Takeda Pharmaceutical Company:
A Global Leader in Gastroenterology

Investor and Analyst Event
March 9th, 2015
W Hotel, New York City

Today's Presenters & Panel

Christophe Weber
President & Chief Operating Officer

Asit Parikh, M.D., Ph.D.
Head of GI Therapeutic Area Unit

Kirsten Detrick,
Vice President , Therapeutic Area Commercial Lead, GI, Global Commercial

Nicole Mowad-Nassar
Vice President, Marketing, Takeda Pharmaceuticals USA

Agenda for Today

09:00~10:00	**Session 1** Introduction: Strategic Roadmap for Profitable Growth Takeda's Position of Strength within the Gastroenterology Space Takeda's GI Portfolio Takeda's GI Drug Discovery Unit
10:00~10:20	**break & refreshments**
10:20~11:10	**Session 2** The IBD Market The US Launch of Entyvio® Entyvio® Global Launch Achieving >$2 Billion in Global Peak Sales The Road to GI Leadership
11:10~12:00	**Q&A Session**
12:00~13:00	**lunch buffet**

Forward-Looking Statements

This presentation contains forward-looking statements regarding the Company's plans, outlook, strategies, and results for the future.

All forward-looking statements are based on judgments derived from the information available to the Company at this time. Forward looking statements can sometimes be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "potential," "target, " "forecast," or "intend" or other similar words or expressions of the negative thereof.

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- For full indication and important safety information of marketed products featured in the presentation, please see from slide 104. Products may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths.

Better Health, Brighter Future

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Introduction:
Strategic Roadmap for Profitable Growth

Takeda's strategic roadmap to deliver sustainable EPS growth

- ***Takeda-ism***
  Patient → Trust → Reputation → Business
- ***Patient and customer centricity***
- ***Global and agile organization fostering talent***
- ***Focused world class innovation engine (R&D)***
- ***Sustaining sales growth***
  Innovation with leadership in GI & Oncology
  Leverage value brands in Emerging Markets
- ***Financial discipline***

Profitable Growth & Creation of Shareholder Value

Two powerful growth engines

INNOVATIVE PRODUCTS

4 THERAPEUTIC AREAS and VACCINES

US, Europe, Japan and Emerging Markets

VALUE BRANDS

BRANDED GENERICS and OTC

Emerging Markets

Promising portfolio that is increasingly focused, innovative and global

Global products

New and Potential Product Approvals	Oncology	CNS	CVM	GI	Vaccine	Other TA
FY2008 - 2012	ADCETRIS® VECTIBIX®	REMINYL®	NESINA® AZILVA® EDARBI® LOTRIGA®	DEXILANT®		COLCRYS® ULORIC® ALVESCO® DAXAS®
FY2013 - 2017	ixazomib alisertib	BRINTELLIX® LATUDA® TAK-375SL	CONTRAVE® trelagliptin	ENTYVIO® TAKECAB®	Norovirus	
FY2018 - 2022	MLN0264 TAK-385 MLN0128	AD-4833/ TOMM40		TAK-114	TAK-003 Dengue	

Assets shown are in Phase 2 or later and have the most substantial financial expectations

8 CNS: Central Nervous System; CVM: Cardiovascular & Metabolic; GI: Gastroenterology; TA: Therapeutic Area

Takeda is a global GI leader

Major marketed products sales: 299 billion yen (FY2013)*

PANTOPRAZOLE

PREVACID® LANSOPRAZOLE

Tecta pantoprazole magnesium

DEXILANT dexlansoprazole

amitiza® lubiprostone

in-licensed from Sucampo

Launched in FY2014

Entyvio® vedolizumab

Takecab®

Pipeline

TAK-114

Life-cycle management programs for Entyvio, Dexilant, Amitiza

9 *includes royalty income

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Takeda's Position of Strength within the Gastroenterology Space

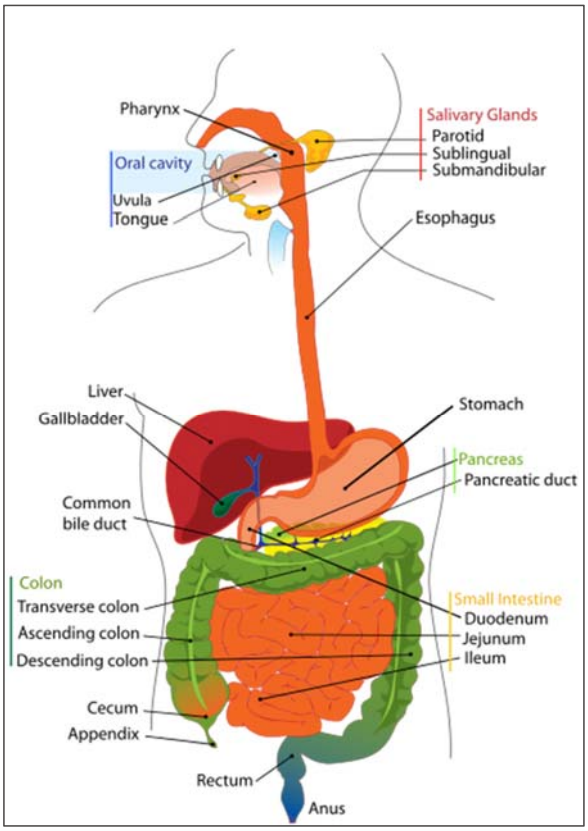
2014-2015: A pivotal time for Takeda gastroenterology

- Gastroenterology (GI) positoned as **a core Therapeutic Areas Unit (TAU)**
- **Entyvio** successfully launched in US and EU for the treatment of Ulcerative Colitis (UC) and Crohn's Disease (CD) (June 2014)
- **Takecab** launched in Japan for acid-related diseases (Feb 2015)
- Territory expansion agreement executed for **Amitiza**
- **GI Drug Discovery Unit** to accelerate innovation and fuel pipeline
- **More than 40 ongoing GI trials** with similar number anticipated for FY2015
- **Significant R&D investment** in GI therapeutic area

How Takeda defines gastroenterology

Treating disorders of the digestive system:

- esophagus
- stomach
- small intestine
- large intestine (colon)
- rectum
- liver
- gallbladder and
- pancreas



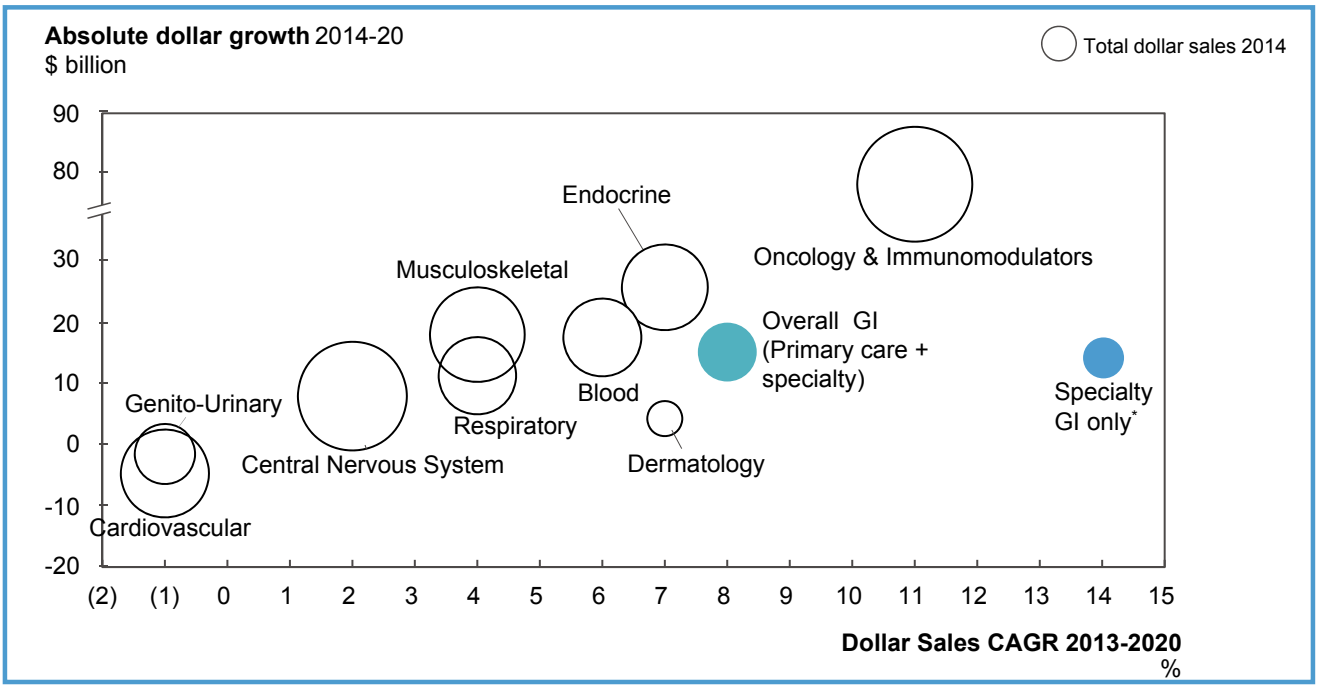
Specialty GI market is projected to be nearly $28 billion in 2020

Indication	Market forecast 2020 (global), $B
Crohn's disease	8.9
Ulcerative colitis	4.8
Irritable bowel syndrome	3.7
Slow transit/spinal inj. constipation	3.6
Nonalcoholic steatohepatitis	3.8
Hepatic encephalopathy	1.5
Primary biliary cirrhosis	<1
Functional dyspepsia	0.4
Primary sclerosing cholangitis	<0.1
Gastroparesis	<0.1
Ileus / ICU gastric stasis	<0.1
Celiac disease	<0.1

Source: EvaluatePharma

The specialty GI category is growing faster than other therapeutic areas

Worldwide, 2014-2020



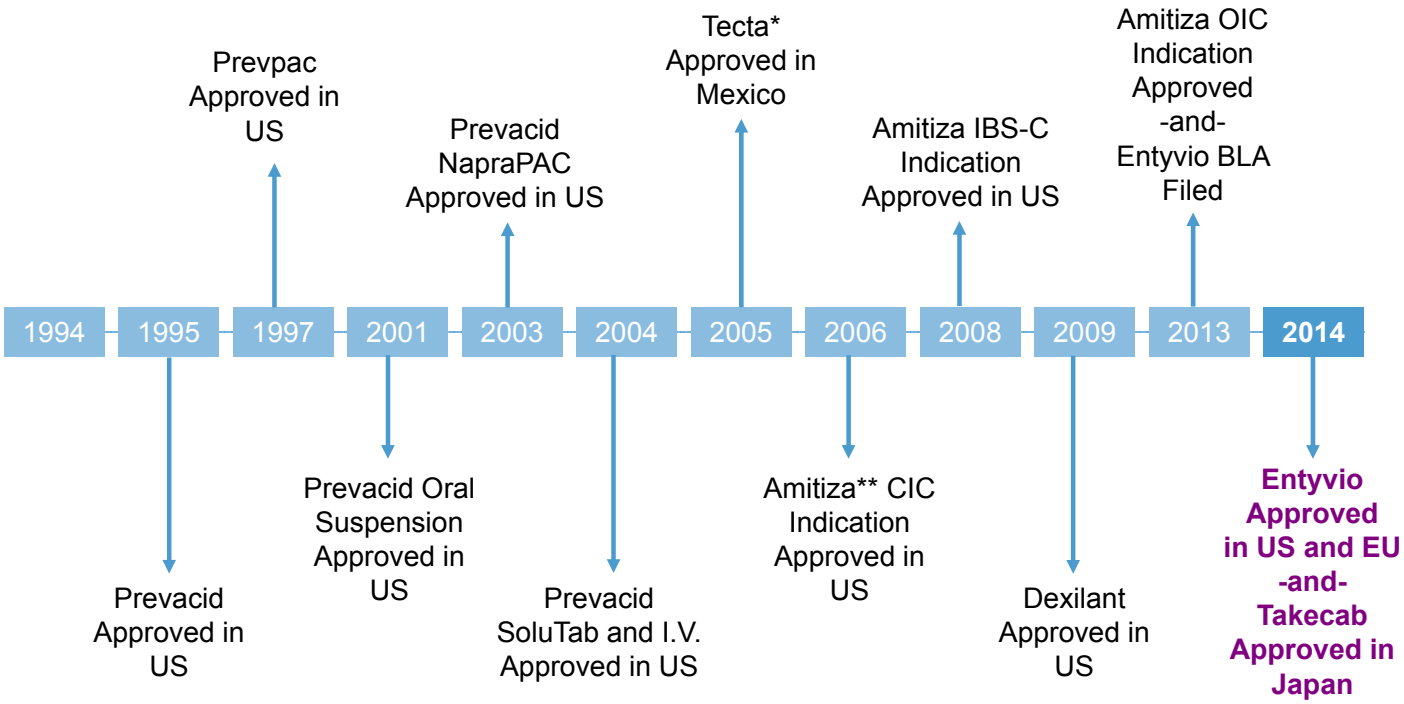
*Defined as Inflammatory Bowel Disease and Hepato-Pancreato-Biliary sub-Therapeutic Areas and select specialty GI indications within motility (e.g., Irritable Bowel Syndrome, gastroparesis, functional dyspepsia)

Source: EvaluatePharma and Internal research and analysis

A strong legacy to build on

Past 25 years make today's Takeda ideally poised for success

Selected milestones:



CIC: Chronic Idiopathic Constipation; IBS-C: Irritable Bowel Syndrome with Constipation;
OIC: Opioid-Induced Constipation; BLA: Biologics License Application

*Tecta was acquired by Takeda as part of the Nycomed acquisition in 2011
**In-licensed from Sucampo
Note: Indications are not written in full

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Takeda's GI Portfolio

Takeda's GI portfolio

Robust diversified portfolio and pipeline

Product / Development code	Category	Phase 2	Phase 3	Registration	Marketed
pantoprazole	Acid-related diseases				●
lansoprazole	Acid-related diseases				●
ulinastatin	Acute pancreatitis				●
Dexilant	Acid-related diseases				●
Amitiza	CIC, IBS-C, OIC*				●
	Pediatric functional constipation		●		
	New formulation		●		
Takecab	Acid-related diseases				●
Entyvio	Ulcerative colitis, Crohn's disease				●
	Primary Sclerosing Cholangitis	Preparing for Phase 3			
	Subcutaneous formulation	Preparing for Phase 3			
TAK-114	Ulcerative colitis	●			

Table shows most advanced stage of development, regardless of region

*CIC: Chronic Idiopathic Constipation, IBS-C: Irritable Bowel Syndrome with Constipation, OIC: Opioid Induced Constipation

Takeda's PPI portfolio totals 274 billion yen, with wide range of indications and formulations

DEXILANT dexlansoprazole

- 1st and only Dual-Delayed Release Proton Pump Inhibitor (PPI) offers two releases in one pill
- US and Emerging Market launches driving growth
- Global growth CAGR of 33% from FY2011 to FY2014 (forecast)

PREVACID LANSOPRAZOLE

- 120 billion yen in FY2013
- Lansoprazole is uniquely differentiated with multiple formulations

PANTOPRAZOLE

- 104 billion yen in FY2013
- IV formulation delivering strong growth in China

amitiza® lubiprostone

Amitiza is in-licensed from Sucampo Pharmaceuticals Inc.
For full indication and important safety information please see from slide 110 in this presentation

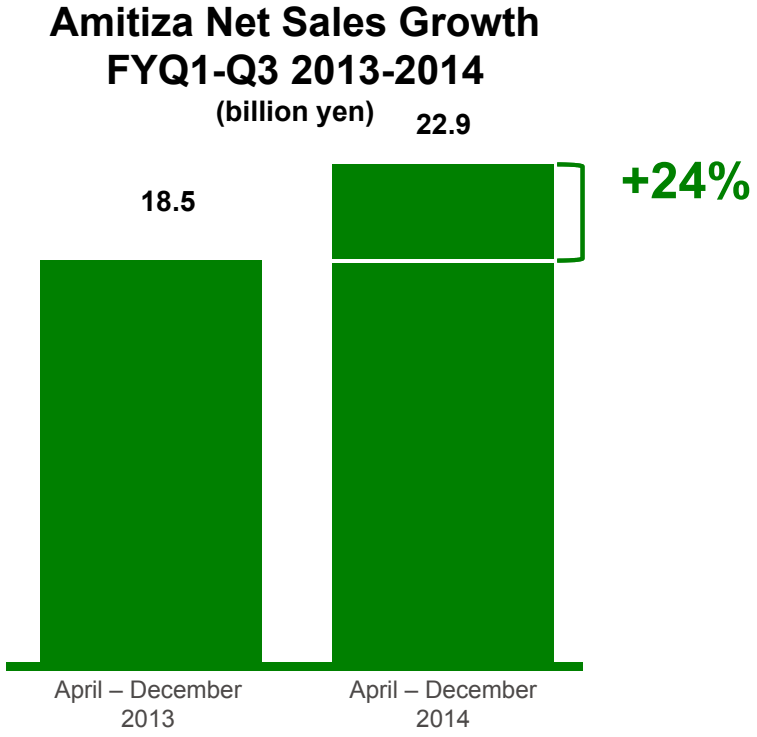
Amitiza® (lubiprostone) activates intestinal chloride channels

- Locally acting chloride channel activator that enhances intestinal fluid secretion without altering serum sodium or potassium
- Specifically activates CIC-2, a normal constituent of the apical membrane of human intestine

Images are an artist's rendition and are for illustration purposes only

- Bypasses the antisecretory action of opiates that results from suppression of secretomotor neuron excitability

Amitiza® continues to show robust growth in the US

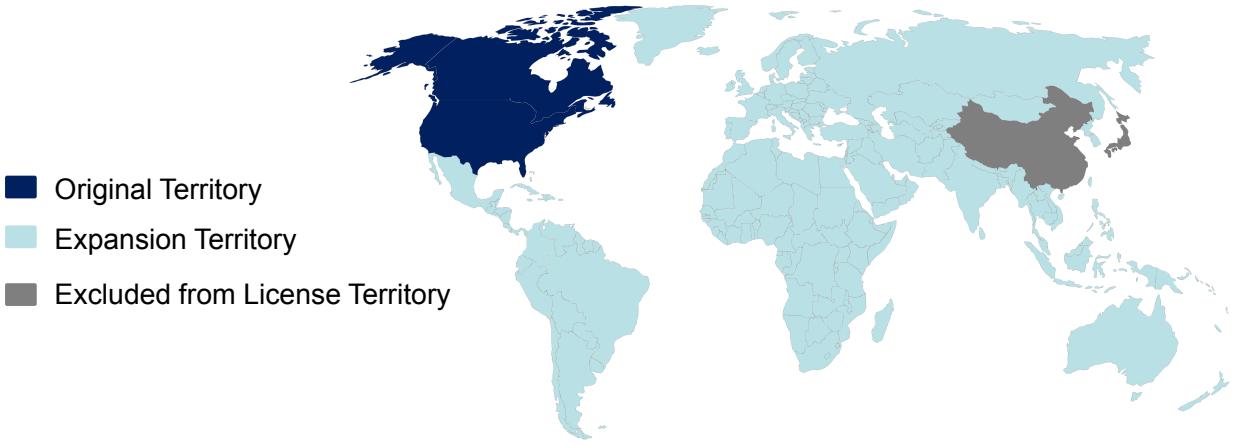


amitiza® lubiprostone

Amitiza is approved in the U.S. for the treatment of chronic idiopathic constipation, irritable bowel syndrome with constipation and opioid-induced constipation

Recent territory expansion agreement bolsters our global GI position

- Original Territory FY2014 revenue forecast: 28 billion yen
  - Planned pediatric labeling and new formulation expected to fuel growth if approved
  - Canadian CIC* approval anticipated in 2015
- Expansion Territory: launches in key Emerging Markets starting in 2017-18
- Global Lifecycle management plan under evaluation

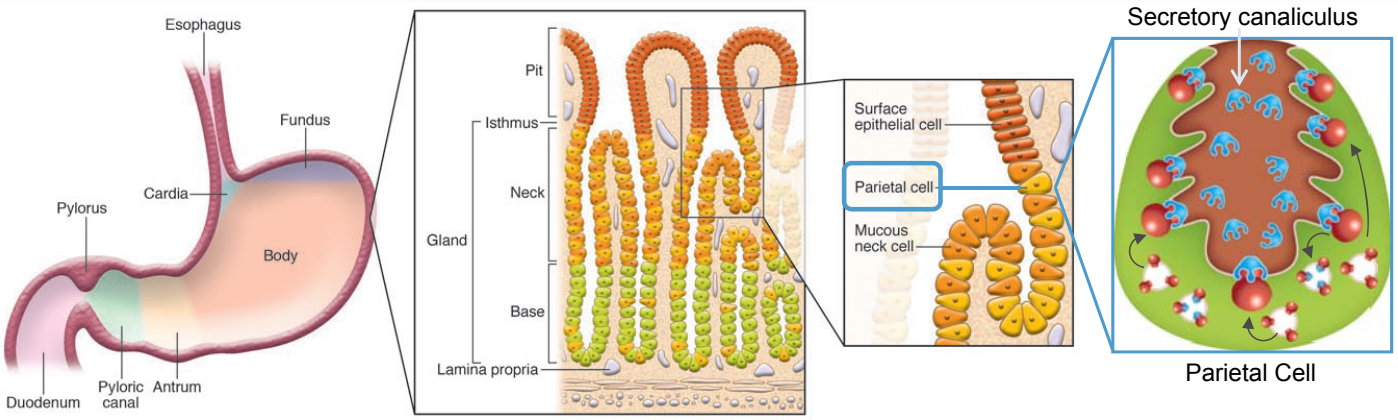


*Chronic Idiopathic Constipation

Takecab®

Takecab (vonoprazan) is approved for acid-related diseases only in Japan

Takecab® (vonoprazan) is a potent, novel Potassium-Competitive Acid Blocker (P-CAB)

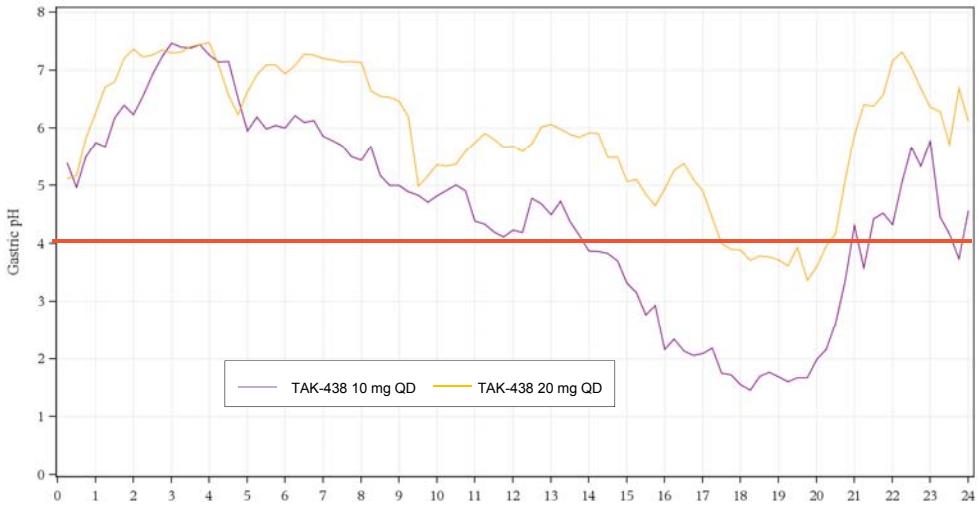


- Reversible inhibitor of proton pump
- Activation of drug by acid/food not needed
- Long half-life (~9h), linear pharmacokinetics up to 40mg
- High extent of 24 hour pH holding time >4
- Less affected by drug metabolism polymorphism (CYP2C19)

Diagram: *J Clin Invest.* 2007;117(1):60-69. doi:10.1172/JCI30111

Takecab® demonstrates rapid gastric acid neutralization

Mean of Median Gastric pH Profiles for TAK-438 Treatment Groups on Day 7*



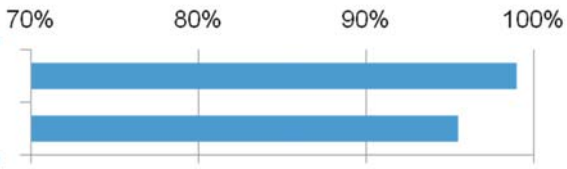
Time (hour)

- Rapid gastric acid neutralization
- Fast onset of action and acid suppression from first dose

*TAK-438 data: TAK-438_107

Takecab® phase 3 data, erosive esophagitis healing:
Takecab is clinically potent

Healing rate up to Week 8		
Takecab	20 mg	99.0% (203 /205)
Lansoprazole	30 mg	95.5% (190 /199)



Difference (%)	95% CI		non-inferiority	
	Lower	Upper	z-value	p-value
3.5	0.362	6.732	5.3945	<0.0001

- Endoscopic Erosive Esophagitis (EE) healing rates at Week 8 were confirmed in the non inferiority analysis vs. lansoprazole
- Post hoc analysis for superiority showed difference in favor of Takecab*

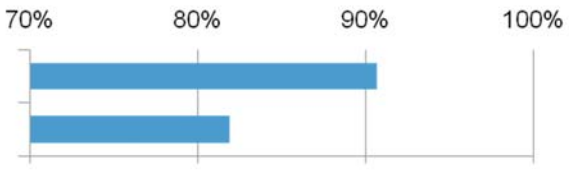
TAK-438/CCT-002 study
CI=confidence interval
*(P = 0.0337; Fisher exact test)

Takecab® phase 3 data, erosive esophagitis healing:
High healing rate of Takecab at 2 weeks

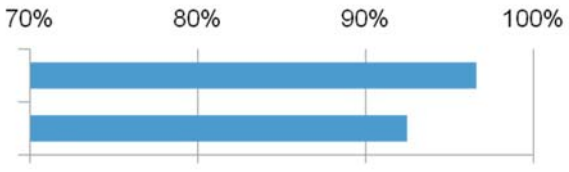
- Secondary endpoints met

Endoscopic EE healing rate up to Week 2 and Week 4

Healing rate at Week 2		
Takecab	20 mg	90.7% (185 /204)
Lansoprazole	30 mg	81.9% (163 /199)



Healing rate up to Week 4		
Takecab	20 mg	96.6% (198 /205)
Lansoprazole	30 mg	92.5% (184 /199)

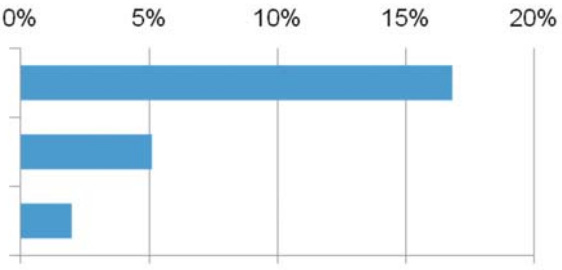


TAK-438/CCT-002 study

Takecab®, EE maintenance phase 3 data
Endoscopic EE Recurrence rates at week 24

p-value <0.0001

EE recurrence rate at Week 24			
Lansoprazole	15mg	16.8%	(33/196)
Takecab	10mg	5.1%	(10/197)
Takecab	20mg	2.0%	(4/201)

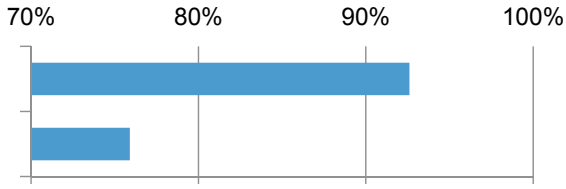


- As per protocol testing, non-inferiority of Takecab 10mg and 20mg to lansoprazole 15mg was confirmed
- Post hoc analysis for superiority showed difference in favor of Takecab*

TAK-438/CCT-003 study
*(Takecab 20mg vs. lansoprazole P<0.0001, Takecab 10mg vs. lansoprazole P=0.0002; Fisher exact test)

Takecab® phase 3 data:
H. pylori high eradication rates

1st Line Eradication Rate			
Takecab	20mg	92.6%	(300/324)
Lansoprazole	30mg	75.9%	(243/320)

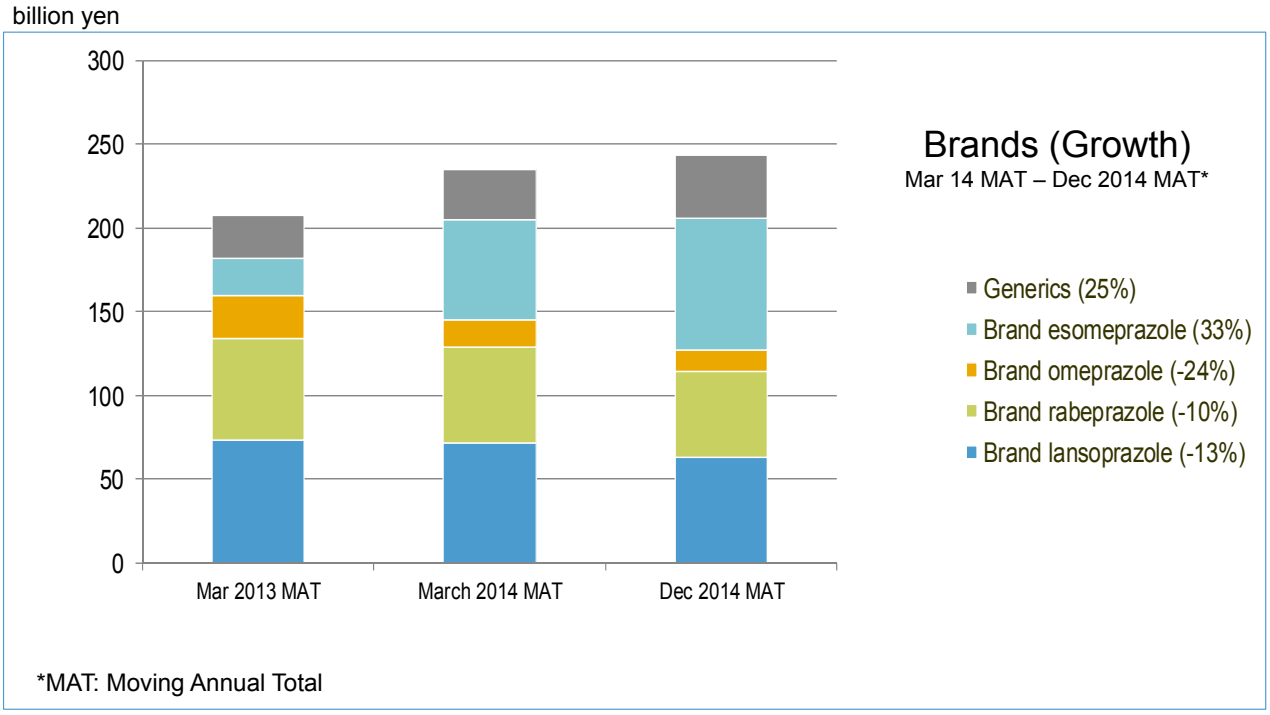


	Difference (%)	95% CI		Non-inferiority test *	
		Lower	Upper	z-value	p-value
Takecab – Lansoprazole	16.7	11.172	22.138	8.7909	**<0.0001**

- Non-inferiority of triple therapy with Takecab/amoxicillin/clarithromycin vs Lansoprazole/amoxicillin/clarithromycin was confirmed
- Post hoc analysis for superiority showed difference in favor of Takecab**

TAK-438/CCT-401 study
**Farrington and Manning test with a non-inferiority margin of 10%
**(p-value: <0.0001; Chi-square test with Yates's continuity correction)

The Japanese anti-acid market is large and still growing even after generic entries of classical PPIs



*MAT: Moving Annual Total

Brand omeprazole includes Omepral tab and Omeprazon tab
Brand rabeprazole includes Pariet tab, Rabecure and Rabefine (H.pylori triple packs)
Brand lansoprazole includes Takepron capsule, Takepron ODT, Takelda (Takepron/ASA FDC), Lansap and Lampion (H.pylori triple packs)

Takecab® now launched in Japan

Japan

- Phase III program focused only on Japan
- Just launched with 7 approved indications
- Takeda and Otsuka co-promotion, two leading GI companies
- Anticipated to be a top 3 revenue generator for Takeda in Japan (over 60 billion yen in sales)
- Patent protection until at least 2026

Otsuka Takeda

Rest of World

- Takeda is reviewing different options for development of Takecab in markets outside of Japan

Entyvio®
vedolizumab

For full indication and important safety information please see from slide 104 in this presentation

Inflammatory Bowel Disease (IBD)

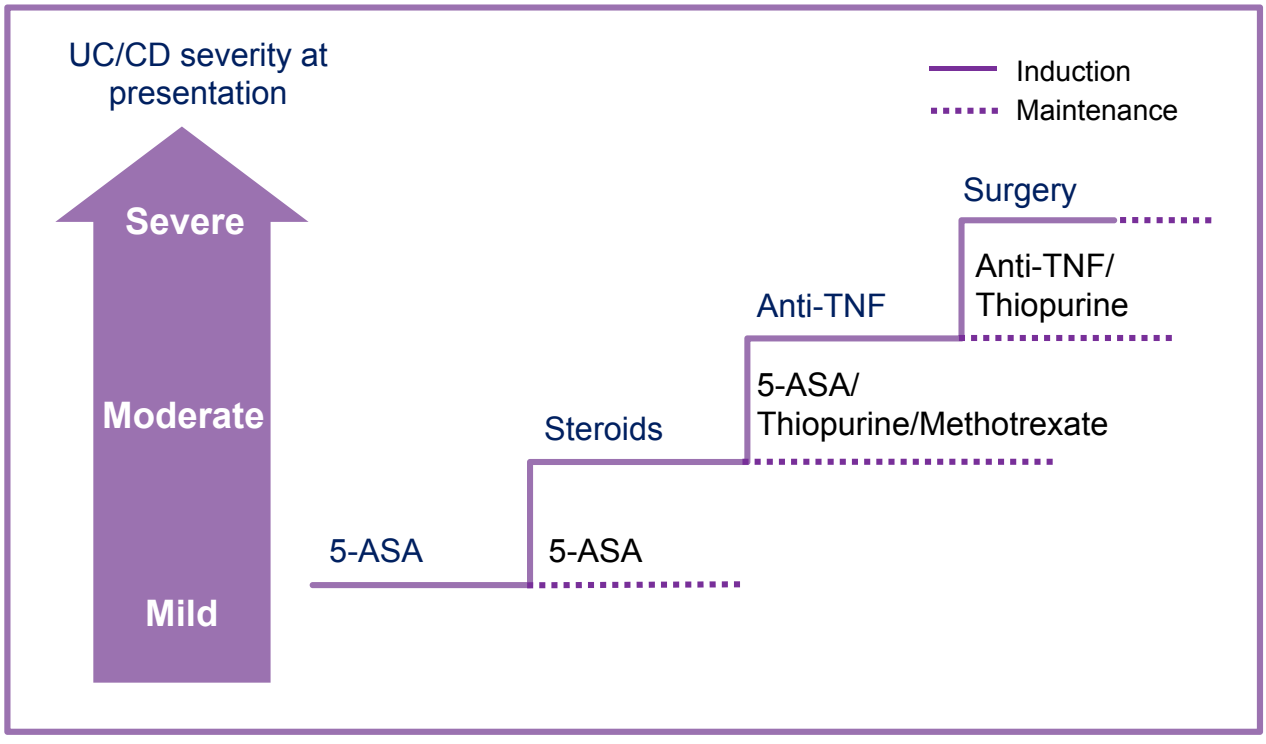
IBD includes two distinct inflammatory diseases of the gastrointestinal tract

1. ***Ulcerative Colitis (UC)*** affects the innermost lining of the large intestine
2. ***Crohn's Disease (CD)*** affects any portion of the GI tract, involves all tissue layers

- UC and CD are chronic conditions affecting 2.6 million patients in the G7 markets[1]
- Symptoms include abdominal pain, diarrhea, rectal bleeding and weight loss
- Lifelong condition that often affects young otherwise healthy individuals
- Complications include strictures, bowel obstruction, need for surgery, and cancer

1 Source: Decision Resources Pharmacor 2014

Inflammatory Bowel Disease (IBD)
Stepwise treatment paradigm

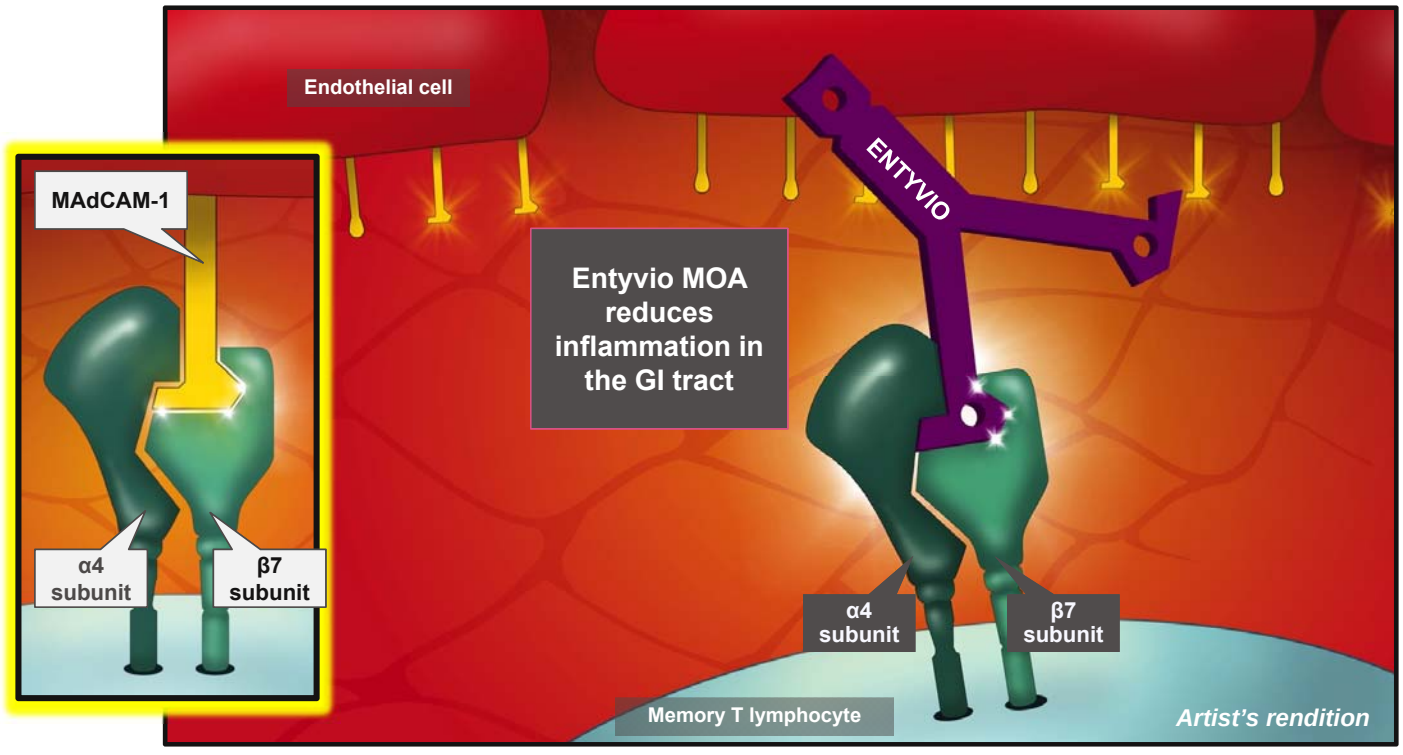


Adapted from Kornbluth and Sachar, Am J Gastroenterol 2010; 105:501–523

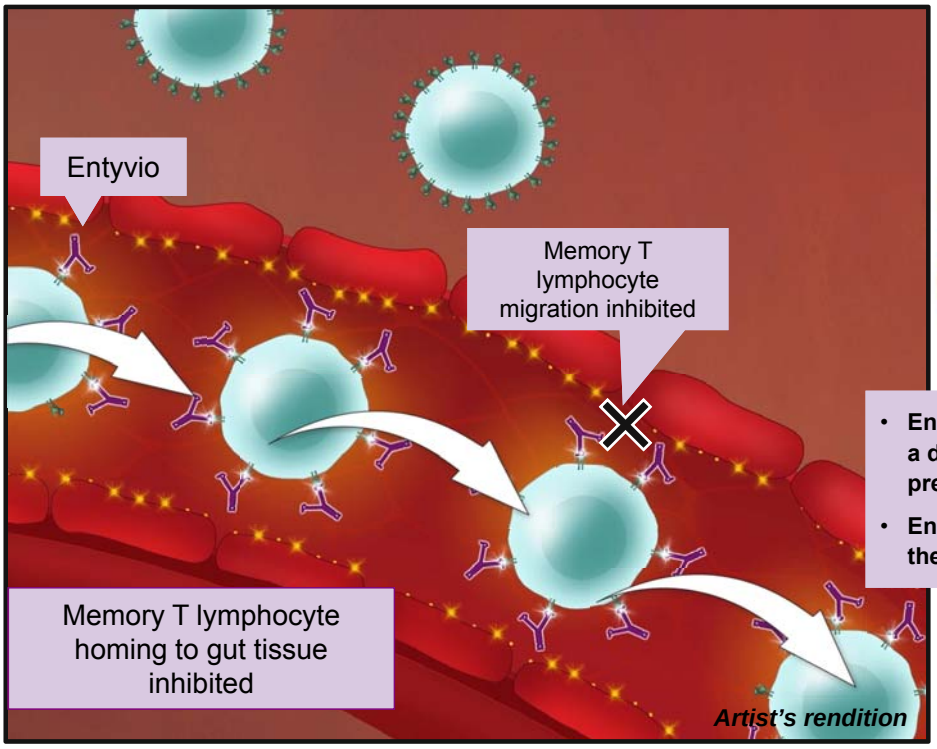
Entyvio® (vedolizumab):
An alternative for patients with UC and CD

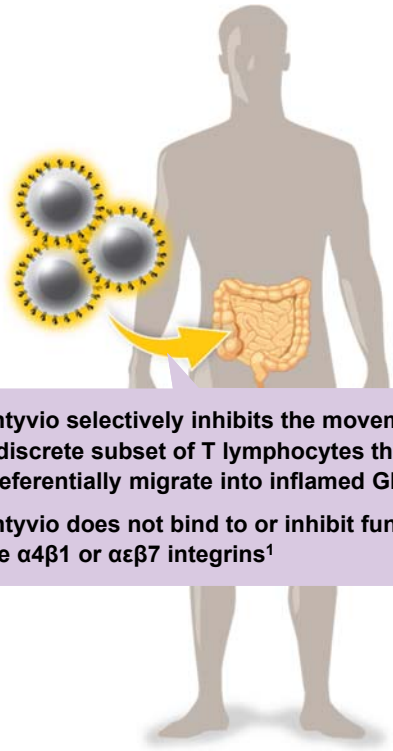
- ***First and only*** biologic engineered for the treatment of moderately to severely active ulcerative colitis and Crohn's disease
- ***First and only*** product in the US and Europe indicated for both anti-TNFα -naïve and anti-TNFα-failure patients, both in UC and CD
- ***First and only*** biologic with a specific binding action designed for a gut-homing inflammatory pathway
- ***First and only*** simultaneous launch in both UC and CD in US and Europe
- No boxed warning in label

Entyvio® is the first biologic to primarily inhibit homing of lymphocytes to the gut



The specific binding action of Entyvio® inhibits lymphocyte trafficking to inflamed gut





- **Entyvio selectively inhibits the movement of a discrete subset of T lymphocytes that preferentially migrate into inflamed GI tissue**
- **Entyvio does not bind to or inhibit function of the α4β1 or αεβ7 integrins[1]**

1. Entyvio [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.

Entyvio® discovery and development

An incredible journey

Early publications

α4β7 integrin mediates lymphocyte binding to the mucosal vascular addressin MAdCAM-1

Cornelia Berlin[1, 6, 7], Ellen L. Berg[1, 7], Michael J. Briskin[1, 7], David P. Andrew[1, 7], Peter J. Kilshaw[2], Bernhard Holzmann[3], Irving L. Weissman[4, 5], Alf Hamann[6], Eugene C. Butcher[1, 4, 7]

Cell 1993

Attenuation of Colitis in the Cotton-top Tamarin by Anti–α4 integrin Monoclonal Antibody

JCI 1992

Daniel K. Podolsky,*‡ Roy Lobb,§ Norval King,‖ Christopher D. Benjamin,§ Blake Pepinsky,§ Prebhat Sehgal,‖ and Michelle deBeaumont*‡

*Gastrointestinal Unit, Massachusetts General Hospital and Department of Medicine, Harvard Medical School; ‡Massachusetts General Hospital/New England Regional Primate Research Center for the Study of Inflammatory Bowel Disease, Boston Massachusetts 02114; §Biogen, Inc., Cambridge, Massachusetts 02142; and ‖New England Regional Primate Research Center, Southboro, Massachusetts 01772

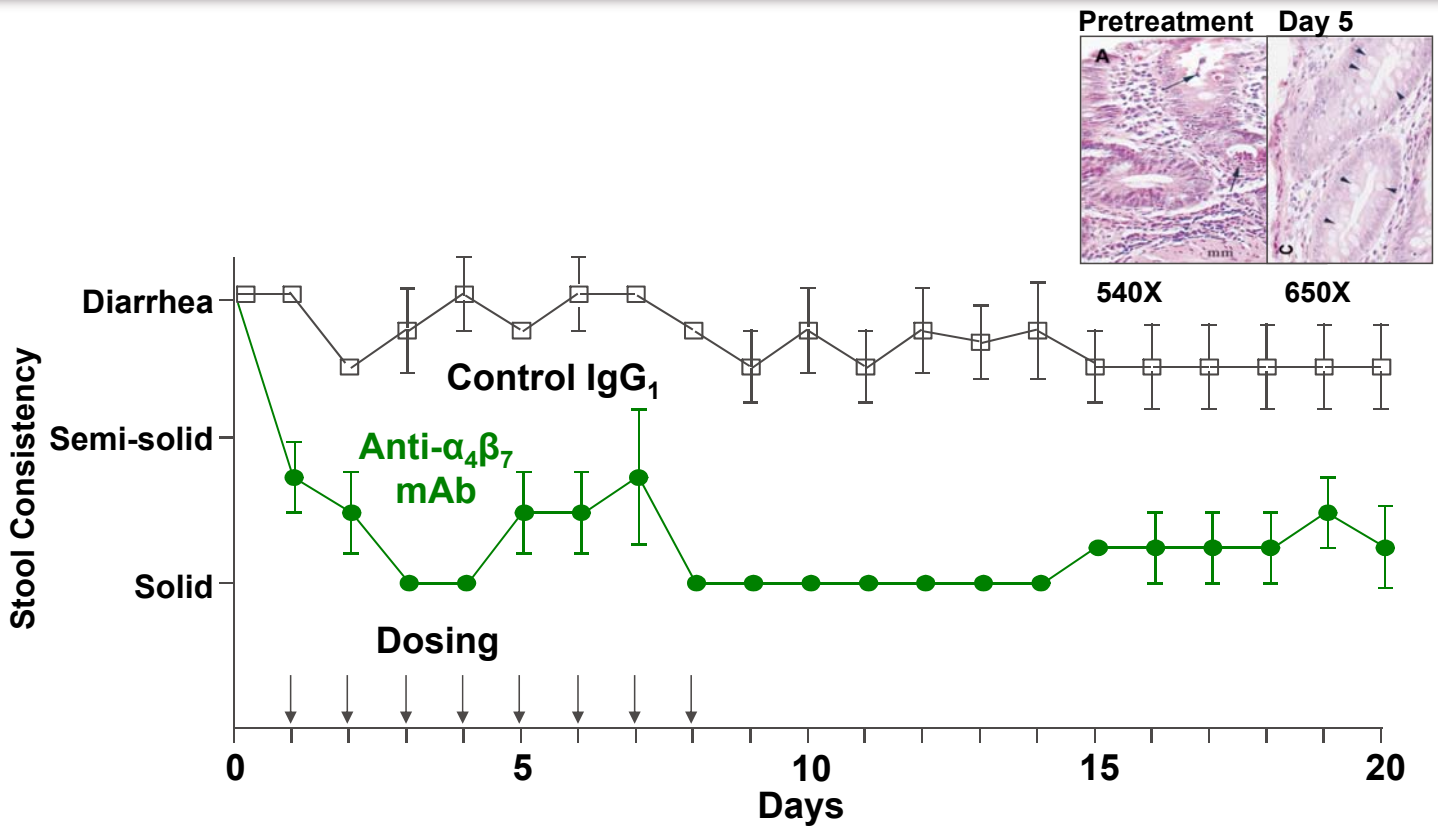
Rapid Resolution of Chronic Colitis in the Cotton-top Tamarin With an Antibody to a Gut-Homing Integrin α4β7

PAUL E. HESTERBERG, DAWN WINSOR–HINES, MICHAEL J. BRISKIN, DULCE SOLER–FERRAN, CHRISTOPHER MERRILL, CHARLES R. MACKAY, WALTER NEWMAN, and DOUGLAS J. RINGLER

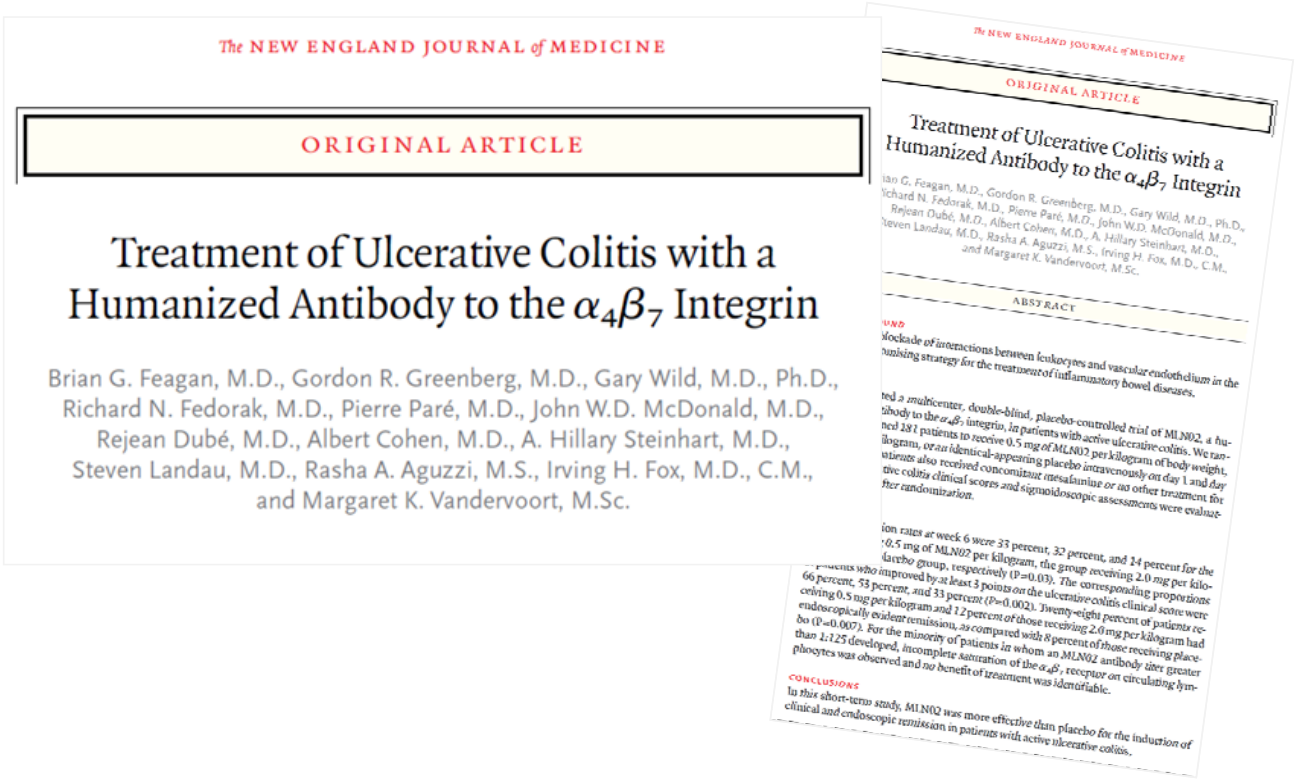
LeukoSite Inc., Cambridge, Massachusetts

Gastroenterology 1996

Blocking $\alpha_4\beta_7$ alleviates chronic diarrhea in monkeys



Hesterberg PE et al. *Gastroenterol* 1996;111:1373–1380.



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Treatment of Ulcerative Colitis with a Humanized Antibody to the $\alpha_4\beta_7$ Integrin

Brian G. Feagan, M.D., Gordon R. Greenberg, M.D., Gary Wild, M.D., Ph.D., Richard N. Fedorak, M.D., Pierre Paré, M.D., John W.D. McDonald, M.D., Rejean Dubé, M.D., Albert Cohen, M.D., A. Hillary Steinhart, M.D., Steven Landau, M.D., Rasha A. Aguzzi, M.S., Irving H. Fox, M.D., C.M., and Margaret K. Vandervoort, M.Sc.

Entyvio® discovery and development

An incredible journey

2014

Entyvio Approved by FDA and EMA

2013

Entyvio name accepted

EMA and FDA Filings

2014

CHMP (EMA) positive opinion

GEMINI UC and CD data published in New England Journal of Medicine

2013

FDA Advisory Committee

gemini™ vedolizumab IBD PROGRAM

2012

GEMINI data presented at Digestive Disease Week

2008

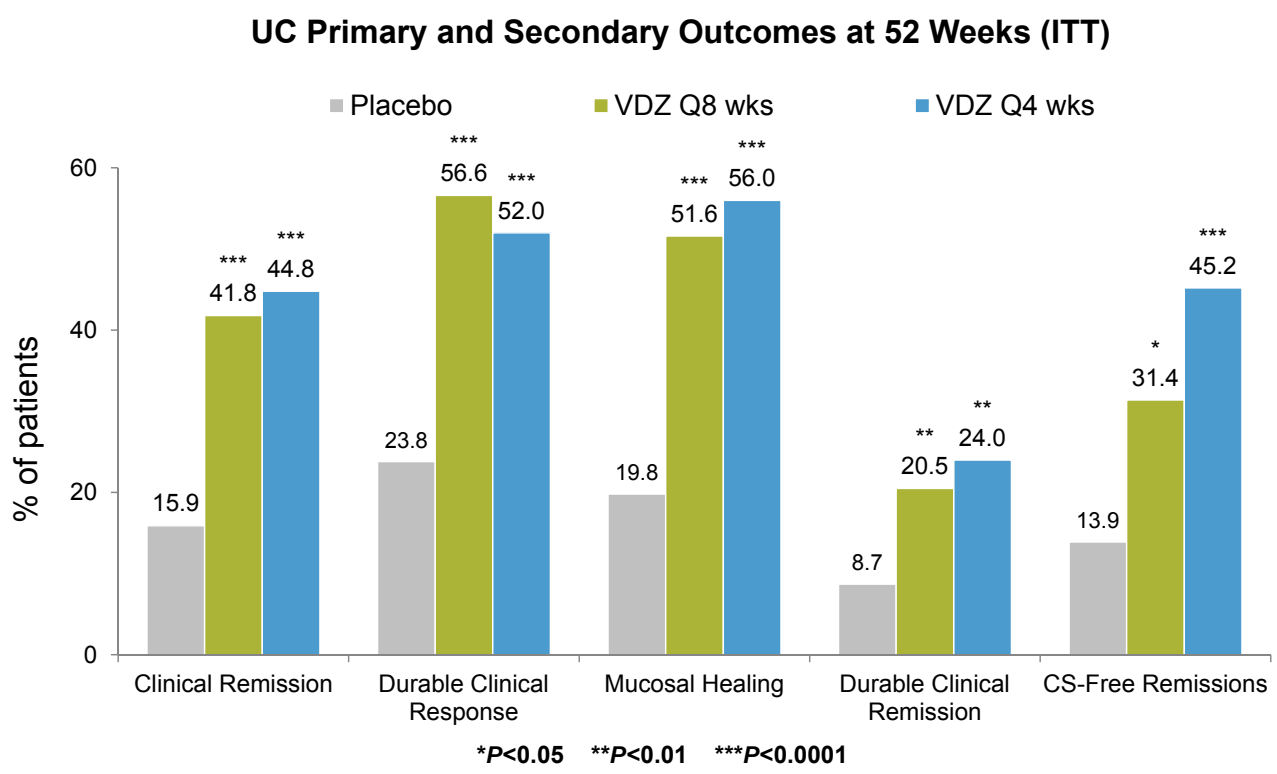
GEMINI Phase III studies initiated

Phase II proof of concept established in IBD

Entyvio precursor discovered

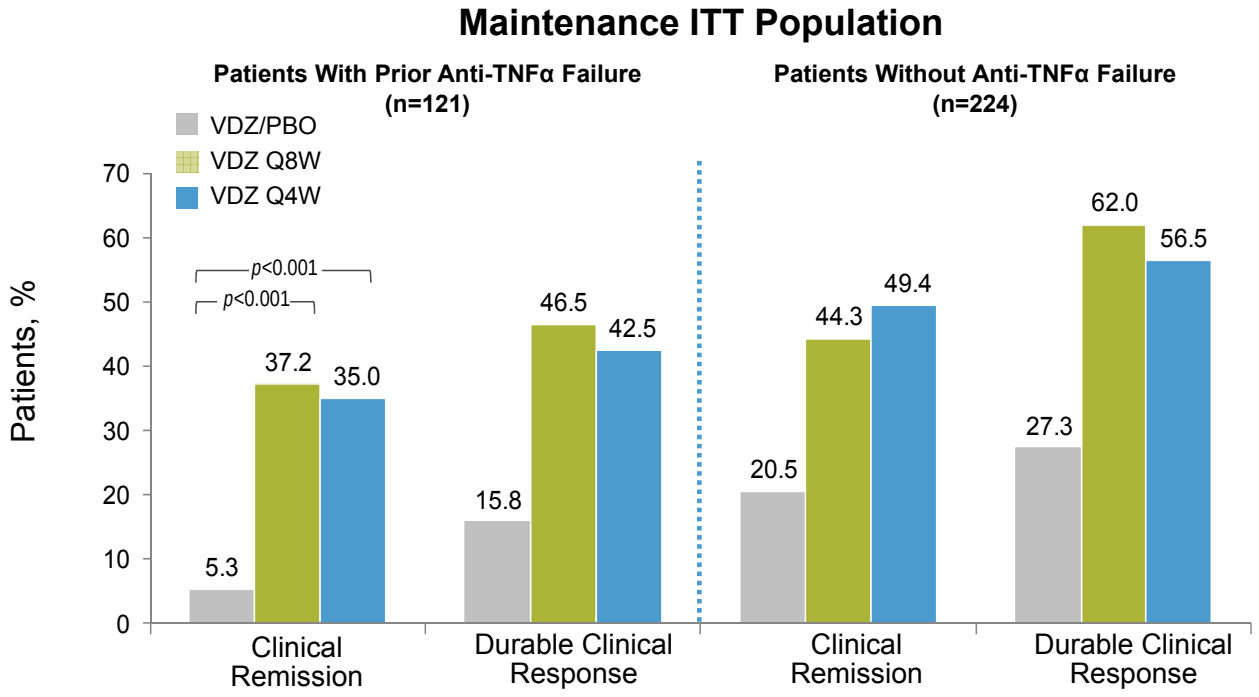
Role of α4β7 integrin in cell trafficking elucidated

Entyvio® ulcerative colitis pivotal data
Powerful results in UC from GEMINI I



VDZ: vedolizumab (Entyvio), ITT: Intention to treat population, CS-Free: Corticosteroid-free
Note: Q4 dosing is not the recommended dosage regimen in the US

GEMINI I: Entyvio® in UC
Benefit with and without prior anti-TNFα failure



VDZ: vedolizumab (Entyvio), ITT: Intention to treat population, TNF: tumor necrosis factor.
Feagan B et al. NEJM 2013; 369 (8): 699-710. Supplementary appendix: Figure S3.
Note: Q4 dosing is not the recommended dosage regimen in the US

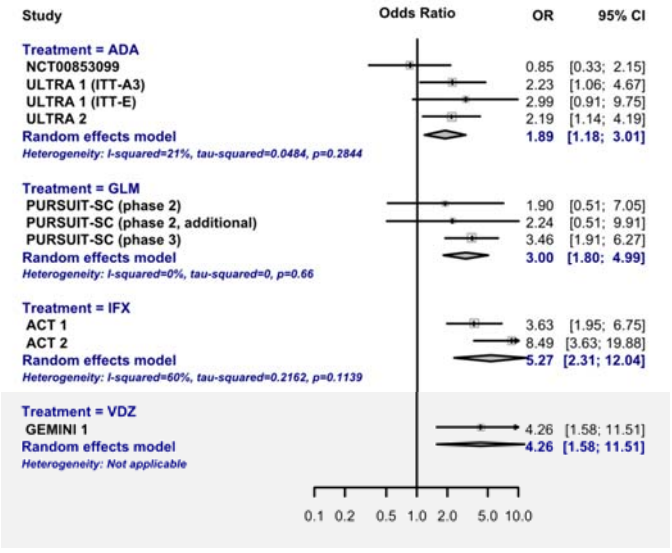
Entyvio® UC Pivotal Data (GEMINI I)

Incidence, %	PLACEBO (n=149)	VEDOLIZUMAB (n=746)
Any AE	46	45
Serious AE	7	3
Common AEs (≥5%)		
Headache	5	8
UC exacerbation	5	3
Infections		
Any	15	14
Serious	2	<1
Infusion related reaction	<1	<1
Malignant neoplasm	0	0

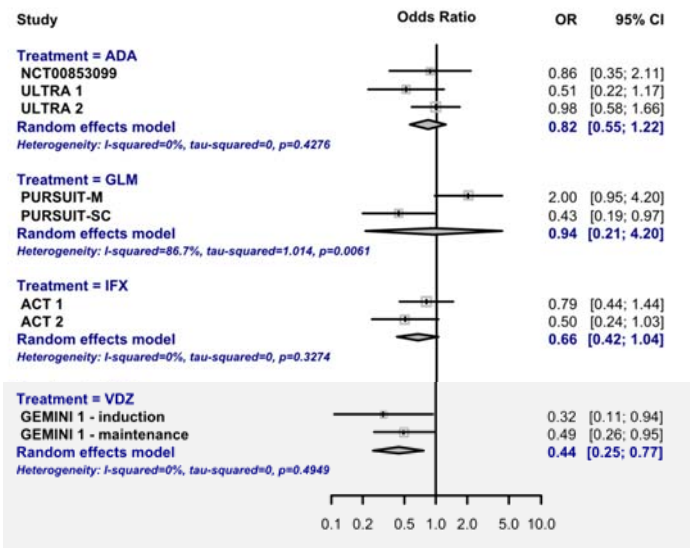
AE: adverse event
Feagan BG et al. NEJM 2013; 369 (8): 699-710. Supplementary Appendix.

Entyvio® demonstrates favorable efficacy and safety in UC meta analysis

Clinical Remission with Induction Rx

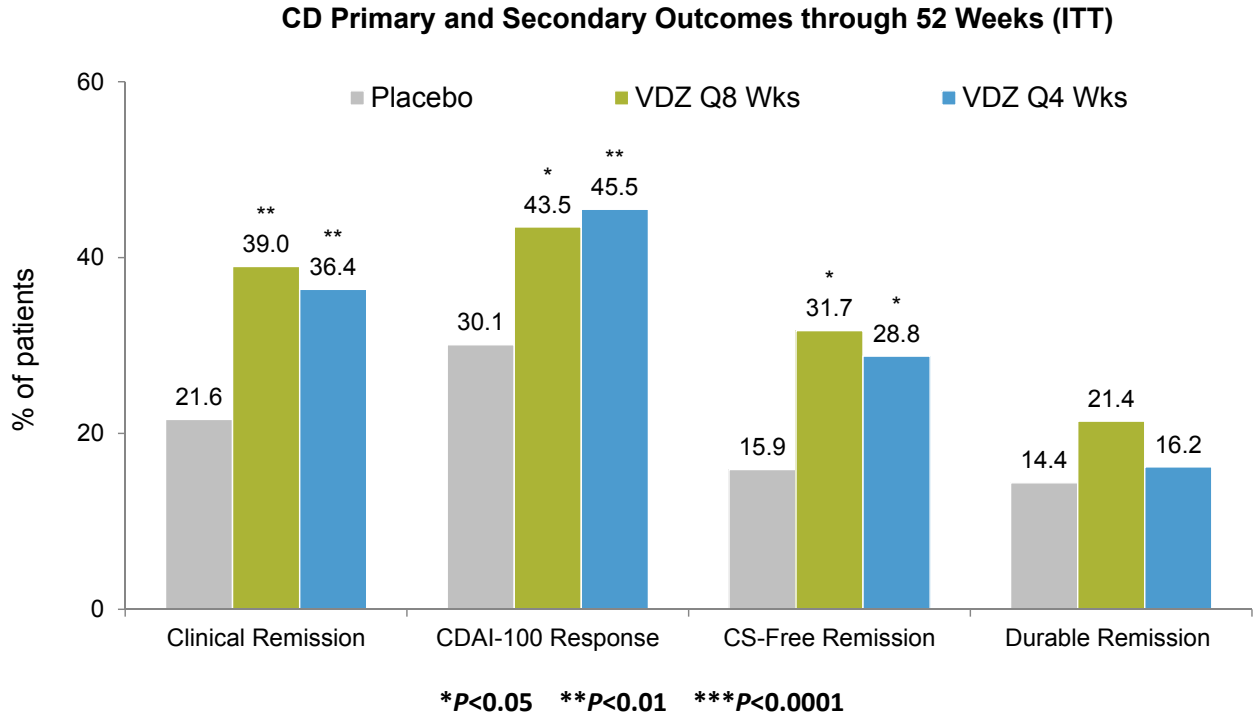


Serious Adverse Events



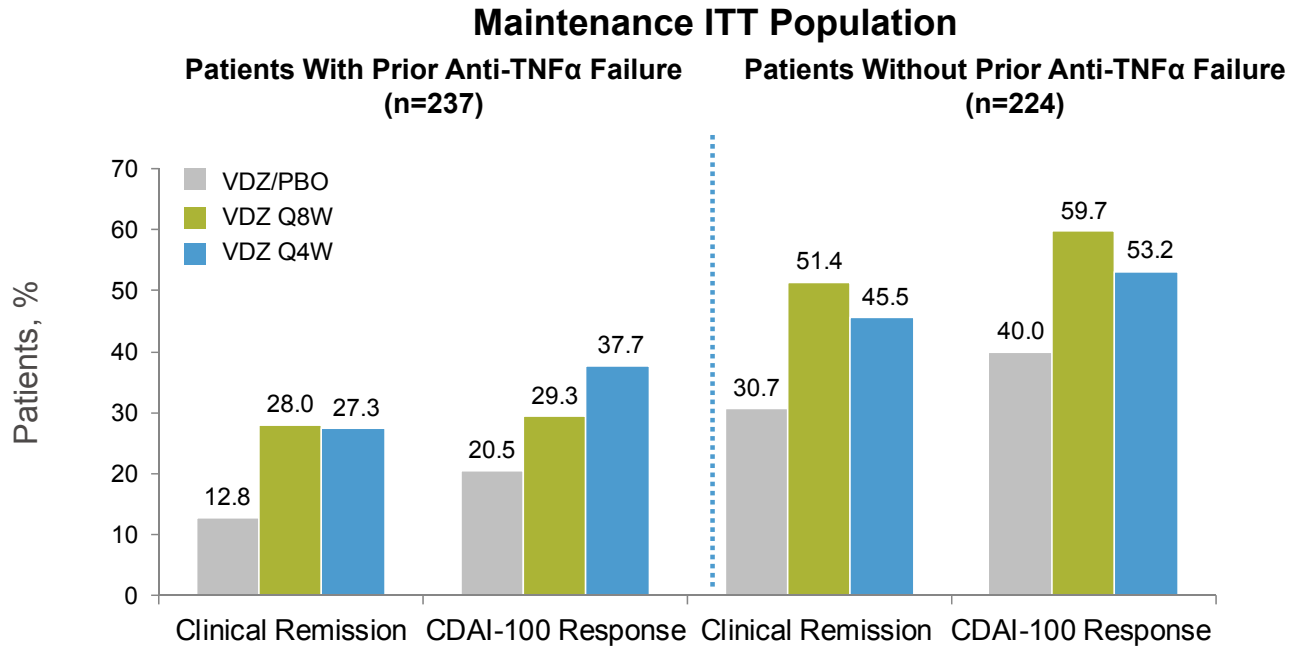
VDZ: vedolizumab (Entyvio), ADA: adalimumab (Humira), IFX: infliximab (Remicade), GLM: golimumab (Simponi)
Danese et al, Annals of Internal Medicine *Ann Intern Med.* 2014;160(10):704-711.

Entyvio® Crohn's disease pivotal data
Impactful results in Crohn's from GEMINI II



CD: Crohn's Disease, VDZ: vedolizumab (Entyvio), ITT: Intention to treat population, CS-Free: Corticosteroid-free, CDAI: Crohn's Disease Activity Index
Note: Q4 dosing is not the recommended dosage regimen in the US

Entyvio® CD pivotal data
Consistency irrespective of prior anti-TNFα exposure



Note: Exploratory sub-population not in the US label. Note: Q4 dosing is not the recommended dosage regimen in the US
Colombel JF et al. Presented at UEGW 20th Annual Meeting 2012.

CD: Crohn's Disease, VDZ: vedolizumab (Entyvio), TNF: tumor necrosis factor., ITT: Intention to treat population, CS-Free: Corticosteroid-free, CDAI: Crohn's Disease Activity Index

Entyvio® CD Pivotal Data (GEMINI II)

Incidence, %	PLACEBO (n=301)	VEDOLIZUMAB (n=814)
Any AE	82	87
Serious AE	15	24
Common AEs in ≥ 10%		
Crohn's Disease	22	20
Arthralgia	13	14
Pyrexia	13	13
Headache	16	12
Nausea	10	11
Abdominal pain	13	10
Upper respiratory tract infection	19	23
Infections	40	44
Serious	3	6
Infusion reaction	5	4
Malignant neoplasm	<1	<1

AE: adverse event
Sandborn WJ et al. NEJM 2013; 369:711-721. Supplementary appendix: Table S6.

Pivotal data from UC and CD published together

Vedolizumab as Induction and Maintenance Therapy for Ulcerative Colitis

Brian G. Feagan, M.D., Paul Rutgeerts, M.D., Ph.D., Bruce E. Sands, M.D., Stephen Hanauer, M.D., Jean-Frédéric Colombel, M.D., William J. Sandborn, M.D., Gert Van Assche, M.D., Ph.D., Jeffrey Axler, M.D., Hyo-Jong Kim, M.D., Ph.D., Silvio Danese, M.D., Ph.D., Irving Fox, M.D., Catherine Milch, M.D., Serap Sankoh, Ph.D., Tim Wyant, Ph.D., Jing Xu, Ph.D., and Asit Parikh, M.D., Ph.D., for the GEMINI 1 Study Group*

ORIGINAL ARTICLE

Vedolizumab as Induction and Maintenance Therapy for Crohn's Disease

William J. Sandborn, M.D., Brian G. Feagan, M.D., Paul Rutgeerts, M.D., Ph.D., Stephen Hanauer, M.D., Jean-Frédéric Colombel, M.D., Bruce E. Sands, M.D., Milan Lukas, M.D., Ph.D., Richard N. Fedorak, M.D., Scott Lee, M.D., Brian Bressler, M.D., Irving Fox, M.D., Maria Rosario, Ph.D., Serap Sankoh, Ph.D., Jing Xu, Ph.D., Kristin Stephens, B.A., Catherine Milch, M.D., and Asit Parikh, M.D., Ph.D., for the GEMINI 2 Study Group*

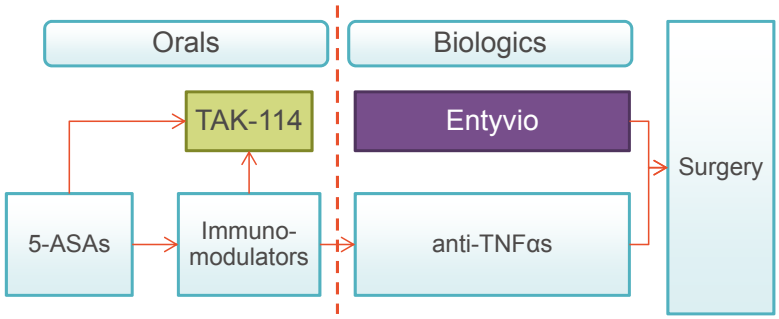
Entyvio® development (2007-2013)
Exemplifies Takeda capabilities

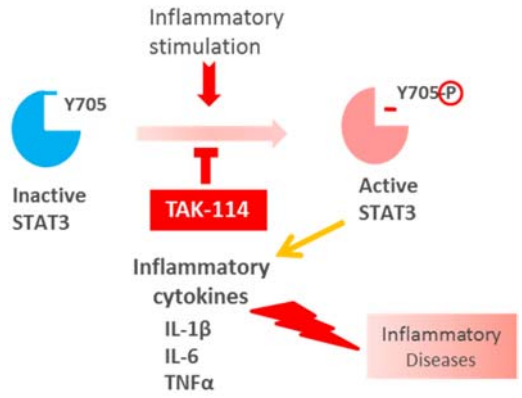
- Studies enrolled ~3000 patients
- Largest IBD clinical program ever conducted, resulting in approval
- Addressed numerous challenges associated with novel mechanism
- Continued mechanistic studies performed during clinical development
  - No impact on peripheral lymphocyte counts in humans[1]
  - No CNS immunosuppressive effect in macaques[2]
  - No effect on human spinal fluid cell counts or number[3]
  - Measurable effect on gut but not systemic immune function in vaccine challenge study in humans[4]

FDA and EMA approval achieved in the same week – historic in IBD

1. Entyvio (vedolizumab) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2014;
2. 2. Fedyk ER, et al. [abstract P-0144]. *Inflamm Bowel Dis*. 2009;15(Suppl 2):S50;
3. Milch C, et al. *J Neuroimmunol*. 2013;264(1-2):123-126; 4. Wyant T, et al. *Gut*. 2015;64(1):77-83.

TAK-114 is an investigational oral STAT3 inhibitor for ulcerative colitis positioned pre-biologic

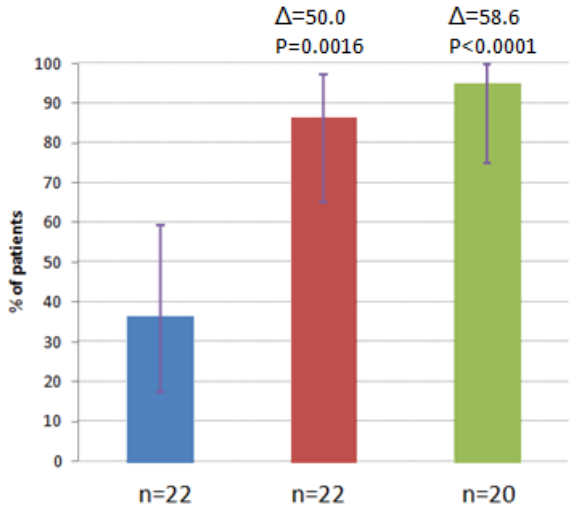




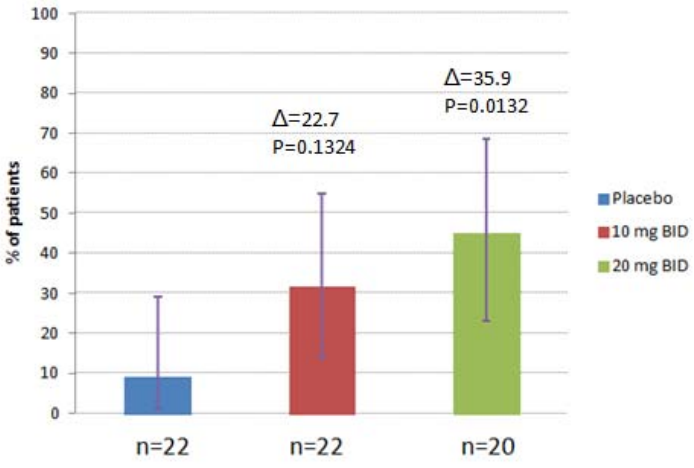
- In-licensed from Natrogen in December 2013
- Positive results in Phase 2a (4 week ulcerative colitis study)
- Oral twice a day dosing
- For moderate to severe UC patients who fail 5-ASAs or other conventional oral therapies

TAK-114 in UC:
Positive results in a 4 week Phase II Study

Clinical Response at Week 4*



Clinical Remission at Week 4*



*Study phase 2a NTI2009UC1: Post-hoc analysis (Completers-Observed data).
Percentage of subjects and exact 95% confidence intervals. P-value is derived from Fisher's exact test.
† Includes correction from published abstract. Wang L, et al. Am J Gastroenterol. 2012;107(Suppl 1):S638.

Better Health, Brighter Future

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Takeda's GI Drug Discovery Unit

Gastroenterology Drug Discovery Unit

- Innovative highly matrixed virtual DD
- Focused on collaborative innovation
- Leverages the best internal & external GI science wherever it exists
- Lean infrastructure provides agility
- Passionate & experienced leadership
- Ambition to be #1 partner of choice

Inflammatory / Immune GI Diseases

Functional Bowel Disorders

Liver Diseases

Motility Disorders

Key external partnerships established in 2014

MONASH University
Institute of Pharmaceutical Sciences

A unique academic fully integrated preclinical drug discovery unit

Queen Mary University of London

Human GI tissue biology, *state of the art* target validation

THE UNIVERSITY of ADELAIDE

World-leading visceral pain laboratories

ADVINUS
A TATA Enterprise

Discovery CRO* - A major partnership with Takeda

*Contract Research Organization

GI Leadership within Reach

GI is an attractive market for further investment

- Global health burden of GI diseases remains substantial
- Key assets Takecab and Entyvio are cornerstones of a diversified portfolio

Takeda will achieve global leadership in GI

- Leveraging existing franchise and CMC/discovery/development capabilities
- Licensing/acquiring additional GI assets as good opportunities present

Agenda for Today

09:00~10:10 **Session 1**
Introduction: Strategic Roadmap for Profitable Growth
Takeda's Position of Strength within the Gastroenterology Space
Takeda's GI Portfolio
Takeda's GI Drug Discovery Unit

10:10~10:20 break & refreshments

10:20~11:20 **Session 2**
The IBD Market
The US Launch of Entyvio®
Entyvio® Global Launch
Achieving >$2 Billion in Global Peak Sales
The Road to GI Leadership

11:20~12:00 **Q&A Session**

12:00~13:00 lunch buffet

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

The IBD Market

IBD has a significant impact on patients and society

IBD Impacts the Lives of Patients

- Physical symptoms
- Increased risk of colorectal cancer
- Impact on quality of life including loved ones
- Lack of general public awareness

High Cost of Care

- High rates of surgery, hospitalizations, complications
- Over $12B in direct and indirect costs in the US[1,2]
- Increased worker absenteeism, non-participation, and sick leave

Significant unmet needs remain

1. Kappelman MD, et al. *Gastroenterol*. 2008;135:1907-1913. **2.** Park KT, et al. *Inflamm Bowel Dis*. 2011;17:1603-1609.

The UC and CD biologic treated segments of the IBD category are ripe for a new entrant

IBD Patient Pool Dynamics (G7 data)

Ulcerative Colitis

1.26 million diagnosed patients[1]

76k patients on biologic therapy[1]

Crohn's Disease

1.03 million diagnosed patients[2]

242k patients on biologic therapy[2]

Patients currently on:[3]

65%	1st Biologic	70%
28%	2nd Biologic	23%
7%	3rd Biologic	7%

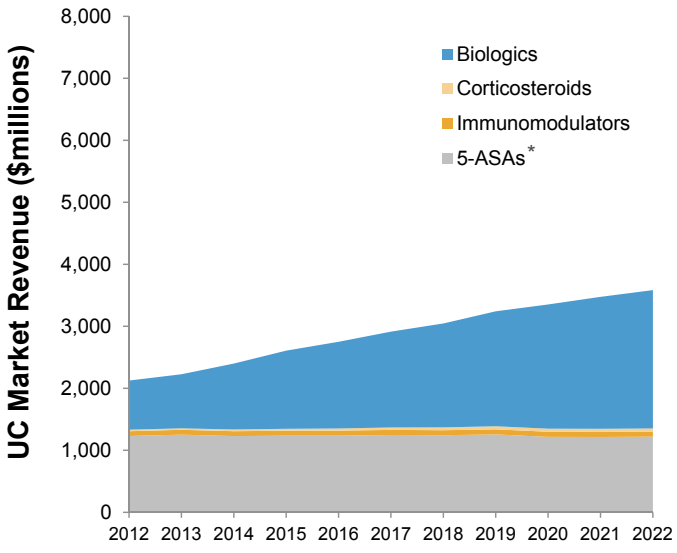
G7: US, France, Germany, Italy, Spain, UK, Japan

1. Decision Resources Pharmacor, G7 UC 2014
2. Decision Resources Pharmacor , G7 CD 2014
3. Internal Research and Analysis、Takeda IBD Physician Conjoint, November 2013

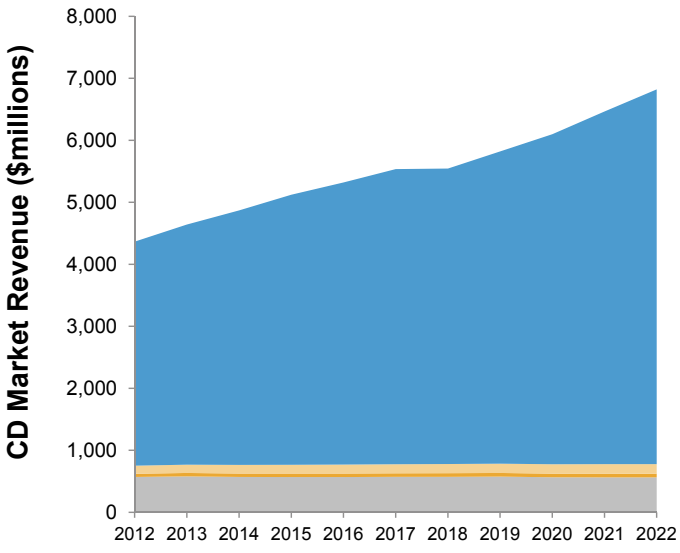
The UC and CD total market will total ~$10 billion by 2022, with biologics accounting for 80% of sales

Projected Market Revenues (G7) 2012-2022

Ulcerative Colitis



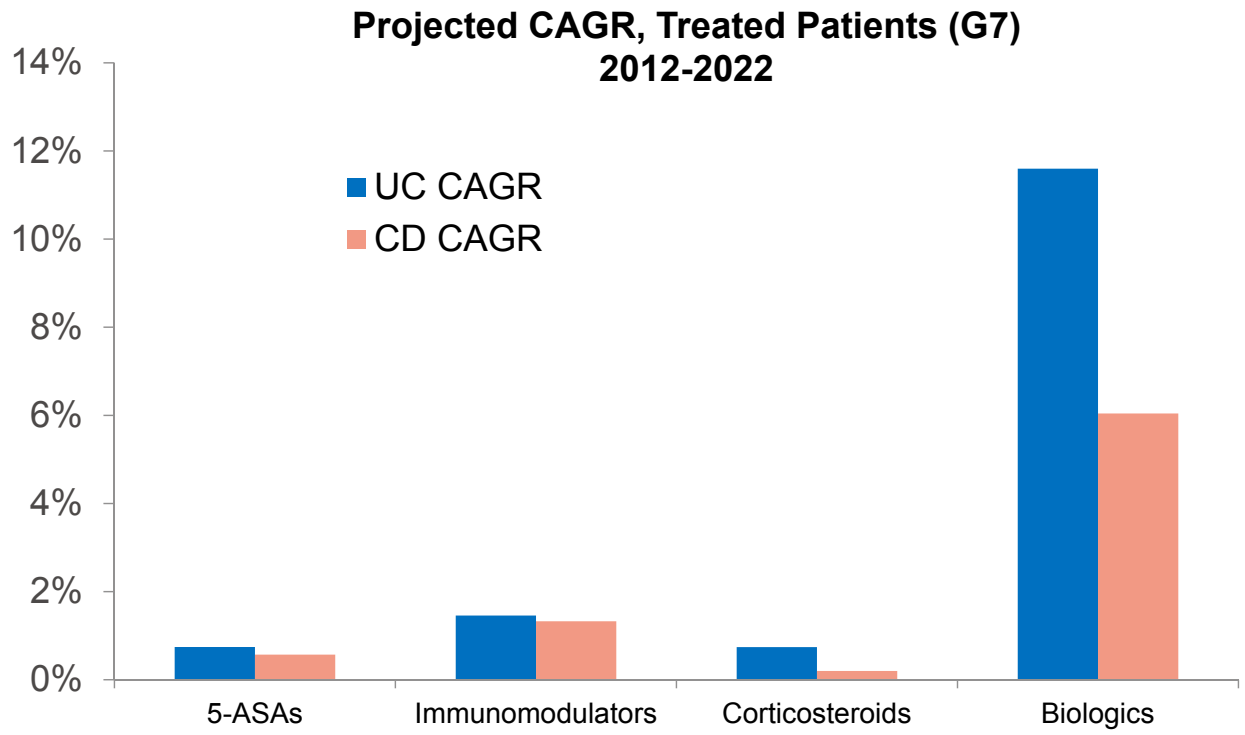
Crohn's Disease



*acetylsalicylic acids

Source: Decision Resources Pharmacor G7 UC and CD Markets, 2014

The biologic treated segment of the UC and CD market will become more prevalent, biotherapy could be used more widely



Source: Decision Resources Pharmacor G7 UC and CD Markets, 2014

Better Health, Brighter Future

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

The US Launch of Entyvio®

A stellar launch in the US, already generating over $112MM in net sales*

US

Entyvio® vedolizumab

Entyvio is now the 3rd largest IBD biologic with a volume share of 6%, surpassing two other biologics[1]

32,000+
Vials shipped to accounts[2]

6,500+
Unique patients using Entyvio[3]

2,000+
Healthcare Professionals have utilized[3]

Top 20
Specialty Launch since 2008, per IMS Health[4]

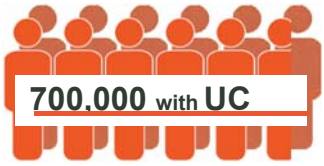
* June-December 2014

[1] Internal analysis, estimated claims and unit sales data as of Dec 2014, [2] Internal analysis of shipment and enrollment data, as of February 13th, 2014, [3] Based on data from EntyvioConnect, [4] Based on internal analysis of IMS Health, NSP (National Sales Perspectives), Nov 2014

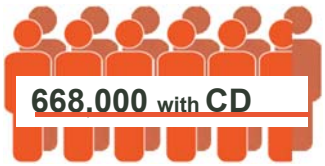
There are nearly 1.5MM patients in the US with IBD, and the market is growing at 8% per year

US

IBD Patient Pool Dynamics (US data)



Biologic Therapy 50,000-60,000



Biologic Therapy 130,000-150,000

$3.5B+ IBD Biologic WAC* Sales (2014)

~200K patients on biologic therapy

Higher penetration in CD vs. UC

Biologic therapy used in patients with moderate-to-severe disease not controlled on conventional agents

Annual growth rate of 8% expected through 2020

UC growth is expected to be nearly 2x GREATER than CD

*Wholesale acquisition cost

1. Datamonitor (2014), 2. Decision Resources (Aug 2014)
3. Internal Research and Analysis (Aug 2014)

Initial customer response has been positive

US

- Physicians like Entyvio's differentiated mechanism of action, remission data, safety profile
- Eager to have an alternative to the TNF class of biologics
- Expressing a desire for more education, research, and experience
- Physicians report that patients are responding well to the discussion of Entyvio as an option*

"We expect vedolizumab (Takeda's Entyvio) ***will…earn gold-standard status*** *for moderate to severe UC in 2018"*
Decision Resources, Feb 2015

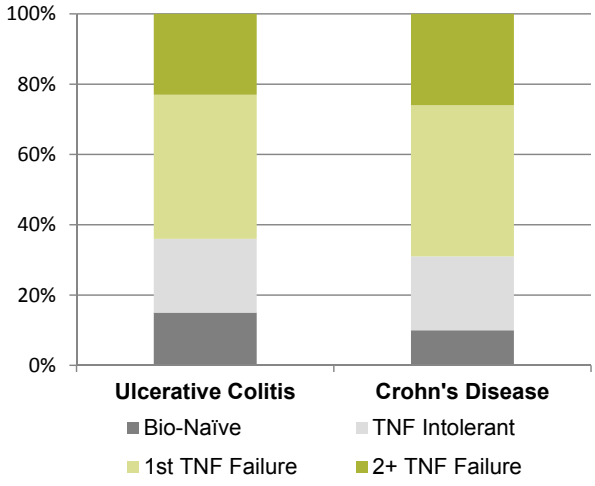
"The introduction of vedolizumab as an additional option will offer ***the possibility of increasing disease-free remission*** *for a greater proportion of patients with…active UC and CD"*
Gastroenterology & Hepatology, Dec 2014

*Internal Research and Analysis (Aug 2014)

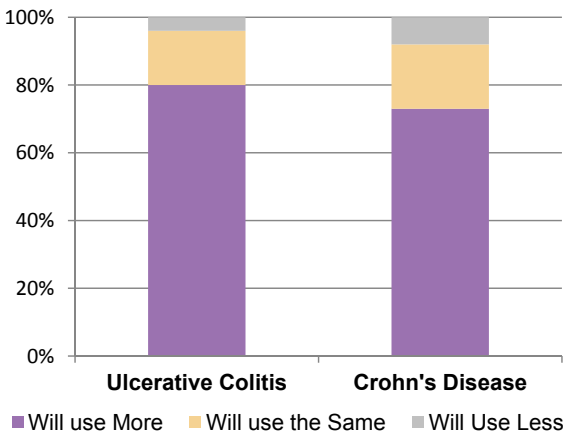
Initial penetration into the biologic-naïve segment is encouraging, and physicians are open to expanding use

US

Around two-thirds of current use is with patients that have failed an ant-TNFα[1]



Nearly 80% of physicians state they will expand Entyvio use…higher than any other IBD biologic[1]

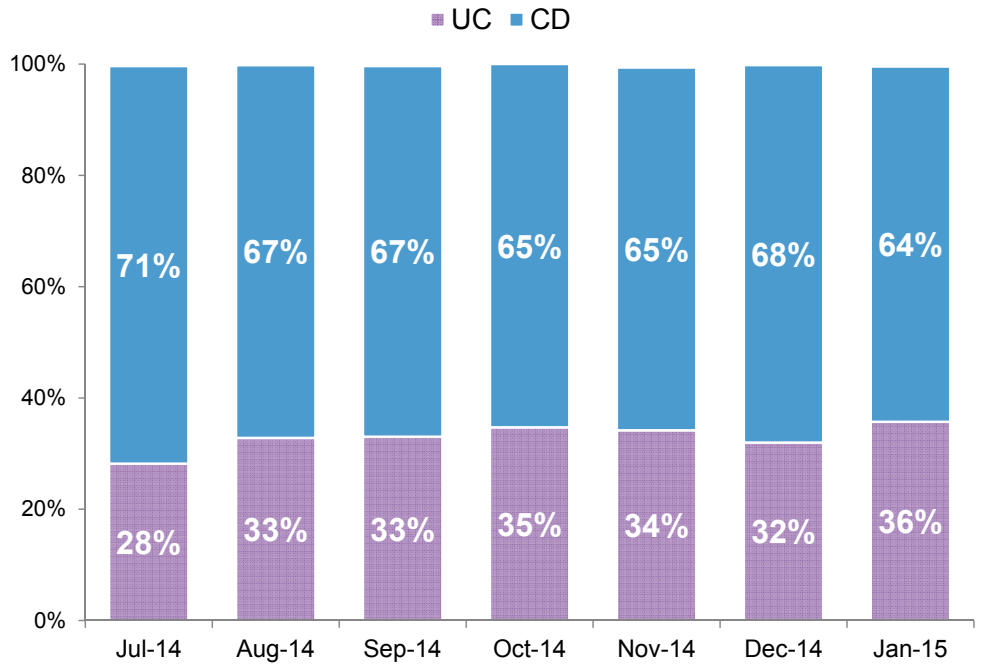


[1] Internal Research and Analysis, ATU quantitative research, Nov 2014, n=151

Entyvio® is being used in both the UC and CD patient populations

US

US - Entyvio Usage by Indication



Source: Internal research and analysis, Feb 2015

Takeda will capitalize on market opportunities to continue growing Entyvio® in the US

US

DISRUPT

Raise awareness to allow doctors to utilize Entyvio with appropriate new or failing patients

DIFFERENTIATE

Address gaps in clinical knowledge through expanded programs and education initiatives

EXPAND

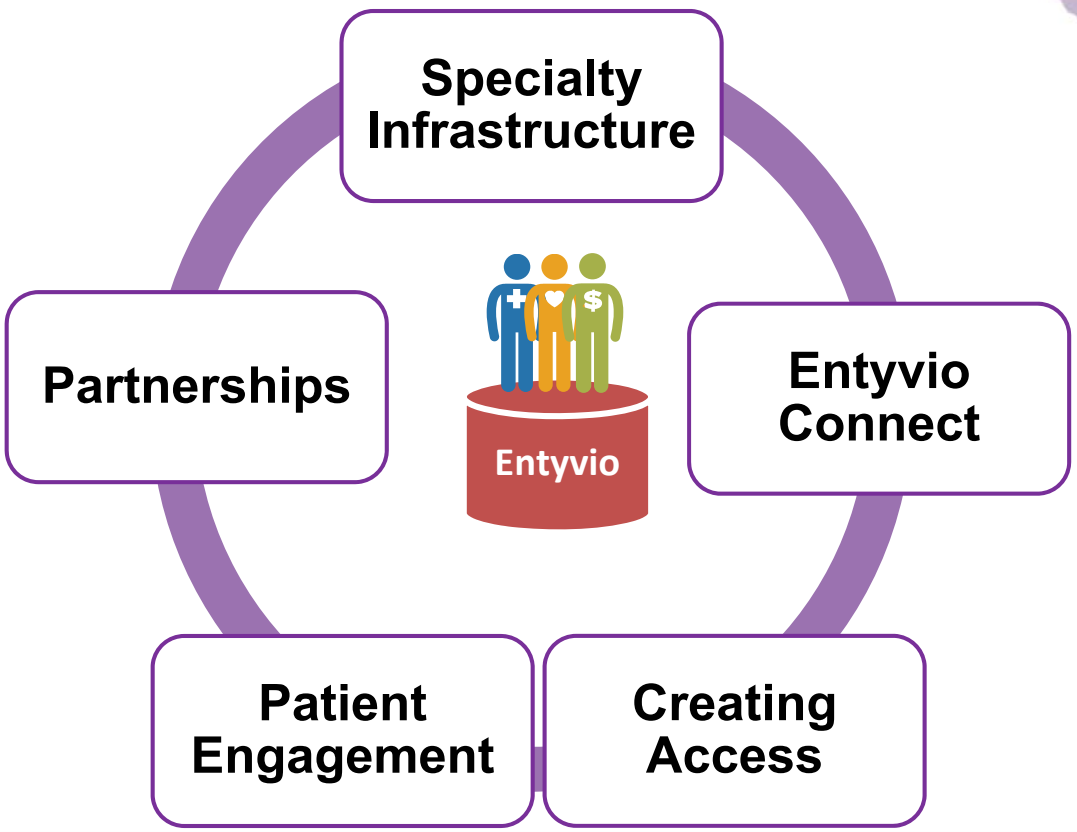
Grow use in ideal patient types where Entyvio may offer a positive benefit-risk profile

DELIVER

A positive brand experience and develop reputation as a partner in IBD care

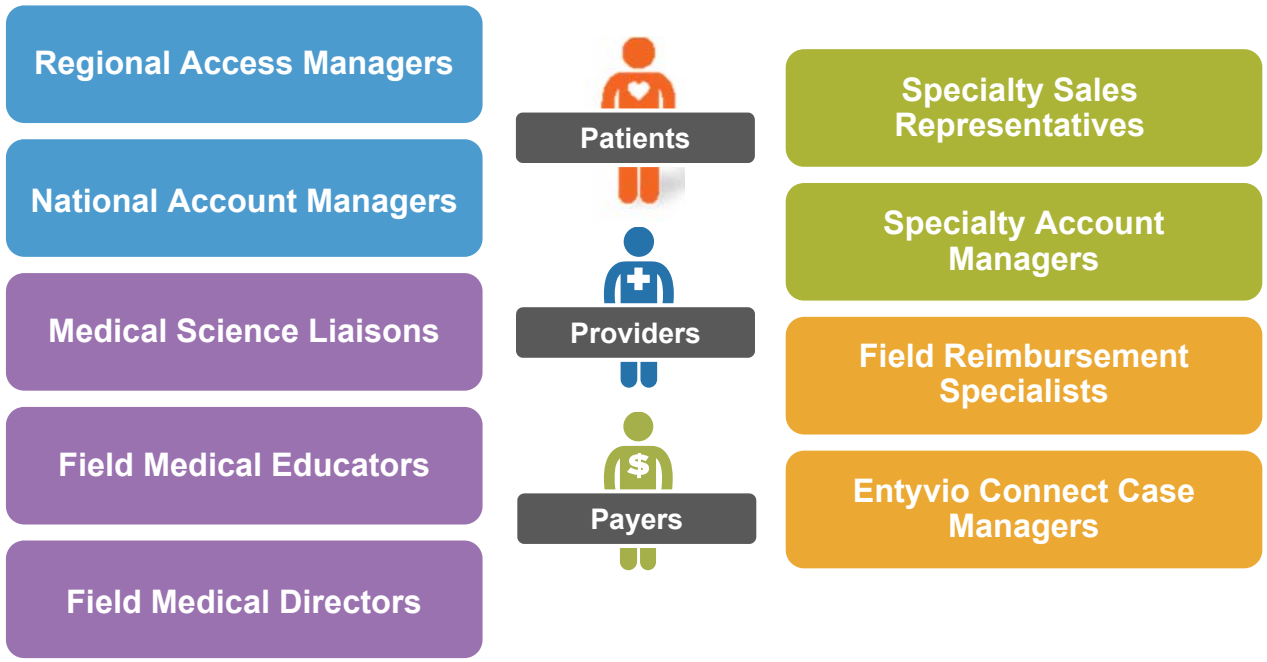
In the US our approach is to meet the unique needs of customers; establishing Takeda as an IBD partner

US



Specialty Infrastructure: developed to support customers with 8 field-based roles and over 200 individuals

US



EntyvioConnect™ is a centralized program offering an integrated portfolio of access services and support

US

EntyvioCONNECT

Access Support Services

- Insurance Verification and Prior Authorization Support
- Billing and Coding Support
- Claims Denial Investigations
- Specialty Pharmacy Coordination

EntyvioConnect Case Managers

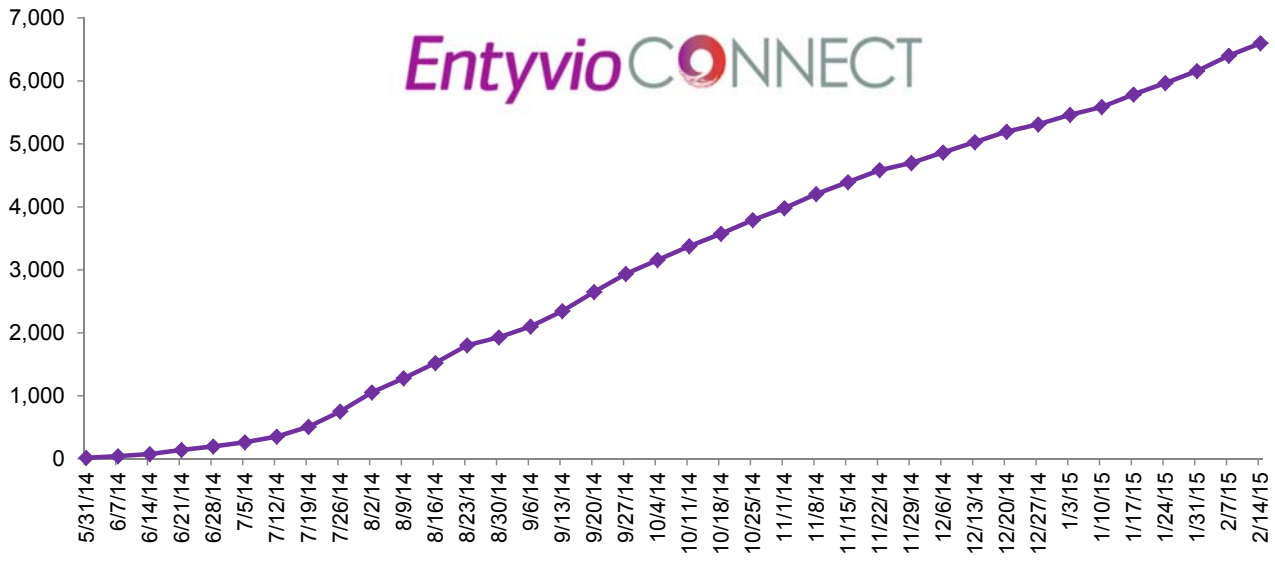
Field Reimbursement Specialists

Patient Coverage Support

- Commercial Co-pay Program
- Uninsured Patient Assistance
- Insurance Foundation Referrals
- National and International Infusion Coordination

EntyvioConnect™ new patient enrollments continue to grow by approx. 200 each week

US



Market Access is in line with launch expectations

US

Commercial Insured Market

- ~80% of IBD biologic patients are commercially insured[1]
- Medicare reimbursement has been secured

Reaction to Entyvio Positive

- Payers respond positively to the clinical and economic profile
- Over 94% of health plans are covering Entyvio[1]

Future efforts to gain more access

- Disease management education and programs
- Exploration of partnerships to pilot value-add services

1 Source: Internal research and analysis, Feb 2014

Supporting and Activating the Patient Community

US

Engage | **Activate** | **Enable**

Resources

In-Office Education

Digital

Access & Support

EntyvioCONNECT

Working closely with the leading advocacy organization

US

CROHN'S & COLITIS FOUNDATION OF AMERICA

Aligning with the CCFA Mission:
To cure Crohn's disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases

For Patients…

Sponsorships for:

- Educational Webcasts and Materials
- Fundraising Walks and Runs
- Various local fundraisers

For Professionals…

Support for:

- Quality of Care Partnerships
- Practitioner Education
- Conference Sponsorship

Entyvio® start in the US supports global >$2 billion target

US

Strong and encouraging launch results…

…a commitment to the IBD Community…

…positioned for continued success

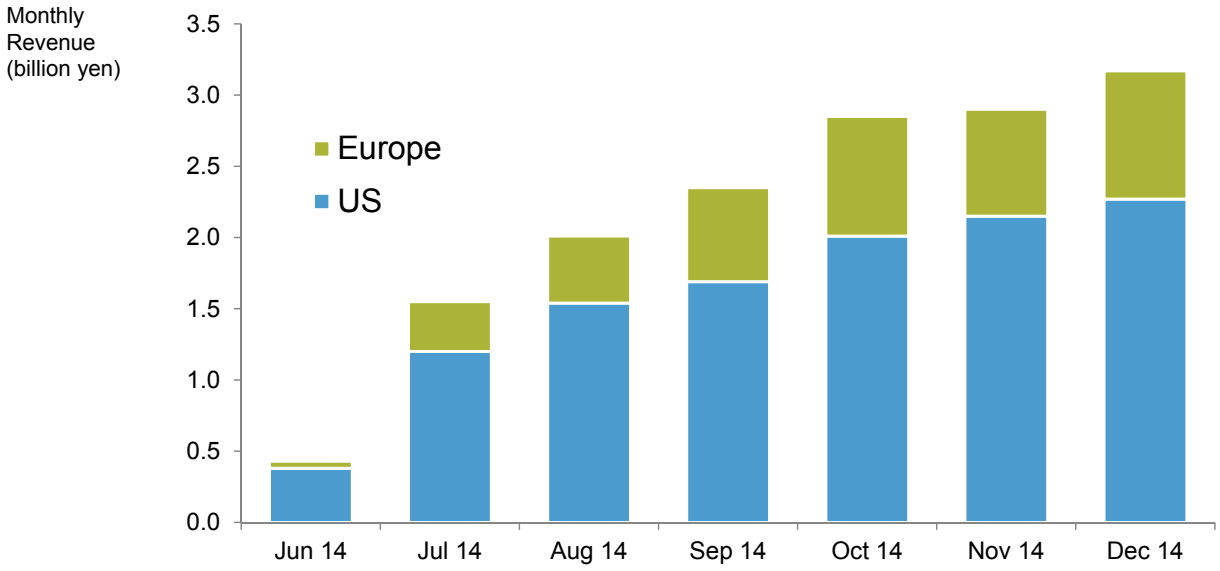
Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Entyvio® Global Launch

Entyvio® has had a promising launch to date, with Europe also contributing significantly to sales

¥16.4 billion launch-to-date ($154 million)*

@Constant currency



*Converted at average rate of 107 yen = $1

The strong uptake of Entyvio® due to a variety of factors

Current IBD treatment options still not adequate to meet need

Regulatory labelling
- Broad indication with descriptive clinical trial sections
- No boxed warning or Risk Evaluation & Mitigation Strategy
- Mechanism of action explanation
- Dose flexibility for some patients (EU only)

Access and reimbursement, due to:
- Early access programs
- Country-level reimbursement assessments (eg, Health Technology Assessment)

Market access results for Entvyio® are encouraging and balanced

UK
Entyvio became the first biologic to receive a provisional "yes" as a maintenance therapy in UC
- Recommended for patients who have not received an anti-TNF or could not tolerate an anti-TNF

Germany
Entyvio is classified at least "as good as" comparable biologic therapies (and can be prescribed without restrictions)

Israel
National Health Basket Committee granted full reimbursement per the Entyvio label for both TNF-naïve and TNF-failure patients in both UC and CD

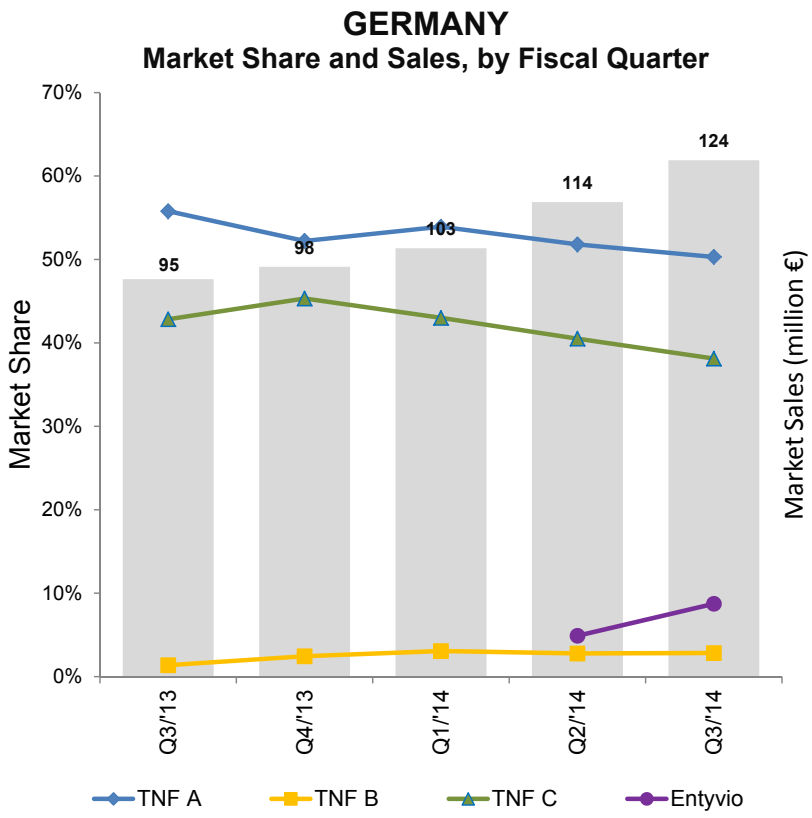
Sweden
TLV officially reimbursed Entyvio for patients not suitable for anti-TNF therapy or who have not reached treatment goals with 1st anti-TNF therapy

Estonia
Fully reimbursed as of Jan. 1, 2015

Switzerland
BAG granted unrestricted reimbursement for anti-TNF naïve and experienced patients in both UC and CD as of Mar 1, 2015

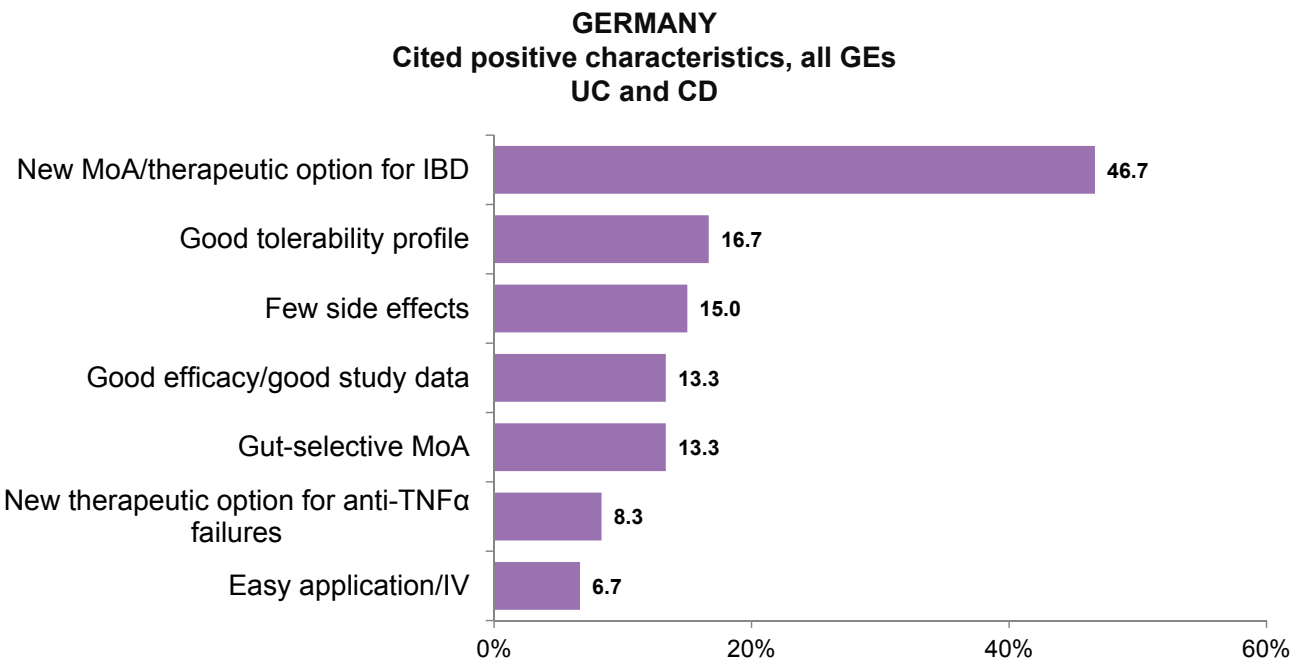
Entyvio® sales from 14 countries so far

Early launch countries in Europe are delivering strong Entyvio® uptake



Source: Internal research and analysis: Germany Retail + Hospital sales, calculated based on data provided by IMS Health (DKM+NPA);

The benefits of Entyvio® are clear to EU physicians in both the UC and CD segments



Source: Internal Research and Analysis、Germany ATU (Oct. – Nov. 2014, n=60 gastroenterologists)
Q35. What do you think are some of the positive product characteristics of Entyvio® (vedolizumab) – independent of whether or not you have already used this biologic? – May choose more than one.

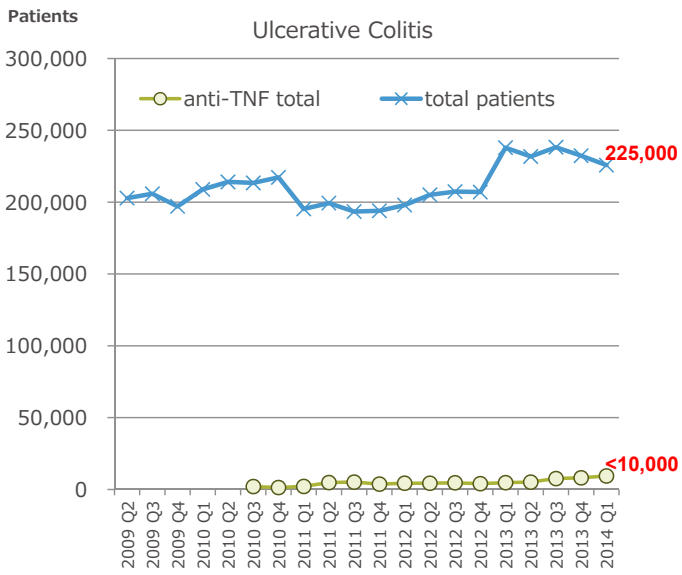
Emerging market physicians are interested in using Entyvio as a 1st line biologic

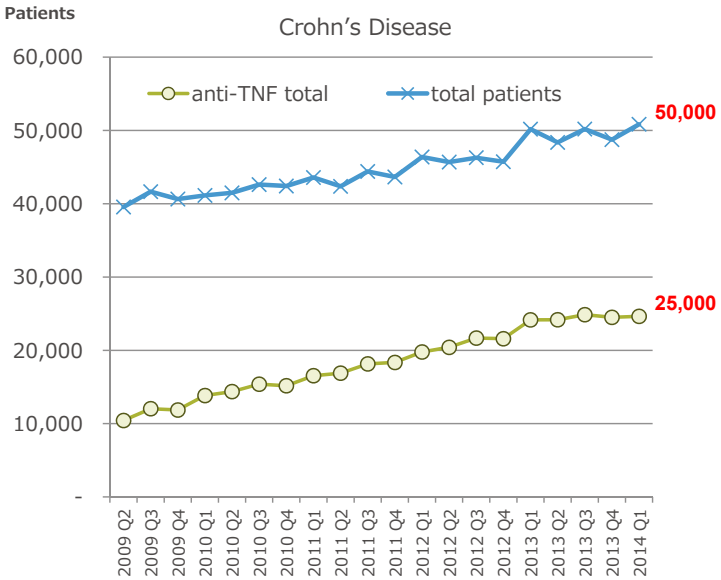
Placement of Entyvio	UC	CD
	Emerging Markets (n=286)	Emerging Markets (n=286)
Before immunomodulators and anti-TNFα	24%	22%
After immunomodulators, before anti-TNFα	38%	39%
TOTAL pre anti-TNF	62%	61%
After 1st anti-TNFα therapy	26%	29%
Alternative to Surgery	11%	10%
Would not consider to use	1%	0%

Source: Internal Research and Analysis, Takeda IBD treatment landscape and evaluation of Biologics in Emerging Markets Market Research – October 2012
Question: Assuming no reimbursement restrictions, where would you most likely use ProductP in your current treatment paradigm?
Markets: Argentina, Australia, Brazil, Mexico, Russia, S Africa, Turkey, Venezuela

Biologic penetration into Japan CD segment is greater than penetration in UC

Total and anti-TNFα treated patients in Japan





Source: Japan Medical Data Center

Better Health, Brighter Future

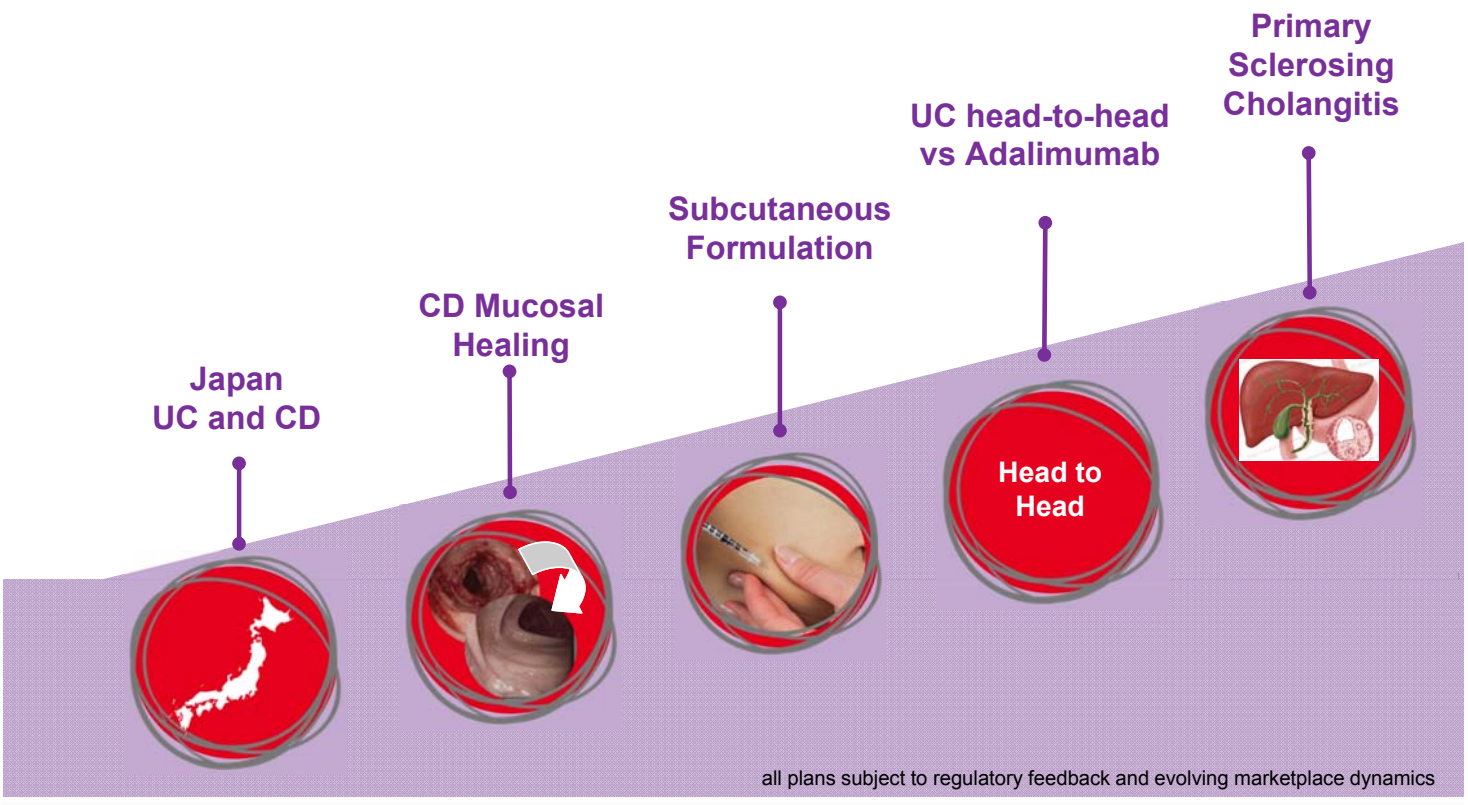
Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Achieving >$2 Billion in Global Peak Sales

Achieving >$2B in global peak sales requires aligned execution against these strategic drivers

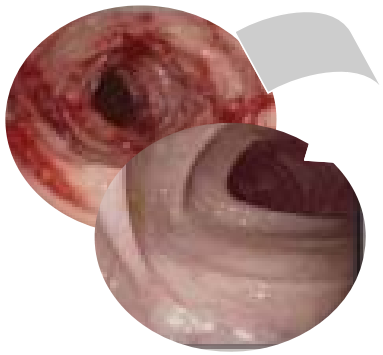
Strategic Driver	Entyvio Executional Mandatory
Penetrate biologic naive patient pool	• Expand IBD efficacy data set • Reinforce safety profile • Facilitate product experience
Raise awareness of Entyvio as an alternative treatment for existing biologic patients	• Increase recognition sub-optimal response • Support evaluative tactics to assess real-world anti-TNFα performance
Lead category in "switch to" preference in anti-TNFα switch patients	• Over-index on share gain in anti-TNFα failures
Enter new segments, deliver new data	• Explore new scientific frontiers

Takeda has an ambitious life-cycle management plan for Entyvio®



all plans subject to regulatory feedback and evolving marketplace dynamics

Planned CD Mucosal Healing trial could provide gold standard data for Entyvio®



Objective:

- To explore the correlation between endoscopy (mucosal healing) with histology (biopsy) and imaging (MRI) in vedolizumab treated patients

Rationale:

- Mucosal healing is increasingly seen as the "gold standard" clinical objective
- Correlates strongly with prolonged remission[1]
- Entyvio would benefit from mucosal healing data in Crohn's disease

[1] Dave et al: Gastroenterology & Hepatology, Vol 8, Issue 1, January 2012
[2] ACG – FDA workshop October 2011 "Feasibility of Mucosal Healing as a Clinically Significant Endpoint in Inflammatory Bowel Disease"

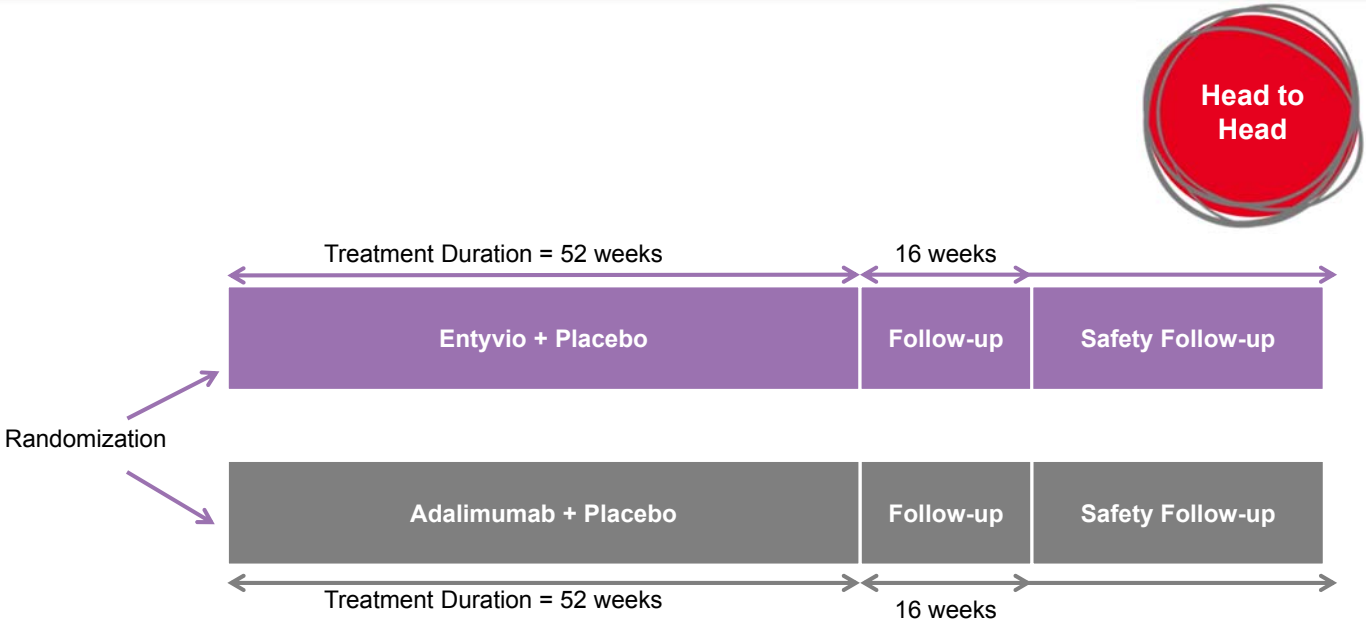
Subcutaneous (SC) program will address patient preference as a strategic LCM opportunity

- SC formulation, if approved, would represent a meaningful convenience for patients, particularly as maintenance therapy
- SC bioavailability confirmed; dose selected for the Phase 3 program will deliver similar exposure with SC as with IV administration.
- Phase 3 trials in both UC and CD are planned to investigate the efficacy, safety, and clinical pharmacology of the SC formulation
- Customers like injections while IV retains key segment appeal[1]

Entyvio could be the **only** IBD biologic to offer both infusion and subcutaneous administration

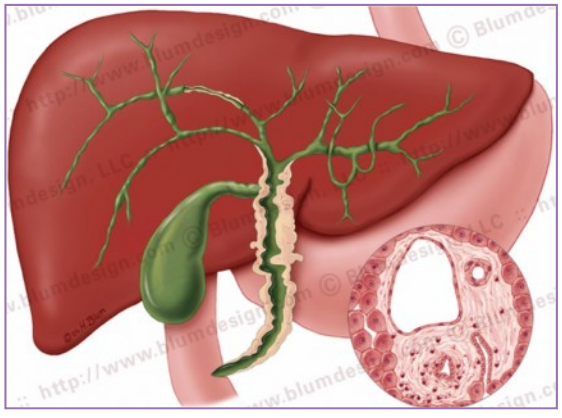
1. Source: Internal Research and Analysis, Physician Conjoint (Europe & Canada and Emerging Markets) (Nov. 2013)

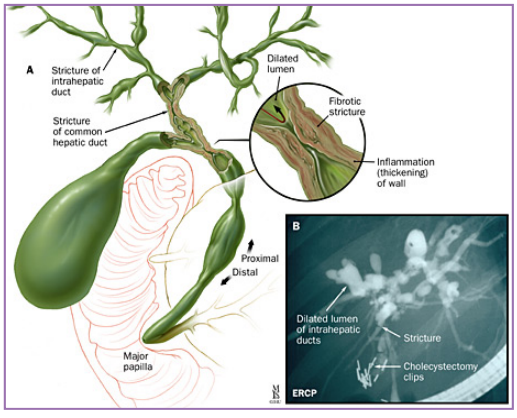
Life Cycle Plans include UC head to head



Primary sclerosing cholangitis (PSC)
Evidence for Entyvio® mechanism in area of high unmet need

- PSC is a progressive inflammatory liver disease resulting in scarring of bile ducts, fibrosis and cirrhosis; patients at risk of liver failure and death with many requiring transplant
- To date, no therapy has been shown to prevent disease progression
- Lymphocyte migration to liver via a4b7-MAdCAM binding (Entyvio mechanism) has been implicated in pathophysiology of PSC[1]

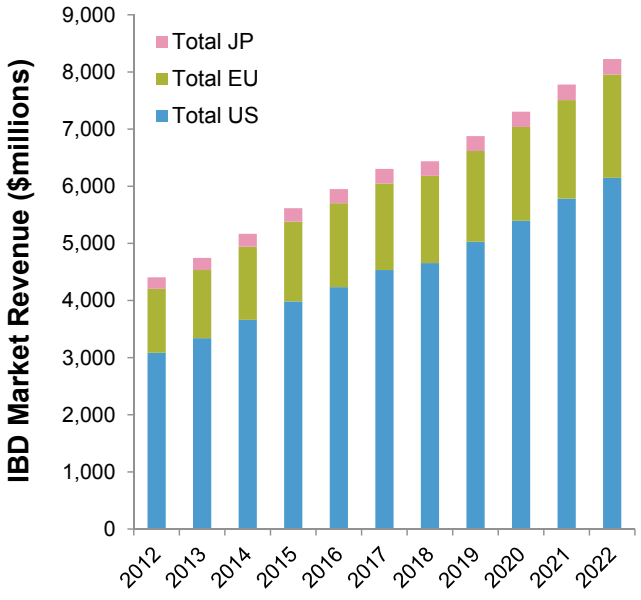




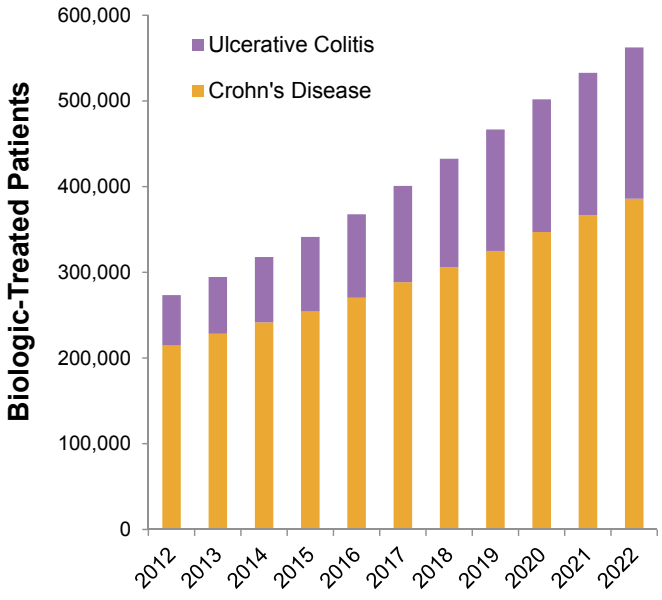
1. Adams DH, Eksteen B. Aberrant homing of mucosal T cells and extra-intestinal manifestations of inflammatory bowel disease. Nat Rev Immunol 2006;6(3):244-51.)

The UC and CD biologics market is large and growing significantly, particularly in UC

UC/CD Biologic Market Revenue



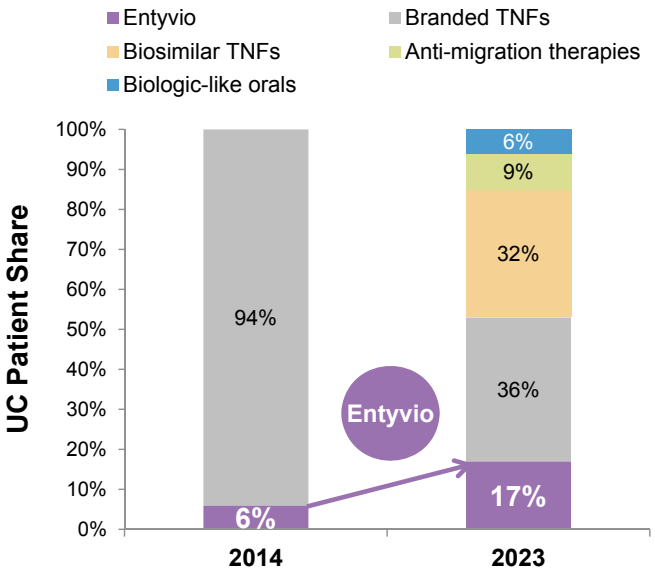
UC/CD Biologic-Treated Patient Population



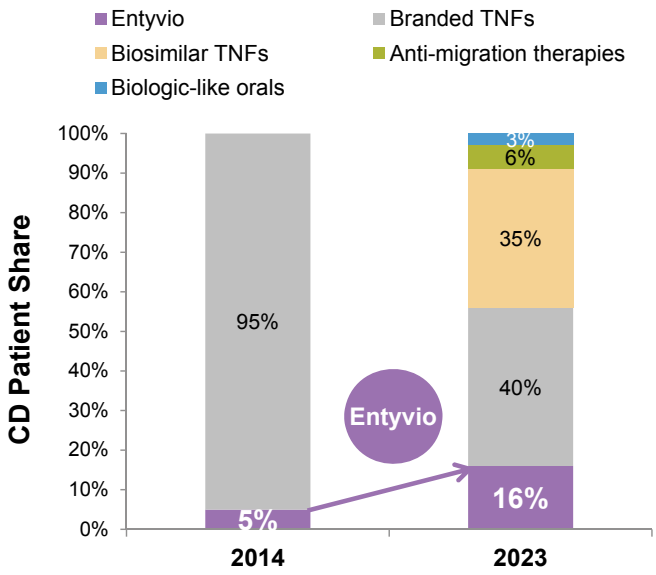
Source: Decision Resources Pharmacor UC and CD Markets, 2014

Achieving a 15-20% global patient share will result in $2 billion in Entyvio® revenues

Evolution of UC Patient Share (G7 Markets)



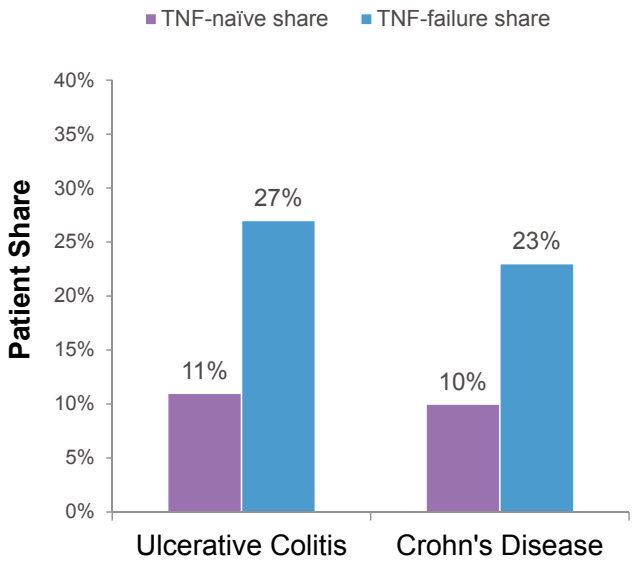
Evolution of CD Patient Share (G7 Markets)



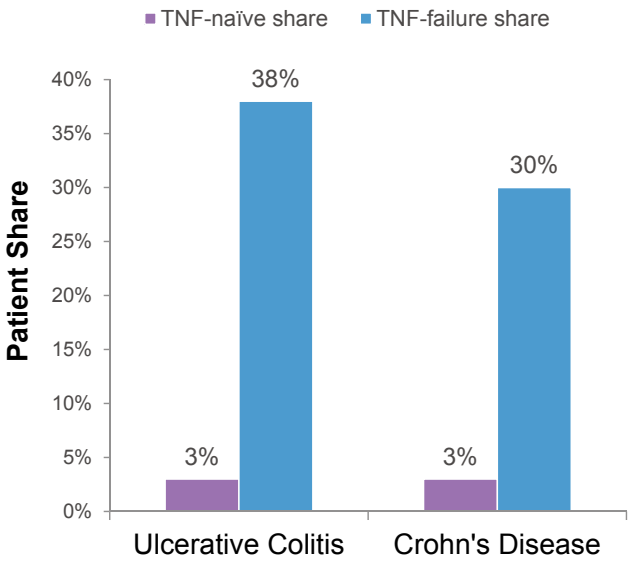
Source: Internal research and analysis

Achieving a 15-20% global patient share will result in $2 billion in Entyvio® revenues

Scenario 1 - Entyvio Patient Share by Line of Therapy (2023)



Scenario 2 – Entyvio Patient Share by Line of Therapy (2023)



97 Source: Internal research and analysis

Entyvio® has a unique opportunity to position itself optimally now and will compete aggressively in future

CURRENT OPPORTUNITY

- No new branded IBD competition expected for 2 years
- Strong patent protection with market exclusivity into next decade

FUTURE DYNAMICS

- **Biosimilar anti-TNFαs** will target current brand anti-TNFs, but Entyvio will be positioned differently
- **Anti-migration therapies** - Although they may offer subcutaneous delivery, Entyvio will have first-mover advantage
- **Biologic-like orals** - Emerging orals have unknown efficacy/safety profiles

98

Takeda will realize the exciting commercial promise of Entyvio® by bringing its therapeutic benefits to patients worldwide

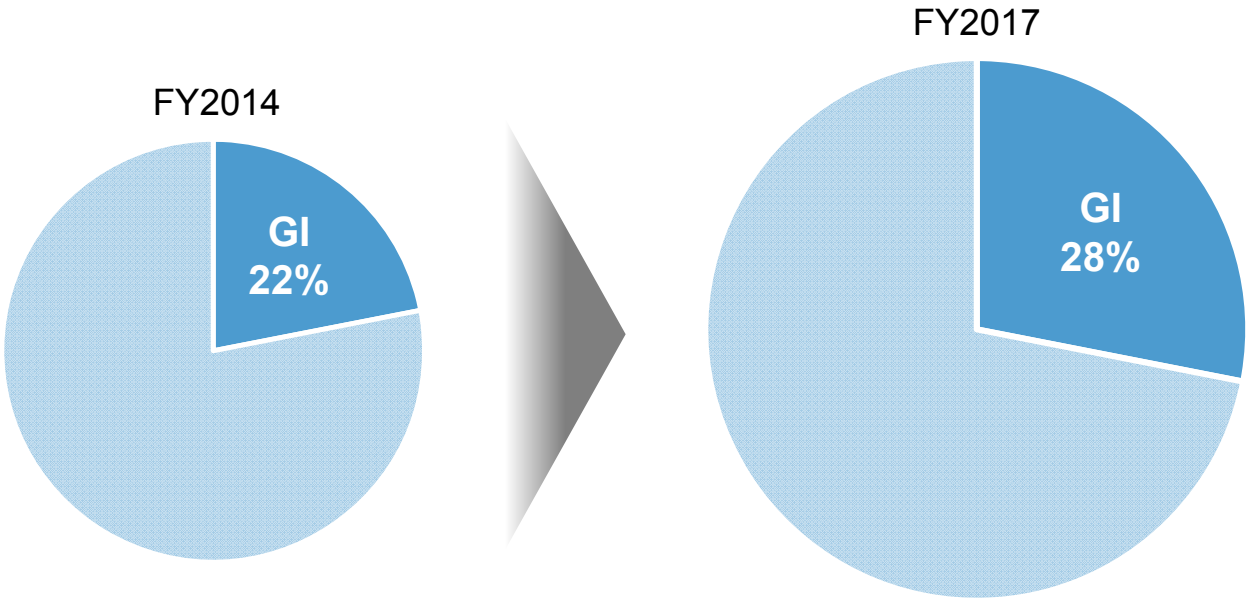
Better Health, Brighter Future

Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

The Road to GI Leadership

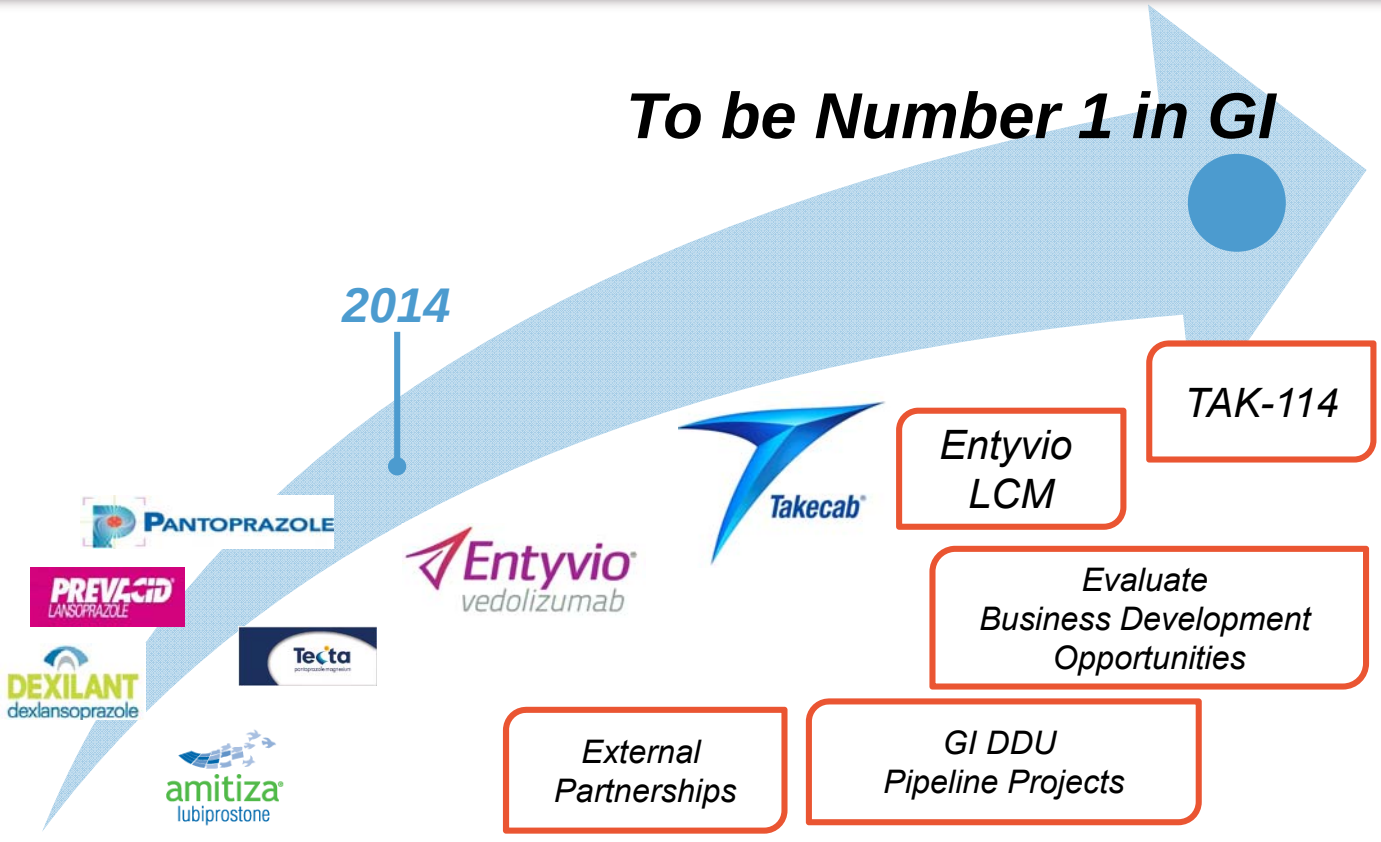
GI products contribute significantly to growth

GI contribution to sales*



*Sales from Japan OTC, non-pharmaceutical businesses, etc. are excluded from the calculation.
Numbers are shown in circa %.

The road to GI leadership



Takeda Pharmaceutical Company: A Global Leader in Gastroenterology

Q&A Session

Christophe Weber, President & Chief Operating Officer
Asit Parikh, M.D., Ph.D., Head of GI Therapeutic Area Unit
Kirsten Detrick, VP, Therapeutic Area Commercial Lead, GI, Global Commercial
Nicole Mowad-Nassar, VP, Marketing, Takeda Pharmaceuticals USA

Entyvio® (vedolizumab) Indication:

(US label)

Adult Ulcerative Colitis (UC)

Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- inducing and maintaining clinical response
- inducing and maintaining clinical remission
- improving the endoscopic appearance of the mucosa
- achieving corticosteroid-free remission

Adult Crohn's Disease (CD)

Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- achieving clinical response
- achieving clinical remission
- achieving corticosteroid-free remission

Please click here for full prescribing information, or visit www.entyvio.com

Entyvio Important Safety Information

(US label)

- ENTYVIO for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.
- Infusion-related reactions and hypersensitivity reactions including anaphylaxis have occurred. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

Please click here for full prescribing information, or visit www.entyvio.com

Entyvio Important Safety Information

(US label)

- Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.
- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.
- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please click here for full prescribing information, or visit www.entyvio.com

Dexilant (dexlansoprazole) Indications:

(US label)

- Healing all grades of erosive esophagitis (EE) for up to 8 weeks (60 mg once daily)
- Maintaining healing of EE and relief of heartburn for up to 6 months (30 mg once daily)
- Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks (30 mg once daily)

•Please see full Prescribing Information, including Medication Guide for DEXILANT.

Dexilant Important Safety Information:

(US label)

- DEXILANT is contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity and anaphylaxis have been reported with DEXILANT use.
- Symptomatic response with DEXILANT does not preclude the presence of gastric malignancy.
- PPI therapy may be associated with increased risk of *Clostridium difficile* associated diarrhea.
- Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.
- Hypomagnesemia has been reported rarely with prolonged treatment with PPIs.
- Most commonly reported adverse reactions were diarrhea (4.8%), abdominal pain (4.0%), nausea (2.9%), upper respiratory tract infection (1.9%), vomiting (1.6%), and flatulence (1.6%).

Please see full Prescribing Information, including Medication Guide for DEXILANT.

Dexilant Important Safety Information:

(US label)

- Do not co-administer atazanavir with DEXILANT because atazanavir systemic concentrations may be substantially decreased. DEXILANT may interfere with absorption of drugs for which gastric pH is important for bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole, erlotinib).
- Patients taking concomitant warfarin may require monitoring for increases in international normalized ratio (INR) and prothrombin time. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Concomitant tacrolimus use may increase tacrolimus whole blood concentrations. DEXILANT may increase serum levels of methotrexate.
- DEXILANT 30 mg should be considered for patients with moderate hepatic impairment.

Please see full Prescribing Information, including Medication Guide for DEXILANT.

Amitiza (lubiprostone) Indications:

(US label)

AMITIZA (lubiprostone) capsules are indicated for the treatment of Chronic Idiopathic Constipation (CIC) in adults and Opioid-Induced Constipation (OIC) in adults with chronic, non-cancer pain (24 mcg twice daily). The effectiveness in patients with OIC taking diphenylheptane opioids (e.g., methadone) has not been established. AMITIZA is also indicated for Irritable Bowel Syndrome with Constipation (IBS-C) in women ≥ 18 years old (8 mcg twice daily).

Please click here for complete Prescribing Information.

Amitiza Important Safety Information:

(US label)

- AMITIZA (lubiprostone) is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating healthcare provider (HCP) to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.
- Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their HCP.
- AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment. Patients should be instructed to discontinue AMITIZA and inform their HCP if severe diarrhea occurs.
- Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their HCP. Some patients have discontinued therapy because of dyspnea.
- In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=1113 vs N=316, respectively) in patients with CIC, the most common adverse reactions (incidence > 4%) were nausea (29% vs 3%), diarrhea (12% vs 1%), headache (11% vs 5%), abdominal pain (8% vs 3%), abdominal distension (6% vs 2%), and flatulence (6% vs 2%).

Please click here for complete Prescribing Information.

Amitiza Important Safety Information:

(US label)

- In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=860 vs N=632, respectively) in patients with OIC, the most common adverse reactions (incidence >4%) were nausea (11% vs 5%) and diarrhea (8% vs 2%).
- In clinical trials of AMITIZA (8 mcg twice daily vs placebo; N=1011 vs N=435, respectively) in patients with IBS-C the most common adverse reactions (incidence > 4%) were nausea (8% vs 4%), diarrhea (7% vs 4%), and abdominal pain (5% vs 5%).
- Concomitant use of diphenylheptane opioids (e.g., methadone) may interfere with the efficacy of AMITIZA.
- The safety of AMITIZA in pregnancy has not been evaluated in humans. Based on animal data, AMITIZA may cause fetal harm. AMITIZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when AMITIZA is administered to a nursing woman. Advise nursing women to monitor infants for diarrhea.
- Reduce the dosage in CIC and OIC patients with moderate and severe hepatic impairment. Reduce the dosage in IBS-C patients with severe hepatic impairment.

Please click here for complete Prescribing Information.