

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): July 12, 2012

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 July 12, 2012, Sucampo Pharmaceuticals, Inc. will meet with investors and make a corporate update presentation at an investor conference in New York City, NY at the JMP Securities Healthcare Conference 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 July 12, 2012.

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: July 12, 2012

By: /s/ CARY J. CLAIBORNE

Name: Cary J. Claiborne

Title: Chief Financial Officer



JMP Securities Healthcare Conference

Peter Lichtlen MD, PhD, BBA, Senior Medical Officer, VP European Operations
12 July 2012

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 Form 10-Q, May 10, 2012 for the year ended Dec. 31, 2011, which the Company incorporates by reference

Two approved drugs from proprietary ion channel activator technology

AMITIZA® (lubiprostone)

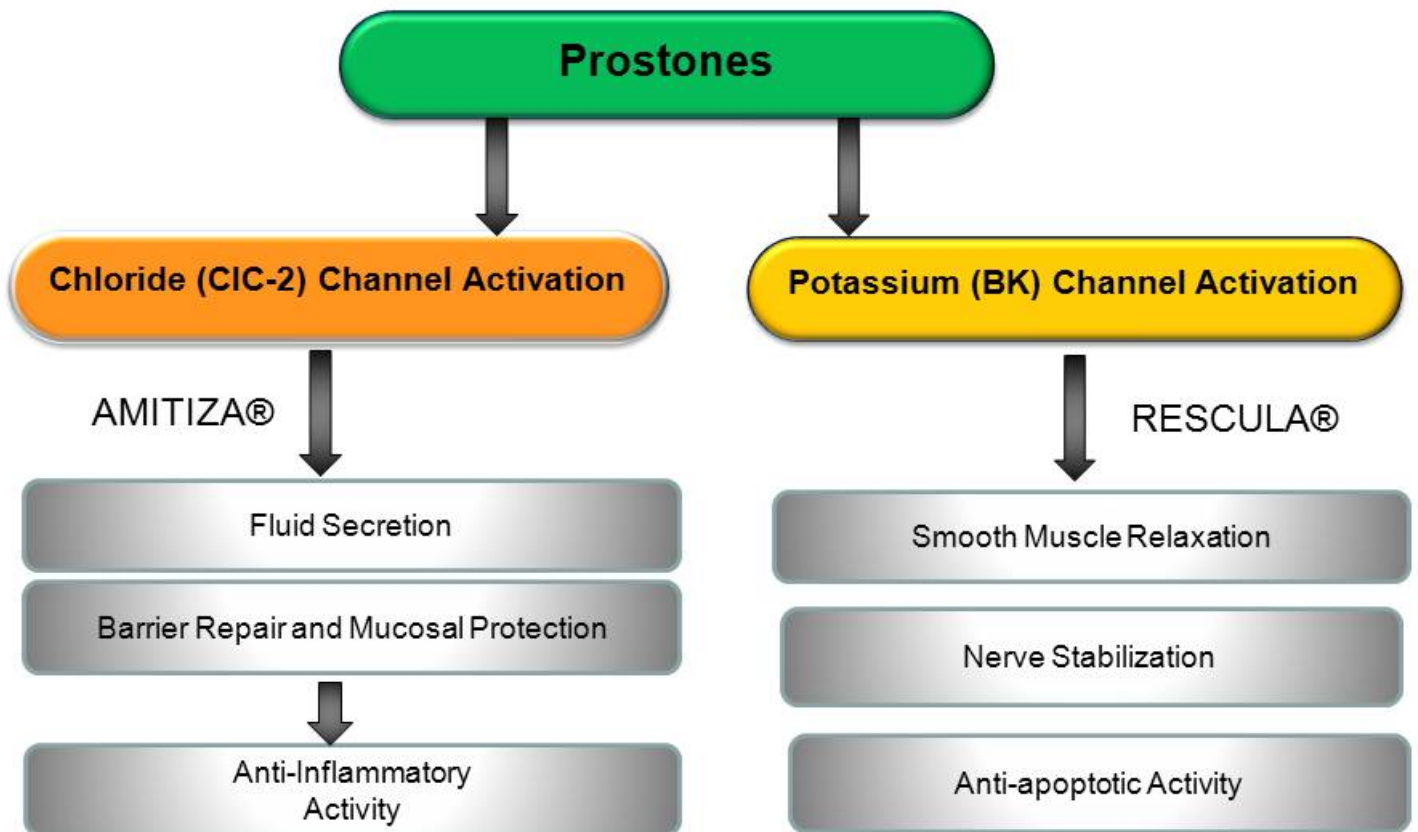
- FDA approved for CIC in adult men/women and IBS-C in adult women aged 18+; sNDA for treatment of OIC and associated signs and symptoms to be filed in July 2012
- Marketed in US by Takeda: 2011 royalty \$41.5M on net sales of \$226.4M
- Limited marketing in Switzerland; CIC filed in UK with expected approval in Q3/2012
- Partnered with Abbott in Japan; NDA approved June 2012, expected launch in Q4/2012
- Patent coverage through 2022

RESCULA® (unoprostone isopropyl)

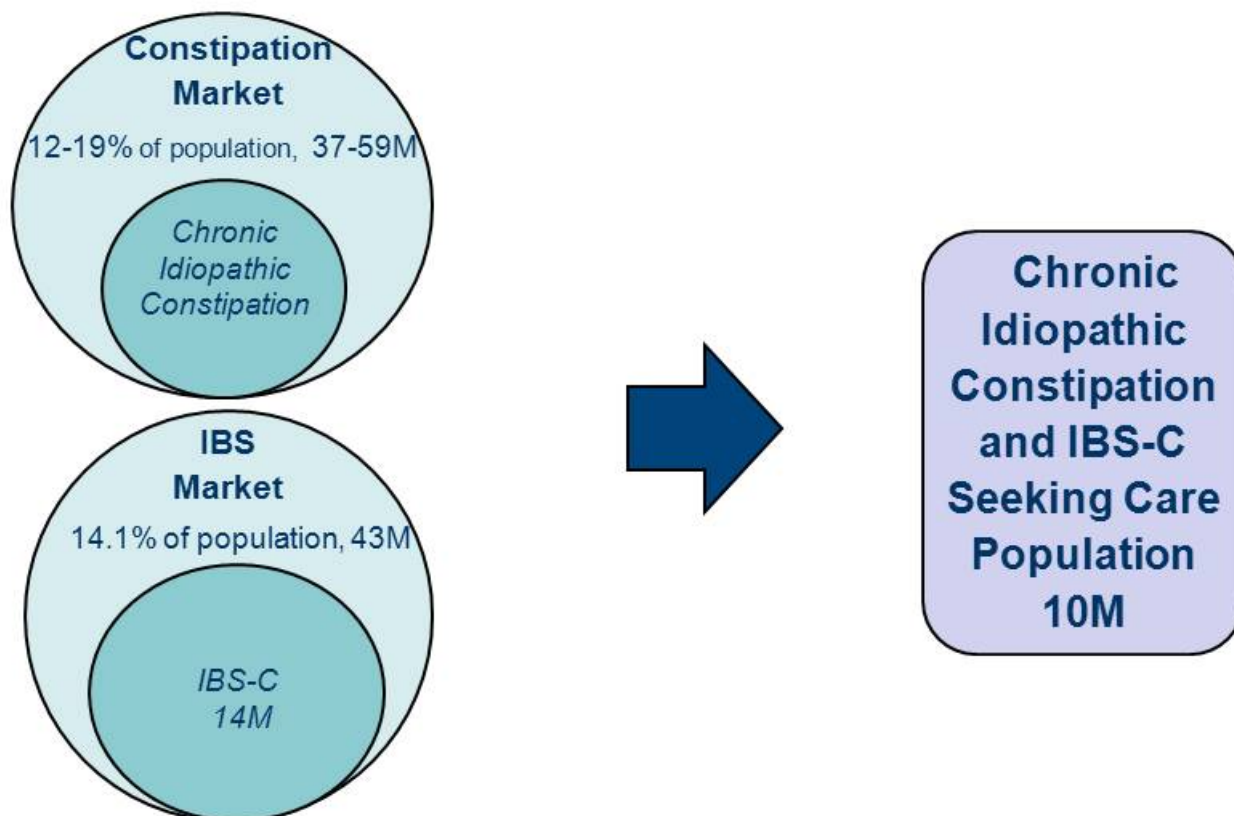
- Re-launch in the US expected for Q4/2012; MAAs to be filed in 2012

Deep pipeline includes prostones and in-licensed candidates
(Small molecules and biologics)

Prostone Mechanism Of Action



Chronic Constipation and IBS-C in the US are Large Markets with Unmet Medical Needs



Source: ¹Higgins, P. D. R. et al. (2004) Epidemiology of Constipation in North America: A Systematic Review. *American Journal of Gastroenterology*, 99(4):750-9. ²Hungin, A.P.S. et al. (2005) IBS in the United States: Prevalence, Symptom Patterns and Impact: Discussion. *Alimentary Pharmacology & Therapeutic*, 21(11):1365-1375. ³Müller-Lissner, S. et al. (2001) Epidemiological Aspects of Irritable Bowel Syndrome in Europe and North America. *Digestion*, 64, 200-204 ⁴Chey, W. et al ⁵Frequency and Bothersomeness of Symptoms, Health Care Seeking Behavior and Satisfaction with Therapy in IBS-C Patients Meeting ROME II Criteria: Results of a Population Based Survey. ⁶Schoenfeld, P. ⁷System Frequency, Health Care Seeking Behavior, and Satisfaction with Therapy among Chronic Constipation Patients: Results of a Population-Based Survey ⁸IMS NPA Data, Dec 2011, current Q, annualized

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CIC vs IBS-C: Criteria Comparison

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*

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*

Longstreth GF, et al. *Gastroenterology*. 2006;130:1480-1491.

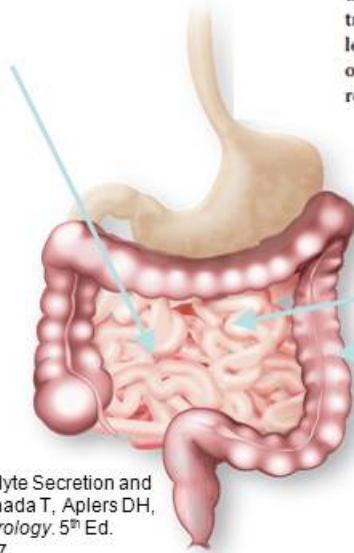
Daily Intestinal Fluid Balance

Daily GI Fluid Balance Affects GI Motility

SECRETION

Endogenous secretions

Saliva	1.5L
Stomach	2.5L
Bile	0.5L
Pancreas	1.5L
Intestines	1.0L
<hr/>	
Total	=7.0L



Evidence for intestinal chloride secretion

Michael Murek, Sascha Kopic and John Geibel

Exp Physiol. 2010 Apr;95(4):471-8

Department of Surgery, Yale University, School of Medicine, 310 Cedar Street, New Haven, CT 06511, USA

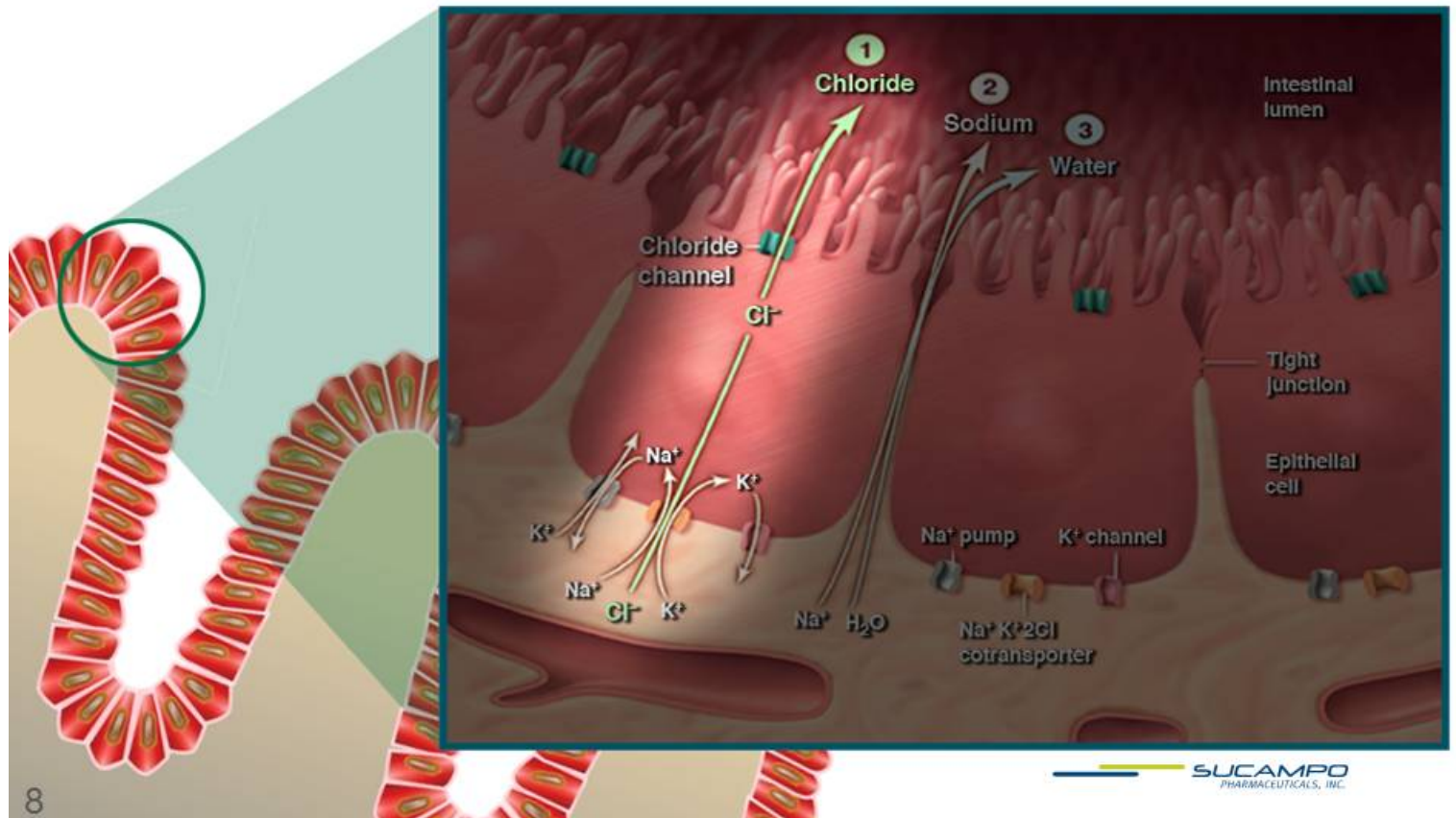
Intestinal fluid secretion is pivotal in the creation of an ideal environment for effective enzymatic digestion, nutrient absorption and stool movement. Since fluid cannot be actively secreted into the gut, this process is dependent on an osmotic gradient, which is mainly created by chloride transport by the enterocyte. A pathological dysbalance between fluid secretion and absorption leads to obstruction or potentially fatal diarrhoea. This article reviews the widely accepted model of intestinal chloride secretion with an emphasis on the molecular players involved in this tightly regulated process.

ABSORPTION

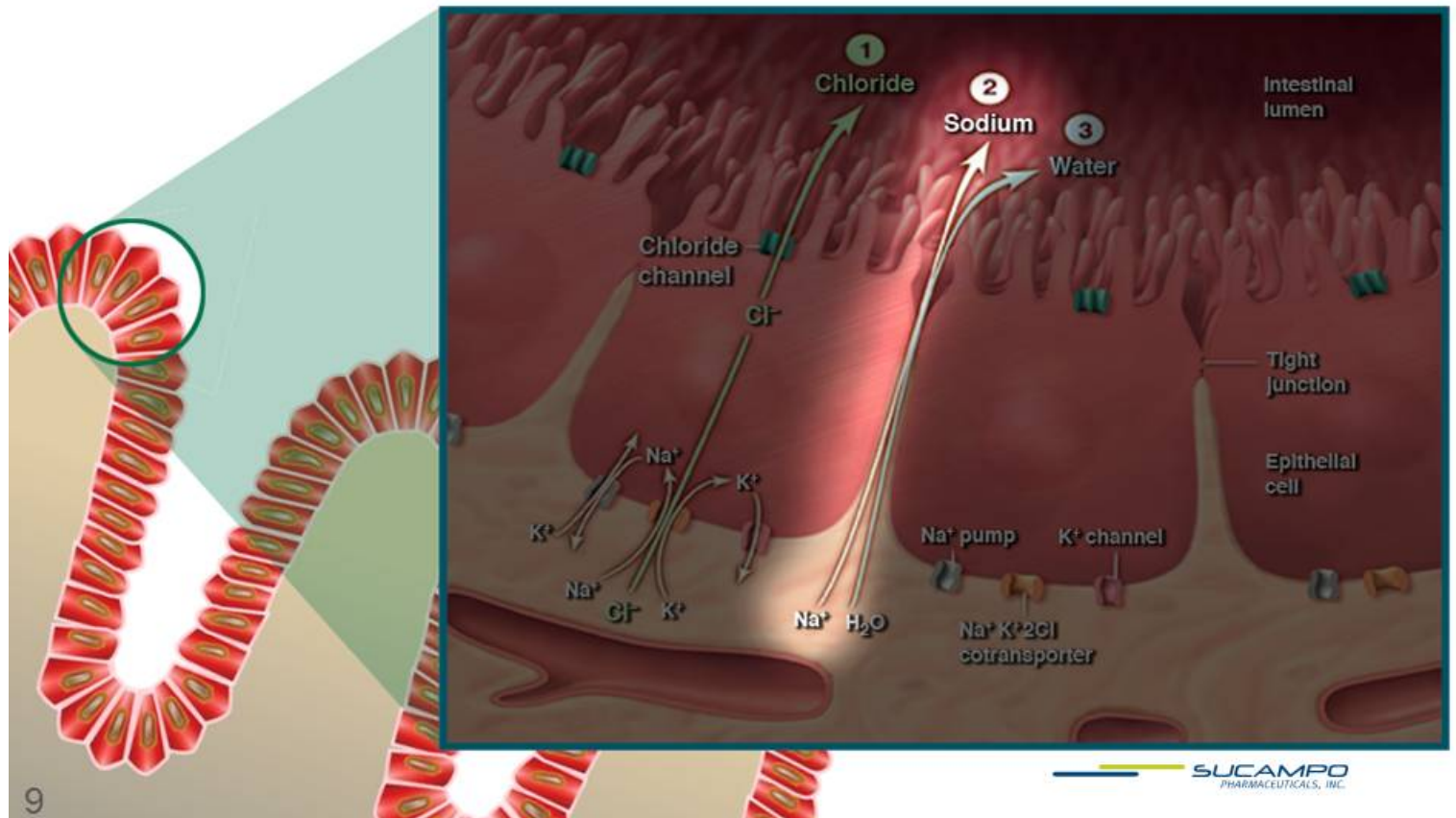
Small intestine absorbs	=7.0L
Colon and rectum absorb	=9.0L
<hr/>	
Total	=9.0L

Keely SJ, Montrose MH, Barrett KE. Electrolyte Secretion and absorption : small intestine and colon. In Yamada T, Aplers DH, Laine L, et al (eds). *Textbook of Gastroenterology*. 5th Ed. Hoboken NJ: Wiley Blackwell; 2009:330-367.

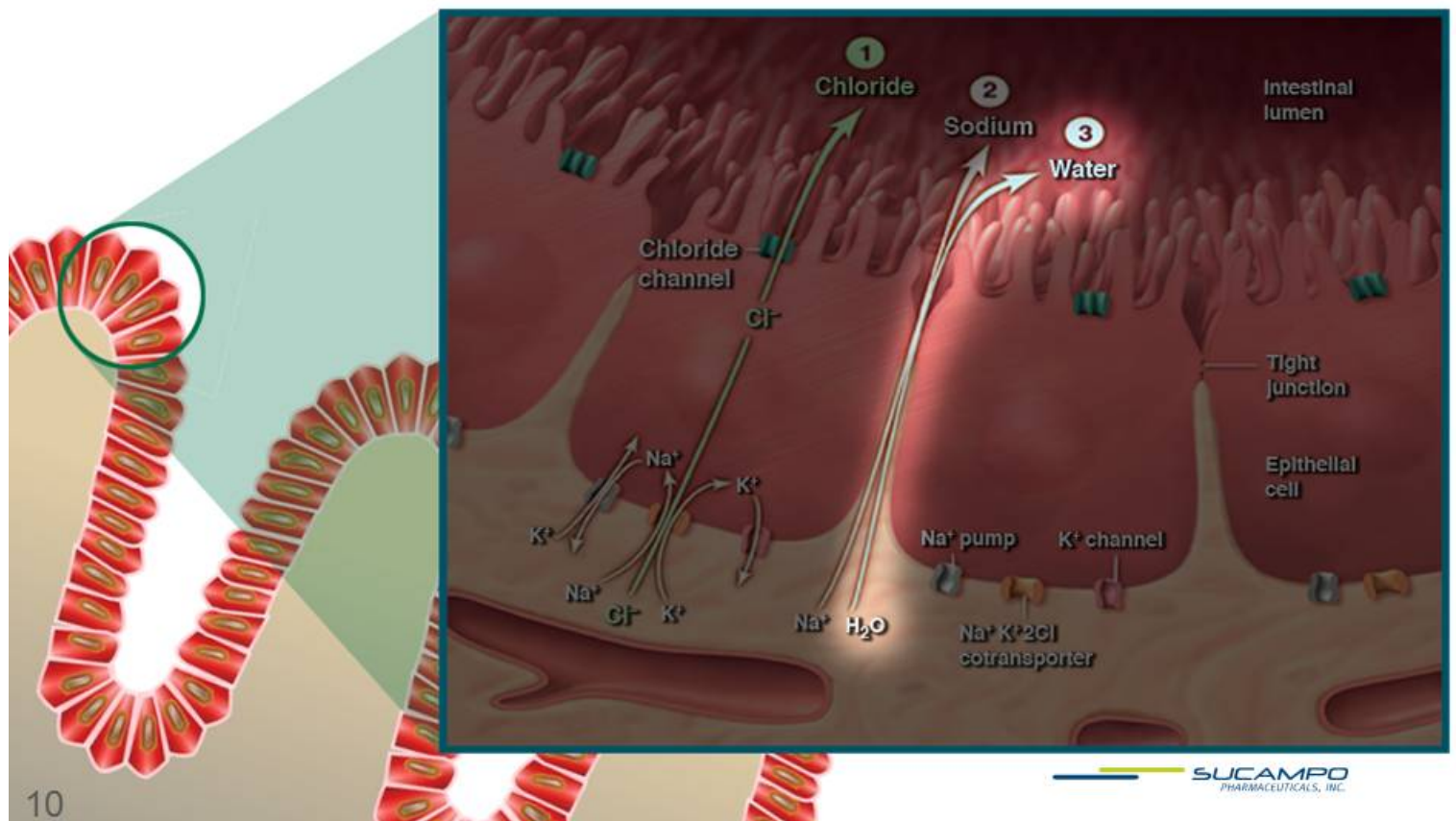
Chloride is a Main Driving Force for Secretion in the Small Intestine



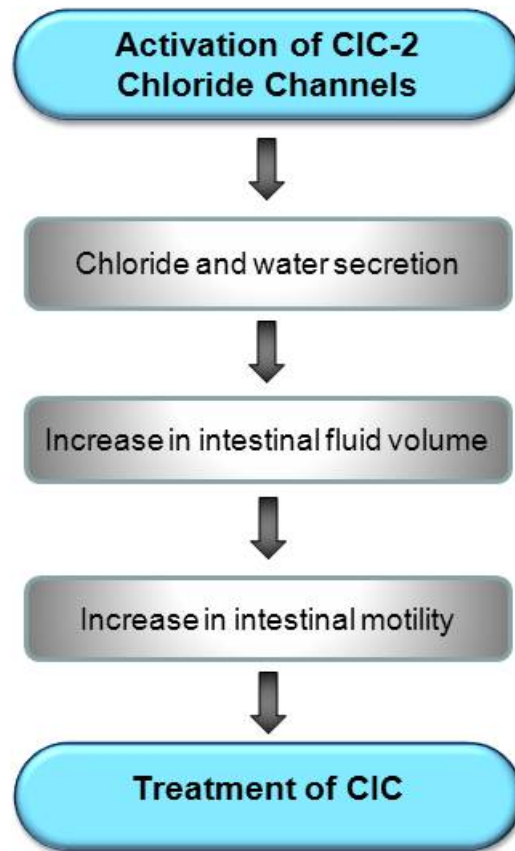
Chloride is a Main Driving Force for Secretion in the Small Intestine



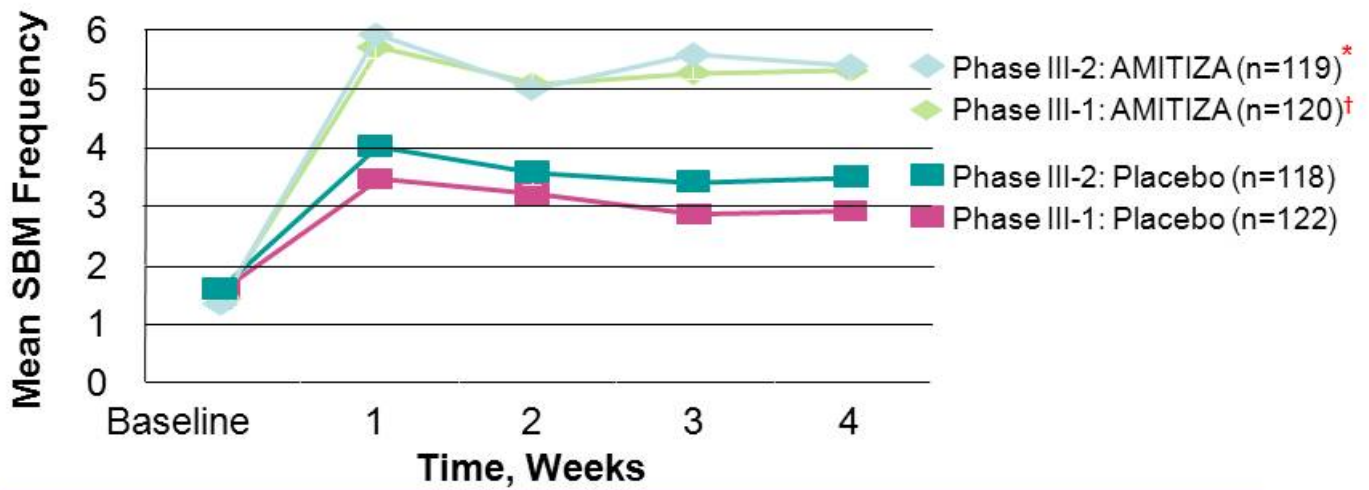
Chloride is a Main Driving Force for Secretion in the Small Intestine



Mechanism Of Action– Lubiprostone For Treatment Of Chronic Idiopathic Constipation (CIC)



AMITIZA (lubiprostone) (24 mcg twice daily): Increased Number of SBMs in Patients with CIC

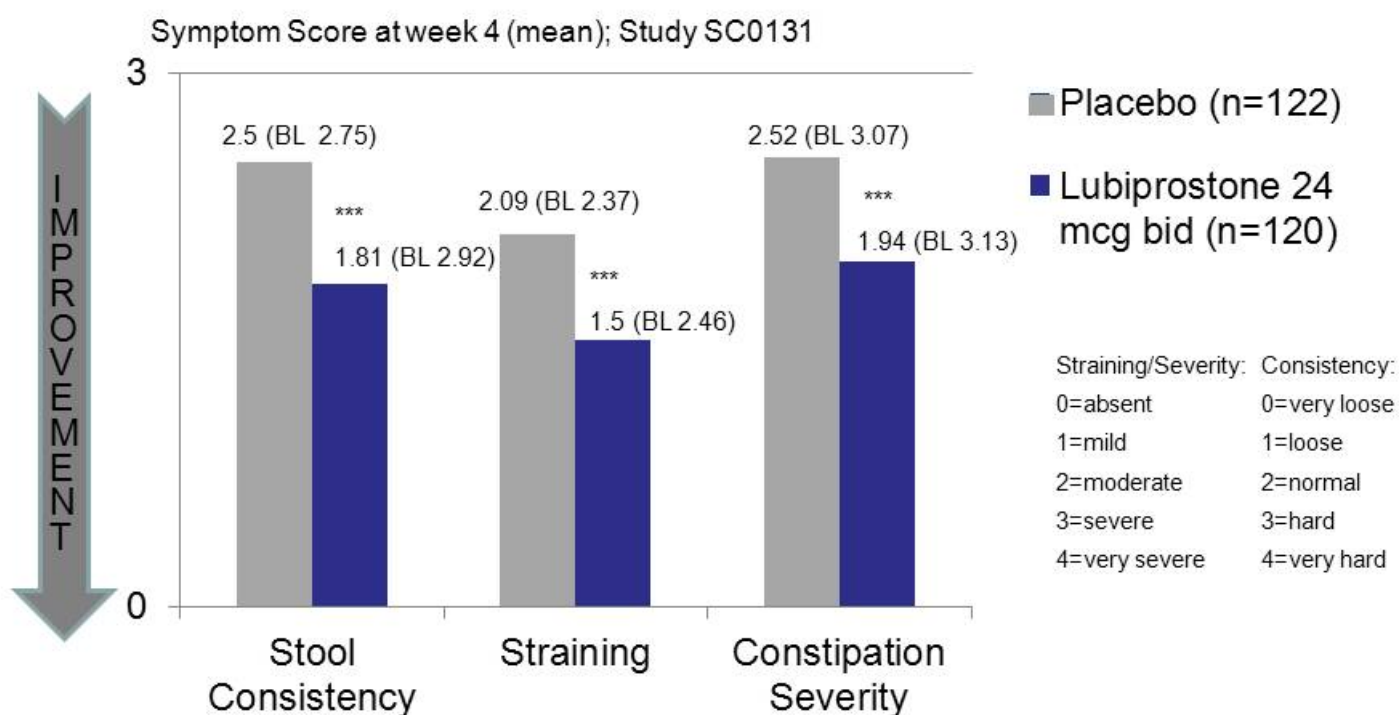


- AMITIZA significantly increased SBMs over baseline, placebo within 1 week
- Efficacy maintained throughout study
- Treatment effect was preserved during long term follow up studies of 6-12 month duration

* $P < 0.05$, † $P < 0.01$, AMITIZA 48 mcg vs placebo at all study weeks.

Data on file, Sucampo Pharma Americas, Inc.

AMITIZA for Chronic Idiopathic Constipation



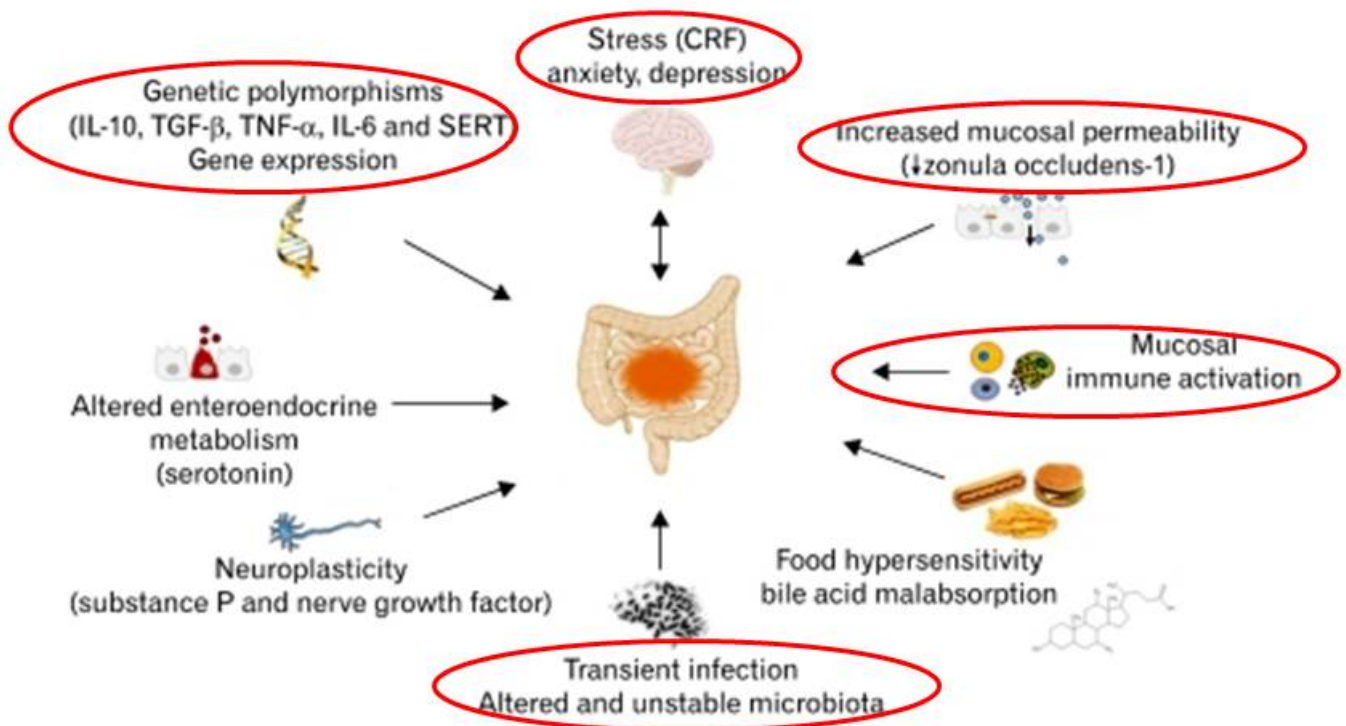
*** $p \leq 0.0003$ vs placebo

Stool consistency, straining and constipation severity improved significantly with lubiprostone vs placebo throughout the 4 weeks

Data on file, Sucampo Pharma Americas, Inc.

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IBS and Mucosal Barrier Function

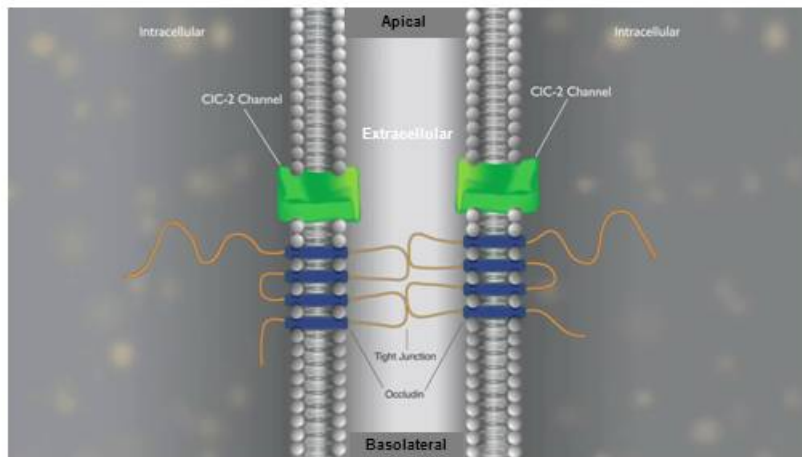
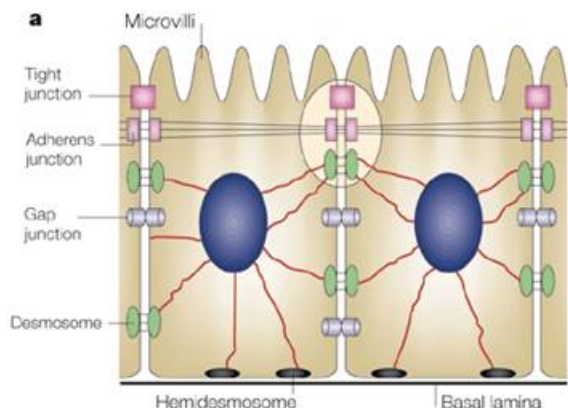


The Immune System in Irritable Bowel Syndrome | *J Neurogastroenterol Motil*, Vol. 17 No. 4 October, 2011

Giovanni Barbara,¹ Cesare Cremon, Giovanni Carli, Lara Bellacosa, Lisa Zecchi, Roberto De Giorgio, Roberto Corinaldesi and Vincenzo Stanghellini

¹Department of Clinical Medicine and Center for Applied Biomedical Research University of Bologna, Bologna, Italy

Lubiprostone Promotes Tight Junction Integrity and Repair



Source of Figure:

Tsukita, S. et al. *Nature Reviews Molecular Cell Biology* 2001;2: 285-293

Recovery of mucosal barrier function in ischemic porcine ileum and colon is stimulated by a novel agonist of the CIC-2 chloride channel, lubiprostone

Adam J. Moeser,¹ Prashant K. Nigot,¹ Kory J. Engelke,² Ryuji Ueno,² and Anthony T. Blikslager¹
¹Department of Clinical Sciences, College of Veterinary Medicine, North Carolina State University, Raleigh, North Carolina; and ²Sucampo Pharmaceuticals, Incorporated, Bethesda, Maryland
Submitted 1 May 2006; accepted in final form 11 October 2006

Am J Physiol Gastrointest Liver Physiol 292: G647–G656, 2007.

Contrasting effects of linaclotide and lubiprostone on restitution of epithelial cell barrier properties and cellular homeostasis after exposure to cell stressors
BMC Pharmacology 2012, **12**:3

John Cuppoletti, Anthony T Blikslager, Jayati Chakrabarti, Prashant K Nigot, Danuta H Malinowska

Activated fluid transport regulates bacterial-epithelial interactions and significantly shifts the murine colonic microbiome

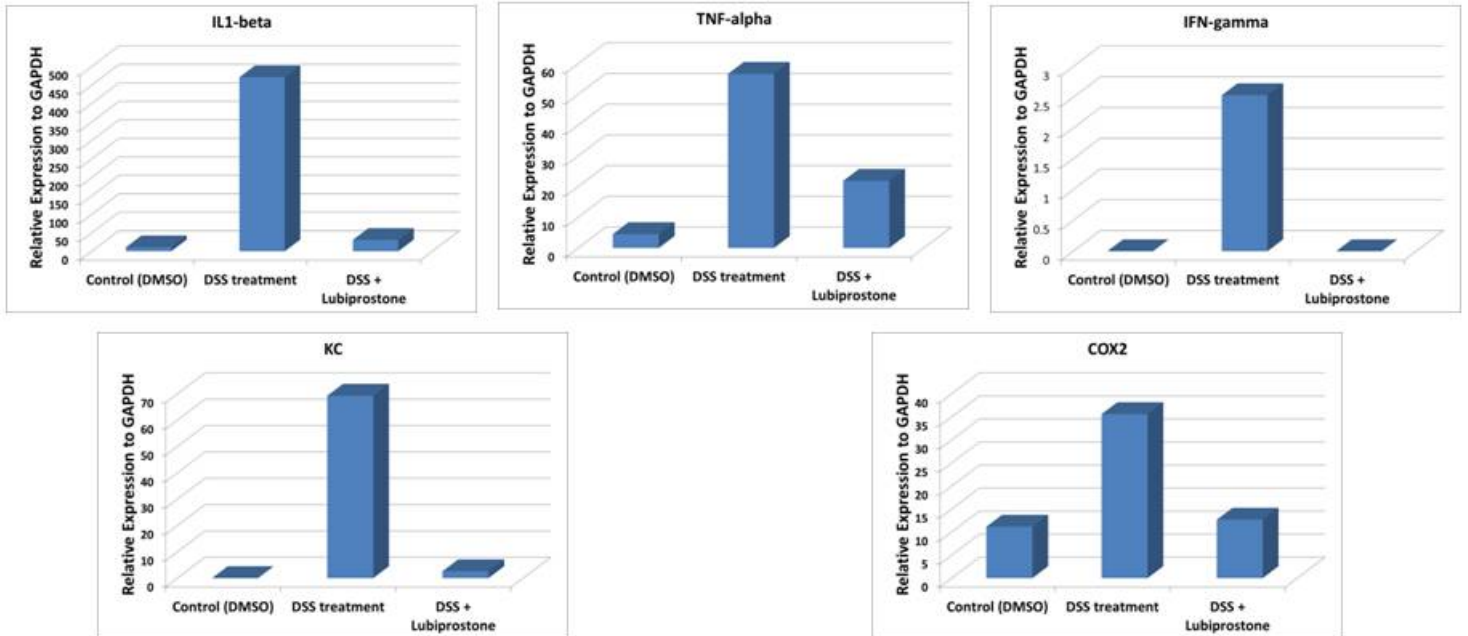
Simon Keely,^{1,2} Caleb J. Kelly,¹ Thomas Weissmueller,^{1,3} Adrienne Burgess,¹ Brandie D. Wagner,⁴ Charles E. Robertson,⁵ J. Kirk Harris⁶ and Sean P. Colgan^{1*}

Gut Microbes 3:3, 1-11; May/June 2012;

- Appropriate chloride secretion and associated mucosal hydration regulates bacterial-epithelial interactions and influences the composition of the intestinal microbiota
- Amitiza shifts the intestinal microbiota towards a physiological state characterized by colonisation with lactobacillus promoting colonic homeostasis
- Active mucosal hydration functions as an innate epithelial defense mechanism preventing colonisation of the intestine with potentially harmful bacteria

Lubiprostone's Effect on Cytokine Expression

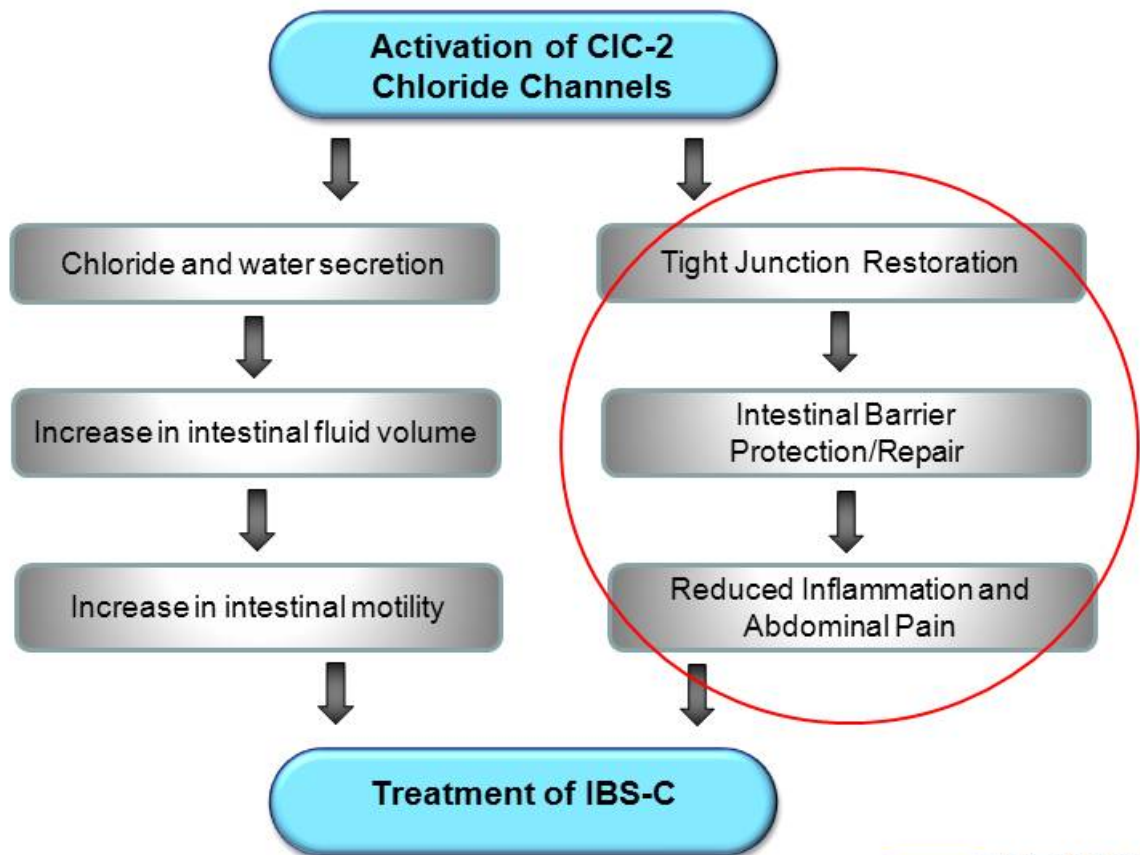
- ▶ Animal Model: Mouse 1.5% DSS-induced colitis
- ▶ Target tissue: Cecum
- ▶ Administration: Lubiprostone (10 μ M) in drinking water for 10 days



Tsukita, S. Annual Scientific Meeting of the Japanese Biochemical Society, Kyoto, Japan, September 2011.

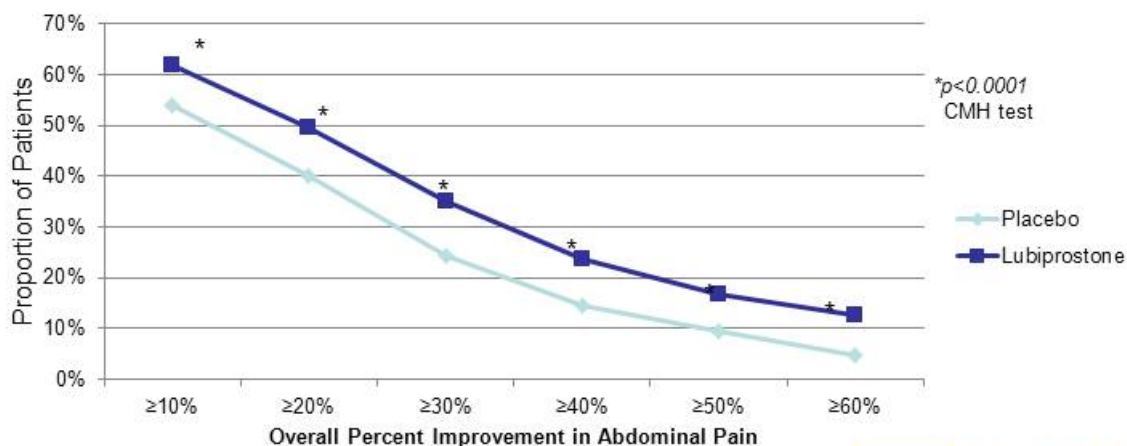
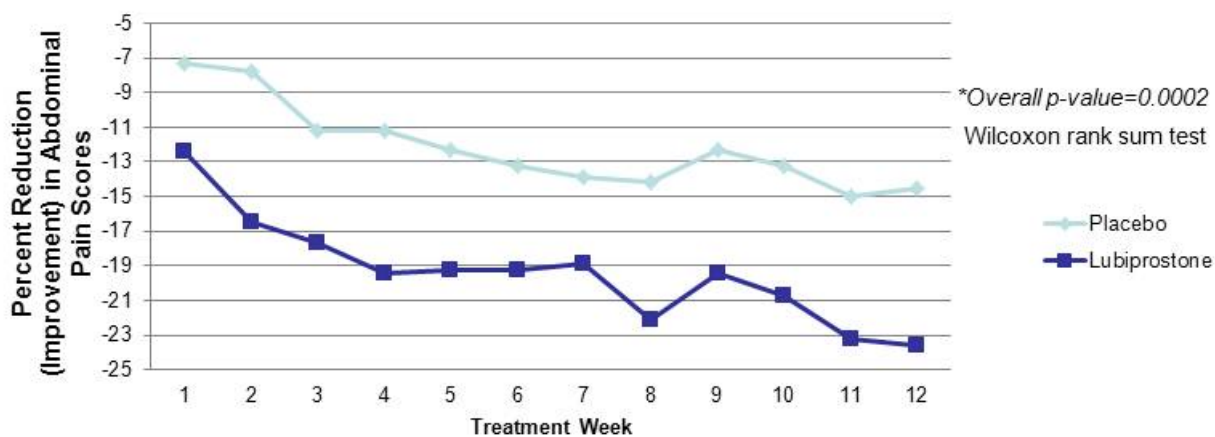


Mechanism Of Action– Lubiprostone For Treatment Of Irritable Bowel Syndrome With Constipation (IBS-C)



Lubiprostone is Particularly Effective in Patients with Severe or Very Severe Pain at Baseline

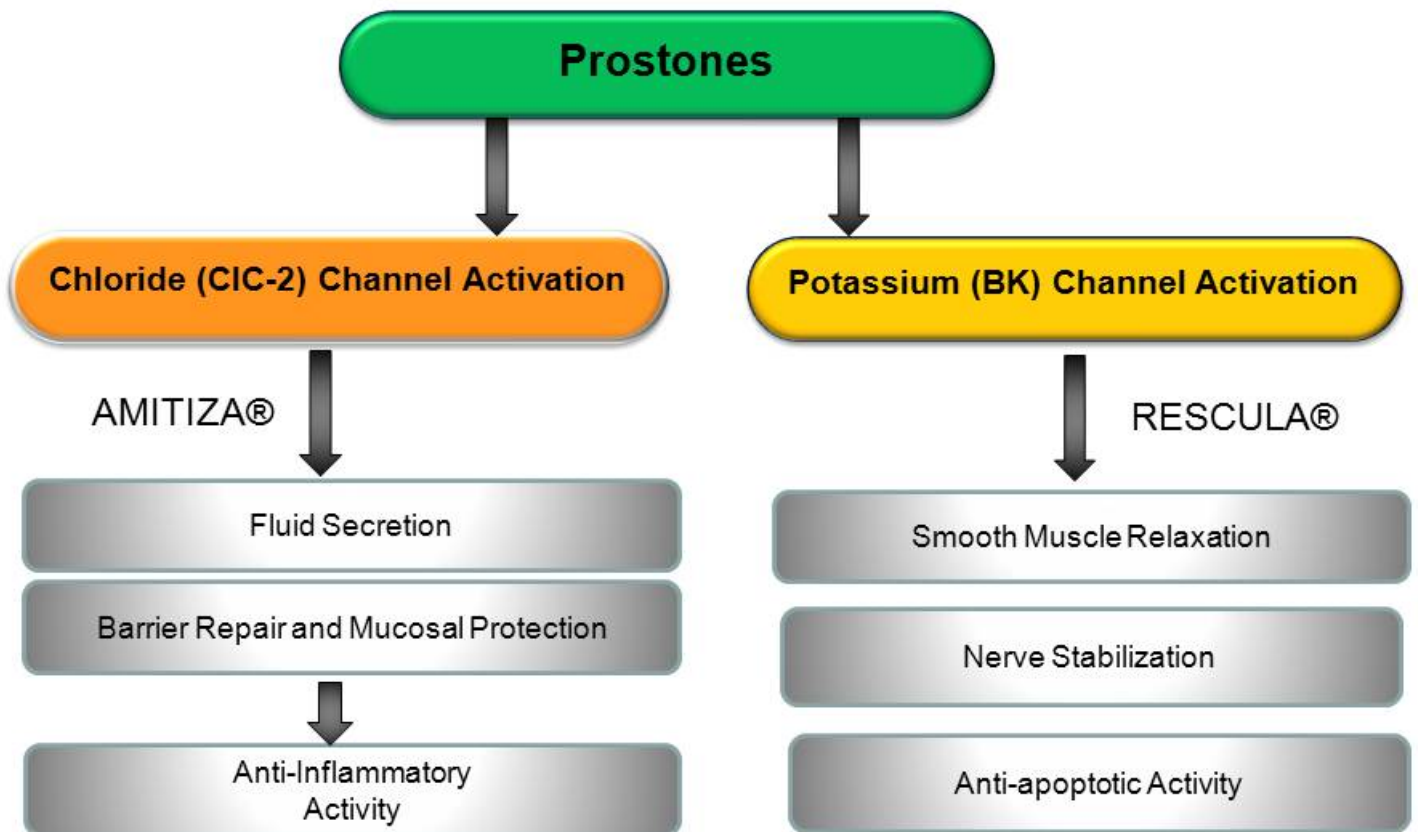
Joswick, T., Wooldegeorgis, F. and Ueno R.
 Patient Response to Lubiprostone for the Treatment of Moderate to Severe
 Irritable Bowel Syndrome With Constipation (BS-C)
 DDW 2012



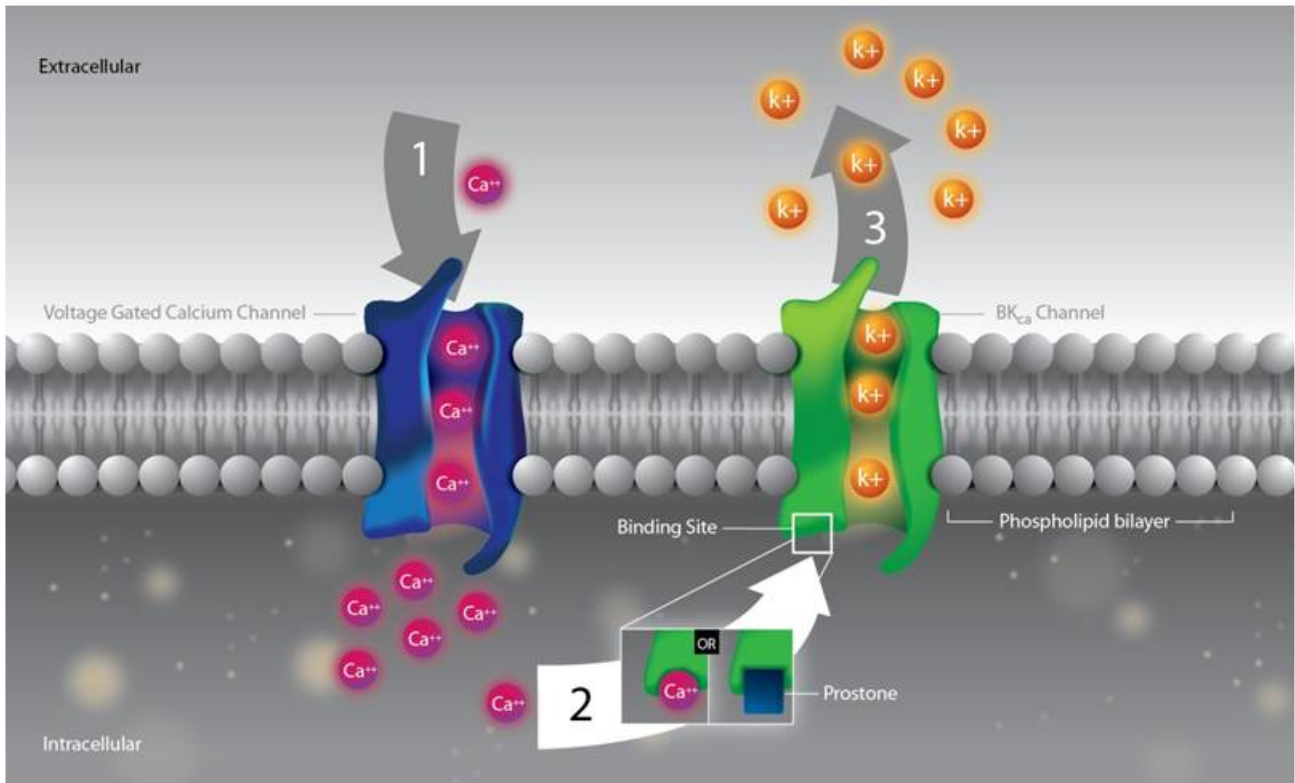
Lubiprostone Summary

- AMITIZA is the only FDA approved treatment for Chronic Idiopathic Constipation (CIC) and IBS-C (patent life extends to 2022)
 - Sucampo will file for OIC non-cancer early Q3 2012
- AMITIZA approved in Switzerland and Japan as well
- Differentiation for AMITIZA
 - Unique MoA: Potent and selective activation of the CIC-2 chloride channel
 - Increases intestinal fluid secretion in electrolyte neutral manner – approved for chronic use in elderly
 - Effectively addresses constipation AND associated signs and symptoms
 - Recovers mucosal barrier function - relieves abdominal pain, discomfort and bloating
 - Proven safety profile (6 years, 6 M Rx) in a market that has seen 3 drugs withdrawn for safety reasons (Lotronex, Zelnorm, & Propulsid)

Unoprostone Isopropyl (Rescula®)



BK Channel Activation Unoprostone Isopropyl Mechanism of Action



Indication: FDA approved for the lowering of intraocular pressure (IOP) in open-angle glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP-lowering medications

- Glaucoma is a neurodegenerative disease, characterized by visual field loss

The molecular basis of retinal ganglion cell death in glaucoma

Mohammadali Almasieh, Ariel M. Wilson, Barbara Morquette, Jorge Luis Cueva Vargas, Adriana Di Polo*

Progress in Retinal and Eye Research 31 (2012) 152–181

- Elevated IOP is a well known risk factor for glaucoma progression

AGIS, I., 2000. The advanced glaucoma intervention study (AGIS): 7. the relationship between control of intraocular pressure and visual field deterioration. *Am. J. Ophthalmol.* 130, 429–440.

- BUT: Only a limited number of patient with elevated IOP develops glaucoma

Friedman, D.S., Wilson, M.R., Liebmann, J.M., Fechtner, R.D., Weinreb, R.N., 2004. An evidence-based assessment of risk factors for the progression of ocular hypertension and glaucoma. *Am. J. Ophthalmol.* 138, 19–31.

- AND: A significant number of glaucoma patients lose vision despite responding well to IOP lowering therapy

Leske, M.C., Heijl, A., Hussein, M., Bengtsson, B., Hyman, L., Komaroff, E., For the Early Manifest Glaucoma Trial Group, 2003. Factors for glaucoma progression and the effect of treatment: the early manifest glaucoma trial. *Arch. Ophthalmol.* 121, 48–56.

Qualitative vs. Quantitative IOP lowering

Is the medication used to achieve the target intraocular pressure in glaucoma therapy of relevance? – An exemplary analysis on the basis of two beta-blockers

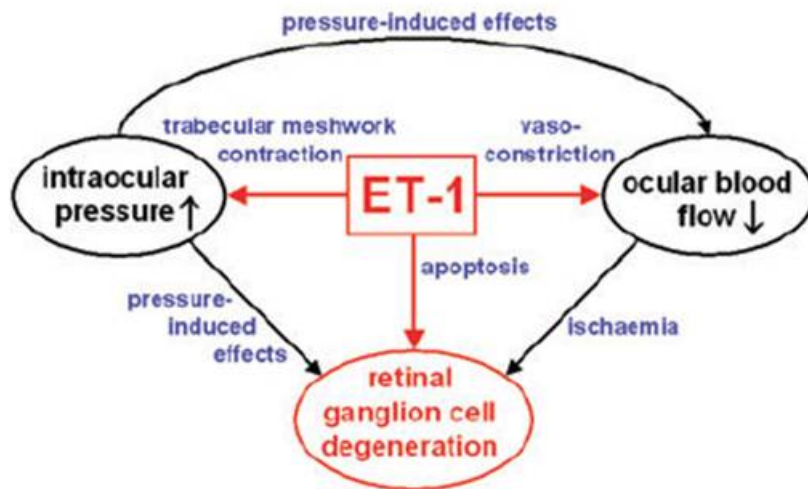
Matthias C. Grieshaber*, Josef Flammer

Department of Ophthalmology, University Hospital of Basel, Basel, Switzerland

Progress in Retinal and Eye Research 29 (2010) 79–93

- Comparing different effective IOP lowering agents, dissociation of IOP lowering and visual field prognosis is observed
- For visual field protection, the mechanism of action of drugs by which IOP is lowered is more important than the absolute reduction of IOP
- Absolute IOP lowering effect is a poor predictive factor for visual field prognosis
- Other mechanistic aspects than IOP lowering are critically important for visual field protection in drug therapy

Endothelin: A central player in glaucoma pathophysiology



Endothelin antagonism as an active principle for glaucoma therapy

Rita Rosenthal and Michael Fromm

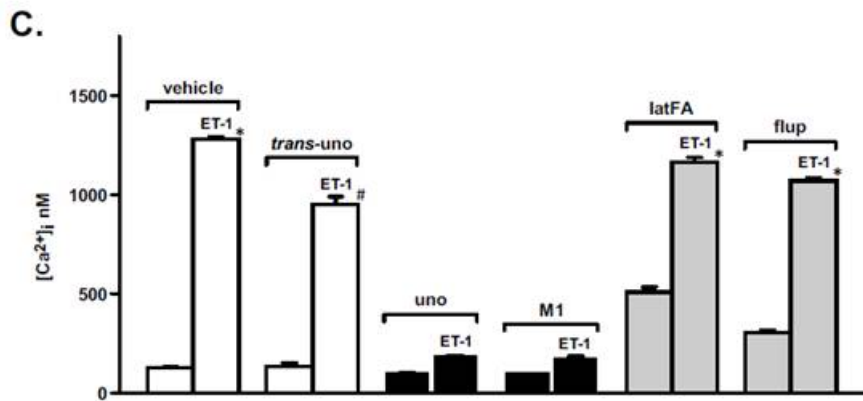
Institute of Clinical Physiology, Charité, Campus Benjamin Franklin, Freie Universität and Humboldt-Universität Berlin, Berlin, Germany

British Journal of Pharmacology (2011) **162** 806–816

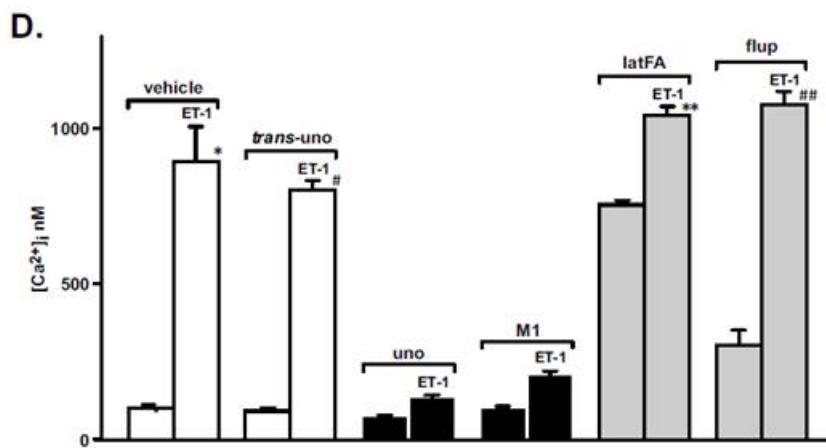
Figure 1

Involvement of endothelin-1 (ET-1) in the pathogenesis of glaucoma. ET-1 causes an increase in intraocular pressure, which directly and via reduced ocular blood flow leads to degeneration of retinal ganglion cells (RGCs). Furthermore, ET-1-induced vasoconstriction generates a decrease in ocular blood flow affecting RGCs. In addition, ET-1 evokes apoptosis of RGCs.

Rescula functionally antagonizes ET-1 activity



Cuppoletti, J., Malinowska, D., Tewari, K., Chakrabarti, J., Ueno, R. Unoprostone Isopropyl and Metabolite M1 Activate BK Channels & Prevent ET-1-Induced [Ca²⁺]_i Increases in Human Trabecular Meshwork and Smooth Muscle. *Invest Ophthalmol Vis Sci*, *in press*.



Unoprostone prevents damage induced by ET-1

Effect of Unoprostone on Topographic and Blood Flow Changes in the Ischemic Optic Nerve Head of Rabbits

Tetsuya Sugiyama, MD, PhD; Yukihiro Mashima, MD, PhD; Yuriko Yoshioka, MD; Hidehiro Oku, MD, PhD; Tsumehiko Ikeda, MD, PhD

Arch Ophthalmol. 2009;127(4):454-459

Results: We found that ET-1 decreased the ONH blood flow, decreased the cells in the ganglion cell layer and inner nuclear layer, enlarged the cup area of the ONH, and reduced the rim area of the ONH. When unoprostone was given with ET-1, no such changes occurred.

Conclusion: Unoprostone can suppress the effects of ET-1 on the circulation and topography of the ONH.

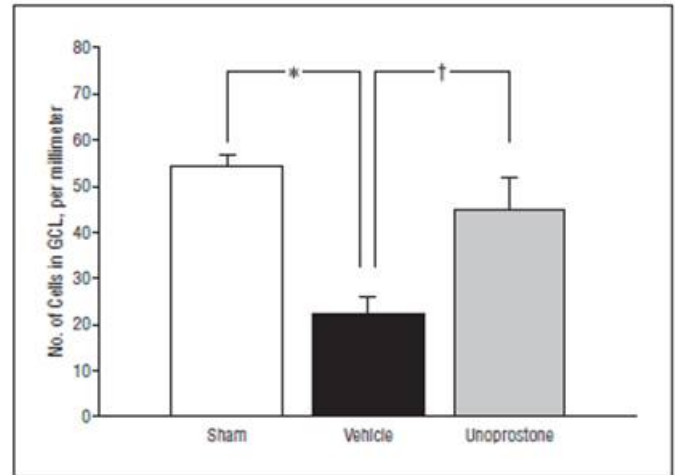
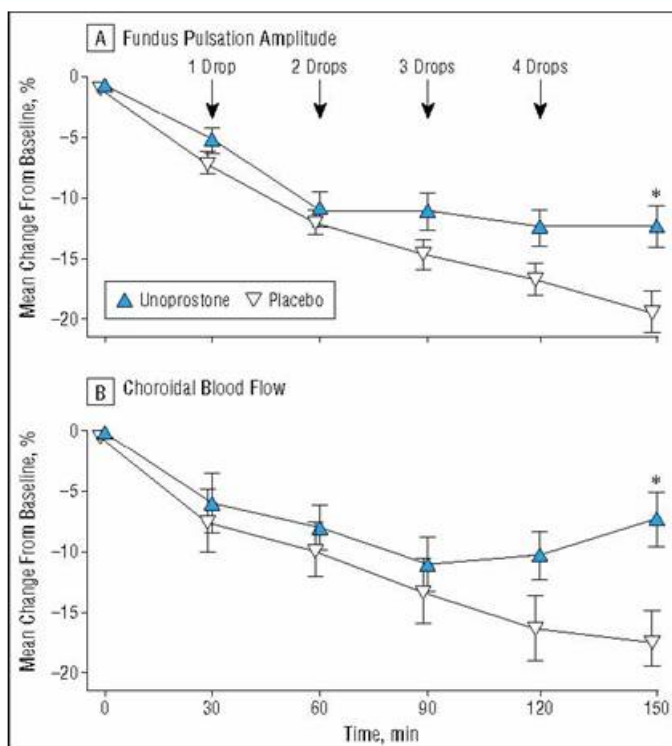


Figure 4. Mean number of cells in the ganglion cell layer (GCL) (n=4). Analysis of variance revealed a statistically significant difference among the 3 groups ($P=.004$) (unpaired t tests, * $P<.01$, † $P<.05$). When unoprostone was given, there was no reduction in the number of GCL cells. Sham indicates sham control; vehicle, endothelin 1 plus vehicle; unoprostone, endothelin 1 plus unoprostone. Error bars indicate SEM.

Unoprostone Isopropyl antagonizes Endothelin-1 induced Reductions in Choroidal Blood Flow in humans



Effects of unoprostone isopropyl or placebo administration on fundus pulsation amplitude (A) and choroidal blood flow (B) in the presence of exogenous endothelin-1 (2.5 ng/kg per minute) in 24 patients. Asterisks indicate significant treatment effects vs placebo, as calculated using repeated-measures analysis of variance. Error bars represent SEM.

Polska et al., Arch Ophthalmol 2002;120:348-352

Clinical evidence for neuroprotection by Unoprostone

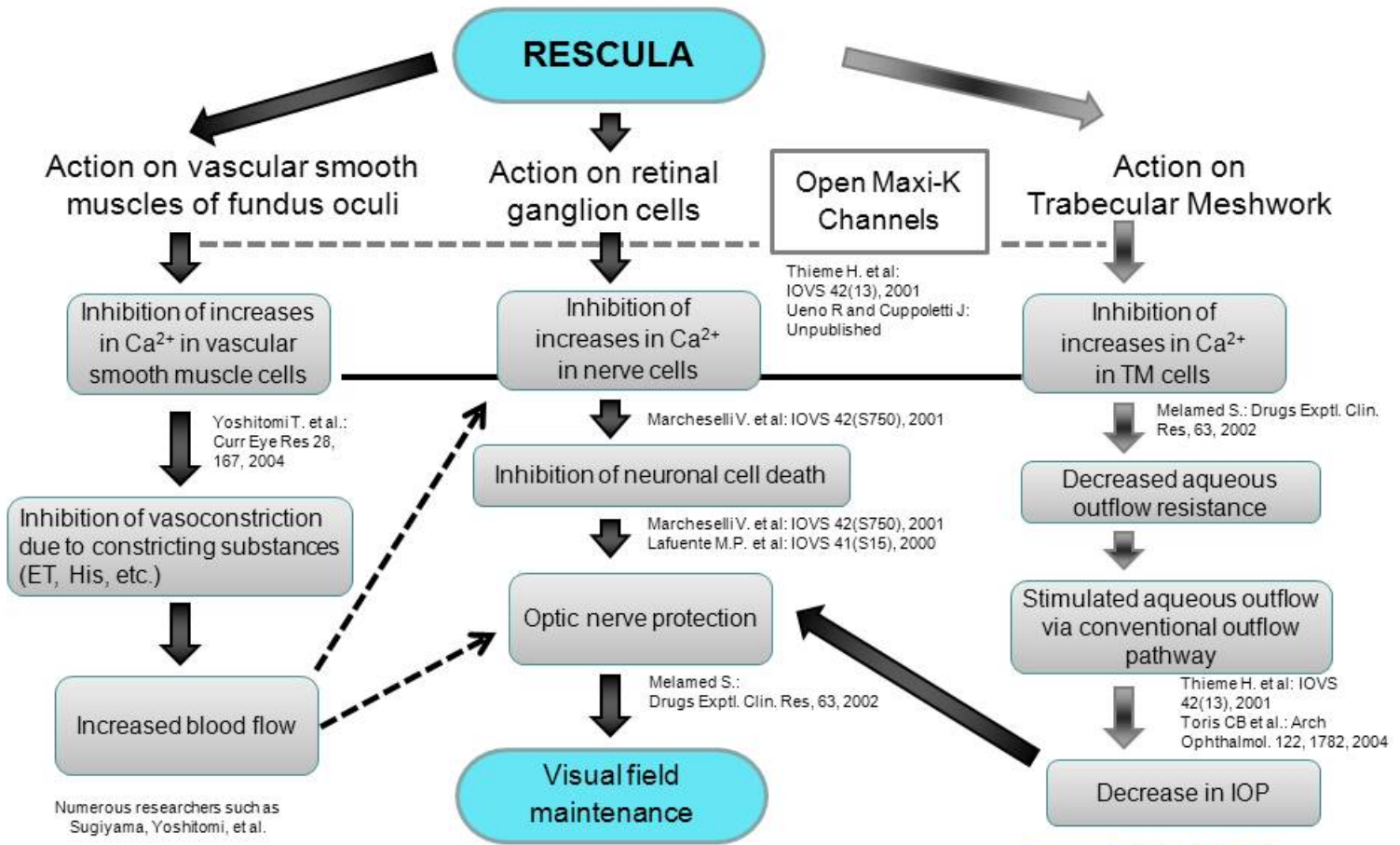
Topical Monotherapy for Normal Tension Glaucoma – Comparison of Long-term Monotherapies in Maintaining Visual Field –

Toshiro ISHIDA¹⁾, Yuji YAMADA²⁾, Toshio KATAYAMA³⁾,
Akira KOSHIBU⁴⁾, Izumi YAMASHITA⁵⁾

GANKA. OPHTHALMOLOGY Vol. 47 No. 8 2005

- A 2-year head-to-head study comparing visual field prognosis was conducted in previously untreated glaucoma patients with unoprostone (49 eyes) and latanaprost (38 eyes)
- Both groups showed significant ($p < 0.001$) reduction of IOP after 24 months
- Unoprostone was significantly superior in preservation of visual field (6.3% vs 26.0% deterioration incidence after 24 months; $p < 0.05$)

Mechanism of Action of RESCULA



ClC-2 activity is critical for photoreceptor integrity

[EMBO J.](#) 2001 Mar 15;20(6):1289-99.

Male germ cells and photoreceptors, both dependent on close cell-cell interactions, degenerate upon ClC-2 Cl(-) channel disruption.

[Bösl MR](#), [Stein V](#), [Hübner C](#), [Zdebik AA](#), [Jordt SE](#), [Mukhopadhyay AK](#), [Davidoff MS](#), [Holstein AF](#), [Jentsch TJ](#).

Source

Zentrum für Molekulare Neurobiologie Hamburg (ZMNH), Universität Hamburg, Martinistrasse 52, D-20246 Hamburg, Germany.

Photoreceptor Degeneration, Azoospermia, Leukoencephalopathy, and Abnormal RPE Cell Function in Mice Expressing an Early Stop Mutation in *CLCN2*

Malia M. Edwards,¹ *Caralina Marín de Eusikova*,¹ *Gayle B. Collin*,¹ *Elaine Gifford*,¹ *Jiang Wu*,² *Wanda L. Hicks*,¹ *Carrie Whiting*,¹ *Nicholas H. Varvel*,³ *Nicole Mabbis*,³ *Bruce T. Lamb*,³ *Jürgen K. Naggert*,¹ *Patsy M. Nishina*,¹ and *Neal S. Peachey*^{2,4,5}

(Invest Ophthalmol Vis Sci. 2010;51:3264–3272)

RESCULA: High Dose Achieved Primary Endpoint in Phase 2a Retinitis Pigmentosa Study

* Trials conducted by licensor company R-Tech Ueno, Ltd.

MP-1 central 2 degrees
Change in mean retinal sensitivity threshold - Group Variations -

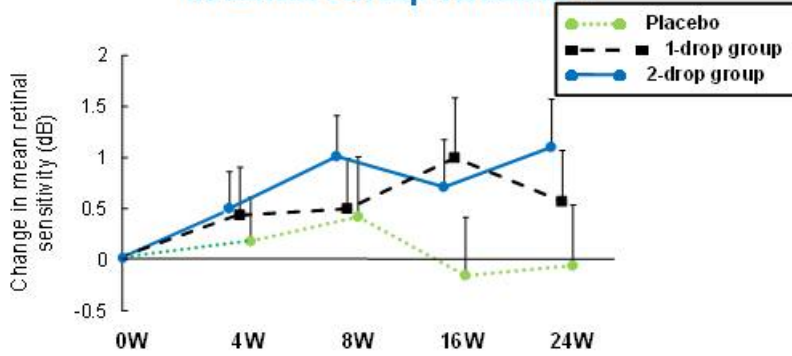
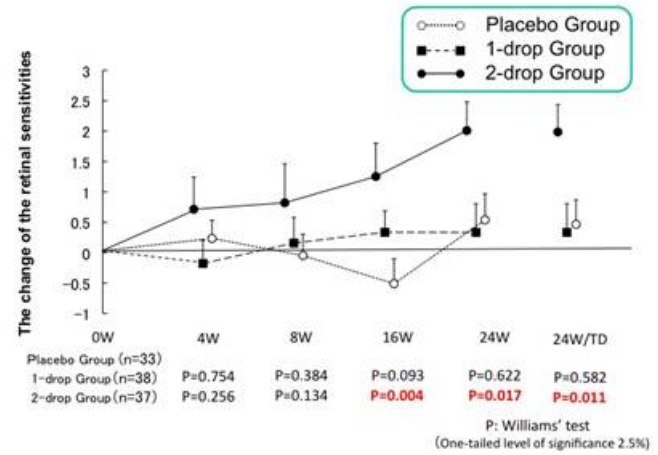


Fig. 2 HFA 10-2 Central 2 degrees Change in mean retinal sensitivity - Group Variation -



The 2-drop group met the primary endpoint ($p=0.018$) of change from baseline in retinal sensitivity threshold in the central 2 degrees, as measured by Microperimeter-1

Yamamoto S, et al. *IOVS* 2011;52:ARVO E-Abstract 4992;
 Sugawara T, et al. *IOVS* 2011;52:ARVO E-Abstract 4994



Unoprostone Isopropyl Summary

- RESCULA is FDA approved for IOP lowering in patients with POAG or ocular hypertension
 - Sucampo will re-launch RESCULA in the US later in 2012
 - Sucampo will re-submit MAAs in Europe later in 2012
- Differentiation of RESCULA
 - Unique MoA: Potent and selective activation dual ion channel activator: BK and CIC-2
 - Functionally antagonizes ET-1 and reduces IOP via relaxation of trabecular meshwork and ciliary muscle (uveoscleral pathway)
 - Improves/stabilizes choroidal blood flow and ONH perfusion
 - Has direct neuroprotective activity with potential for label extension in glaucoma, RP and beyond
 - Is well tolerated and has a favorable safety profile as compared to prostaglandins

Recent Developments

- **AMITIZA approved for treatment of chronic constipation (excluding constipation caused by organic diseases) in Japan, June 2012**
 - Marketing partner: Abbott Japan Ltd.
 - Launch anticipated in 4Q/2012

- **Arbitrators in dispute with Takeda disagreed with Sucampo's claims; marketing, development and royalty contract terms remain in place**
 - 2011 royalty revenue: \$41.5 million on net sales of US\$226 million
 - Sucampo will move forward with Takeda to improve patient access

Sucampo Pharmaceuticals' 2012 Value Drivers

AMITIZA

- In the U.S., filing of an sNDA for the treatment of OIC in adult non-cancer patients mid-year
- In the UK, get approval for CIC
- In the UK and Switzerland, file MAAs for the treatment of OIC in adult non-cancer patients
- In Japan, receive regulatory approval in 2Q2012, a pricing decision in 3Q2012 and a launch in 4Q2012

RESCULA

- In the US, obtain further improvements in the label to reflect current scientific understanding in advance of the launch later this year
- In the EU and Switzerland, file MAAs for lowering of IOP in patients with POAG or ocular hypertension
- Further progress research and development on unoprostone isopropyl's potential for neuro-protection



JMP Securities Healthcare Conference

Peter Lichtlen MD, PhD, BBA, Senior Medical Officer, VP European Operations

12 July 2012

Addendum

Sucampo's Prostone Technology and Commercial Opportunities

Intellectual Property



Commercial Opportunities

Novel class of compounds discovered by our founder Dr Ueno

Sucampo owns 543 issued patents covering the prostone area

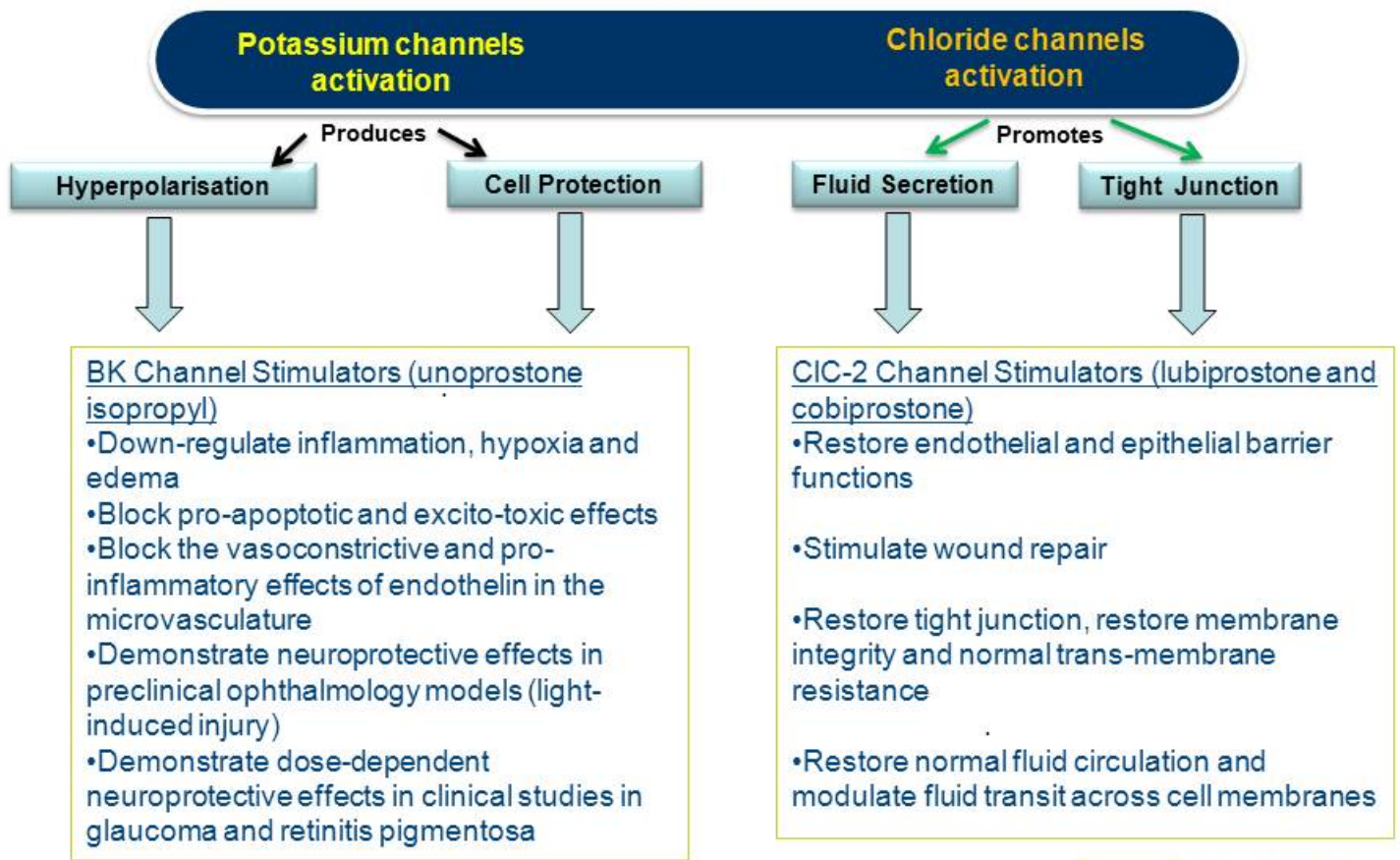
Unique mechanism of action as ion channel activators

Initial focus in Gastrointestinal and Ophthalmology disease areas

2 Commercial Products with multiple indications

Pipeline of future opportunities involving new compounds, new indications and new therapeutic areas

Proprietary Platform Technology: Prostones Work As Potassium and Chloride Channel Activators



Patient Perception



Physician Perception



Intestinal Barrier Function and Tight Junction Integrity

Curr Opin Pharmacol. 2011 Dec;11(6):586-92. Epub 2011 Oct 13.

The shifting interface between IBS and IBD.

Spiller R, Lam C.

NIHR Biomedical Research Unit, Nottingham Digestive Diseases Centre, University Hospital, Nottingham NG7 2UH, United Kingdom. robin.spiller@nottingham.ac.uk

Abstract

Recent data developing from the study of postinfectious IBS has challenged the belief that IBS is a purely psychological disorder. Distinct abnormalities of the gut mucosa have been reported including immune activation and increased release of inflammatory mediators with some overlap with IBD. New studies show that genetic factors which predispose to IBD are also associated with IBS. A common feature is impaired gut barrier function which appears to precede the development of IBD while in IBS it may be the result of either a preceding infection or psychosocial stress. Stress can activate mast cells which are a feature in most but not all IBS series. Anti-inflammatory treatments targeting activated mast cells may benefit IBS patients but currently the evidence is weak and larger trials are needed. Changes in the commensal microbiota have been recently described with a "dysbiosis" in CD characterised by reduced diversity. Inconsistent changes have also been described in IBS but studies controlling for antibiotic use and differences in diet and bowel habit are needed before definitive conclusions can be made.

The Expression and the Cellular Distribution of the Tight Junction Proteins Are Altered in Irritable Bowel Syndrome Patients With Differences According to the Disease Subtype

Nathalie Bertiaux-Vandaele, MD^{1,6}, Stéphanie Beutheu Youmba, MSc^{2,6}, Liliana Belmonte, PharmD, PhD², Stéphane Leclaire, MD, PhD^{1,6}, Michel Antonietti, MD¹, Guillaume Gourcerol, MD, PhD^{2,3}, Anne-Marie Leroi, MD, PhD^{2,3}, Pierre Déchelette, MD, PhD^{2,4}, Jean-François Ménard, PhD¹, Philippe Ducrotté, MD, PhD^{1,2} and Moïse Coëffier, PhD^{2,4}

Am J Gastroenterol 2011; 106:2165–2173;



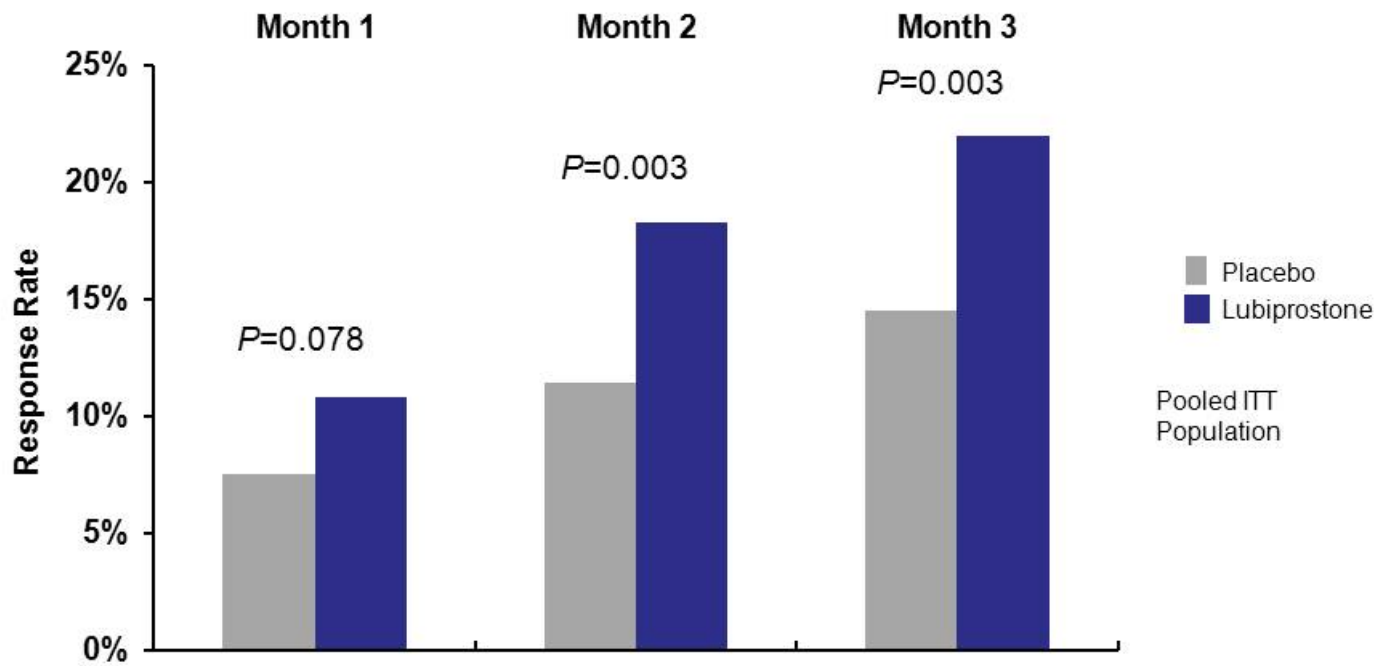
AMITIZA IBS-C Study Design “Rigorous 7 Point Scale”

- Balanced 7-point Likert scale
 - Demonstrates overall symptom relief
 - More restrictive definition than other global outcome measures
- “How would you rate your relief of IBS symptoms (abdominal discomfort/pain, bowel habits, and other IBS symptoms) over the past week compared to how you felt before entering the study?”

Significantly relieved	No Change	A little bit worse
Moderately relieved		Moderately worse
A little bit relieved		Significantly worse
- Monthly Responder – subject reported a symptom rating of at least “moderately” relieved or greater for 4 of 4 weeks within a month or “significantly relieved” for at least 2 of 4 weeks within a month.

AMITIZA IS THE ONLY CURRENTLY FDA-APPROVED DRUG FOR IBS-C

AMITIZA IBS-C Monthly Responder Rate Patients Continued to Improve



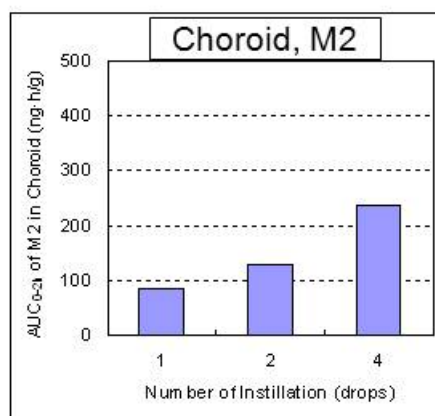
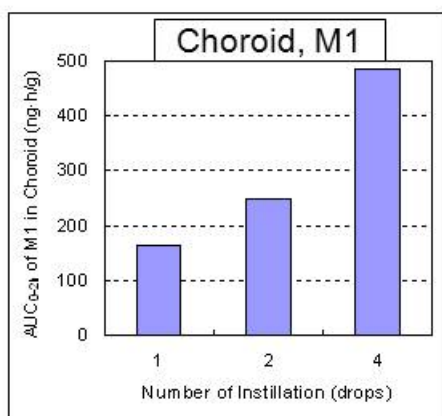
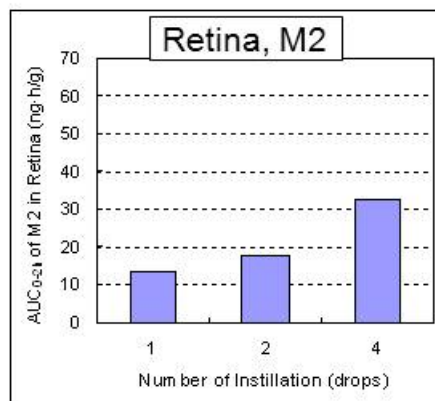
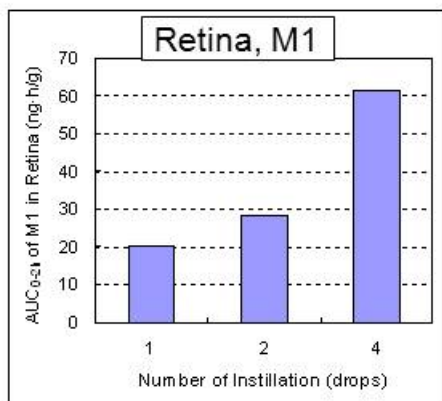
- 4/4 weeks with \geq “moderately relieved” OR
- \geq 2/4 weeks with “significantly relieved”

Safety Profile of Lubiprostone

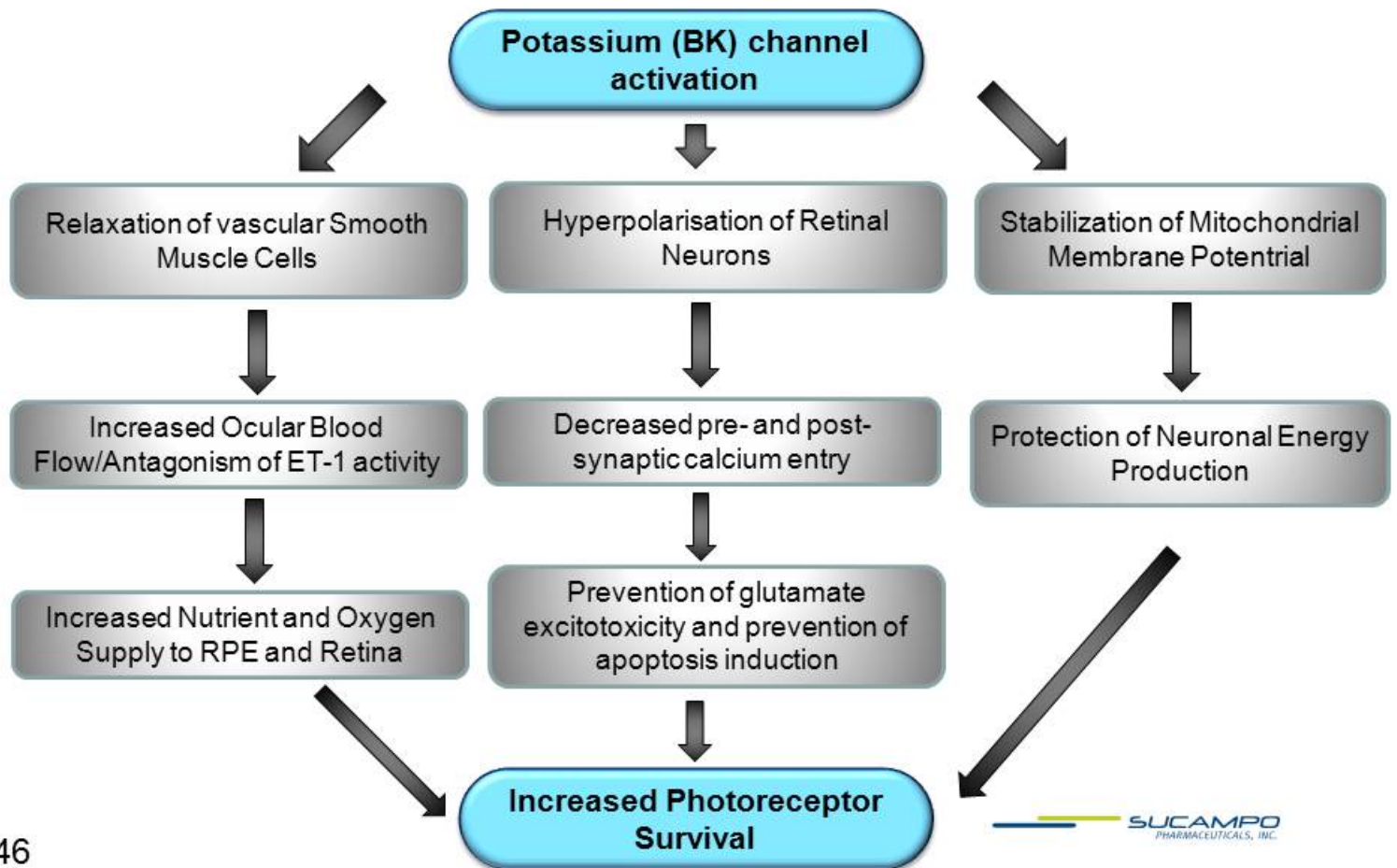
- Well tolerated in short-term (4 weeks) and long-term (6–12 months) trials
- Most common adverse events included nausea, diarrhea, and headache
- No clinically significant changes in serum electrolyte levels in adults, including elderly patients
- Low likelihood of drug-drug interactions
- Pregnancy category C
- No change in safety profile postmarketing (6 years, 6M prescriptions)

Concentration of M1 in Retina/Choroid in Rabbits: Effect of Repeated Instillation of 1, 2, or 4 Drops

AUC_{0-2hrs} of M1 and M2 in Retina or Choroid after Rabbit Ocular Instillation



Mechanism Of Action– Unoprostone For Treatment Of Retinitis Pigmentosa



Clinical evidence for neuroprotection by Unoprostone

Long-Term Effects on Visual Fields of Unoprostone for Normal-Tension Glaucoma

– Six-Year Follow-up –

Ichiro Ogawa and Kazumi Imai

Shibata City (Jikokai Ogawa Eye Clinic)

Purpose : To investigate the long-term (6 years) effect of monotherapy with unoprostone on visual fields in patients with normal-tension glaucoma (NTG).

Method:

We studied 11 males and 37 females with normal-tension glaucoma, for a total of 48 cases (48 eyes). The unoprostone ophthalmic solution was instilled twice daily, and the observation period was 72.7 ± 10.1 months. Measurements using a Humphrey 30-2 perimetry were made an average of 7.3 ± 1.7 times, and a determination of the progression of visual field constriction was made based on whether or not the mean deviation (MD) in the linear circuit analysis was significant ($p < 5\%$) in the analysis of the probability for change in the visual fields for all of the cases.

Results: Nine eyes (18.8%) out of the 48 eyes were determined to be progressive. The mean progression per year for all of the cases was -0.31 ± 0.54 dB (mean value \pm standard deviation, hereinafter the same), while the mean progression was -1.09 ± 0.57 dB in the progressive group. The MD for all of the cases was -7.2 ± 6.0 prior to the treatment and -8.5 ± 7.3 dB after the treatment. The corrected pattern standard deviation (CPSD) for all of the cases was 5.7 ± 3.6 prior to the treatment and 6.5 ± 3.9 dB after the treatment. The intraocular pressure was 13.7 ± 3.0 prior to the treatment and 12.0 ± 2.2 mmHg after the treatment. A study of the clinical factors for the progressive eyes and for the non-progressive eyes showed that a large number of cases with progressive eyes were observed in cases with MD and CPSD progression from prior to the start of treatment, even with long-term use of unoprostone.

Conclusions: When comparing the results with reports of the various long-term observations of the visual field in untreated patients with normal-tension glaucoma, it can be inferred that the **use of unoprostone ophthalmic solution is considerably effective in maintaining the visual field over a long period of time.**

(Folia Ophthalmologica Japonica 54: 571-577, 2003)

Switching from latanoprost to unoprostone

Changes in eyelid and cilia after switching from latanoprost to unoprostone

Masako Izumi*¹ Kenji Inoue Masato Wakakura Jiro Inouye
Hiroschi Matsuo*² Takeshi Hara*³ Goji Tomita*²

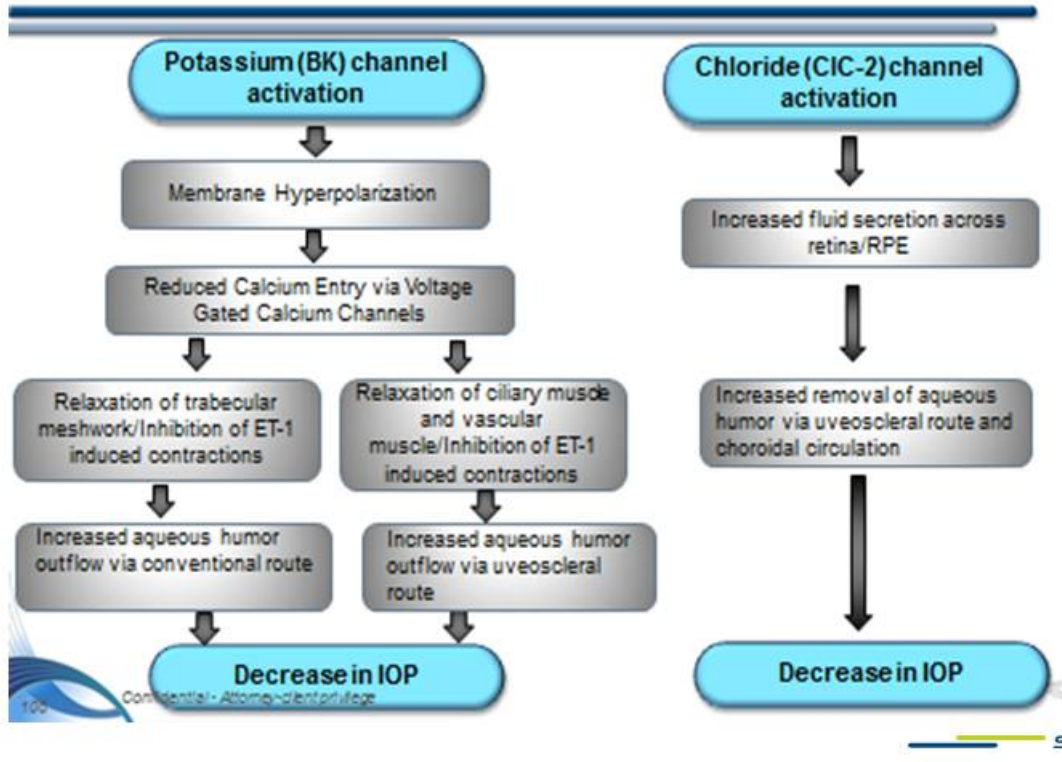
*¹ Inouye Eye Hosp *² Dept of Ophthalmol, Univ of Tokyo Grad Sch of Med *³ Hara Eye Hosp

Abstract. Treatment with latanoprost induced eyelid pigmentation, hypertrichosis, elongation or thickening of cilia in 35 eyes of 21 patients with glaucoma or ocular hypertension. Latanoprost was switched to unoprostone in these patients. These complications were photographed before and 6 months after switching. The intraocular pressure (IOP) averaged 14.2 ± 2.2 mmHg before and 14.5 to 15.8 mmHg up to 6 months after switching. There was no significant change in IOP except at 2 months after switching. There was no difference in visual field defect before and 6 months after switching. Photographic evaluation showed improved eyelid pigmentation in 29%, hypertrichosis in 42%, elongation in 44% and thickening of cilia in 44% of eyes. Questionnaire studies showed subjectively improved eyelid pigmentation in 71%, hypertrichosis in 92%, elongation in 44% and thickening of cilia in 44% of eyes. *Rinsho Ganka (Jpn J Clin Ophthalmol) 60(5): 837-841, 2006*

Jpn. J. Clinic. Ophthalmol. 60(5): 837-841, 2006

Unoprostone is a dual ion channel activator: CIC-2

Mechanism Of Action– Unoprostone For Treatment Of Glaucoma



Prostones' Current and Potential Indications

Approved or in Advanced Development

Gastrointestinal

- ✓ Chronic Idiopathic Constipation (CIC)
- ✓ Constipation Predominant Irritable Bowel Syndrome (IBS-C)
- ✓ Opioid induced constipation
- ✓ Gastric ulcer
- ✓ Inflammatory bowel disease (IBD)

▶ Additional Potential Indications

CNS

- ✓ Schizophrenia
- ✓ Spinal Stenosis
- ✓ Alzheimer's disease
- ✓ Parkinson's disease
- ✓ Epilepsy

Oncology

- ✓ Mucositis/Stomatitis
- ✓ Chemoprotection
- ✓ Secondary prevention (adjuvant)

Ophthalmology

- ✓ Glaucoma
- ✓ Retinitis Pigmentosa*
- ✓ Dry AMD

Pulmonary

- ✓ Chronic obstructive pulmonary disease (COPD)
- ✓ Asthma
- ✓ Cystic Fibrosis etc

* Trials conducted by licensor company R-Tech Ueno, Ltd.

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JMP Securities Healthcare Conference

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12 July 2012