



## GBoo1 Phase 2 Clinical Trial Topline Results

October 13, 2020

# Forward Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding the potential for the LEDA Study results to allow for the design of a well-powered Phase 3 program for GBoo1 and our plans to discuss such results with global regulatory authorities to inform potential partnerships or strategic alternatives; potential plans to advance GBoo1; the potential of GBoo1 to serve asthma patients; and expected cash runway, our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements.

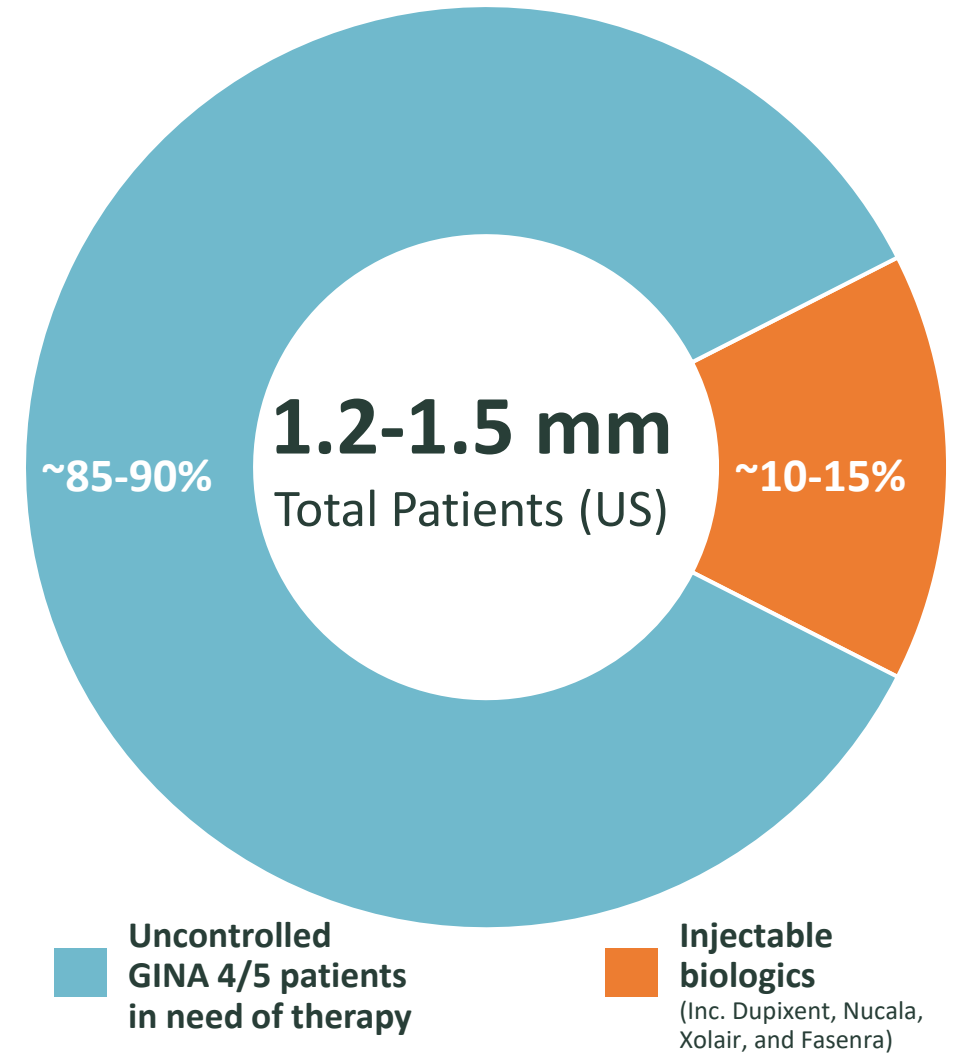
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This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

# A High Unmet Need Remains for Patients with Uncontrolled Severe Asthma

- There are up to 1.5 million patients in the US with uncontrolled moderate-to-severe eosinophilic asthma
- A small minority are treated with approved biologic agents
- An additional ~1.5 million patients without elevated eosinophils are living with uncontrolled asthma in the US
- No new oral therapies in over 20 years (montelukast)

## Uncontrolled GINA 4/5 Patients With High Eos.

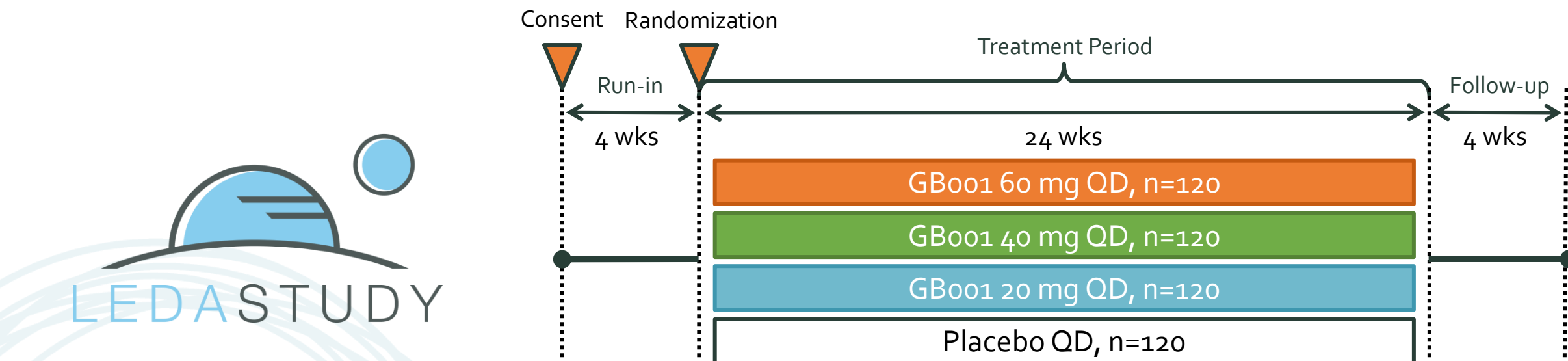


# GBoo1: Oral DP<sub>2</sub> Antagonist for the Treatment of Severe Asthma

- GBoo1 is a potent, insurmountable antagonist of the DP<sub>2</sub> receptor
- DP<sub>2</sub> antagonism has shown the potential to inhibit recruitment of airway eosinophils and reduce airway inflammation
- GBoo1 exhibits prolonged receptor residence time and extended pharmacodynamic effects
- Previously demonstrated clinical effects on asthma worsening in steroid withdrawal setting
- Topline results of LEDA and TITAN Phase 2 studies announced today

# Phase 2b LEDA Study Design and Overview

A Phase 2b, randomized, double-blind, placebo-controlled, dose-ranging, multi-center trial to evaluate the efficacy and safety of GB001 as maintenance therapy in adult patients with moderate-to-severe asthma



Patient Population	480 adult moderate-to-severe eosinophilic asthma patients on SOC therapy (ICS + additional controller)
Endpoints	<b>Primary:</b> Proportion of Patients Who Experience Asthma Worsening by Week 24 <b>Secondary:</b> Time to First Asthma Worsening, Annualized Severe Exacerbation Rate, AM PEF, FEV <sub>1</sub> , Asthma Control

# Goals for LEDA Study

1. Evaluate whether once-daily, oral GBoo1 has a clinically meaningful impact on efficacy outcomes relevant to anti-inflammatory mechanism (asthma worsening and severe exacerbation) to inform effects and statistical powering on potential registrational Phase 3 endpoints
2. Dose-range to understand effect of efficacy and safety outcomes to determine dose selection for future trials
3. Identify the optimal Phase 3 patient population

# Definition of the LEDA Primary Efficacy Endpoint: *Proportion of Patients Experiencing Asthma Worsening by Week 24*

- Asthma worsening defined as a patient meeting **ANY one of the following 5 components at ANY time by Week 24:**
  1. AM PEF  $\leq$  75% of mean baseline AM PEF on 2 consecutive days
  2. FEV<sub>1</sub> < 80% of baseline
  3. Increase in rescue medication use from baseline of  $\geq$  6 puffs/day on 2 consecutive days
  4. Increase in ACQ-5 score of  $\geq$  0.5 compared to baseline
  5. Occurrence of a Severe Asthma Exacerbation, defined as deterioration of asthma that leads to the use of systemic corticosteroids for at least 3 days, hospitalization, or an Emergency Department visit
- Asthma worsening was evaluated as both a proportion (primary endpoint) and time-to-event (key secondary endpoint)
- Prior use of this endpoint has primarily been in steroid withdrawal designs (e.g. prior Phase 2 study of GBoo1<sup>1</sup>)

# Baseline Characteristics in Phase 2b LEDA Study

Characteristic	Overall Population (N=480)
Age – mean (SD)	51.8 (12.92)
Female, n (%)	308 (64.2)
ICS High, n (%)	287 (59.8)
Asthma Duration (years) – mean (SD)	20.566 (14.312)
Number of exacerbations in last 12 months – mean (SD)	1.7 (1.11)
2 or more exacerbations in the prior 12 months, n (%)	231 (48.1)
1 exacerbation + ACQ-5 $\geq$ 1.5 at screening, n (%)	248 (51.7)
Blood eosinophils (cells/uL) – mean (SD)	464 (372)
FeNO (ppb) – mean (SD)	43.01 (37.275)
Pre-bronchodilator FEV <sub>1</sub> (L) – mean (SD)	1.918 (0.608)
Percent predicted (%) – mean (SD)	60.32 (12.191)
FEV <sub>1</sub> /FVC (ratio) – mean (SD)	0.624 (0.111)
Post-bronchodilator FEV <sub>1</sub> (L) – mean (SD)	2.269 (0.719)
FEV <sub>1</sub> reversibility (%) – mean (SD)	22.13 (15.985)
AM PEF (L/min) – mean (SD)	297.937 (109.866)
Rescue med usage (puffs/day) – mean (SD)	2.147 (2.144)
ACQ-5 score – mean (SD)	2.43 (0.896)

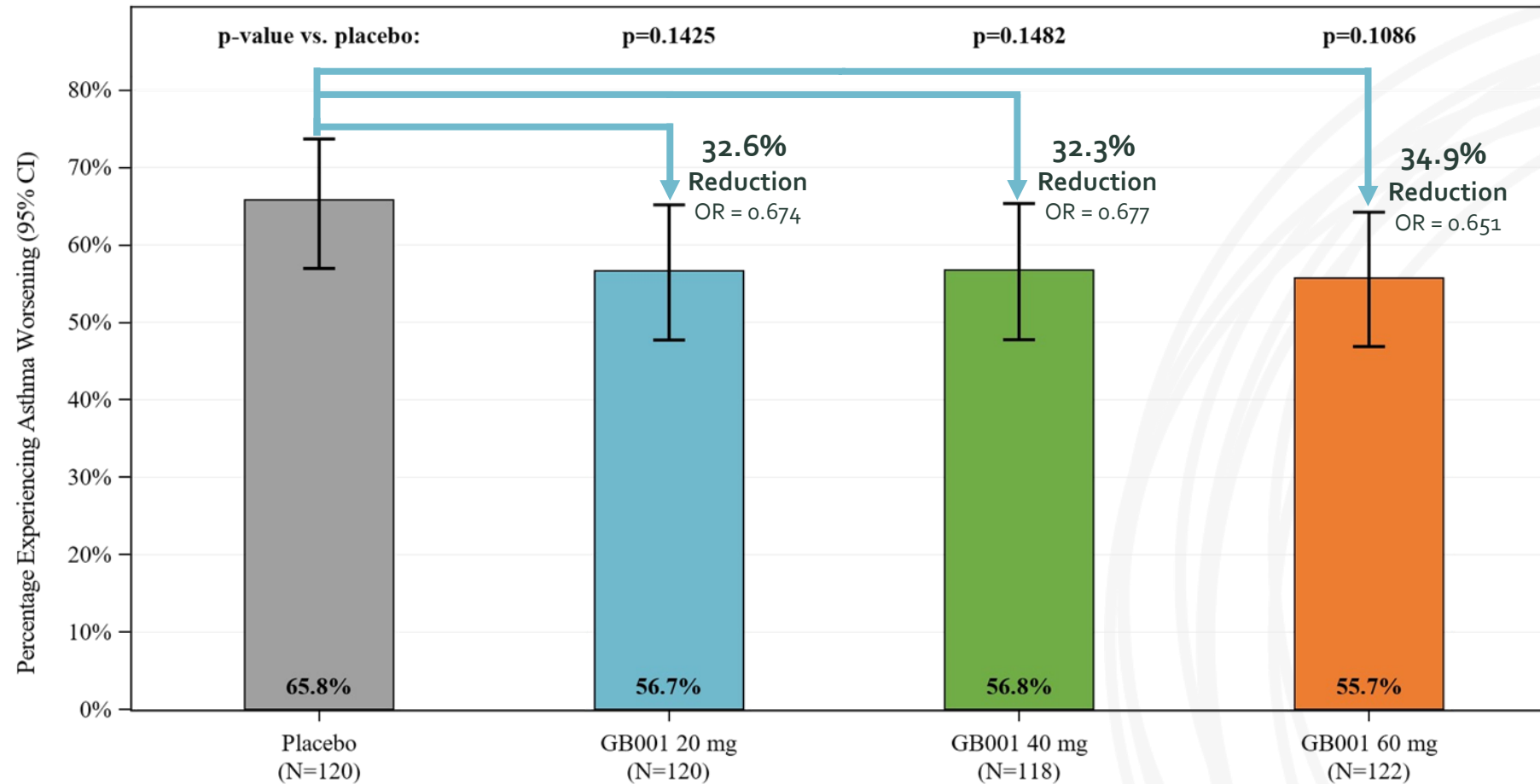
Note: Baseline characteristics were generally well balanced across the 4 treatment groups.



# Summary of Phase 2b LEDA Primary and Secondary Endpoints

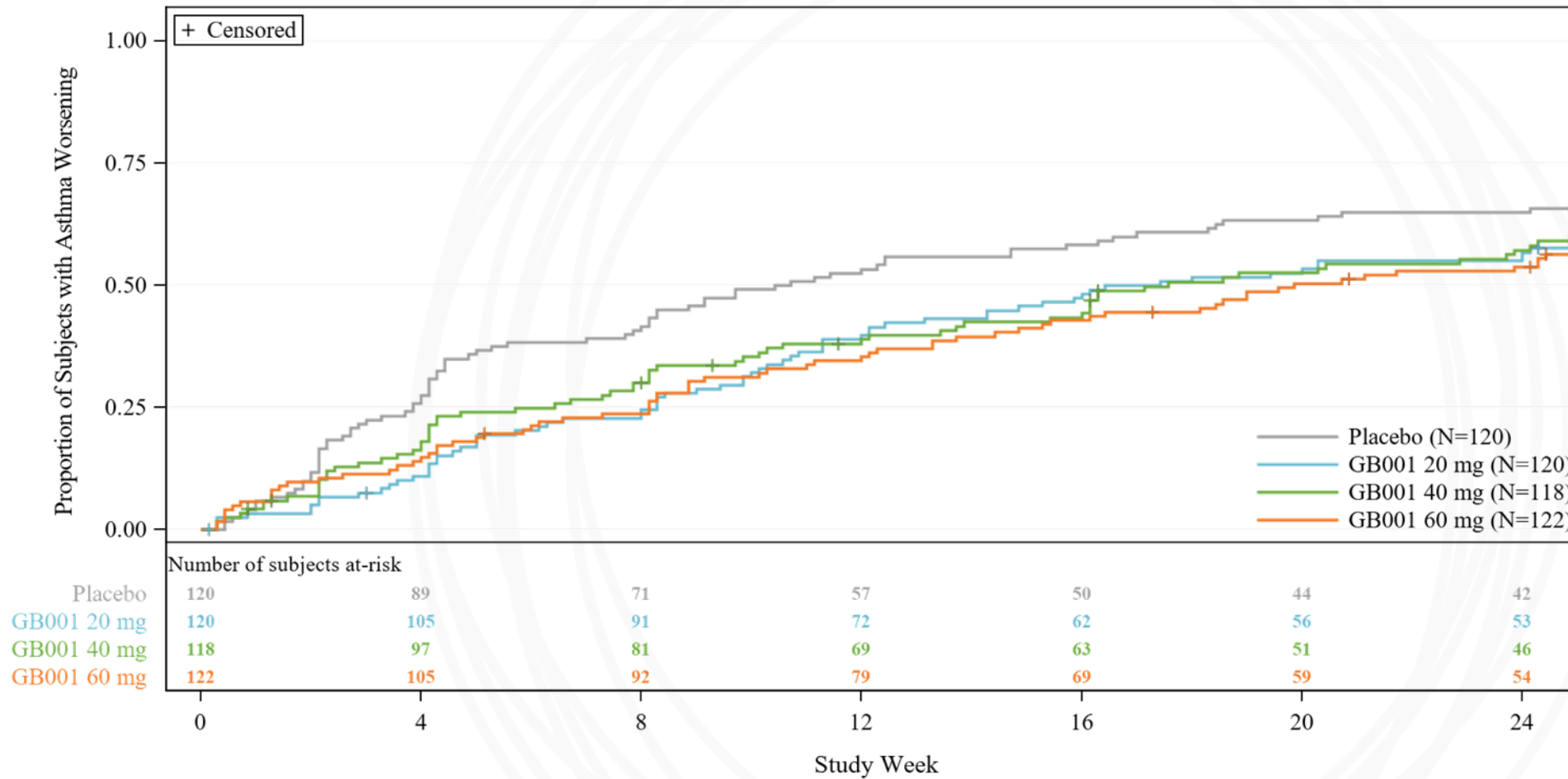
- GBoo1 groups did not meet the primary endpoint of proportion of patients who experience asthma worsening by week 24
  - **However, consistent numeric reductions in the odds of asthma worsening of 32% to 35% observed (p-values: 0.1086 to 0.1482) across GBoo1 groups**
- **GBoo1 20 mg and 60 mg groups significantly improved time to first asthma worsening (20 mg, 28% risk reduction,  $p=0.0466$ ; 60 mg, 30% risk reduction,  $p=0.0304$ ), with GBoo1 40 mg also demonstrating a numeric effect (23%,  $p=0.1222$ )**
- Numeric improvements in annualized severe exacerbation rate, lung function (morning peak flow and FEV<sub>1</sub>), and asthma control (ACQ-5) observed
- Consistent treatment effect in all GBoo1 groups across clinical endpoints suggests all doses met the biological threshold for clinical response
- Preliminary identification of patient subgroup with potential to enrich patient selection and enhance treatment response

# LEDA Primary Endpoint: *Proportion of Patients who Experience Asthma Worsening by Week 24*



**GB001 Achieved Consistent Numeric Reductions on Primary Endpoint**

# LEDA Key Secondary Endpoint: *Time to First Asthma Worsening*



## GB001 vs Placebo

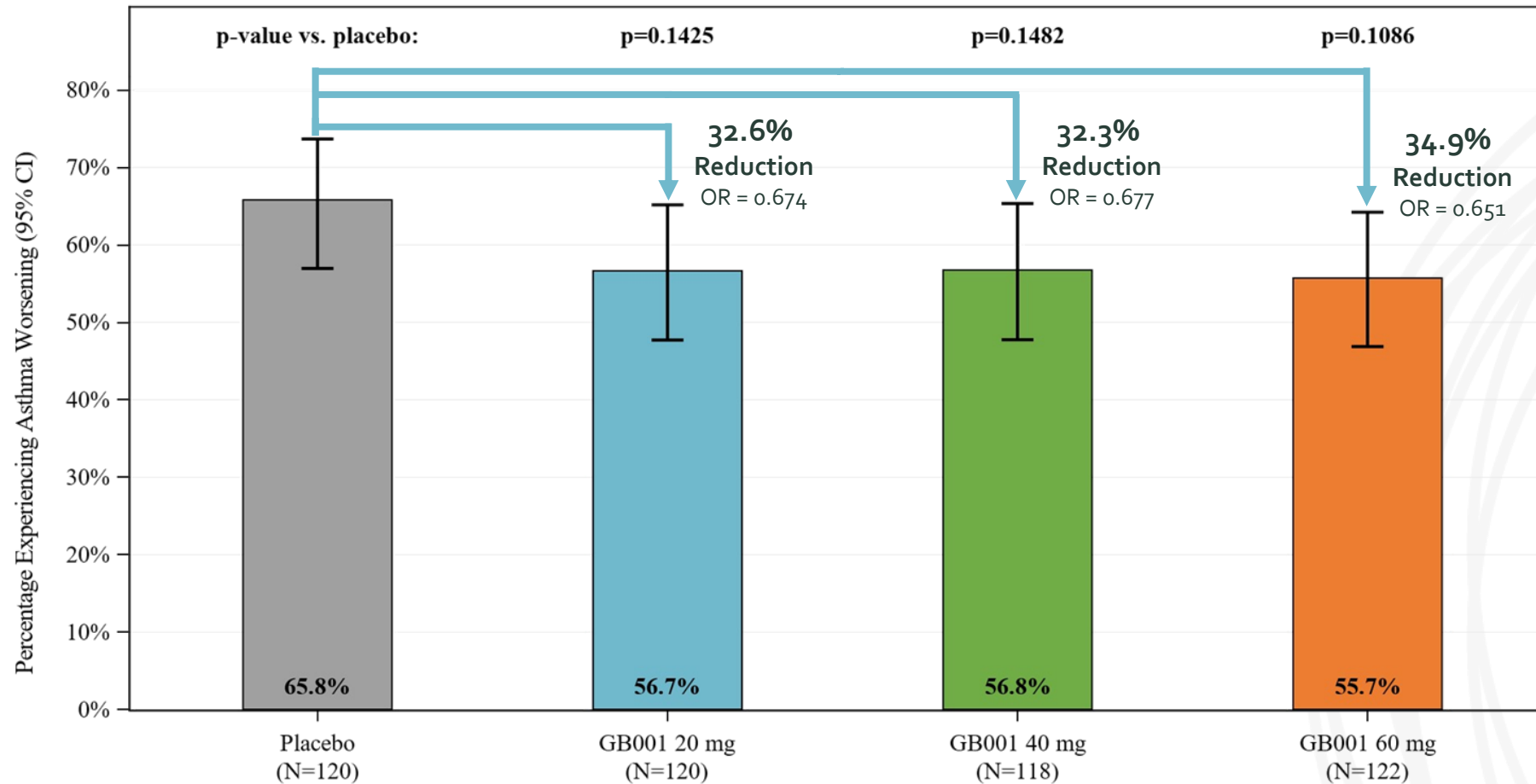
**20 mg:** HR=0.719,  
Reduction=28.1%,  
p=0.0466

**40 mg:** HR=0.773,  
Reduction=22.7%,  
p=0.1222

**60 mg:** HR=0.698,  
Reduction=30.2%,  
p=0.0304

**GB001 20 mg & 60 mg significantly improved time to first asthma worsening**

# LEDA Primary Endpoint: *Proportion of Patients who Experience Asthma Worsening by Week 24*

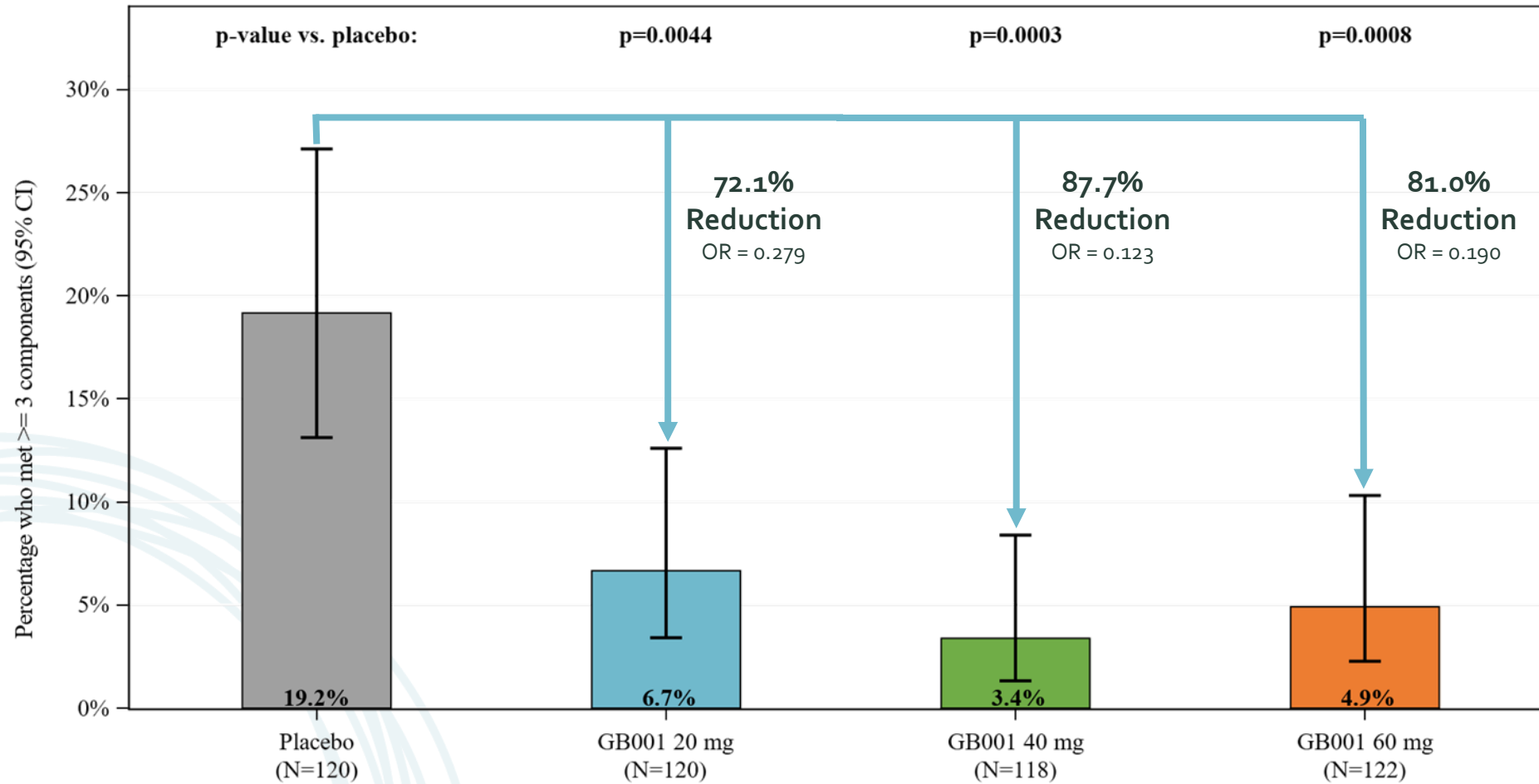


## Post-Hoc Pooled GB001 Analysis

Primary endpoint showed 33.3% reduction across pooled GB001 treatment groups (20 mg, 40 mg, 60 mg) as compared to placebo (p = 0.0678)

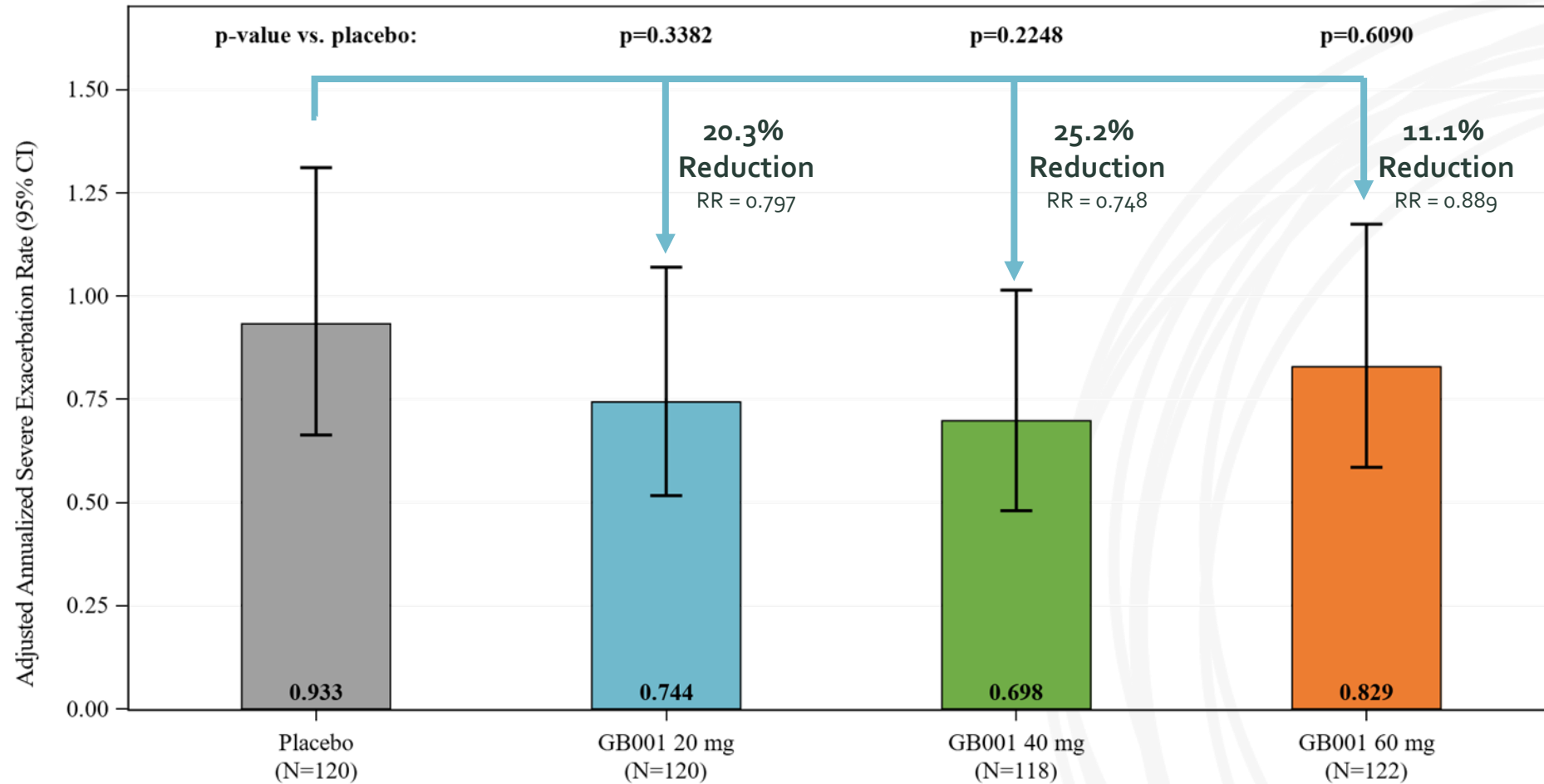
**Pooled Analysis of GB001 treatment groups approaches statistical significance**

# LEDA Post Hoc Analysis: *Proportion of Patients who Experience Severe Asthma Worsening by Week 24*



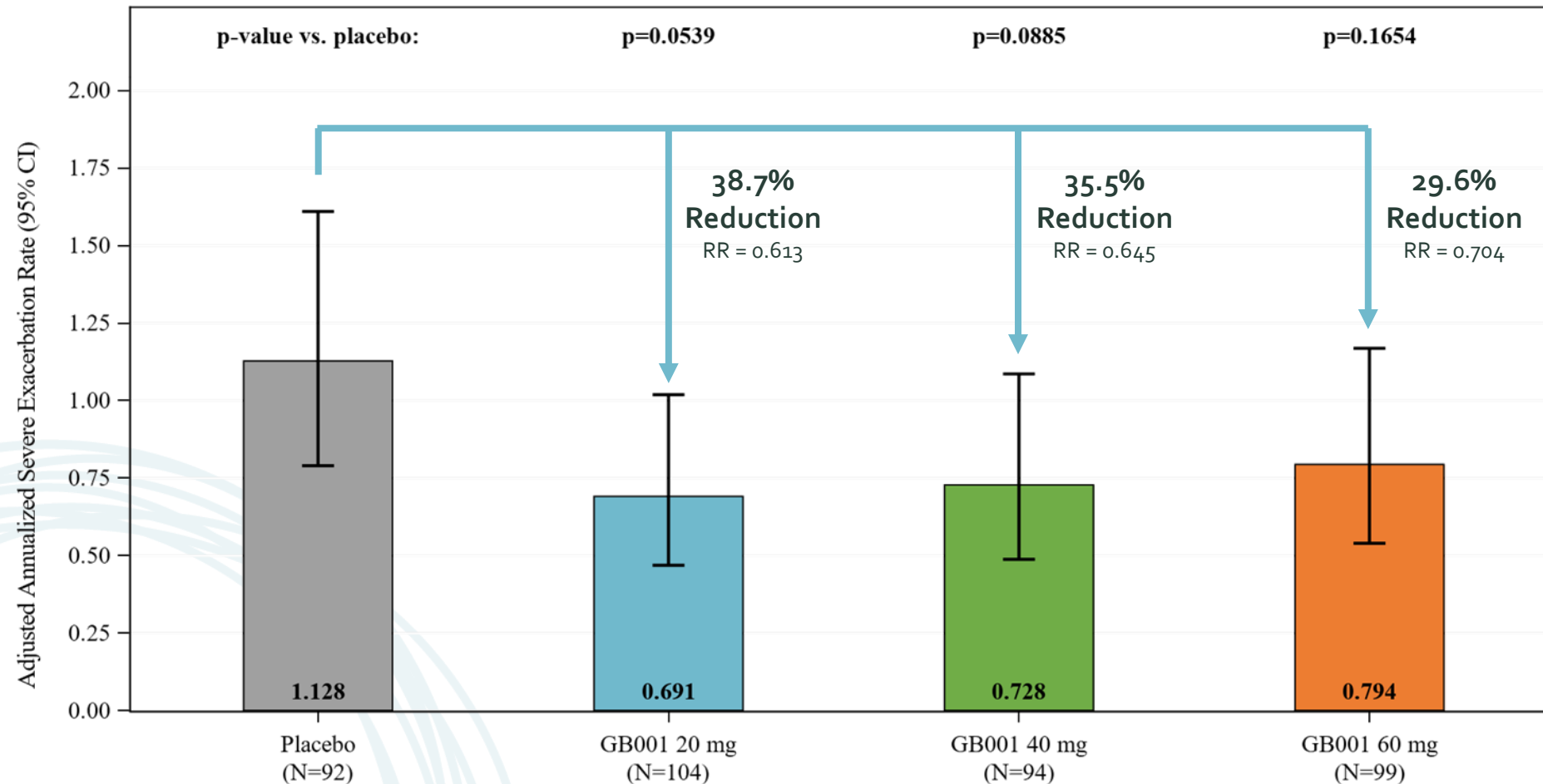
**GB001 significantly reduced the proportion of patients with severe asthma worsening, defined as meeting  $\geq 3$  components of the primary endpoint**

# LEDA Secondary Endpoint: *Annualized Severe Asthma Exacerbation Rate (AER)*



Although 24-Week Study Not Powered for This Endpoint, Numeric Reductions on AER Observed

# LEDA Post Hoc Analysis: AER in Selected Patient Subgroup



## Comparison to Overall Population

% Reductions:  
20% (20 mg)  
25% (40 mg)  
11% (60 mg)

Preliminary identification of a patient subgroup has potential  
to enrich patient selection and enhance treatment response

# Summary of LEDA Safety Profile

- Incidence of adverse events was generally comparable across treatment groups:
  - 65.8% Placebo, 65.8% GBoo1 20 mg, 69.5% GBoo1 40 mg, 68.0% GBoo1 60 mg
- Adverse events of interest (liver chemistry elevations leading to study drug discontinuation) occurred more frequently in GBoo1 60 mg (4.1%, n=5) than placebo (0.8%, n=1), GBoo1 20 mg (0.8%, n=1), or GBoo1 40 mg (1.7%, n=2)
- One adverse event of interest was an SAE of liver chemistry elevations meeting Hy's Law criteria in GBoo1 60 mg. The patient was asymptomatic during the event, which was reversible and resolved without sequelae



# LEDA Incidence of Adverse Events by Preferred Term 5% or Greater in Any Group

Preferred Term – n (%)	Placebo (N=120)	GBoo1 20 mg (N=120)	GBoo1 40 mg (N=118)	GBoo1 60 mg (N=122)	Total GBoo1 (N=360)
Number of patients with an Adverse Event	79 (65.8)	79 (65.8)	82 (69.5)	83 (68.0)	244 (67.8)
Nasopharyngitis	19 (15.8)	23 (19.2)	29 (24.6)	17 (13.9)	69 (19.2)
Headache	11 (9.2)	14 (11.7)	14 (11.9)	13 (10.7)	41 (11.4)
Aspartate aminotransferase increased	2 (1.7)	2 (1.7)	4 (3.4)	13 (10.7)	19 (5.3)
Alanine aminotransferase increased	1 (0.8)	2 (1.7)	3 (2.5)	13 (10.7)	18 (5.0)
Sinusitis	3 (2.5)	4 (3.3)	11 (9.3)	3 (2.5)	18 (5.0)
Hypertension	2 (1.7)	3 (2.5)	7 (5.9)	5 (4.1)	15 (4.2)
Upper respiratory tract infection	7 (5.8)	3 (2.5)	8 (6.8)	4 (3.3)	15 (4.2)
Diarrhoea	3 (2.5)	6 (5.0)	1 (0.8)	4 (3.3)	11 (3.1)
Pruritus	1 (0.8)	1 (0.8)	2 (1.7)	8 (6.6)	11 (3.1)
Rhinitis	6 (5.0)	1 (0.8)	2 (1.7)	7 (5.7)	10 (2.8)
Bronchitis	6 (5.0)	4 (3.3)	1 (0.8)	1 (0.8)	6 (1.7)

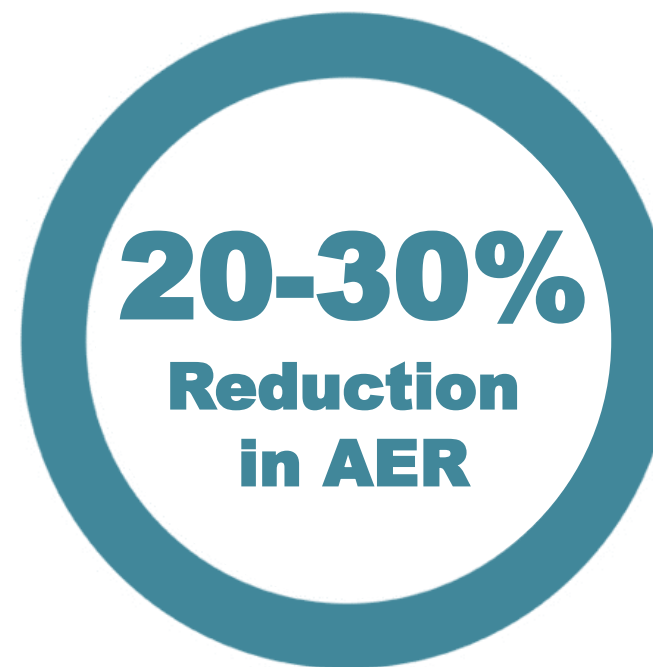
# Summary of Phase 2b LEDA Results

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- Consistent treatment effect in all GBoo1 groups across clinical endpoints suggests all doses met the biological threshold for clinical response
- Incidence of adverse events was generally comparable across treatment groups; liver enzyme elevations were observed more frequently in 60 mg dose group

# Market Research Suggests GBoo1's Target Profile is Compelling for an Oral Therapy



**Exacerbation Data Was Viewed at the Most  
Important Measure of Efficacy in  
Moderate-to-Severe Asthma Clinical Trials<sup>1</sup>**



**Efficacy Threshold for Surveyed  
Physicians to Find an Oral Asthma  
Therapeutic to be Compelling<sup>2</sup>**

<sup>1</sup> (N=200) Survey of allergists and pulmonologists; 2019

<sup>2</sup> (N=37) Interviews of asthma KOLs, Specialists, and PCP's; 2019

AER = annualized severe exacerbation rate

# TITAN Phase 2 Study in Chronic Rhinosinusitis – Topline Results

- TITAN: 16-week, Phase 2 study in patients with chronic rhinosinusitis (CRS), both with and without polyps, randomized 97 patients to GBoo1 40 mg or placebo
- Study failed to meet primary endpoint of change from baseline in SNOT-22 score and secondary endpoints
- GBoo1 40 mg was generally well tolerated with a similar safety profile as LEDA

- LEDA Phase 2b suggests potential of oral DP<sub>2</sub> pathway inhibition for the treatment of patients with uncontrolled severe asthma
- Gossamer will discuss these results and next steps for clinical development with global regulatory authorities and continue partnering discussions
- Full results from LEDA will be presented at future medical conference

# Robust Pipeline with Four Clinical-Stage Product Candidates

PROGRAM	CLASS (Route of Admin.)	INDICATION	RESEARCH	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	RIGHTS
GB001	DP2 Antagonist (Oral)	Moderate-to-Severe Eosinophilic Asthma	Phase 2b LEDA Study Completed					Worldwide (except Japan)
GB001	DP2 Antagonist (Oral)	Chronic Rhinosinusitis (with and without nasal polyps)	Phase 2 TITAN Study Completed					Worldwide (except Japan)
GB002	PDGFR Inhibitor (Inhaled)	Pulmonary Arterial Hypertension	Phase 1b Ongoing – Add'l Patients Dosed in Q3 / 4 Phase 2 Screening Patients – TORREY Study					Worldwide
GB004	HIF-1 $\alpha$ Stabilizer (Oral)	Inflammatory Bowel Disease	Phase 2 Screening Patients – SHIFT-UC Study					Worldwide
GB1275	CD11b Modulator (Oral)	Oncology, Solid Tumors	Phase 1/2 Ongoing					Worldwide

As of 6/30/20, Gossamer reported \$600mm in cash and cash equivalents; expected to provide cash runway to 2024

*Thank you to all patients, caregivers,  
investigators, and Gossamer employees  
who participated in and contributed to  
these studies!*