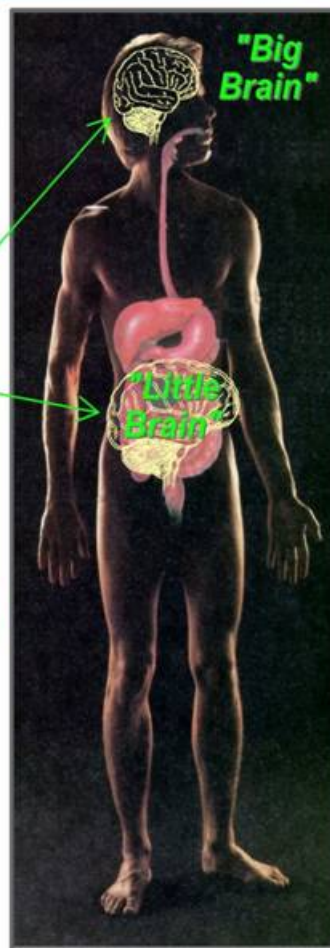
**Jackie D. "Jack" Wood,
MSc, PhD, AGAF**

*Professor of Physiology & Cell Biology
and Internal Medicine*

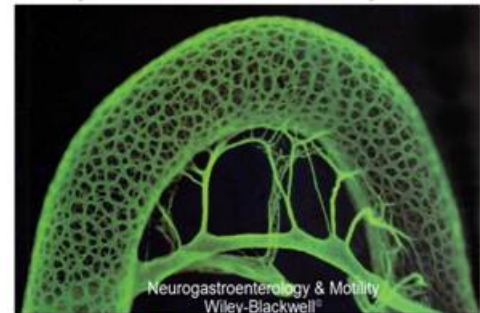
Enteric Nervous System is a Brain-In-The-Gut

Integrated Neural Circuits

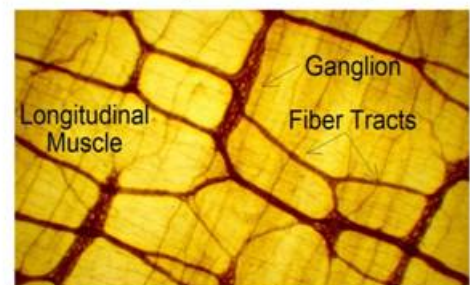
1. Program Library
2. Feedback Control
3. Reflexes
4. Information Processing



Brain-In-The-Gut (100 Million Neurons)

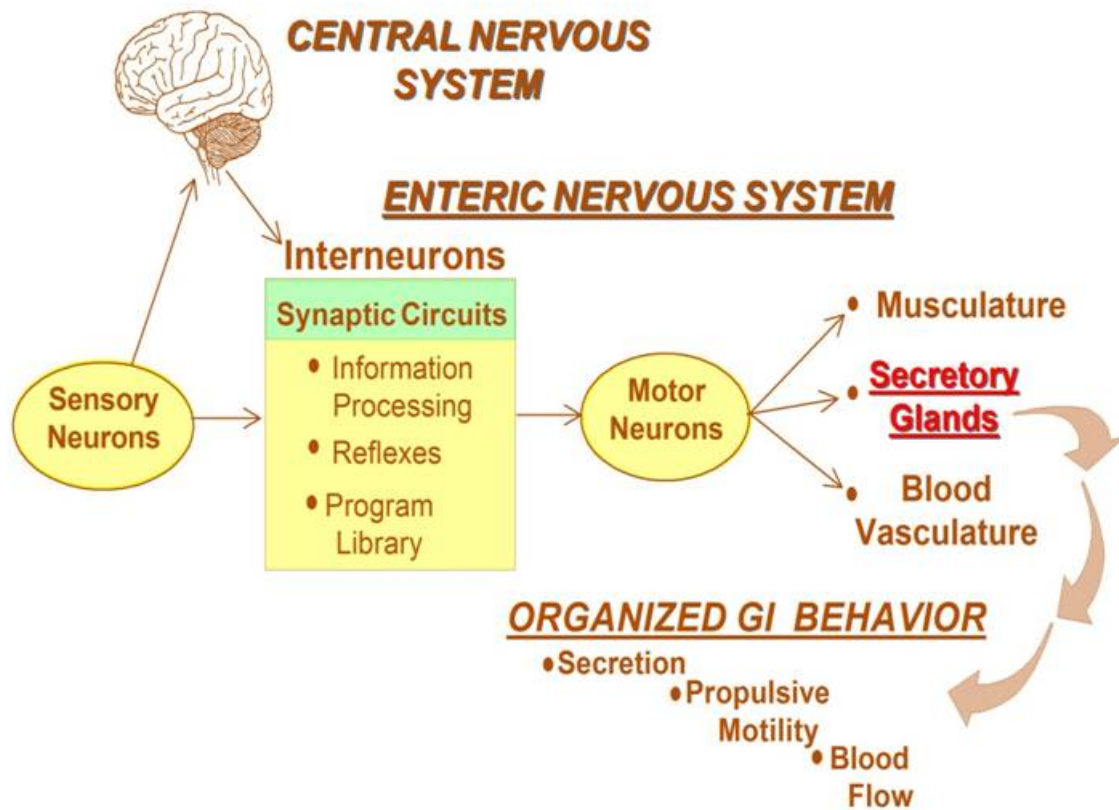


ENS (Little Brain)



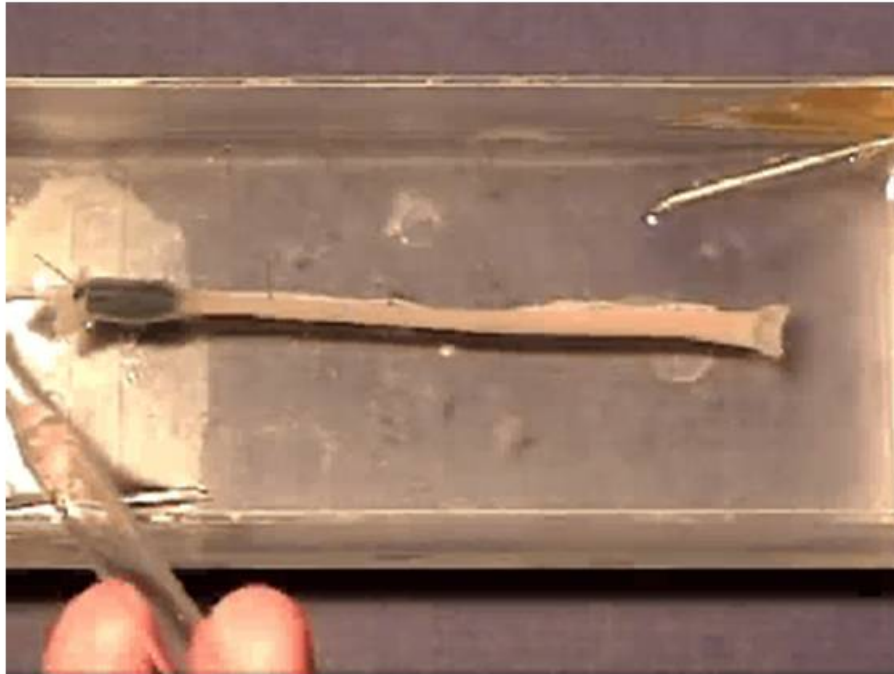
Myenteric Plexus

Mucosal Secretion: Enteric Nervous Control



Enteric Nervous System

Intestinal Propulsive Motility Requires a Functioning Enteric Nervous System:



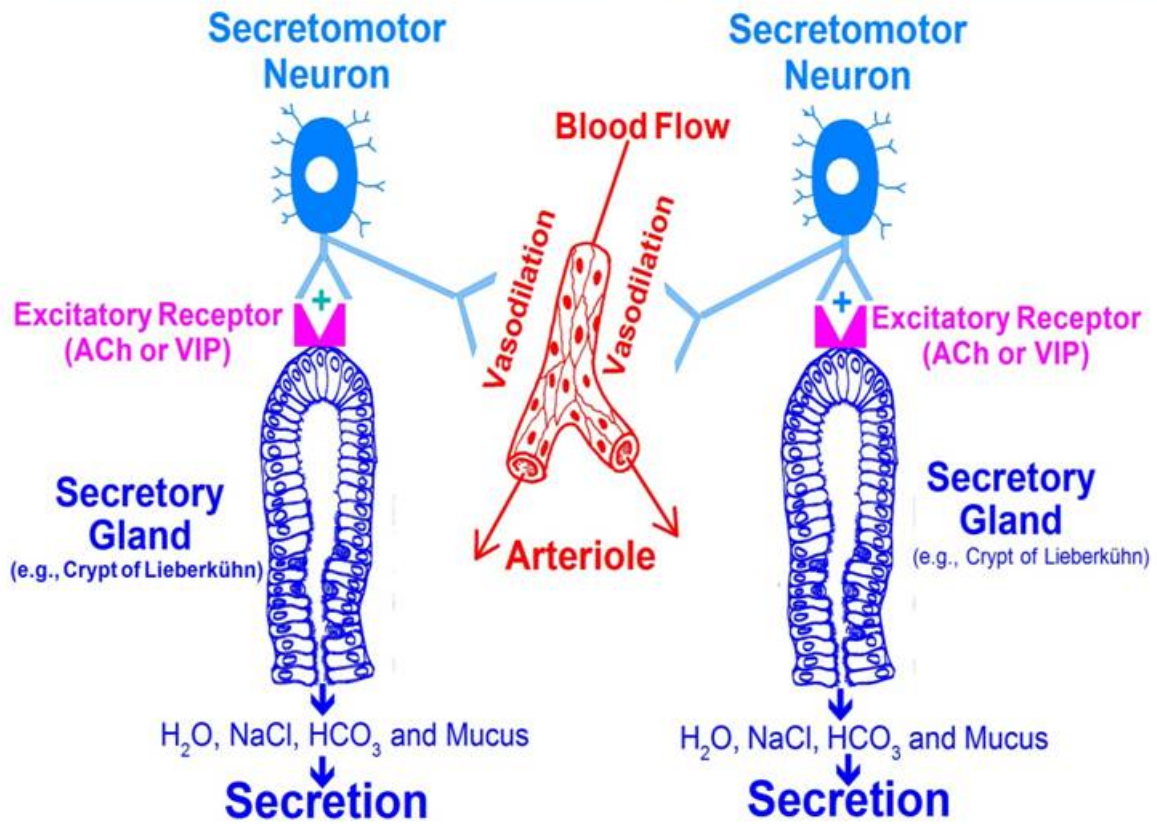
Enteric Nervous System (cont'd)

Intestinal Propulsive Motility Requires a Functioning Enteric Nervous System:



TETRODOTOXIN

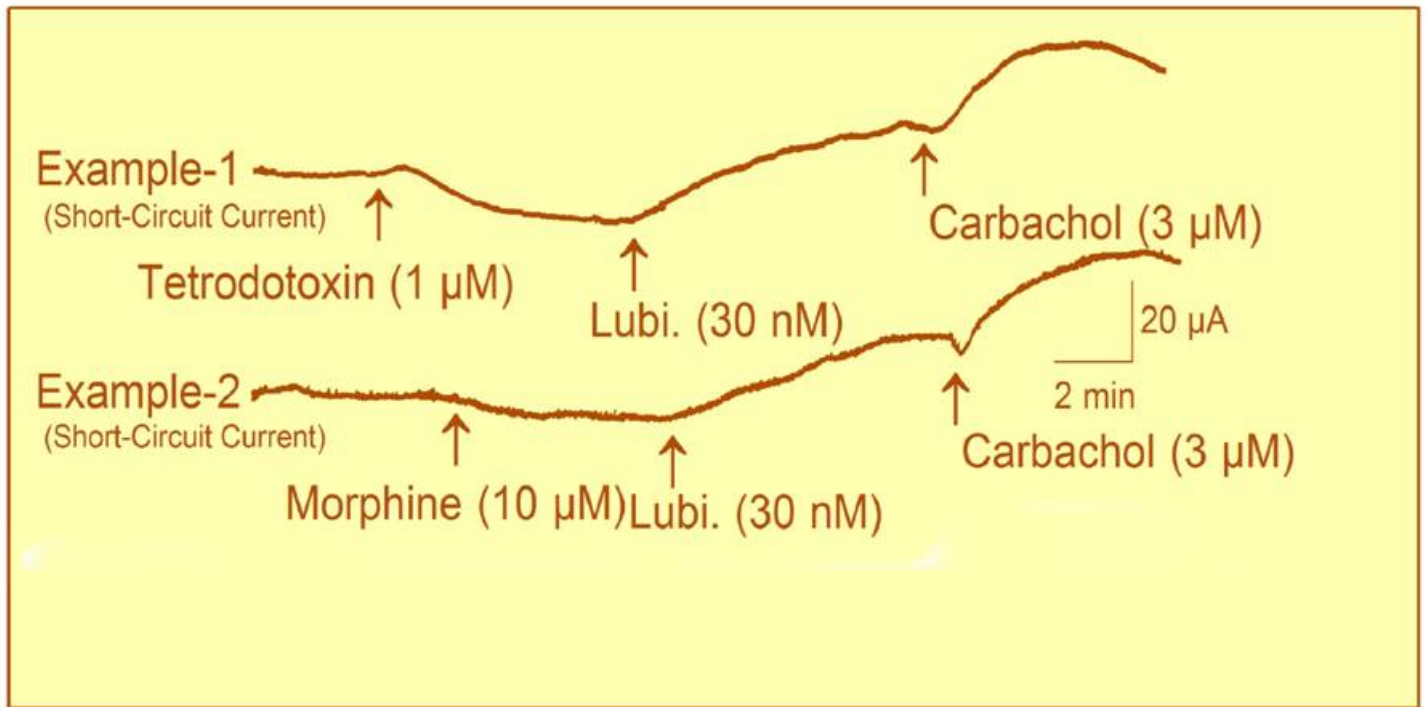
Enteric Secretomotor Neurons



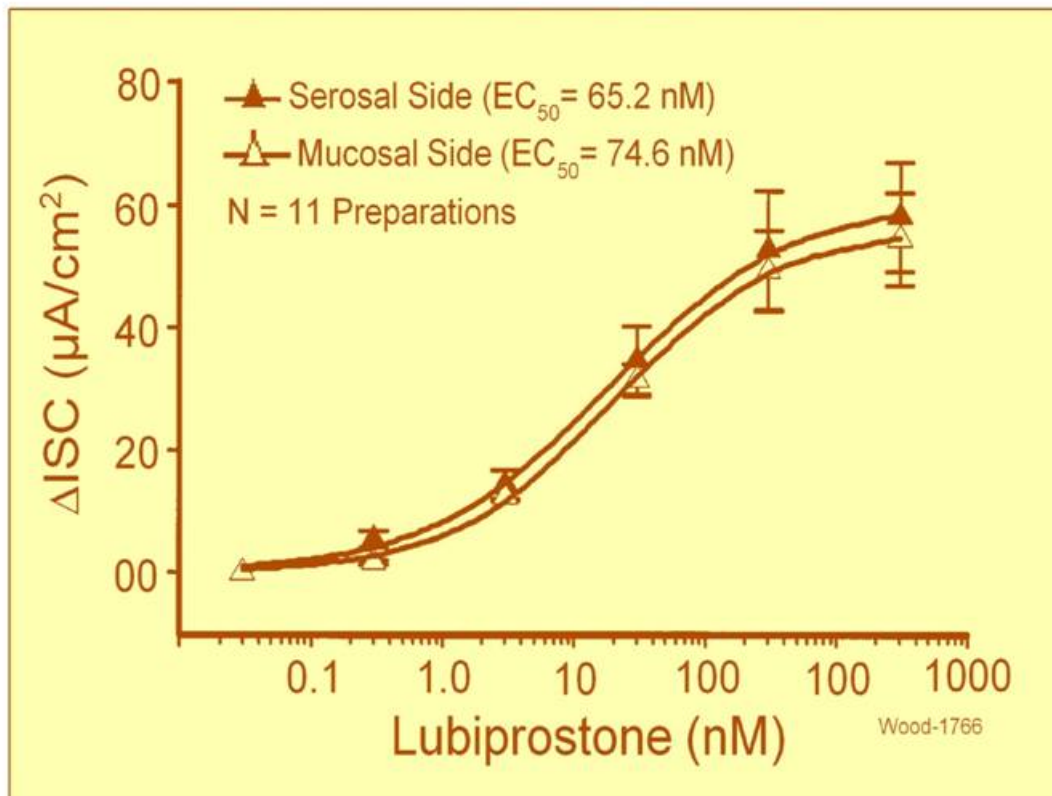
Ussing Chambers are Used to Study Mucosal Secretion



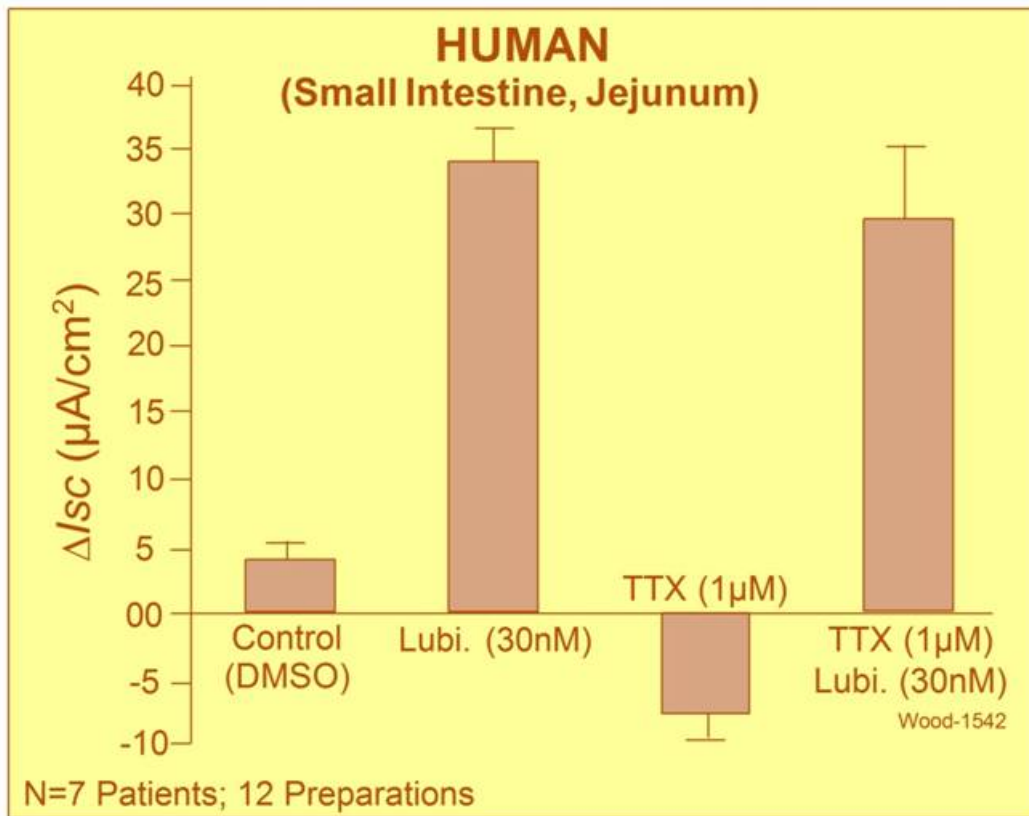
Ussing Chamber Examples: Pharmacological Analysis



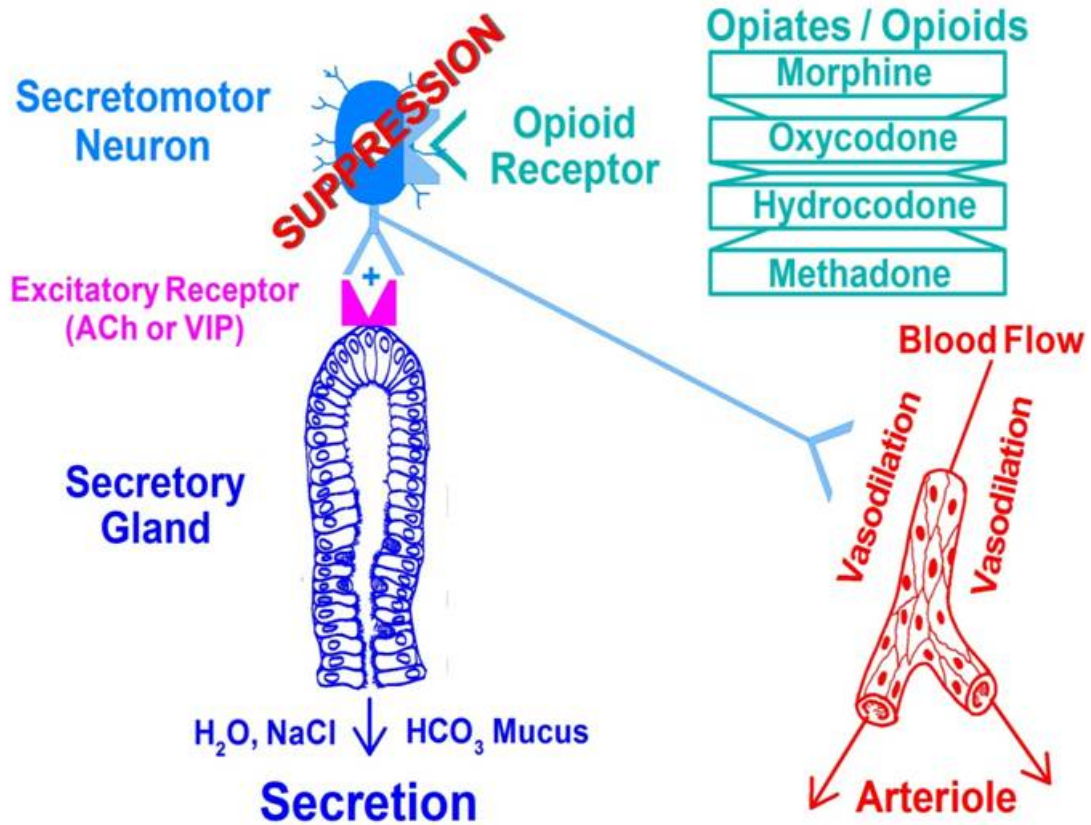
Human Small Intestine (Jejunum)



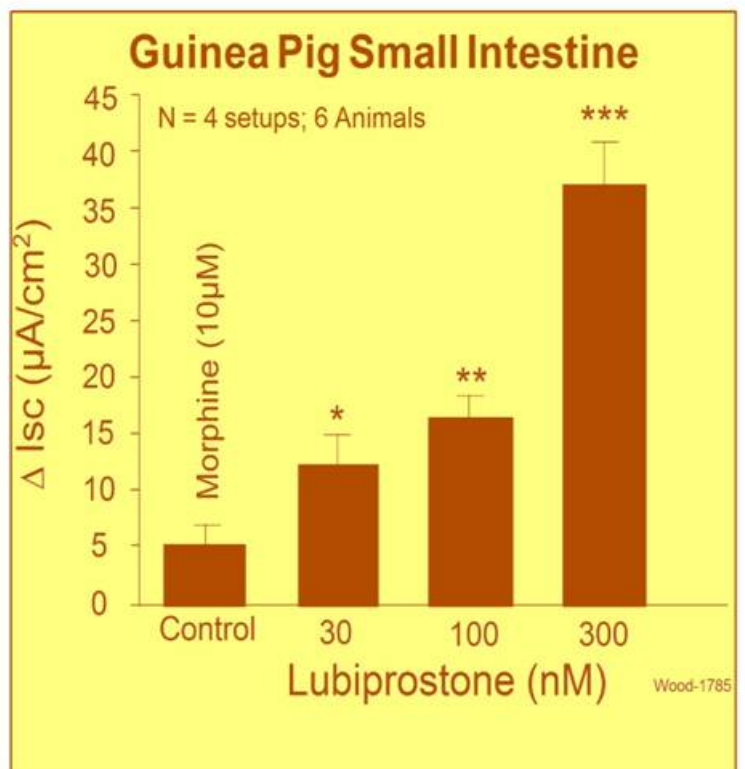
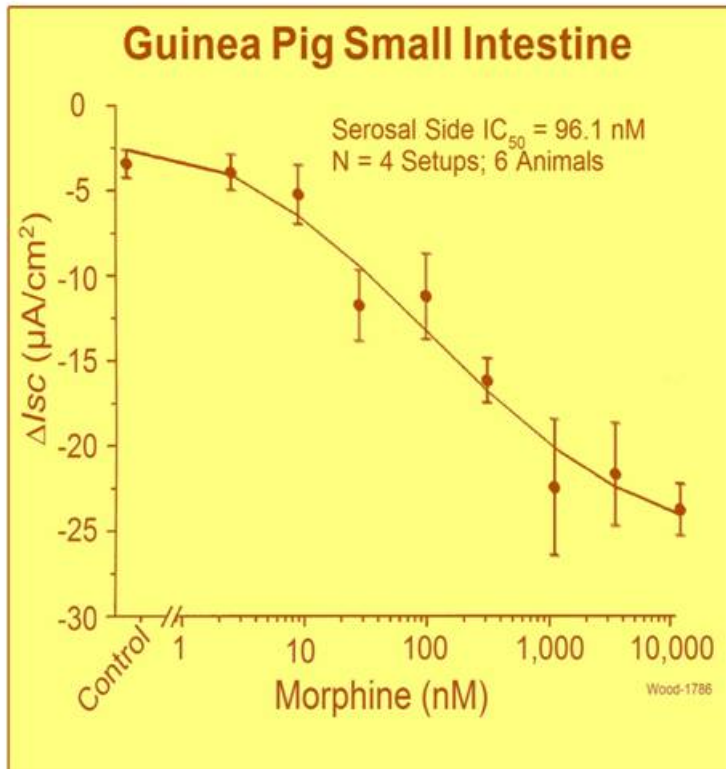
Tetrodotoxin: Neural Blockade



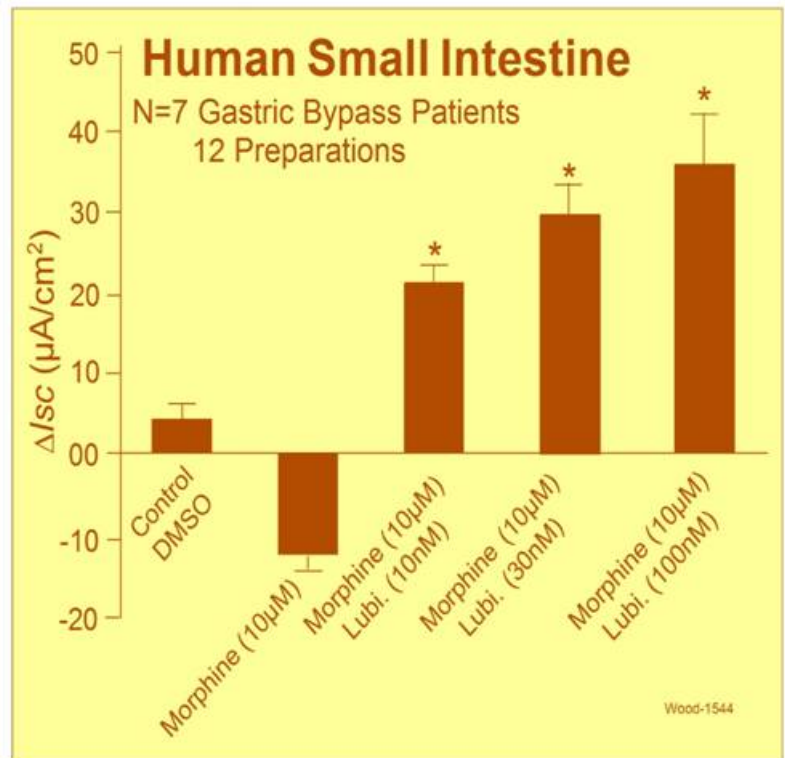
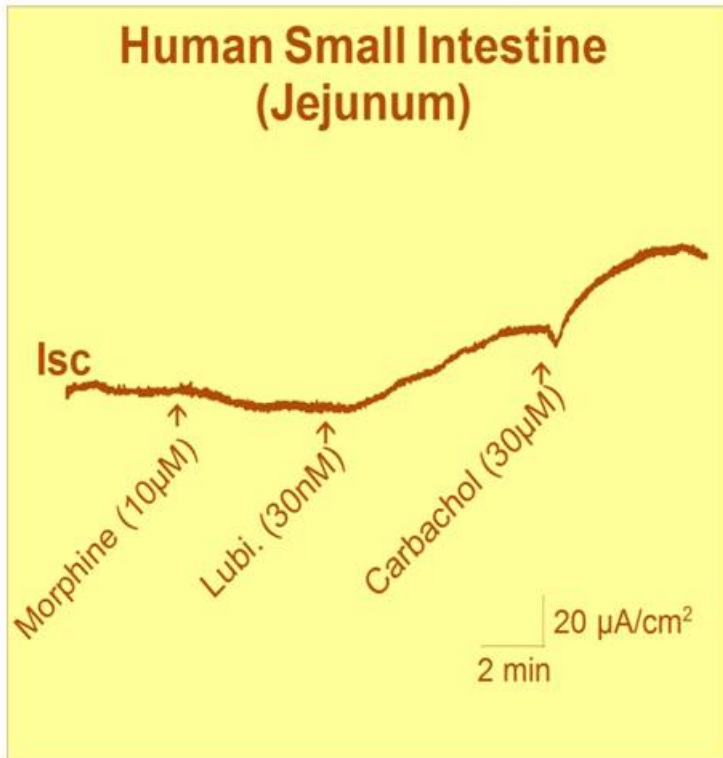
Opiates and Opioid Drugs Suppress Secretomotor Neurons



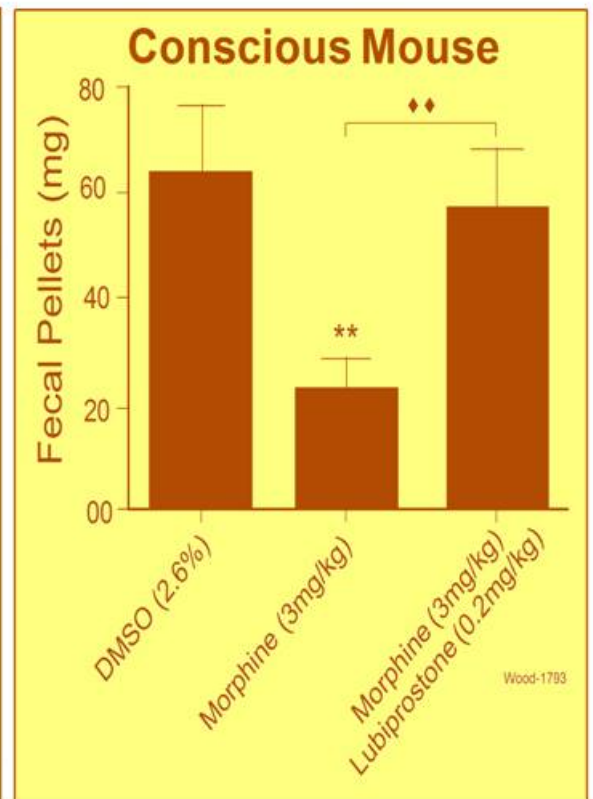
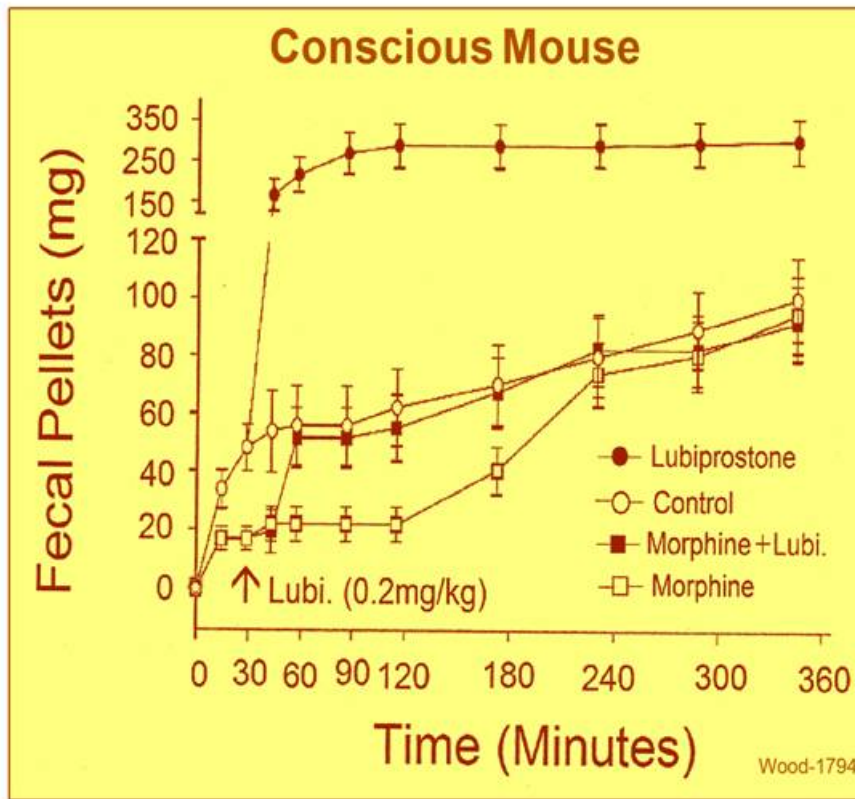
Lubiprostone Reverses Morphine-Induced Suppression of Secretion



Lubiprostone Reverses Morphine-Induced Suppression of Secretion (cont'd)



Lubiprostone Reverses Morphine-Induced Suppression of Fecal Output



Conclusions

1. Opiate/opioid drugs induce constipation by suppression of neurogenic mucosal secretion and with reduced liquidity of the contents in the intestinal lumen as a consequence.
2. Opiate/opioid drugs reduce intestinal liquidity by suppressing the excitability of secretomotor neurons in the brain-in-the-gut.
3. AMITIZA acts directly on the epithelial secretory glands to stimulate mucosal secretion and thereby increase the liquidity of the contents in the intestinal lumen.
4. AMITIZA acts to bypass the negative secretory actions of opiates/opioids on enteric secretomotor neurons by directly stimulating the intestinal secretory glands to secrete H₂O and NaCl.

AMITIZA Life Cycle Management

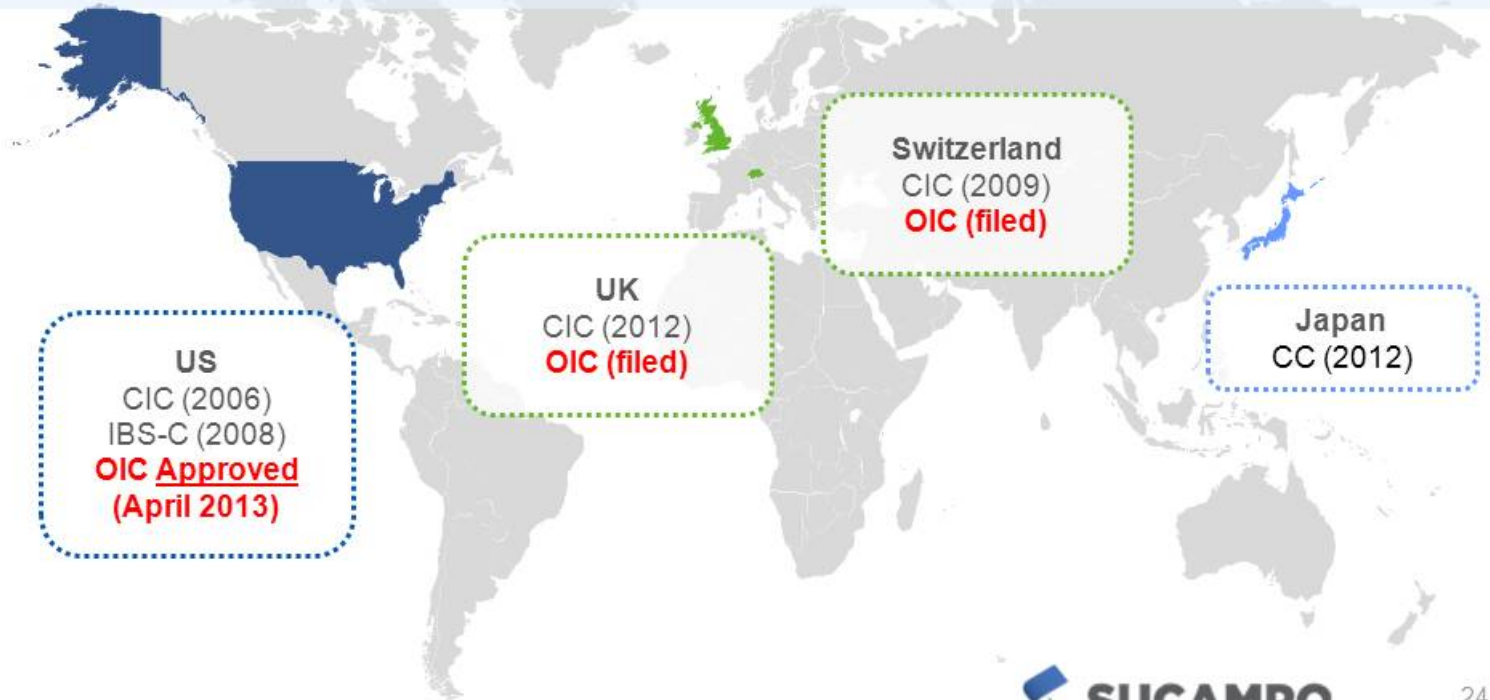


Taryn R. Joswick

Vice President, Clinical Development

Global AMITIZA Approvals and Regulatory Filings

AMITIZA has been used for >7 y with 7M prescriptions by patients suffering from chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C)



OIC Development Program Overview

- **Three 12-week pivotal studies conducted in patients with diagnosis of OIC due to chronic use of opioids for non-cancer pain**
 - Two studies met respective primary efficacy endpoints, while one did not demonstrate statistically significant difference in favor of AMITIZA
- **One long-term safety extension study (exposure up to 12 months) was also conducted**

OIC Label Overview: Indications and Usage

----- INDICATIONS AND USAGE -----

Amitiza is a chloride channel activator indicated for:

- Treatment of chronic idiopathic constipation in adults (1.1)
- Treatment of opioid-induced constipation in adults with chronic, non-cancer pain (1.2)
- Treatment of irritable bowel syndrome with constipation in women \geq 18 years old (1.3)

Limitations of Use:

Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established (1) (14.2)

NO RESTRICTIONS ON DURATION OF AMITIZA USE, AND NO RESTRICTIONS ON AMITIZA USE BASED ON GENDER OR AGE, FOR OIC

OIC Label Overview: Adverse Reactions

Table 2: Percent of Patients with Adverse Reactions (OIC Studies)

System/Adverse Reaction ¹	Placebo	Amitiza 24 mcg Twice Daily
	N = 632 %	N = 860 %
Gastrointestinal disorders		
Nausea	5	11
Diarrhea	2	8
Abdominal pain	1	4
Flatulence	3	4
Abdominal distension	2	3
Vomiting	2	3
Abdominal discomfort ²	1	1
Nervous system disorders		
Headache	1	2
General disorders and site administration conditions		
Peripheral edema	< 1	1

¹Includes only those events associated with treatment (possibly, probably, or definitely related, as assessed by the investigator).

²This term combines “abdominal tenderness,” “abdominal rigidity,” “gastrointestinal discomfort,” “stomach discomfort”, and “abdominal discomfort.”

OIC Label Overview: Adverse Reactions (cont'd)

The most common adverse reactions (incidence > 4%) in OIC were nausea and diarrhea.

Nausea: Approximately 11% of patients who received Amitiza 24 mcg twice daily experienced nausea; 1% of patients had severe nausea and 2% of patients discontinued treatment due to nausea.

Diarrhea: Approximately 8% of patients who received Amitiza 24 mcg twice daily experienced diarrhea; 2% of patients had severe diarrhea and 1% of patients discontinued treatment due to diarrhea.

Less common adverse reactions: The following adverse reactions (assessed by investigator as probably or definitely related to treatment) occurred in less than 1% of patients receiving Amitiza 24 mcg twice daily in clinical studies, occurred in at least two patients, and occurred more frequently in patients receiving study drug than those receiving placebo: fecal incontinence, blood potassium decreased.

7 DRUG INTERACTIONS

No *in vivo* drug–drug interaction studies have been performed with Amitiza.

Based upon the results of *in vitro* human microsome studies, there is low likelihood of pharmacokinetic drug–drug interactions. *In vitro* studies using human liver microsomes indicate that cytochrome P450 isoenzymes are not involved in the metabolism of lubiprostone. Further *in vitro* studies indicate microsomal carbonyl reductase may be involved in the extensive biotransformation of lubiprostone to the metabolite M3 [see *Clinical Pharmacology (12.3)*]. Additionally, *in vitro* studies in human liver microsomes demonstrate that lubiprostone does not inhibit cytochrome P450 isoforms 3A4, 2D6, 1A2, 2A6, 2B6, 2C9, 2C19, or 2E1, and *in vitro* studies of primary cultures of human hepatocytes show no induction of cytochrome P450 isoforms 1A2, 2B6, 2C9, and 3A4 by lubiprostone. Based on the available information, no protein binding–mediated drug interactions of clinical significance are anticipated.

Interaction potential with diphenylheptane opioids (e.g. methadone): Non-clinical studies have shown opioids of the diphenylheptane chemical class (e.g., methadone) to dose-dependently reduce the activation of CIC-2 by lubiprostone in the gastrointestinal tract. There is a possibility of a dose-dependent decrease in the efficacy of Amitiza in patients using diphenylheptane opioids.

12.1 Mechanism of Action

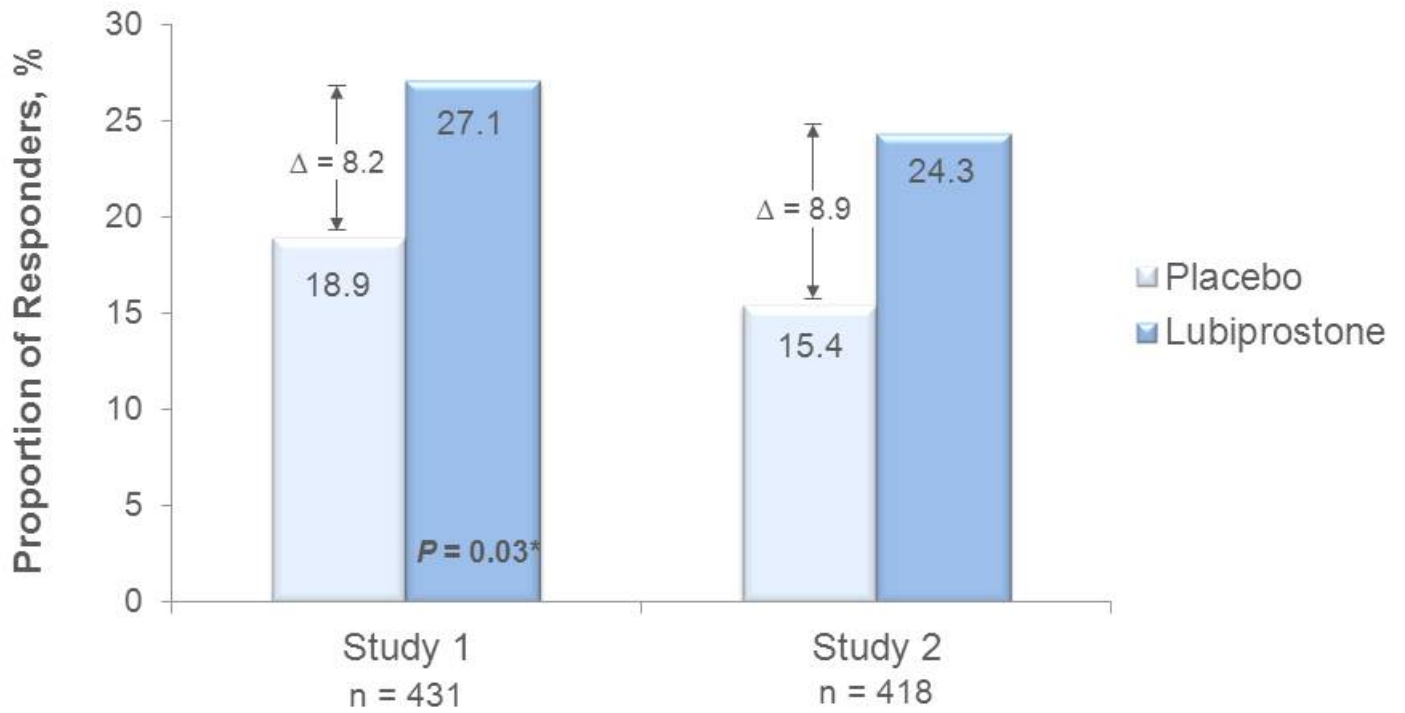
Lubiprostone is a locally acting chloride channel activator that enhances a chloride-rich intestinal fluid secretion without altering sodium and potassium concentrations in the serum. Lubiprostone acts by specifically activating ClC-2, which is a normal constituent of the apical membrane of the human intestine, in a protein kinase A-independent fashion.

By increasing intestinal fluid secretion, lubiprostone increases motility in the intestine, thereby facilitating the passage of stool and alleviating symptoms associated with chronic idiopathic constipation. Patch clamp cell studies in human cell lines have indicated that the majority of the beneficial biological activity of lubiprostone and its metabolites is observed only on the apical (luminal) portion of the gastrointestinal epithelium.

Lubiprostone, via activation of apical ClC-2 channels in intestinal epithelial cells, bypasses the antisecretory action of opiates that results from suppression of secretomotor neuron excitability.

Activation of ClC-2 by lubiprostone has also been shown to stimulate recovery of mucosal barrier function and reduce intestinal permeability via the restoration of tight junction protein complexes in *ex vivo* studies of ischemic porcine intestine.

Overall Spontaneous Bowel Movement (“SBM”) Response in OIC Patients



*Statistically significant ($P \leq 0.05$)

See Reference 2

Competitive Landscape

EXPECT NO MARKET CHALLENGE FOR AMITIZA USE FOR OIC NON-CANCER PATIENTS FOR UP TO 2 YEARS



Competitive Landscape (cont'd)

“...the Division has communicated that it believes a very large, well-controlled, chronic administration trial will have to be conducted to assess the safety of any mu-opioid antagonist prior to market approval for the treatment of patients with OIC who are taking opioids for chronic, non-cancer pain... While it is not possible to definitively determine the duration of our discussions with the FDA regarding this matter, at this time we anticipate a conclusion could be reached during 2013.” – excerpt from **Salix press release on 3/5/13**

“Salix has disclosed in regulatory filings that it might terminate its development program Relistor subcutaneous injection for treatment of OIC in chronic non-cancer pain patients, and that additional information and additional guidance from the FDA could result in the termination of its oral OIC Relistor development program.” –excerpt from **Progenics 10K released 3/15/13**

“We are currently evaluating our Phase 3 strategy due to potentially evolving FDA requirements for this class of drug.” –excerpt from **Theravance 10K released 2/26/13**

Summary and Outlook for AMITIZA

- **Well positioned to serve expanding population of patients with CIC, OIC and IBS-C**
 - 7M prescriptions used over past 7 years with favorable benefit-risk profile
- **AMITIZA currently approved for three indications with additional LCM opportunities:**
 - Expand global approvals and launches for AMITIZA worldwide
 - Develop and seek approval for AMITIZA in pediatric constipation
 - Currently unmet medical need; no approved prescription medications
 - Develop liquid formulation of AMITIZA for long-term care market
 - Evaluate potential of AMITIZA for new indications, such as mixed irritable bowel syndrome

AMITIZA in Clinical Practice



Brooks D. Cash, MD, FACG, AGAF

*Professor of Medicine, USUHS
Deputy Commander for Medicine, Walter
Reed National Military Medical Center
Bethesda, MD, USA*

Functional Constipation ROME III Criteria

- 1. Must include 2 or more of the following:**
 - a. Straining with 25% of defecations
 - b. Lumpy or hard stools in 25% of defecations
 - c. Sensation of incomplete evacuation for at least 25% of defecations
 - d. Sensation of anorectal obstruction for at least 25% of defecations
 - e. Manual maneuvers to facilitate at least 25% of defecations (eg, digital evacuation, support of the pelvic floor)
 - f. Fewer than 3 defecations per week
- 2. Loose stools are rarely present without the use of laxatives**
- 3. There are insufficient criteria for IBS**
 - ✦ *Above met for the last 3 months*
 - ✦ *Symptom onset at least 6 months prior to diagnosis*

See Reference 3

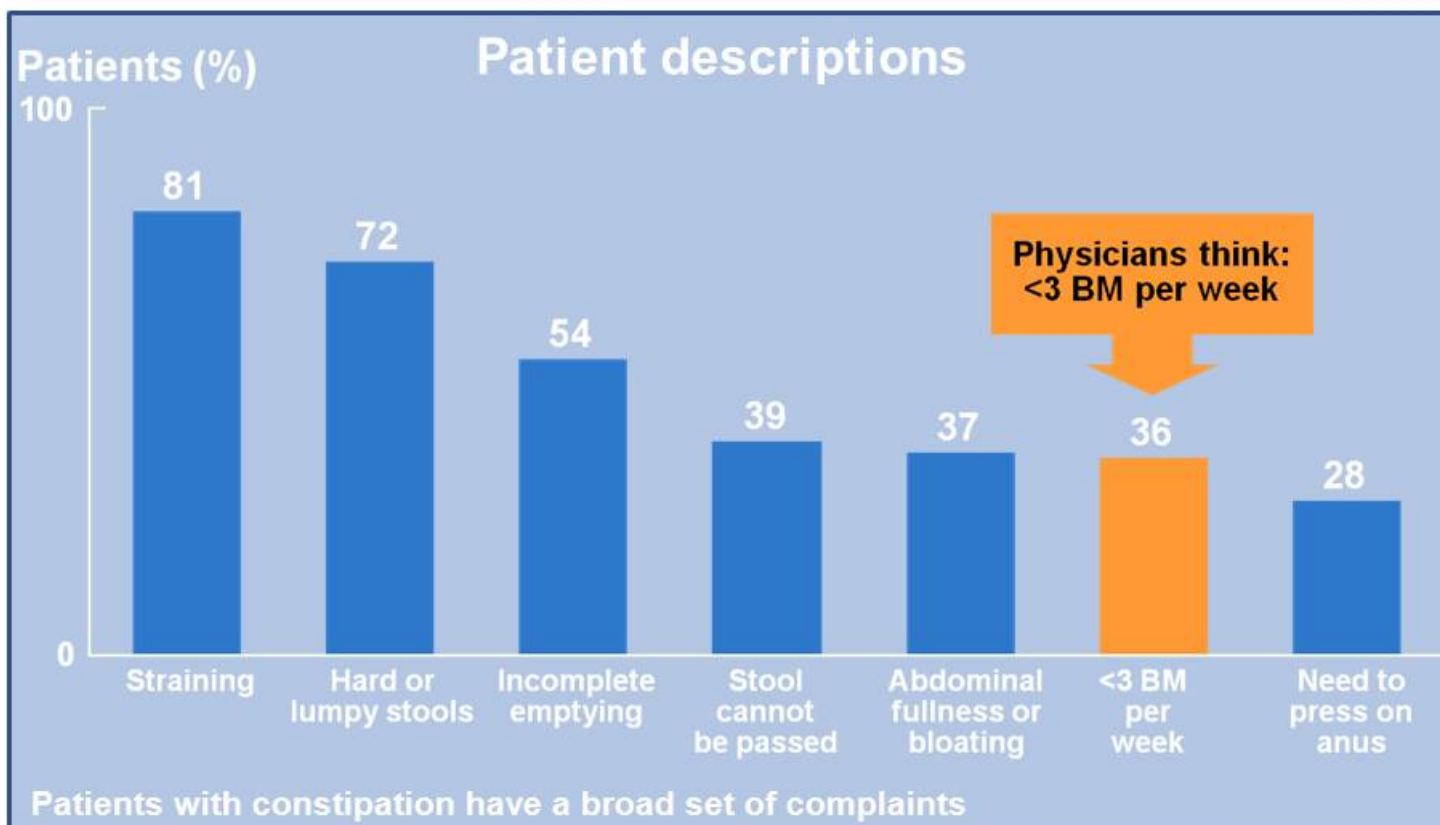
IBS ROME III Criteria

Recurrent abdominal pain or discomfort at least 3 days per month in the last 3 months associated at least 2 of these:

1. Improvement with defecation
 2. Onset associated with a change in frequency of stool
 3. Onset associated with a change in form (appearance) of stool
- ✦ *Above met for the last 3 months*
 - ✦ *Symptom onset at least 6 months prior to diagnosis*

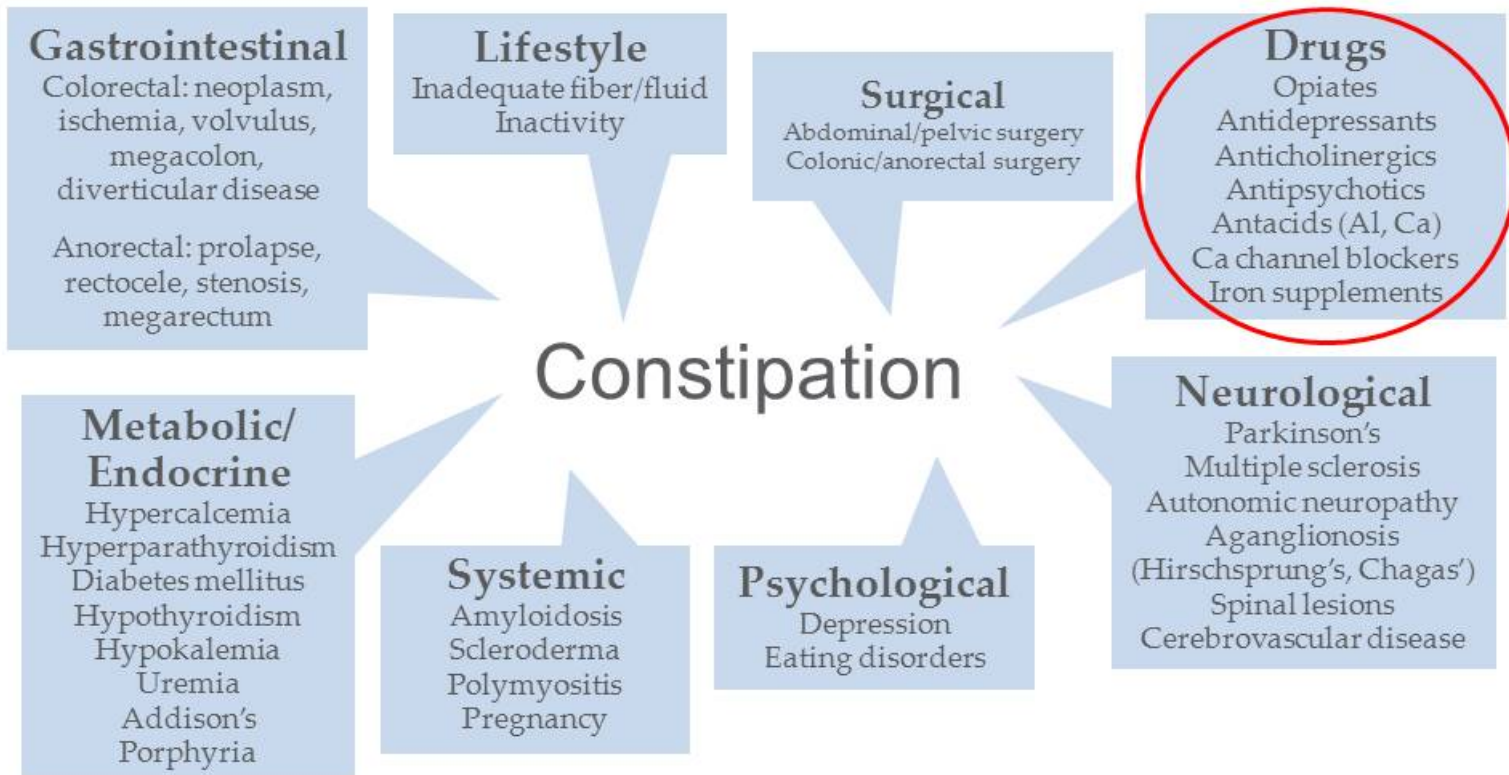
*Chronic Idiopathic Constipation and Opioid-Induced Constipation reference the Functional Constipation ROME III Criteria

Constipation Symptoms: Physician vs. Patient Perception



See Reference 4

Constipation: Secondary Causes



See References 5-6

AMITIZA Clinical Overview

Lubiprostone: A GI system targeted bicyclic functional fatty acid

activates...

Chloride channel (ClC-2) in the apical membrane of the GI epithelium

causing...

Increased chloride secretion

leading to...

Increased intraluminal fluid in the gut

facilitating...

Intestinal transit and easy passage of stool

resulting in...

Alleviation of symptoms

See References 2, 7-9

AMITIZA Safety Profile

- **No gender restriction in CIC or OIC; approved for use in women with IBS-C in US**
- **No black box warning**
- **Well tolerated in short-term (4 weeks) and long-term (6-12 months) trials; no limitation on duration of use**
- **Proven long-term exposure in CIC and IBS-C**
- **Rapid onset in CIC: 57%–63% of patients respond within 24 h**
- **Most common adverse events included nausea, diarrhea, and headache**
- **Low likelihood of drug-drug interactions**

See Reference 2

230M annual prescriptions for opioid use in the US

- **Estimates of the frequency of OIC vary from 15–90%²**
 - Opioids increase chloride absorption and delay GI motility
- **OIC is the most common reason for discontinuation of opioid therapy**
- **Impact of OIC:**
 - Creates more distress for pain patients (often more significant than primary pain indication)
 - Increases costs of care
 - Discontinuation of analgesics
 - Negative impact on HRQOL

Challenges Inherent in OIC

- **Improve Awareness of Pathophysiology and Costs of OIC**
 - Patients
 - Clinicians
 - Caregivers
- **Promote Screening for OIC**
 - Proactive intervention
 - Repeated assessment
- **Promote Patient Education**
- **Increase Awareness of Treatment Options for OIC**
 - Benefits of therapy/risks of failure to intervene
 - Therapeutic approaches/evidence of effectiveness

Treatment Priorities

**Aim to relieve constipation symptoms,
not necessarily increase the number of BMs**

**Identifying the underlying cause is important
so appropriate treatment can be initiated**

Treatment decisions should be based on:

Degree to which symptoms affect patient's life

Results achieved with agents in the past

Patient preference

Clinical judgment

Oral Treatment Options

Bulk laxatives

- Insoluble fiber: bran 20 gm/day
- Soluble fiber: methylcellulose, psyllium

Osmotic laxatives

- Polyethylene glycol (PEG) 21 gm/day
- Lactulose and sorbitol (carbohydrate laxatives that are poorly absorbed by gut)
- Phosphate or magnesium

Stimulant (irritant) laxatives

- Anthraquinones: cascara, aloe, senna
- Castor oil
- Diphenylmethanes: bisacodyl

Chloride channel activator^{*^}

- Lubiprostone 8-24 mcg BID

GC-C receptor agonist[^]

- Linaclotide 145-290 mcg/day

* FDA approved for OIC; ^ FDA approved for CIC, IBS-C

AMITIZA Approval for OIC

- **sNDA received priority review and approval**
 - Lack of effective alternatives
 - Prevalence of condition
 - Burden of condition
- **Based on results of two phase 3 trials and longer term open label study**
- **Counteracts the electrolyte absorbent effects of opioids**

Role of AMITIZA in Clinical Practice

- **Proven efficacy in clinical trials and durable clinical experience**
- **AGA Technical Review 2013**
 - Trial of bulking agents, lifestyle modifications first line therapy
 - Pharmacologic therapy appropriate for failures to above modifications
 - More likely to be required in drug-induced and slow-transit constipation
 - AMITIZA one of two FDA approved therapies for CIC/IBS-C and only FDA approved oral therapy for OIC

AMITIZA in GI Practice Pearls: One Clinician's Perspective

- **Set realistic goals; target most bothersome symptoms**
- **Administer with food (8-24 mcg BID)**
 - Once daily dosing effective in many patients
 - Rapid onset of effect, typically within first 24 hours
 - Eliminate other laxative therapies prior to initiating AMITIZA
- **Equally effective across sexes, age ranges**
- **Indefinite treatment period; no need for drug holiday**
- **Can be used to treat secondary constipation**
- **If response present, but not complete, consider addition of low doses of other laxative families**

Marketing Overview



Greg A. Deener
*Senior Vice President,
Marketing Strategy and
Implementation*

OIC Market is Substantial

Constipation is the longest lasting common side effect of chronic opioids;
dose adjustment of opioids does not reduce

4.5M Chronic Opioid Patients

3.8M with Non-Cancer Pain

2.3M with Moderate
Constipation

.26M with Severe
Constipation

Market:
2.5M

See Reference 14-15

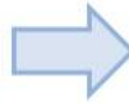
AMITIZA in OIC

- **Currently, 80% of the market is stool softeners, OTC laxatives and prescription PEGs**
- **Use of AMITIZA is limited in OIC (no promotion) due to lack of awareness that AMITIZA is effective in OIC and low awareness among pain specialists**
- **Build awareness that AMITIZA is the first and only medicine for OIC among PCPs and pain specialists**
 - Launch to current targets and expand the number of targets
 - Launch began May 13

AMITIZA OIC Launch: Build on Strengths and Heritage

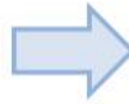
7M prescriptions over 7 years

Pregnancy warning removed from label

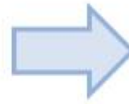


**Build on Strength
in Long-Term Safety**

	AMITIZA	MiraLax
Provides Sustained Relief	74.7	67.7
Relieves Bloating/Discomfort	72.2	61.8
Relieves Abdominal Pain	71.5	62.4
Low Incidence of Diarrhea	64.1	57.8



**Build on Strength
in Efficacy¹⁶**



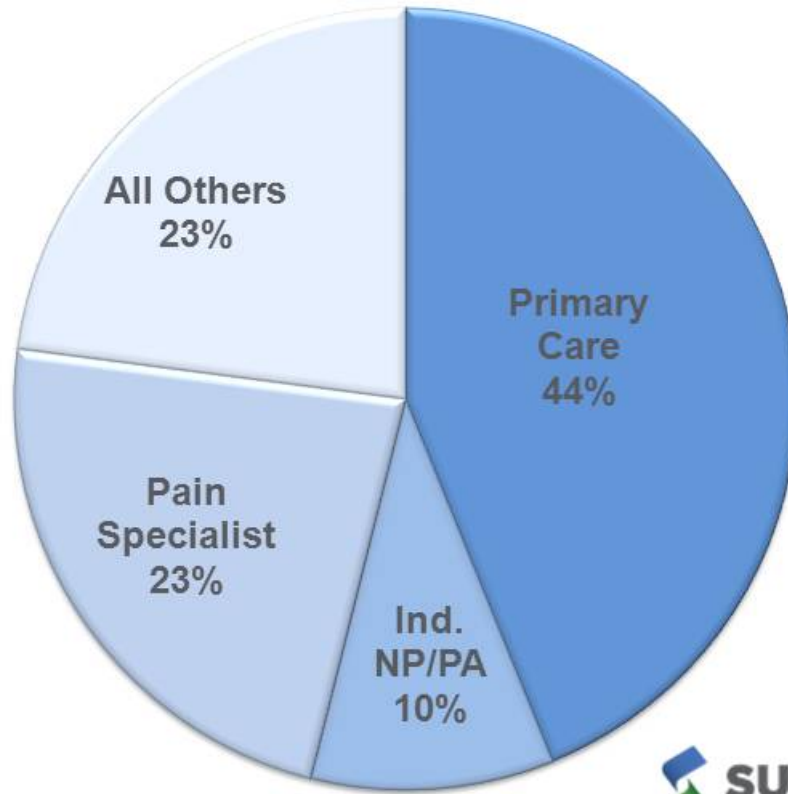
**Build on Strength
in Managed Care Access**

*Over 92% of covered lives have either Tier 2 or Tier 3 coverage

See References 16-17

Three-Quarters of Opioid Chronic Pain Prescriptions are in Primary Care and Pain Specialists

Long-Acting Opioid Prescriptions by Specialty



See Reference 15

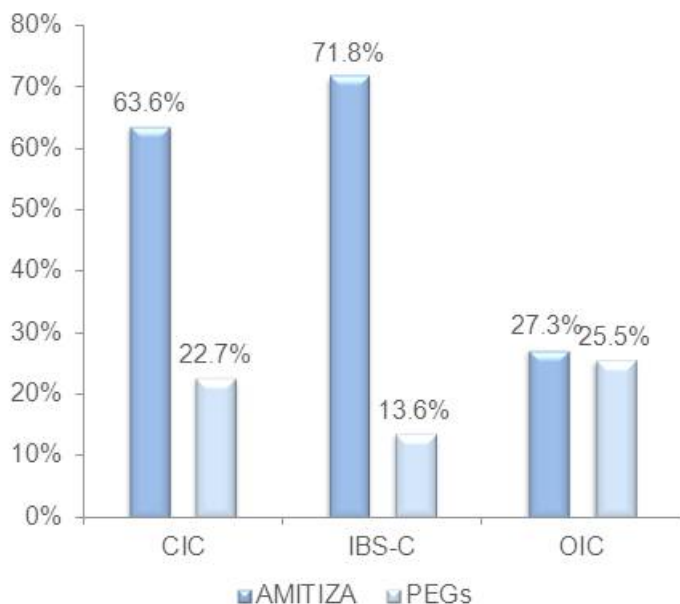
Strategy to Grow AMITIZA

Target	Goal
PCPs who already write AMITIZA	+OIC
Pain Specialists	
GIs	

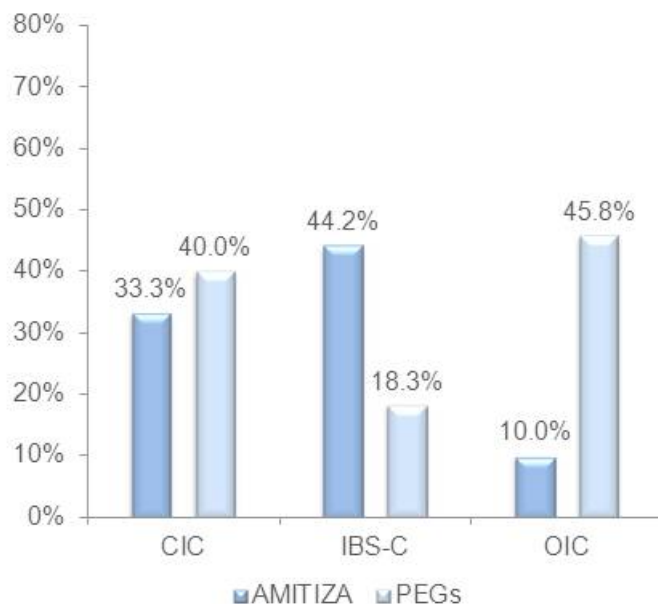
Target	Goal
PCP Non-Writers	+CIC +IBS-C +OIC

OIC: Increase Prescriptions in Current Writers and Relaunch AMITIZA to Non-Writing PCPs

Top of Mind (Unaided) Awareness of AMITIZA vs. PEGs Among Primary Care Writers of AMITIZA



Top of Mind (Unaided) Awareness of AMITIZA vs. PEGs Among Non-Writers of AMITIZA



See Reference 17

AMITIZA is Building on Strengths

AMITIZA offers a simple solution for chronic constipation conditions

Safe → Effective → No Hassle

- This is an opportunity to grow the entire AMITIZA brand
- Full OIC launch by commercialization partner Takeda on May 13, 2013 with resources necessary to gain awareness among both PCPs and pain specialists
 - Priority review for first and only medicine for the treatment of OIC in adults with chronic, non-cancer pain
 - Build upon our 7 year safety and efficacy heritage
 - Already have superior access and distribution

Closing Remarks



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and SVP, Sales and Marketing*

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