BLU-5937 Update & Chronic Cough KOL Meeting

July 16, 2019

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Introduction & Agenda

Roberto Bellini

President & CEO

BELLUS Health

Agenda

I. Introduction & Agenda
Roberto Bellini
President & CEO
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II. Review of Chronic Cough and Potential Treatments
Prof. Jacky A. Smith, MB, ChB, FRCP, PhD
University of Manchester

III. BLU-5937, A Highly Selective P2X3 Antagonist for Chronic Cough – Preclinical & Phase 1
Dr. Denis Garceau
Vice President, Drug Development
BELLUS Health

IV. BLU-5937 – Phase 2 Study
Prof Jacky A. Smith MB, ChB, FRCP, PhD
University of Manchester

V. Commercial Considerations
Darren Eskow
Managing Director
Bluestar Bioadvisors

VI. P2X3 Platform Potential
Dr. Denis Garceau
Vice President, Drug Development
BELLUS Health

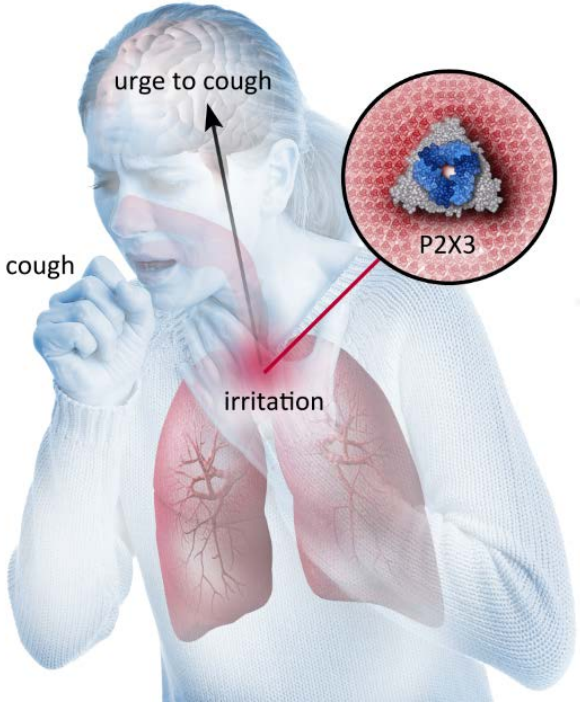
VII. Summary and Q&A

Review of Chronic Cough and Potential Treatments

Prof. Jacky A. Smith, MB, ChB, FRCP, PhD

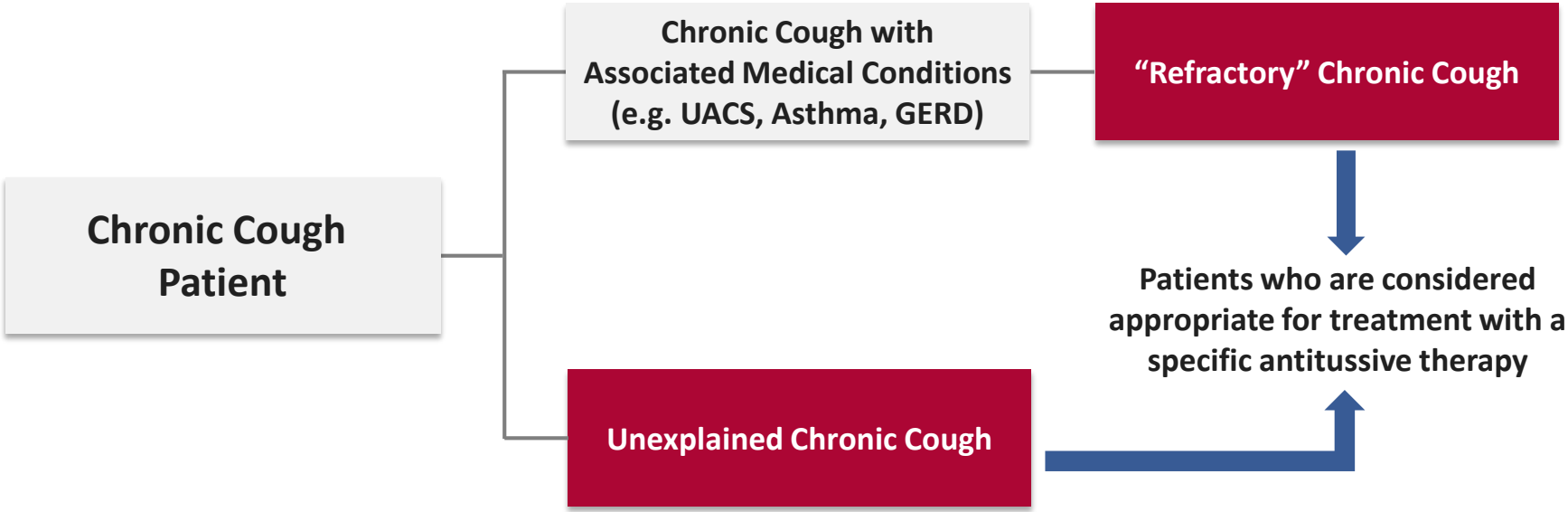
University of Manchester

Chronic Cough Overview



- Chronic Cough: Lasts > 8 weeks
- Patient characteristics:
  - Average age: Mid 50s - Early 60s
  - More prevalent in women (~65%)
- Chronic cough may be associated with:
  - Pulmonary diseases (e.g. asthma, COPD, bronchiectasis, IPF, lung cancer)
  - Extra-pulmonary disorders (e.g. allergic rhinitis, gastroesophageal reflux)
  - Use of some drugs (e.g. ACE inhibitors)
  - No specific causes (unexplained cough; idiopathic)
- Current standard of care is to treat the underlying disease

The Refractory or Unexplained Chronic Cough Diagnostic Pathway



Refractory/Unexplained Chronic Cough Takes Substantial Toll on Patients

PHYSICAL

- Fatigue and Sleep Deprivation
- Vomiting
- Incontinence
- Headache
- Chest Pain
- Rib Fracture

SOCIAL

- Interference with lifestyle, work, and leisure
- Difficulty conversing
- Embarrassment of coughing in public

PSYCHOSOCIAL

- Anxiety
- Anger
- Depression
- Distress

Few Treatment Options Create a Substantial Unmet Need

Chronic cough requires a safe, effective therapy that is non-narcotic and non-sedating

OPIOIDS

- Can be efficacious
- Limited use, due to side effects
- Potential for addiction

BENZONATATE

- Anesthetizes the stretch receptors in the lungs
- Temporary relief
- Potential serious side effects if capsule is broken

DEXTROMETHORPHAN

- Key ingredient in OTC cough suppressants
- Limited efficacy

GABAPENTIN /PREGABALIN

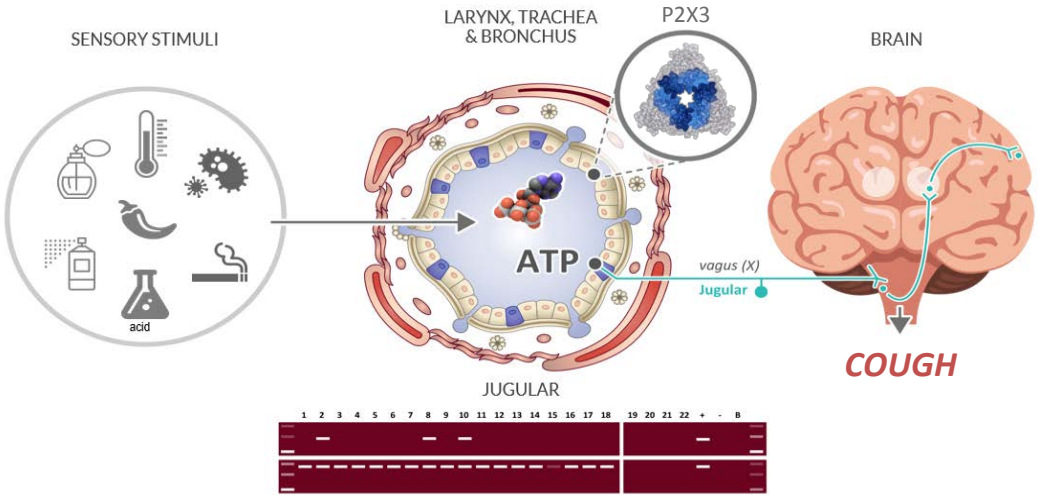
- Neuromodulators with variable efficacy and significant CNS side effects

SPEECH THERAPY

- Has shown some efficacy, especially in combination with pharmacotherapy

Cough Hypersensitivity & The Role of P2X3 in Refractory or Unexplained Chronic Cough

P2X3 is a rational target to treat cough hypersensitivity in refractory/unexplained chronic cough



Kwong et al 2008 AJP Lung cell Mol Physiol 295 L858-65

Cough Hypersensitivity

- Exaggerated sensation of the urge to cough, reflecting a disorder of the primary sensory neurons that innervate the airways and lung
- Cough is triggered by innocuous stimuli, such as perfume, cold air, exercise, stress, laughing, or talking; referred to as allotussia

Role of P2X3 Receptors

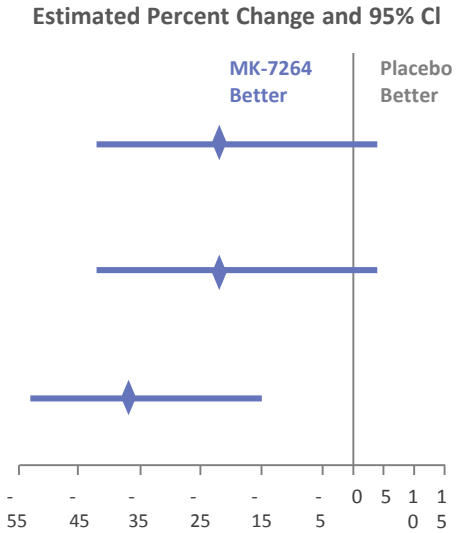
- ATP gated ion channels expressed in C-fiber neurons in the upper airways
- ATP released from damaged or inflamed tissues in the airways acts on P2X3 receptors triggering a feeling of irritation, causing the urge to cough

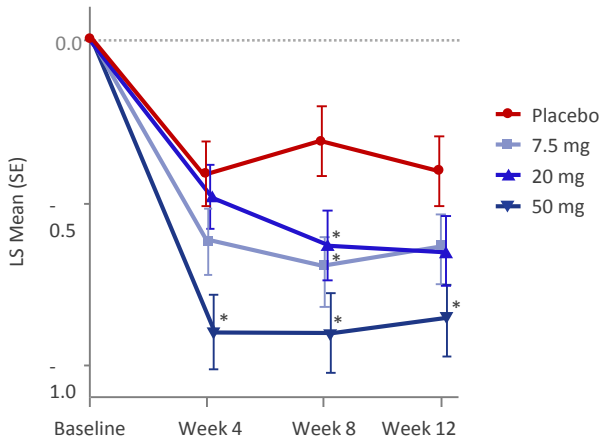
P2X3 Receptor: Clinically Validated Target

MK-7264 Phase 2b Study (257 patients; 12 weeks)

MK-7264 showed reduction in awake cough frequency of **57% vs baseline and 37% vs placebo** at 50mg dose

MK-7264 Dose Levels	Estimated % Change (95% CI)	*P*-Value
7.5 mg	-22 (-41.8, 4.6)	0.0971
20 mg	-22.2 (-42, 4.3)	0.0928
50 mg	-37 (-53.3, -14.9)	0.0027





Merck & Co., *MK-7264 in Chronic Cough: Update on Clinical Development Programme*; 10th International Symposium on Cough; June 2018

MK-7264 Phase 2b: Side Effect Profile

P2X3 is safe and well-tolerated, except for taste effect

Most Frequent Adverse Events (≥ 5%)

Preferred Term	7.5 mg BID MK-7264 (n=63)	20 mg BID MK-7264 (n=63)	50 mg BID MK-7264 (b=63)	Total MK-7264 (n=189)	Placebo (n=63)
Dysgeusia	6 (9.5%)	21 (33.3%)	30 (47.6%)	57 (30.2%)	3 (4.8%)
Hypogeusia	0	11 (17.5%)	15 (23.8%)	26 (13.8%)	1 (1.6%)
Headache	4 (6.3%)	12 (19.0%)	4 (6.3%)	20 (10.6%)	3 (4.8%)
Upper Respiratory Tract Infection	5 (7.9%)	9 (14.3%)	6 (9.5%)	20 (10.6%)	2 (3.2%)
Ageusia	0	3 (4.8%)	13 (20.6%)	16 (8.5%)	1 (1.6%)
Paraesthesia Oral	4 (6.3%)	5 (7.9%)	4 (6.3%)	13 (6.9%)	5 (7.9%)
Cough	2 (3.2%)	5 (7.9%)	5 (7.9%)	12 (6.3%)	2 (3.2%)
Hypoaesthesia Oral	2 (3.2%)	4 (6.3%)	5 (7.9%)	11 (5.8%)	3 (4.8%)
Nausea	0	4 (6.3%)	6 (9.5%)	10 (5.3%)	0
Urinary Tract Infection	3 (4.8%)	5 (7.9%)	2 (3.2%)	10 (5.3%)	2 (3.2%)
Dry Mouth	2 (3.2%)	3 (4.8%)	3 (4.8%)	8 (4.2%)	6 (9.5%)

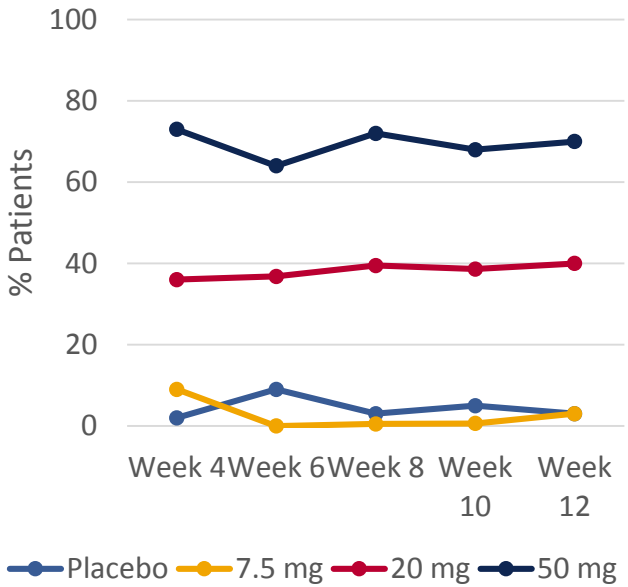
12-Week study; N=257

- P2X3 class effects include taste effect, numbness, and nausea

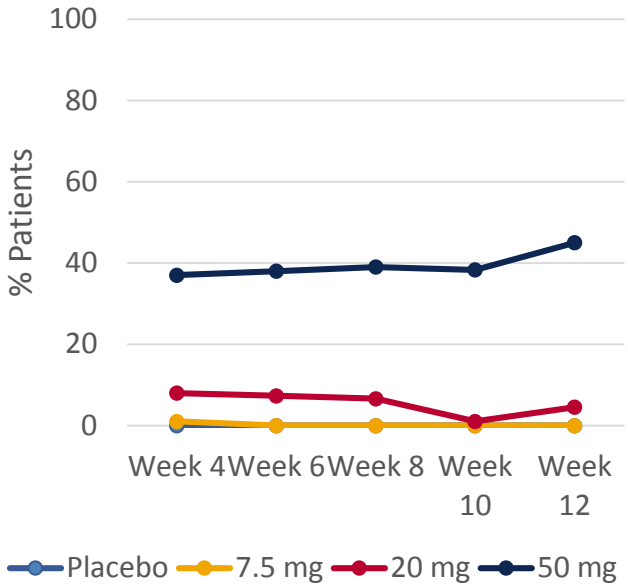
Merck & Co., Presentation of gefapixant Phase IIb data; American Thoracic Society; May 2017

Adverse Events

- 80% of patients reported taste events at 50mg
- 40% reported taste events as very/extremely bothersome
- 10% of patients dropped out due to taste effect
- Taste-related adverse effects are persistent over time, and are reversible upon treatment cessation



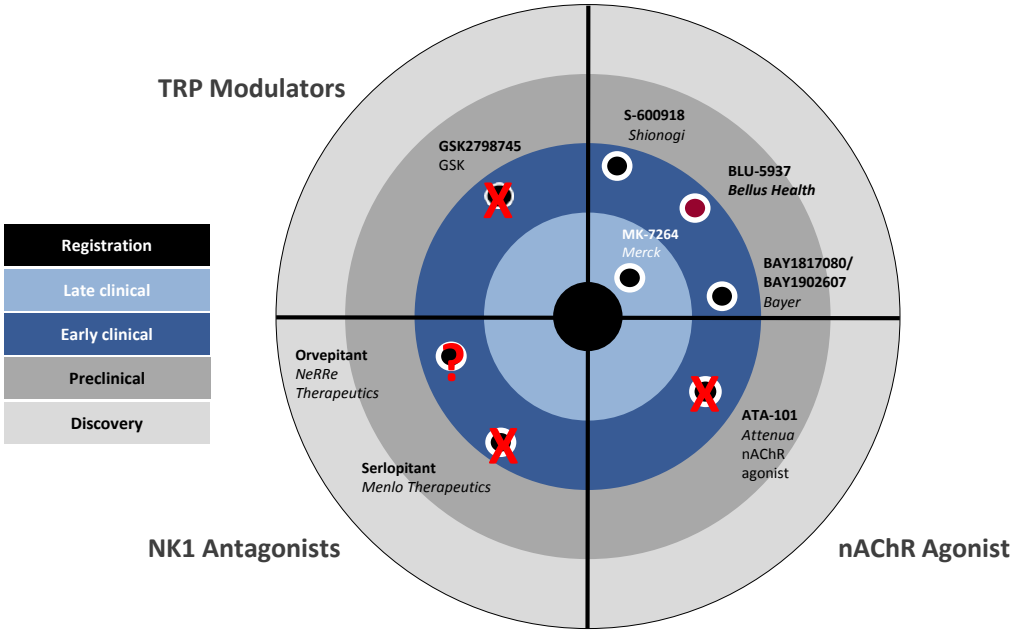
Taste Effect



Very or Extremely Bothersome Taste Effect

Merck & Co., Presentation of gefapixant Phase IIb data; American Thoracic Society; May 2017

Mechanisms in Development for Chronic Cough Have Faced Challenges



TRP Modulators

- All TRP modulators tested in-clinic to date have failed
- **GSK2798745** (GSK), a TRPV4 antagonist, terminated in Phase 2, following futility analysis

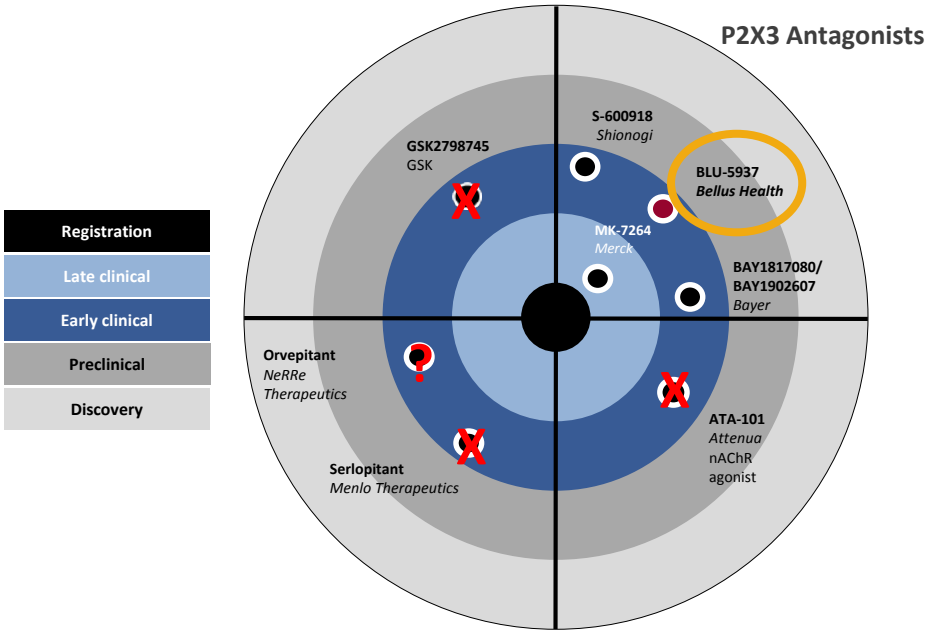
NK1 Antagonists

- **Serlopitant** (Menlo) development terminated due to lack of efficacy in Phase 2 study
- **Orvepitant** (NeRRe) missed its Phase 2 primary endpoint of cough frequency reduction; certain secondary endpoints positive

nAChR Agonist

- **ATA-101** (Attenua) Phase 2 study failed

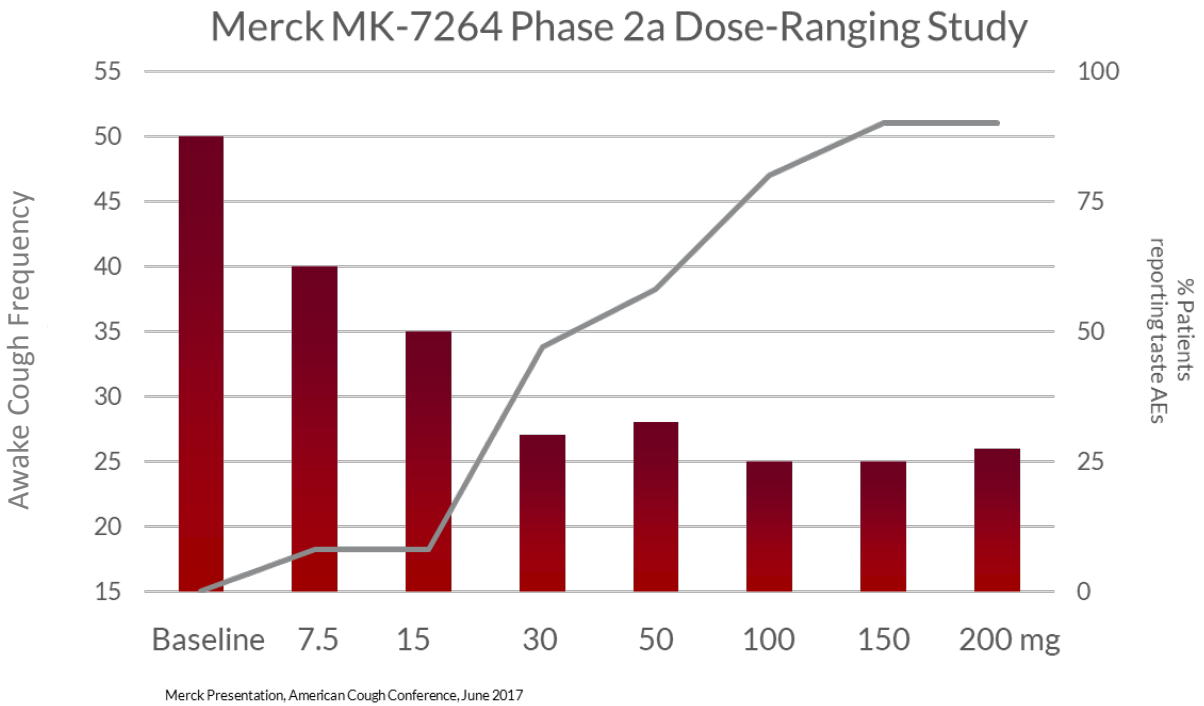
P2X3 has Shown to be the Only Clinically Validated Treatment Approach to Date



P2X3 Antagonists

- Clinically validated pathway, with proven antitussive effect
- Merck's **MK-7264** has two Phase 3 studies ongoing, with completion dates in mid-2020 and 1H 2021
- BELLUS' **BLU-5937** had little to no taste effect in Phase 1; initiating Phase 2 study mid-2019
- Shionogi's **S-600918** reported positive Phase 2 data in Japan-only single-dose trial; moving to dose ranging study
- Bayer's **BAY1817080** & **BAY1902607** Phase 2 studies expected to be completed in 2H 2019

MK-7264 Dose Escalation Studies



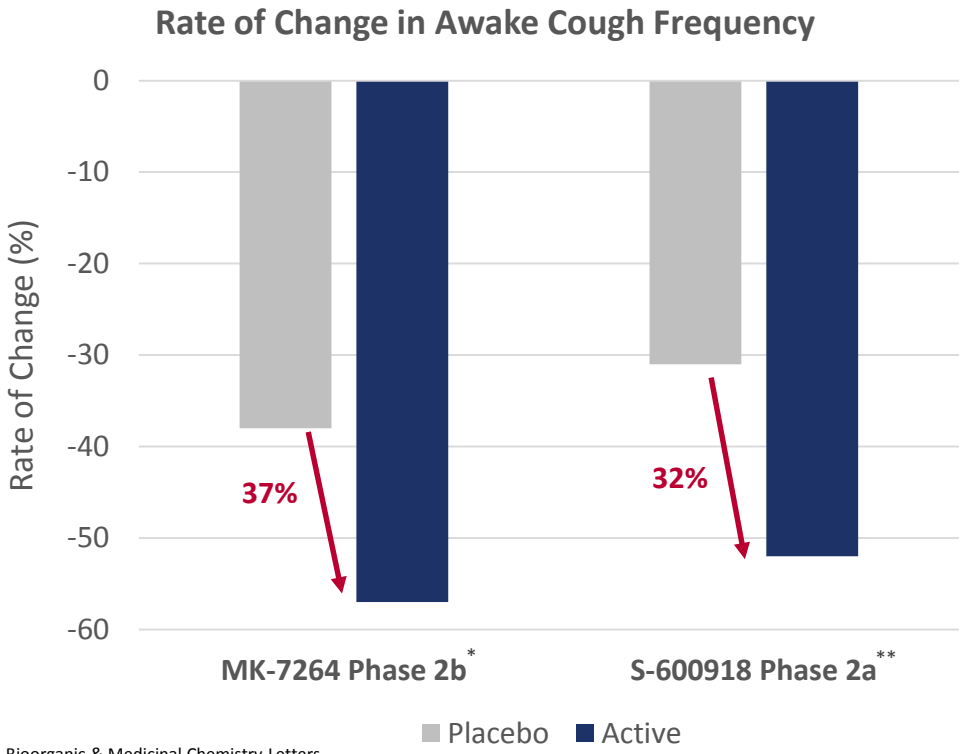
Merck Presentation, American Cough Conference, June 2017

Crossover design; 4-day forced dose escalation; 2 cohorts from 7.5mg-50mg and 50mg-200mg

- Inhibition of **P2X3** linked to efficacy
- Inhibition of **P2X2/3** linked to taste effect

Shionogi's Phase 2 Data Provides Clinical Validation for a Selective P2X3 Antagonist Approach in Reducing Cough

- S-600918 efficacy comparable to gefapixant
- Rate of taste effect not reported
- S-600918 selectivity has not been disclosed
  - Potentially similar to selectivity of only published Shionogi compound (173x selective for P2X3 vs. P2X2/3)[1]
- Shionogi moving into dose-finding Phase 2 study



[1]Tobinaga et al., 2017. Pyrrolinone derivatives as a new class of P2X3 receptor antagonists. Bioorganic & Medicinal Chemistry Letters
*Merck & Co., Presentation of gefapixant Phase IIb data; American Thoracic Society; May 2017
**Shionogi & Co., Ltd., Research and Development at Shionogi Presentation; March 2019

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P2X3 Competitive Landscape

Best-in-class selectivity for P2X3, supports potential best-in-class profile

	BEST-IN-CLASS SELECTIVITY FOR P2X3	FIRST-IN-CLASS P2X3 ANTAGONIST	SECOND GENERATION P2X3 ANTAGONISTS	
Company	Bellus Health	MERCK / Afferent Pharmaceuticals	BAYER	SHIONOGI
Candidate	**BLU-5937**	MK-7264	BAY '080 & BAY '607	S-600918
Dosing	**50-100mg BID**	15mg BID 45mg BID	BID	QD
P2X3 vs. P2X2/3 Selectivity	**~ 1500x**	2-7x	25-125x*	173x**
Anti-Tussive Effect †	**High**	High	High	High
Taste Interference†	**Low/None**	High	Moderate/Low	Moderate/Low
Development Phase	**Phase 2**	Phase 3	Phase 2	Phase 2^

* Bayer selectivity range of 419 P2X3 antagonists described in Bayer US patent 10,183,937 (may not be BAY1817080 or BAY1902607)
** Shionogi selectivity value presented in Tobinaga et al., 2017 for a representative, single, optimized P2X3 antagonist generated by Shionogi (may not be S-600918)
† Effect on taste and anti-tussive effect are company estimates based on animal data, clinical data, dose, human P2X3 potency, and human P2X3 vs. P2X2/3 selectivity
^ Phase II study conducted in Japan

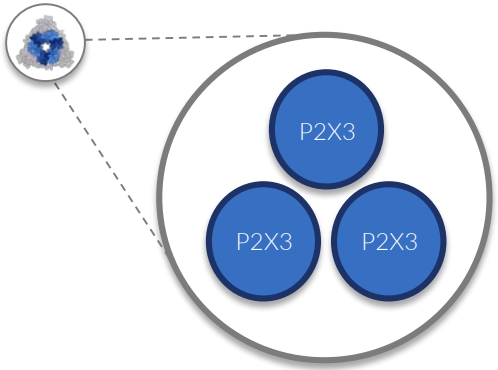
BLU-5937, A Highly-Selective P2X3 Antagonist for Chronic Cough – Preclinical & Phase 1

Dr. Denis Garceau,
Vice President, Drug Development
BELLUS Health

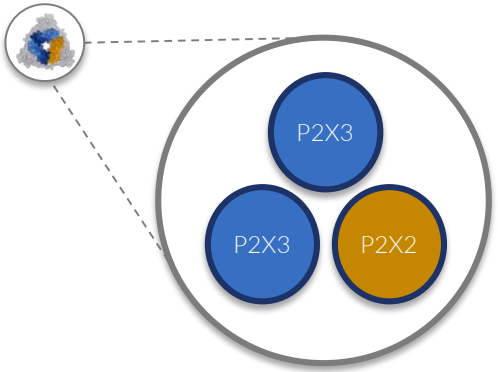
Targeting P2X3 to Treat Chronic Cough

Hypothesis: Selective inhibition of P2X3 homotrimeric receptors would reduce cough, with little or no impact on taste perception.

BLU-5937: High Potency (IC_{50} = 25 nM) and Selectivity (1500X) for P2X3 vs. P2X2/3



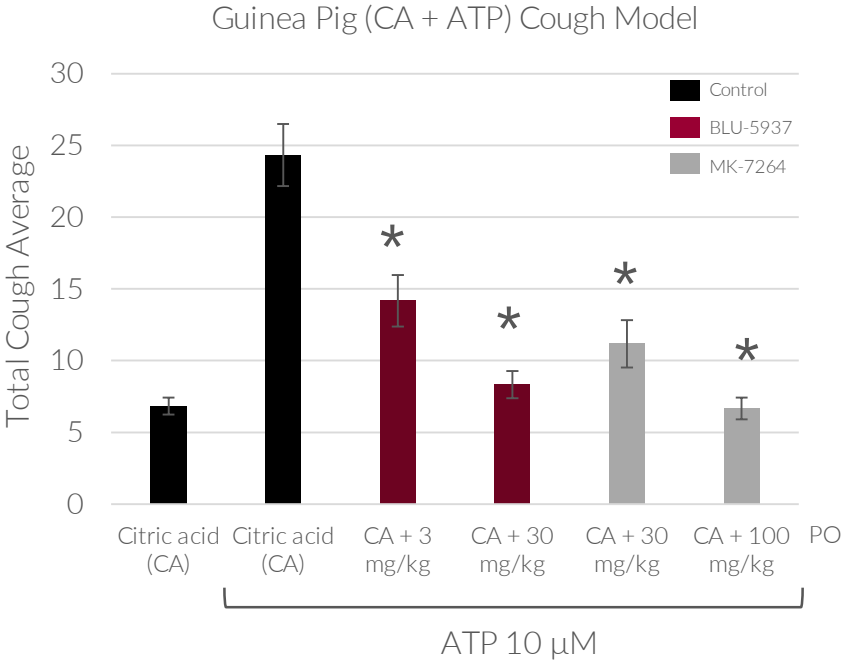
P2X3 homotrimeric receptors are linked to cough hypersensitivity

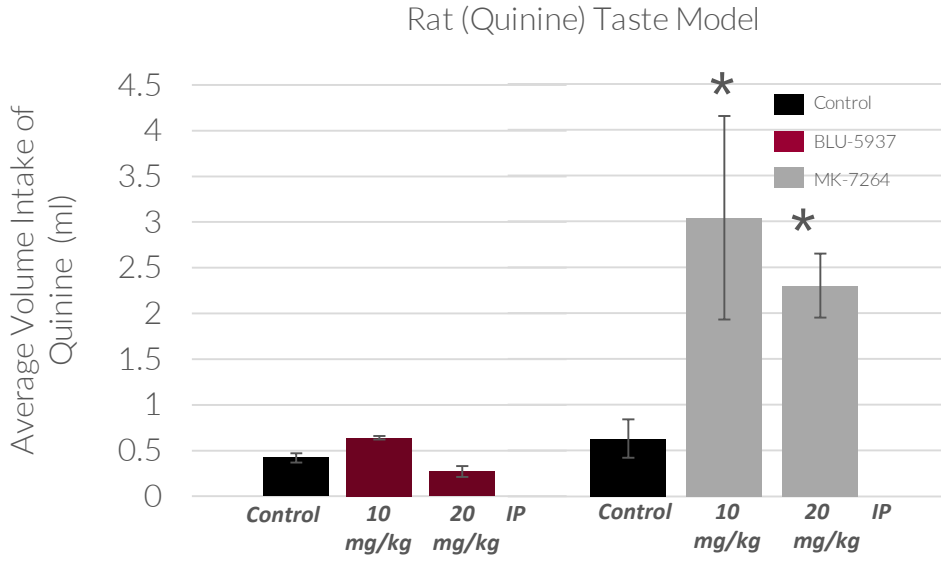


P2X2/3 heterotrimeric receptors are linked to taste function

BLU-5937: Preclinical Proof-of-Concept

At doses that blocked P2X3 but not P2X2/3 receptors, BLU-5937 reduced cough with no taste effect





Validated Efficacy Target—Clinical

Selective S-600918 has comparable efficacy to low selectivity MK-7264

Reduction in Cough Frequency

MERCK

MK-7264 Phase 2B
(50mg BID)

57% Nominal

37%* Placebo Adjusted

Merck & Co ATS Presentation, May 22, 2017;
*p<0.01

SHIONOGI

S-600918 Phase 2A
(Dose Undisclosed)

53% Nominal

32%* Placebo Adjusted

Research/ and Development at Shionogi
Presentation, March 14 2019; **p=0.055

BLU-5937: Drug-Like Characteristics

EXCELLENT PHYSIO-CHEMICAL PROPERTIES

- Solubility
- Permeability

GOOD ORAL BIOAVAILABILITY (ACROSS NUMEROUS ANIMAL SPECIES)

- 48-80%

GOOD METABOLIC STABILITY IN HUMAN HEPATOCYTES OR LIVER MICROSOMES

- BID dosing confirmed in Phase 1
- Eliminated primarily through hepatic metabolism
- Low potential of DDI

DOES NOT CROSS BLOOD-BRAIN BARRIER

- No adverse effect on general behavior, neurological function in rats
- Non-sedative

7-DAY, 28-DAY TOXICITY STUDIES (RAT AND DOG)

- High safety margin in preclinical toxicity studies
- Main toxicity target organ at high doses (≥ 300 mg/kg/day); GI tract
- Irritation of GI mucosa; emesis; reduction in weight gain

BLU-5937: Phase 1 Study Design

Design: A randomized, double-blind, placebo-controlled, escalating single dose followed by escalating multiple dose Phase 1 study conducted in 90 healthy adult subjects

Objective: To test the safety, tolerability, and pharmacokinetic profile of BLU-5937

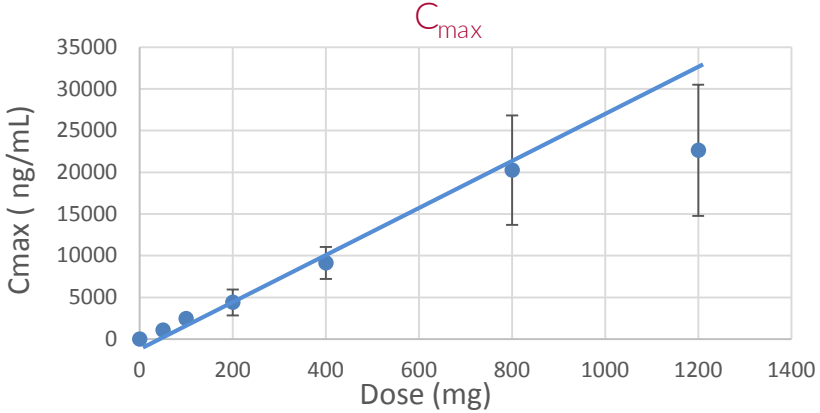
Single Ascending Dose (SAD)

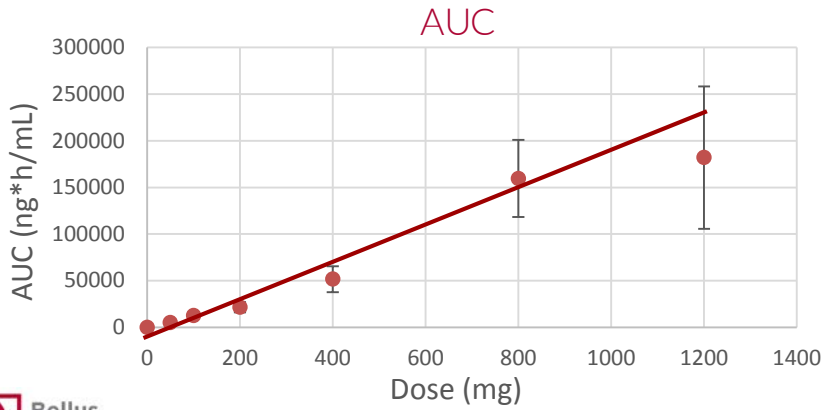
- N=60 healthy subjects
- 6 cohorts of 10 subjects (8 active; 2 placebo) administered single doses of 50mg to 1200mg
- Food effect tested at 200mg in one cohort

Multiple Ascending Dose (MAD)

- N=30 healthy subjects
- 3 cohorts of 10 subjects (8 active; 2 placebo) administered multiple doses of 100mg, 200mg, and 400mg BID for 7 days

BLU-5937: Excellent PK Profile in Healthy Subjects





Observations:

- BLU-5937 is rapidly absorbed (T_{max} ~1h)
- Systemic exposure increases dose-proportionally
- Plasma half-life of 4-9 hours supports BID dosing
- No significant effect of food on PK
- No significant systemic accumulation over 7 days

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BLU-5937 Human Predicted Doses (50-100 mg BID)

BLU-5937 predicted dose expected to be 50-100mg BID, based on achieving at least 5x drug free plasma to IC50 ratio

	Dose	Plasma concentration at maximal efficacy (ng/ml)	Plasma concentration (nM)	Free plasma concentration (nM)	IC50 for P2X3 (nM)	Ratio free plasma concentration / IC50
BLU-5937 Exposure - Guinea Pig Cough Model	30 mg/kg	2031	4400	700	126	5.6
MK-7264 Exposure in Phase 2b	50 mg	300*	850	383	76	5.0
BLU-5937 Exposure (Cave) in Phase 1	50 mg	408	890	125	25	5.0

BLU-5937 free fraction in humans (14%); free fraction in guinea pig (16%)
MK-7264 MW (353); free fraction in human (45%), free fraction in guinea pig (68.6%)

Ford A. The 8th Annual Pain & Migraine Therapeutics Summit; 2014
Merck & Co., Presentation of gefapixant Phase IIb data; American Thoracic Society; May 2017

BLU-5937: Safe & Well-Tolerated

Incidence of Most Frequent Adverse Events (>5% Incidence) in All Cohorts (SAD + MAD)

AEs N (%)	Placebo (n=18)	50mg (n=8)	100mg (n=16)	200mg (n=16)	400mg (n=16)	800mg (n=8)	1200mg (n=8)	Total BLU-5937 (n=72)
Taste Alteration	0 (0%)	0 (0%)	1 (6%)	0 (0%)	6 (38%)	5 (63%)	2 (25%)	14 (19%)
Headache	1 (6%)	0 (0%)	2 (13%)	1 (6%)	1 (6%)	2 (25%)	2 (25%)	8 (11%)
Hypoaesthesia	0 (0%)	0 (0%)	0 (0%)	3 (19%)	2 (13%)	3 (38%)	0 (0%)	8 (11%)
Dizziness	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (13%)	1 (13%)	1 (13%)	4 (6%)
Nausea	1 (6%)	0 (0%)	0 (0%)	1 (6%)	1 (6%)	2 (25%)	2 (25%)	6 (8%)
Dyspepsia	0 (0%)	0 (0%)	1 (6%)	0 (0%)	2 (13%)	1 (13%)	0 (0%)	4 (6%)

- No serious adverse event; >80% of AEs were mild; no significant effect on vital signs, ECG, laboratory
- Potential P2X3 class-related side effects include: taste effects, hypoaesthesia, nausea
- One subject had mild liver enzyme elevation (400mg BID) that normalized at follow up; not associated with increased bilirubin

Low Incidence of Taste Effect at Predicted Therapeutic Doses

Incidence of Taste AEs (All Cohorts SAD + MAD)

	50 mg (n=8)	100 mg (n=16)	200 mg (n=16)	400 mg (n=16)	800 mg (n=8)	1200 mg (n=8)
Dysgeusia	0 (0%)	1 (6.3%)	0 (0%)	6 (37.5%)	5 (62.5%)	2 (25%)
Hypogeusia	0 (0%)	0 (0%)	0 (0%)	1 (6.25%)	1 (12.5%)	0 (0%)
Ageusia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Ratio plasma C_{max} / IC_{50} hP2X3	12.9	29.4	52.4	108.7	240.9	269.4
Ratio plasma C_{max} / IC_{50} hP2X2/3	0.01	0.03	0.05	0.11	0.25	0.28

- One out of 24 subjects (4.2%) reported taste effect at the anticipated therapeutic doses (50-100mg)
- No complete taste loss (ageusia) at any dose
- Increase incidence of taste effect correlates with inhibition of P2X2/3 at supra-therapeutic doses (400-1200 mg)

Best-in-Class Taste Tolerability Profile

	Incidence and Severity of Taste Effect AEs at Estimated Comparative Therapeutic Doses	
	BLU-5937 (50-100mg) (n=24)	**Gefapixant[1] (50mg) (n=57)**
Dose(s)	**50 and 100mg single dose, and 7 day BID cohorts**	50mg BID arm for 12 weeks
Subjects	**Healthy Volunteers**	Refractory Chronic Cough
Taste Alteration	**<5%**	48%
Partial Taste Loss	**0%**	24%
Complete Taste Loss	**0%**	20%
All Taste AEs	**<5%**	81%

[1]Merck & Co Presentation of gefapixant Phase 2b data at American Thoracic Society 2017
[2]A. Morice et al,The Effect of MK-7264, a P2X3 antagonist, on Cough Reflex Sensitivity in a Randomized Crossover Trial of Healthy and Chronic Cough Subjects

Conclusions

BLU-5937 has excellent PK and safety/tolerability profile

- ✓ Linear PK, twice-daily dosing, no food interaction
- ✓ Only one mild, transient, and sporadic taste alteration at predicted therapeutic doses

These data represent the first evidence that a highly selective P2X3 antagonist is associated with an improved taste safety profile in humans.

Results support advancing to Phase 2

RELIEF: A Randomized, Double-Blind, Placebo-Controlled, Crossover, Dose Escalation Study of BLU-5937 in Subjects with Unexplained or Refractory Chronic Cough—BLU-5937 Phase 2 Study

Prof. Jacky A. Smith, MB, ChB, FRCP, PhD

University of Manchester

Clinical Studies in Chronic Cough

Recent learnings in clinical studies have provided a clear path for development and approval of chronic cough drugs

Crossover Design

- Efficient for Phase 2 proof-of-concept
- Allows for multiple dose assessment in limited number of patients
- Results confirmed in longer-term study

Endpoints

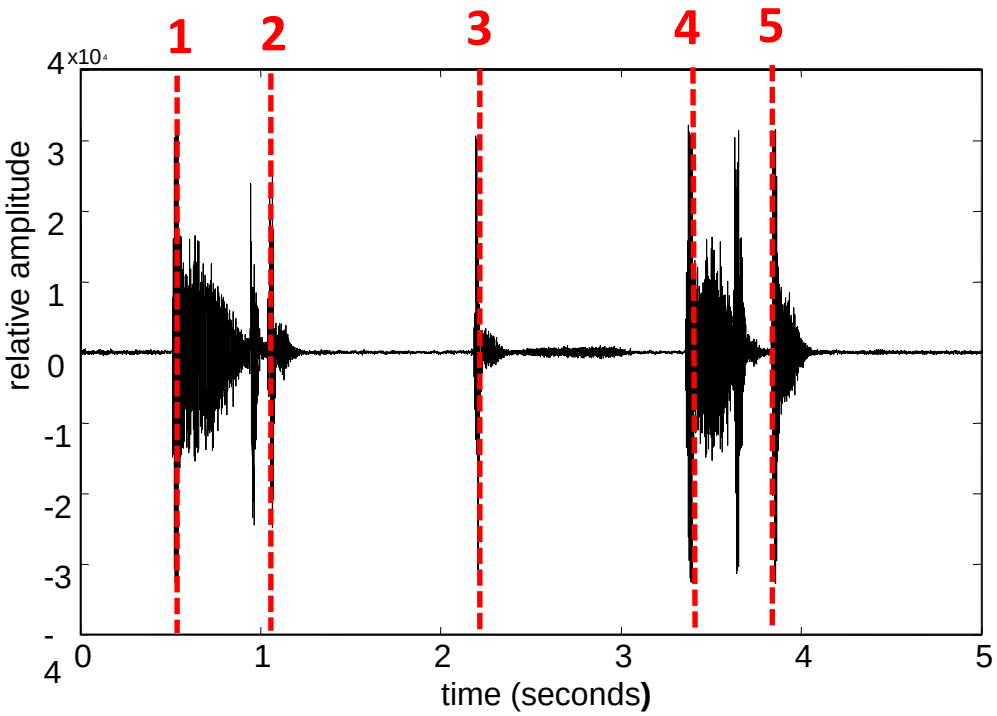
- Reduction in awake cough frequency, as measured by cough recorder
- Good correlation between cough frequency and patient reported outcomes
- Potential for placebo effect

Regulatory

- At least two large Phase 3 studies required for approval, including important safety database to support chronic use
- Primary efficacy endpoint is 24-hour cough frequency reduction using validated cough recorder

Vitalograph's Vitalojak Cough Recorder

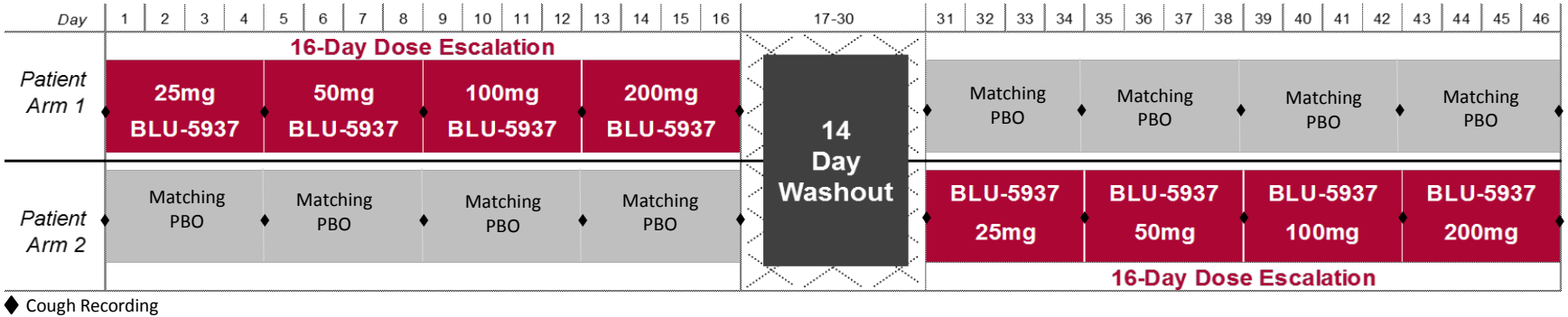
- CE mark
- FDA 510k registration
- 99.9% sensitivity



Vitalograph's Vitalojak is a validated cough recorder **accepted** by FDA

Phase 2 Study: Overview of Study Design

- Randomized, double-blind, placebo-controlled and 2-periods crossover design
- ~65 unexplained or refractory chronic cough patients
- 12 trial sites in UK and USA
- 4 dose levels with forced escalation at 4-day intervals (25/50/100/200mg, twice daily)
- Awake and 24-hour cough recording at end of each dose intervals
- 2-week screening period and 2-week follow-up with cough recordings



Phase 2 Study: Experienced Sites

- 12 sites in total; 9 UK, 3 US
- All sites experienced with conducting chronic cough studies, including at least one P2X3 antagonist

- Many sites are chronic cough centers of excellence with access to significant basin of patients
- Relatively few competing studies on-going

Phase 2 Study: Main Entry Criteria

Inclusion Criteria

- Unexplained or refractory chronic cough for ≥ 1 year
- Cough count ≥ 10 coughs/hour, at screening
- Score ≥ 40 on cough severity VAS at screening

Exclusion Criteria

- Diagnosis of COPD, bronchiectasis, IPF
- Current/former smokers (within 6 months)
- FEV1/FVC < 60%
- History of upper respiratory tract infection or recent significant change in pulmonary status within 4 weeks of baseline

Prohibited Medications

- Anti-cough medications; (dextrometorphan, gabapentin, pregabalin, opioids)
- Long-term oral steroids (prednisone)
- Medications to treat underlying disease/allergies (inhaled steroids, antihistamines) must be on stable doses for at least 8 weeks prior to screening visit

Phase 2 Study: Efficacy & Safety Endpoints

Primary Efficacy Endpoint:

- Change from baseline in awake cough frequency (cough recorder) at end of each dose level

Principal Secondary Efficacy Endpoints:

- Change from baseline in:
  - 24-hour cough frequency at end of each dose level
  - Cough severity, as measured with VAS at the end of each dose level
  - Leicester cough questionnaire total score at the end of each treatment period
- Global Rating of Change Scale at the end of each dose level
- Percent of subjects with ≥ 30, 50, 75% reduction in awake cough count from baseline at end of each dose level

Safety Endpoints:

- AEs; vital signs; ECG; clinical laboratory; BLU-5937 plasma levels
- Spontaneous taste disturbance AEs

Timeline

IND/CTA FILING

Q1-Q2 2019

- IND cleared with US FDA
- Clinical Trial Application cleared with UK MHRA

PHASE 2 START

July/August 2019

- US sites have started recruiting
- UK sites start recruiting end-July/early-August
- First patient dosed end-July/August

PHASE 2 DATA

Mid-2020

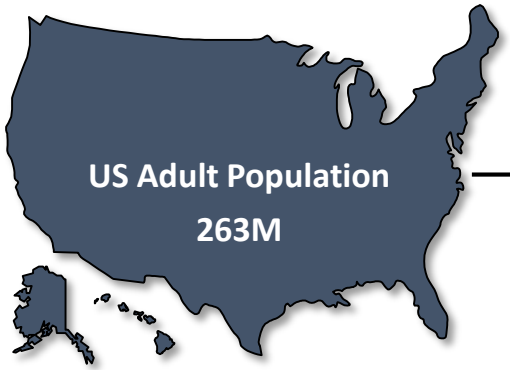
- Topline safety and efficacy data readout

Commercial Considerations:

Darren Eskow
Managing Director
Bluestar Bioadvisors

Prevalence of Refractory/Idiopathic Chronic Cough

Addressable Patient Population



26.3M or 10%
Chronic Cough Patients

2.6M
Primary addressable patients
(Idiopathic/Treatment refractory
> 1 year)

9.1M
Secondary addressable patients
(Treatment Refractory
> 8 weeks < 1 year)

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Pricing & Reimbursement

BLU-5937 Comparable Price Analogs

	Indication	Addressable US Patient Population	Market Dynamics	2019 WACC/mo
Linzess (linaclotide) capsules	Chronic idiopathic constipation	35M	Genericized	$424
amitiza lubiprostone	IBS with constipation	4M	Genericized	$371
ADVAIR DISKUS	Adult asthma and Adult COPD	18.4M 12M	Highly competitive, several generics	$394
Aptiom (eslicarbazepine acetate) tablets	Partial onset seizures	1M	Highly competitive	$968

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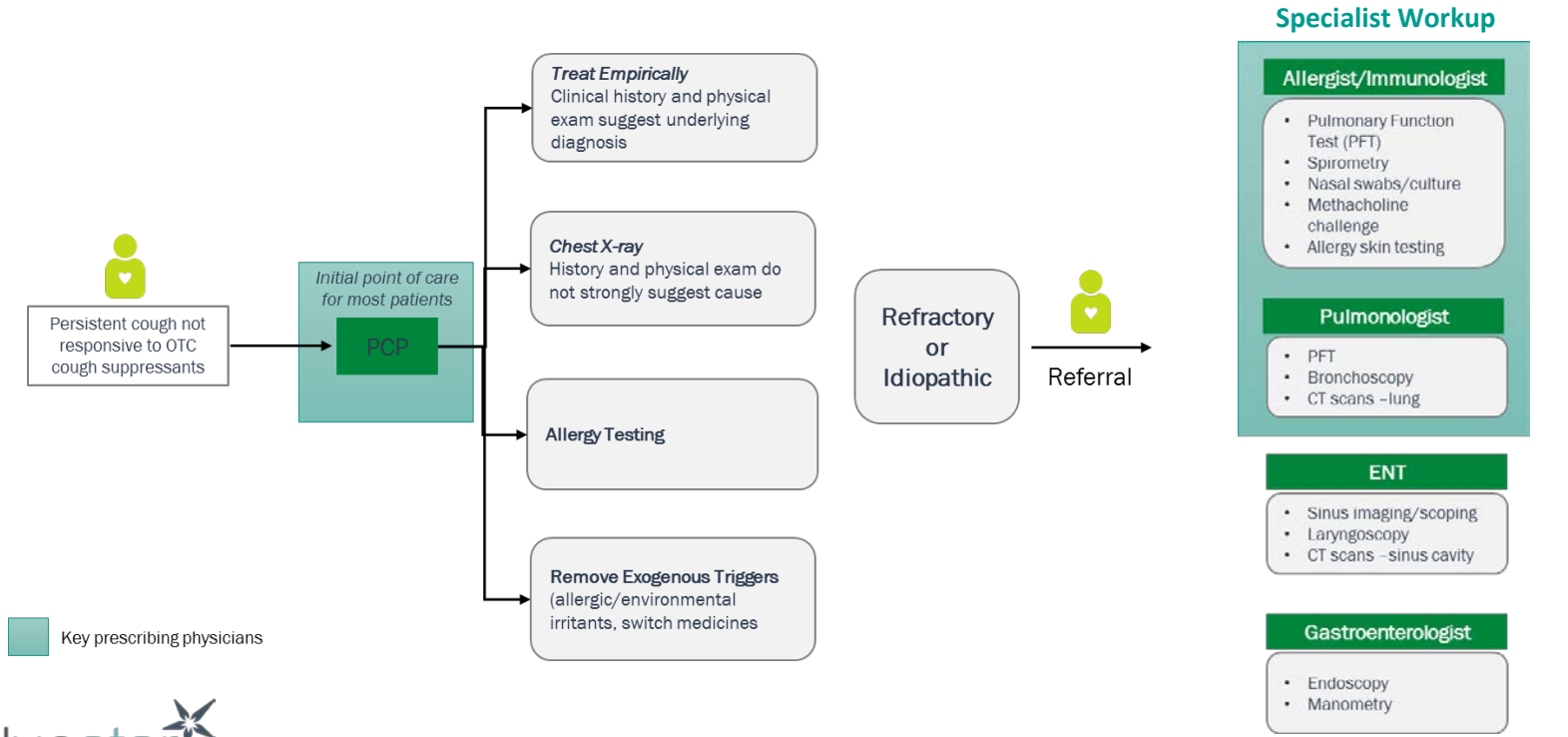
The Patient Journey—Diagnosis & Treatment

Primary Care Physician: Initial Physical Exam and Clinical History



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P2X3 Platform Potential

Dr. Denis Garceau,

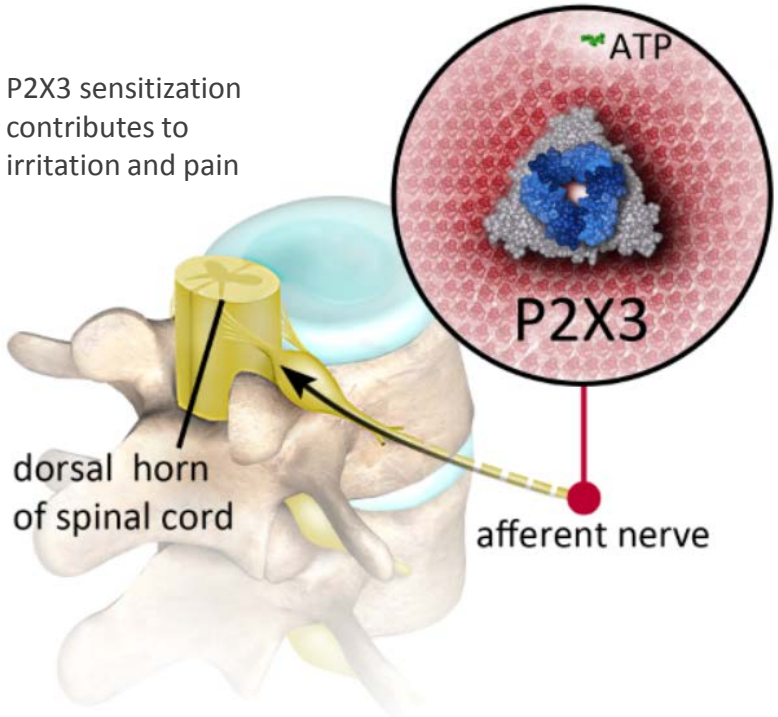
Vice President, Drug Development

BELLUS Health

Potential for Broad Applicability

Inhibition of P2X3 receptors has therapeutic potential in a number of other indications

P2X3 sensitization contributes to irritation and pain



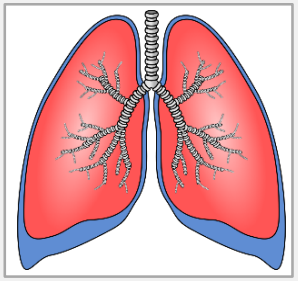
OTHER INDICATIONS LINKED TO P2X3 HYPERSENSITIZATION

- Hypersensitive cough
- Migraine
- Hypertension
- Bronchoconstriction
- Sleep apnea
- IBS
- Pruritus
- Bladder pain
- Endometriosis pain
- Neuropathic pain

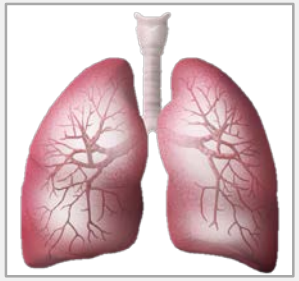
Potential for Pipeline in a Product

Recent P2X3 Studies and Indications Being Pursued

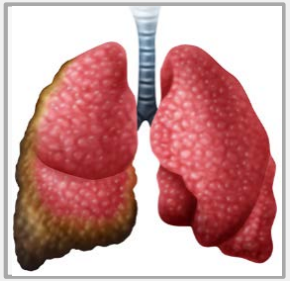
Cough Indications



ACUTE COUGH
Phase II study conducted by Merck



CHRONIC COUGH
Programs on-going at Merck, Bellus Health, Shionogi and Bayer



IPF COUGH
Phase II study conducted by Merck

Other Indications

ENDOMETRIOSIS PAIN
Phase II study started by Merck

OBSTRUCTIVE SLEEP APNEA
Phase II study started by Merck

UNDISCLOSED INDICATION
Bellus preclinical studies ongoing

Summary and Q&A