Bellus HEALTH

BLU-5937 Phase 1 Data and Corporate Update

November 20th, 2018

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Summary

Lead program

BLU-5937

for chronic cough

Large population with high unmet need

Clinically validated target

Phase 1 data: Excellent PK profile, safe and well-tolerated, significantly differentiated to first in class

Phase 2 starting in mid-2019

Listed on the Toronto Stock Exchange

TSX - BLU

Experienced

management with track record of execution

$18.1M

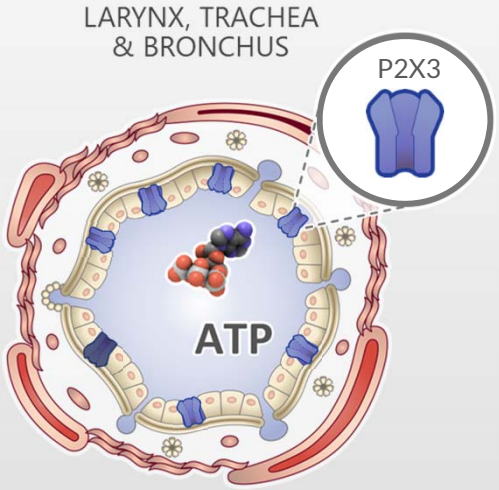
cash as of September 30th

Developing drugs with value to patients and shareholders

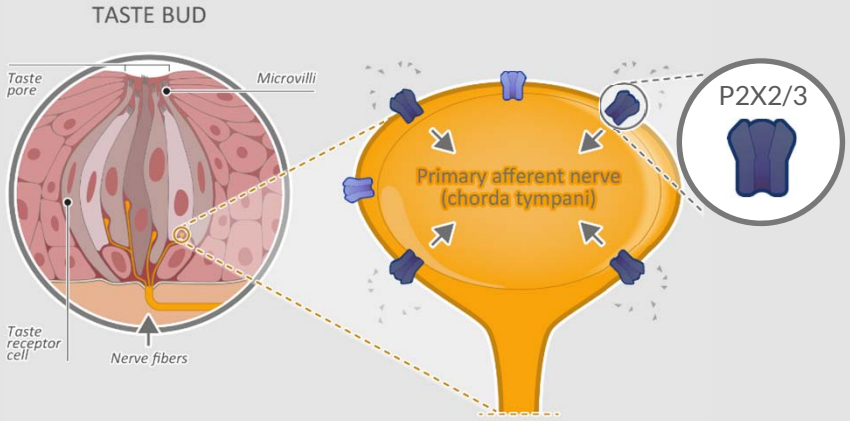
Project Hypothesis

P2X3 and P2X2/3 are ATP-gated ion channels that transmit sensory signals:

P2X3 homotrimers have primary role in **cough reflex**

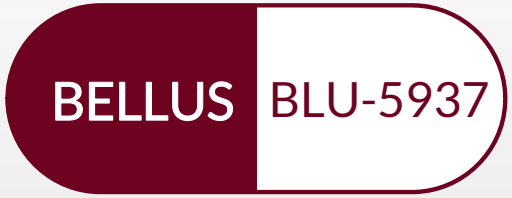


P2X2/3 heterotrimers have major role in **taste**



Opportunity for highly selective P2X3 antagonist to reduce cough and maintain taste (no P2X2/3 inhibition)

Our Solution



Highly potent

P2X3 antagonist

Low nM IC_{50}

Highly selective

P2X3 antagonist

~1500X selectivity vs P2X2/3

BLU-5937 has key characteristics to test hypothesis and already validated in animal models

Phase 1 Study Design

Key Objectives

- Assess Safety
- Assess Tolerability including Taste Effect
- Assess Pharmacokinetic Profile and Select Doses for Phase 2

Single Ascending Dose

N = 60 healthy adult subjects

6 cohorts of 10 subjects (8 active: 2 placebo) administered single dose

Single doses of 50mg to1200mg

Food interaction tested in 1 cohort (200mg)

Multiple Ascending Dose

N = 30 healthy adult subjects

3 cohorts of 10 subjects (8 active: 2 placebo) administered multiple dose

Doses of 100, 200 and 400mg BID for 7 days

Phase 1 designed to assess safety, tolerability (including taste effect) and pharmacokinetic profile

Pharmacokinetic Profile and Dosing

Pharmacokinetic Profile

- Rapidly absorbed (Tmax ~1h)
- Systemic exposure increases dose proportionally up to 800mg
- Plasma half-life of ~5 hours
- No significant food effect
- No significant drug systemic accumulation

Excellent PK Profile

Dosing

Optimal projected therapeutic dose of: 50-100mg BID

Based on achieving targeted receptor inhibition & efficacy seen in preclinical studies and on achieving comparative drug blood levels of clinically validated comparator (gefapixant at 50mg BID)

Excellent PK profile supporting estimated optimal efficacy dose of 50mg or 100mg BID

Most Frequent Adverse Events

Incidence of Adverse Events (>5% Incidence in Single and Multiple Ascending Dose Cohorts)								
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 (6.3%)	0 (0%)	6 (37.5%)	5 (62.5%)	2 (25%)	14 (19.4%)
Headache	1 (5.6%)	0 (0%)	2 (12.5%)	1 (6.3%)	1 (6.3%)	3 (37.5%)	2 (25%)	9 (12.5%)
Numbness oral /face	0 (0%)	0 (0%)	0 (0%)	3 (18.8%)	2 (12.5%)	3 (37.5%)	0 (0%)	8 (11.1%)
Dizziness	1 (5.6%)	0 (0%)	0 (0%)	0 (0%)	4 (25%)	1 (12.5%)	1 (12.5%)	6 (8.3%)
Nausea	1 (5.6%)	0 (0%)	0 (0%)	1 (6.3%)	1 (6.3%)	2 (25%)	2 (25%)	6 (8.3%)
Heartburn	0 (0%)	0 (0%)	1 (6.3%)	0 (0%)	2 (12.5%)	1 (12.5%)	0 (0%)	4 (5.6%)

* Number of subjects presenting an AE; Verbatim terms

Safe and well tolerated at projected optimal therapeutic dose range

- Incidence of adverse events on BLU-5937 (47%) similar to placebo (56%)
- No serious adverse event (SAE) reported
- No subject withdrew prematurely due to adverse event
- No clinically significant effect on vital signs and ECG
- No significant trends of changes in laboratory tests
- >80% of AEs were mild
- Only one severe AE (general numbness and body pain) and same subject had mild liver enzyme elevation at 400mg BID that normalized at follow up; no concomitant increase in bilirubin

Safe and well tolerated particularly at projected optimal therapeutic doses

Minimal Taste Effect at Therapeutic Doses

	Incidence of Taste AEs (All SAD and MAD Cohorts)					
	50mg (n=8)	100mg (n=16)	200mg (n=16)	400mg (n=16)	800mg (n=8)	1200 mg (n=8)
Taste alteration	0 (0%)	1 (6.3%)	0 (0%)	6 (37.5%)	5 (62.5%)	2 (25%)
Partial taste loss	0 (0%)	0 (0%)	0 (0%)	1 (6.25%)	1 (12.5%)	0 (0%)
Complete taste loss	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Low incidence of taste AEs particularly at optimal projected therapeutic doses (1/24 = <5%)

1 subject at 100mg BID had transient dysgeusia (2 episodes on day 1 out of 7 days of dosing)

- No complete taste loss at any dose
- One subject out of 24 (4.2%) reported mild-to-moderate taste alteration at the anticipated therapeutic doses (50-100 mg)
- No taste loss or taste alteration at 200 mg
- At supra-therapeutic doses (200 to 1200 mg), two subjects out of 48 (4.2%) reported mild, transient partial loss of taste
- Incidence of taste alteration was higher at supra-therapeutic doses of 400 to 1200 mg (incidence ranging from 25% to 62.5%)
- All taste adverse events were transient and sporadic in nature; one rated moderate, all others mild

No to minimal taste effect at projected therapeutic doses; taste AEs at supra-therapeutic doses are generally mild and transient in nature

Best in Class Taste AE Profile

	Incidence and Severity of Taste Effect AEs at Estimated Comparative Therapeutic Doses	
	BLU-5937 (50-100 mg) (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%**	21%
All taste AEs	**<5%**	81%

	Incidence and Severity of Taste Effect AEs at Comparative Supra-therapeutic Doses		
	BLU-5937 (200-400 mg) (n=32)	**Gefapixant[2] (100 mg) (n=12)**	**Gefapixant[2] (100 mg) (n=24)**
Dose(s)	**200 and 400mg single dose and 7 day BID cohorts**	Single dose 100mg	Single dose 100mg
Subjects	**Healthy volunteers**	Healthy volunteers	Refractory chronic cough
Taste alteration	**19%**	75%	67%
Partial taste loss	**3%**	8%	0%
Complete taste loss	**0%**	50%	29%

At estimated therapeutic doses, BLU-5937 has significantly improved taste effect profile versus gefapixant

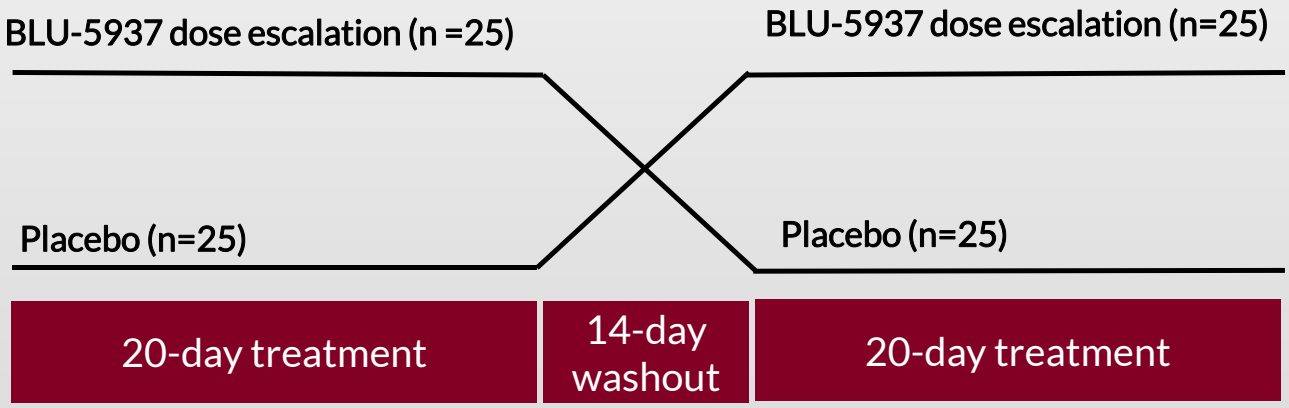
Single dose and healthy volunteer comparative data at supra-therapeutic doses also show significant improvement in taste effect profile with BLU-5937

[1]Merck & Co Presentation of gefapixant Phase 2b data at American Thoracic Society 2017
[2]Effect of Gefapixant (MK-7264/AF-219) on Cough Reflex Sensitivity in Healthy and Chronic Cough Participants (MK-7264-014), clinicaltrials.gov, NCT02476890

Taste effect profile significantly improved with BLU-5937 vs gefapixant

Phase 2 Study Design

- N≈50 unexplained/refractory chronic cough patients; diagnosis >1 year
- ~10 sites in UK and US
- 5 dose levels escalated at 4-day intervals (25mg – 400mg BID)
- Primary endpoint: Reduction in awake cough frequency using cough recorder
- Safety and tolerability assessment, including taste effect



Study expected to start in mid-2019 with top-line results in mid-2020

Conclusions

- Excellent pharmacokinetic profile
- Projected optimal therapeutic doses of 50-100mg BID
- Safe and well tolerated
  - Significantly differentiated compared to first in class gefapixant with no taste loss and little to no taste alteration at therapeutic doses (50-100mg BID)
- Phase 1 results support moving forward with Phase 2 study in mid-2019

BLU-5937 has the potential to be best-in-class treatment for chronic cough

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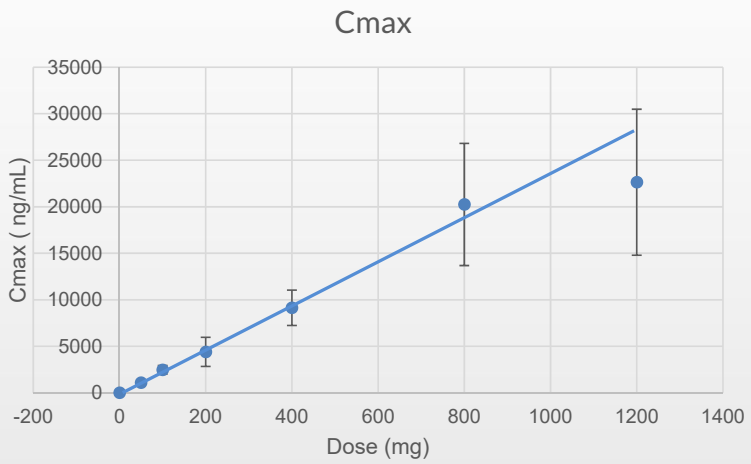
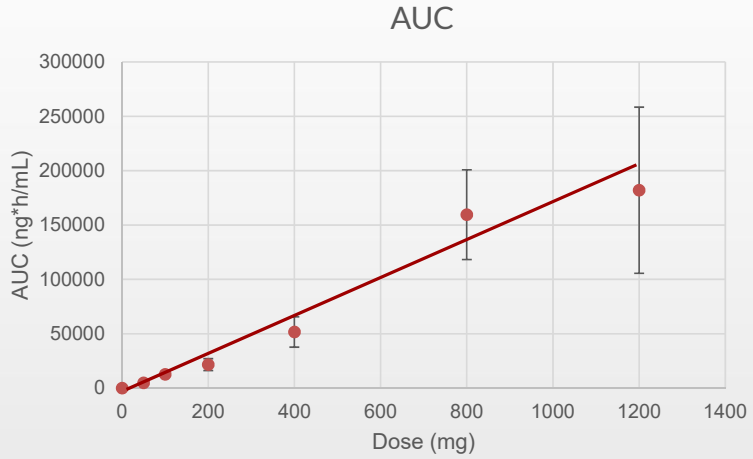
Appendix

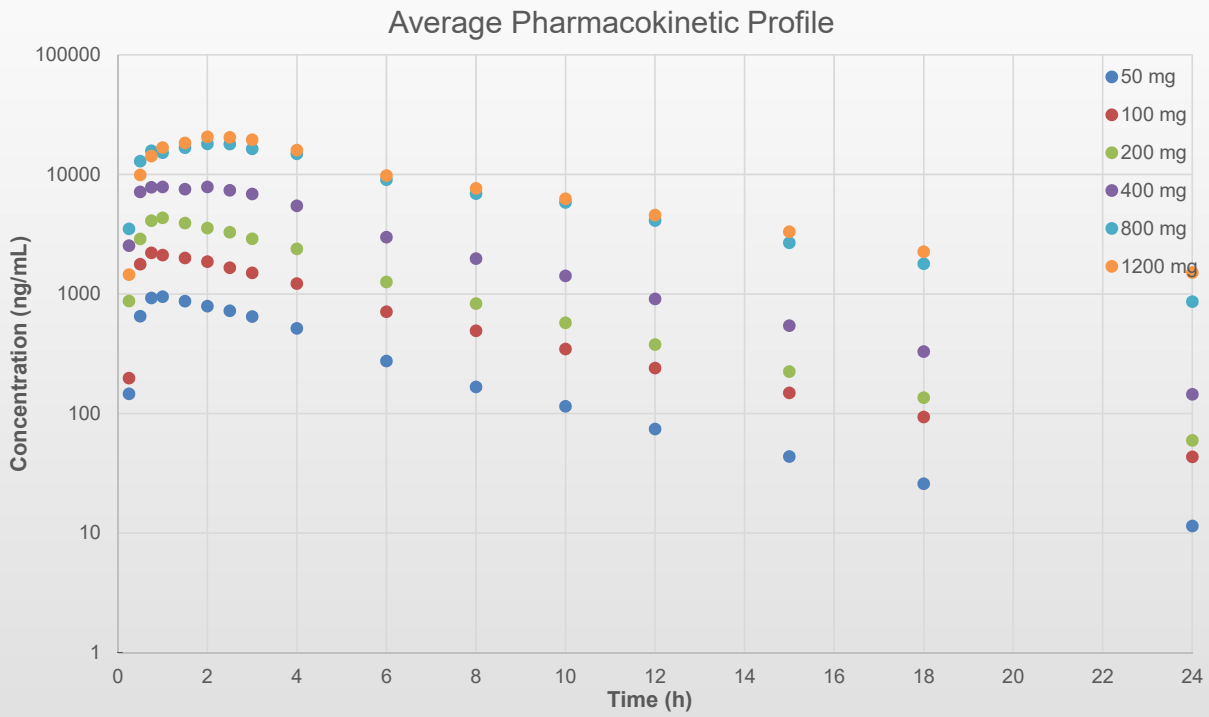
PK Profile: Single Ascending Dose





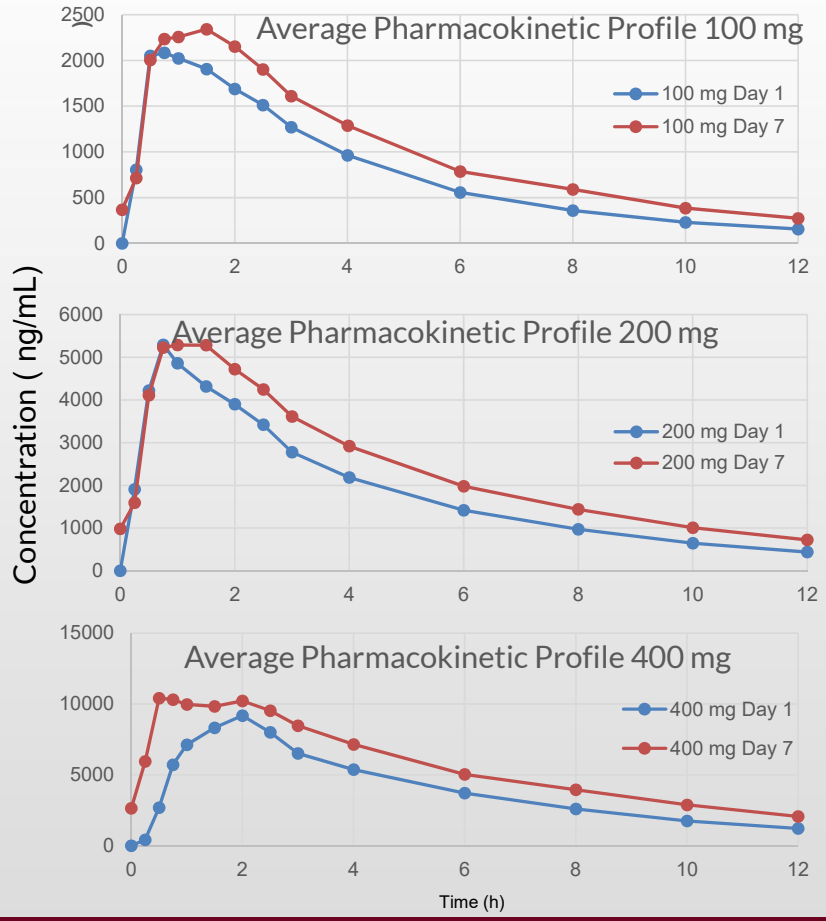
- BLU-5937 is rapidly absorbed (Tmax ~1h)
- Systemic exposure increases dose proportionally up to 800 mg
- Plasma half-life of 4-5 hours supports BID dosing
- No significant effect of food on PK (<15% on Cmax; no effect on AUC)
- No significant drug systemic accumulation over 7 days

PK Profile: Single Ascending Dose Plasma Concentration Over Time



Dose proportional increase in BLU-5937 systemic exposure up to 800 mg

PK Profile: Multiple Ascending Dose Plasma Concentration Over Time



	Day1	Day7
Cmax (ng/mL)	2420	2570
$AUC_{0\text{-}12h}$ (ng*h /mL)	9397	12269

	Day1	Day7
Cmax (ng/mL)	5289	5692
$AUC_{0\text{-}12h}$ (ng*h /mL)	NA	NA

NA; Data not available yet

	Day1	Day7
Cmax (ng/mL)	9859	11720
$AUC_{0\text{-}12h}$ (ng*h /mL)	47926	68412

No significant accumulation of BLU-5937 upon repeated dosing

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