UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 13, 2020

GOSSAMER BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38796**	**47-5461709**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3013 Science Park Road
San Diego, California, 92121
(Address of Principal Executive Offices) (Zip Code)

(858) 684-1300
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	GOSS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On October 13, 2020, Gossamer Bio, Inc. (the "Company") issued a press release reporting the clinical data results discussed in Item 8.01 below. The full text of the press release is attached as Exhibit 99.1 to this Current Report. The slides attached as Exhibit 99.2 to this Current Report contain certain additional information related to the clinical data results discussed in Item 8.01 below. The Company intends to present the slides during a conference call and live webcast with the investment community on October 13, 2020, at 8:00 a.m. EDT.

The information contained in this Item 7.01, including in Exhibits 99.1 and 99.2 hereto, is being "furnished" and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On October 13, 2020, the Company announced topline results from the Company's Phase 2 trials in patients with moderate-to-severe eosinophilic asthma and chronic rhinosinusitis. The LEDA Phase 2b trial in patients with moderate-to-severe eosinophilic asthma failed to meet its primary endpoint, though consistent and meaningful numeric reductions in the odds of asthma worsening as compared to placebo (n=120) were observed across all GB001 groups: 33% (p=0.1425), 32% (p=0.1482), and 35% (p=0.1086), for the GB001 20 mg (n=120), 40 mg (n=118), and 60 mg (n=122) groups, respectively. In addition, statistically significant improvements in the key secondary endpoint of time to first asthma worsening as compared to placebo were observed for GB001 20 mg and 60 mg (28% and 30% risk reduction, p=0.0466 and p=0.0304, respectively), with GB001 40 mg also demonstrating a numeric improvement (23%, p=0.1222).

Consistent reductions for each GB001 group as compared to placebo were seen across all individual components of the asthma worsening endpoint. In a post-hoc analysis, the odds of experiencing severe asthma worsening (i.e. meeting three or more worsening components) were significantly reduced in all three GB001 groups as compared to placebo (72%, 88%, and 81% reductions, p=0.0044, 0.0003, and 0.0008, for GB001 20 mg, 40 mg, and 60 mg, respectively).

In addition to the primary endpoint of asthma worsening, the expected Phase 3 registrational endpoint of annualized severe exacerbation rate, or AER, was evaluated as a secondary endpoint. While AER is typically formally evaluated in large Phase 3 studies with a one-year duration, reductions as compared to placebo were seen for each GB001 group (GB001 20 mg: 20%; 40 mg: 25%; 60 mg: 11%), although not statistically significant.

Numeric improvements in lung function, as measured by morning peak expiratory flow and pre-bronchodilator FEV1, and asthma control, as measured by the Asthma Control Questionnaire were also observed for all three GB001 groups compared to placebo. The trial also provided the opportunity to investigate subgroups based on clinical characteristics and biomarkers. In a post-hoc analysis, a subgroup of patients was preliminarily identified with enhanced treatment response that could allow for the enrollment of an enriched patient population in future studies.

The incidence of adverse events was generally comparable across treatment groups: 65.8% placebo, 65.8% GB001 20 mg, 69.5% GB001 40 mg, and 68.0% GB001 60 mg. Adverse events of interest (liver chemistry elevations leading to study drug discontinuation) occurred more frequently in GB001 60 mg (4.1%, n=5) than placebo (0.8%, n=1), GB001 20 mg (0.8%, n=1), or GB001 40 mg (1.7%, n=2). One adverse event of interest was a serious adverse event of liver chemistry elevations meeting Hy's Law criteria in the GB001 60 mg group. The patient was asymptomatic during the event, which was reversible and resolved without sequelae.

The Company plans to discuss the data from the LEDA Phase 2b trial with global regulatory authorities to inform its thinking on potential partnerships or strategic alternatives.

The proof-of-concept TITAN trial enrolled 97 patients with chronic rhinosinusitis with and without nasal polyps and assessed treatment with GB001 40 mg vs. placebo over 16 weeks. Neither the primary nor the secondary endpoints of the study were met. The Company does not plan to continue further development of GB001 in chronic rhinosinusitis.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 13, 2020
99.2	Slide Presentation entitled "GB001 Phase 2 Clinical Trial Topline Results"

Forward-Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: our plans to discuss the LEDA Study results with global regulatory authorities to inform potential partnerships or strategic alternatives; potential plans to advance GB001; and the potential of GB001 to serve asthma patients. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of our plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the Company may not proceed into Phase 3 clinical trials for GB001, including because the LEDA Study results may not support continued clinical development of GB001; topline results the Company reports is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory authorities may not agree with the Company's interpretation of such results; disruption to our operations from the recent global outbreak of the COVID-19 pandemic, including clinical trial and regulatory meeting delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; potential delays in the commencement, enrollment and completion of any future clinical trials of GB001 and the success of any such trials; the Company may not be successful in establishing strategic partnerships or collaborations and may not realize the benefits of such arrangements; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; the Company may use its capital resources sooner than it expects; and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GOSSAMER BIO, INC.

Date: October 13, 2020

By: /s/ Christian Waage
Christian Waage
Executive Vice President & General Counsel

Gossamer Bio Announces Topline Results for Phase 2 Trials of Oral GB001 in Asthma and Chronic Rhinosinusitis

- Primary endpoint of asthma worsening not met in LEDA Study, however consistent numeric reductions ranging from 32-35% observed across all three GB001 groups -

- Statistically significant improvements in key secondary endpoint of time to first asthma worsening of 28% and 30% observed for 20 mg and 60 mg doses of GB001, respectively; 23% improvement observed in 40 mg group -

- TITAN Study in chronic rhinosinusitis did not meet primary or secondary endpoints -

- Gossamer to hold webcast to discuss trial results at 8:00 am EDT -

SAN DIEGO--(BUSINESS WIRE)--October 13, 2020-- Gossamer Bio, Inc. (Nasdaq: GOSS), a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology, today announced topline results from its Phase 2b LEDA trial in patients with moderate-to-severe eosinophilic asthma and its Phase 2 TITAN trial in patients with chronic rhinosinusitis.

“While we did not achieve statistical significance on the primary endpoint in the LEDA study, we are encouraged by the consistent results observed for all three doses of once-daily, oral GB001 therapy across the primary and secondary endpoints,” said Sheila Gujrathi, M.D., Co-Founder and Chief Executive Officer of Gossamer. “We believe these data provide important information for designing a well-powered Phase 3 program for GB001 in severe asthma. We plan to engage in global regulatory discussions in order to inform our thinking around potential partnerships or strategic alternatives for this program.”

“The results of the robust LEDA Study are meaningful and help us to further understand the DP2 pathway in asthma,” said Bruce Levy, M.D., Chief, Division of Pulmonary and Critical Care Medicine at Brigham and Women’s Hospital and Professor of Medicine at Harvard Medical School. “I believe GB001 as an oral treatment has the potential to serve the high unmet need of patients with uncontrolled severe asthma.”

LEDA Phase 2b Trial Design

The LEDA trial enrolled 480 patients with uncontrolled, moderate-to-severe eosinophilic asthma and assessed the effect of oral GB001 add-on therapy to standard of care over 24 weeks, comparing three dose groups of once-daily, oral GB001 (20 mg, n=120; 40 mg, n=118; and 60 mg, n=122) to placebo (n=120).

The primary endpoint, asthma worsening, included five components and was chosen for its sensitivity in detecting deterioration in clinical outcome measures known to be correlated with exacerbations. A patient was considered to have experienced asthma worsening if they met any of the five components by Week 24. This endpoint has previously been used in the context of steroid withdrawal studies, including a prior Phase 2 trial of GB001.

LEDA Primary and Secondary Endpoint Results

The primary endpoint of the trial was not met, though consistent and meaningful numeric reductions in the odds of asthma worsening as compared to placebo were observed across all GB001 groups: 33% (p=0.1425), 32% (p=0.1482), and 35% (p=0.1086), for the GB001 20 mg, 40 mg, and 60 mg groups, respectively. In addition, statistically significant improvements in the key secondary endpoint of time to first asthma worsening as compared to placebo were observed for GB001 20 mg and 60 mg (28% and 30% risk reduction, p=0.0466 and p=0.0304, respectively), with GB001 40 mg also demonstrating a numeric improvement (23%, p=0.1222).

Consistent reductions for each GB001 group as compared to placebo were seen across all individual components of the asthma worsening endpoint. In a post-hoc analysis, the odds of experiencing severe asthma worsening (i.e. meeting three or more worsening components), were significantly reduced in all three GB001 groups as compared to placebo (72%, 88%, and 81% reductions, p=0.0044, 0.0003, and 0.0008, for GB001 20 mg, 40 mg, and 60 mg, respectively).

In addition to the primary endpoint of asthma worsening, the expected Phase 3 registrational endpoint of annualized severe exacerbation rate, or AER, was evaluated as a secondary endpoint. While AER is typically formally evaluated in large Phase 3 studies with a one-year duration, reductions as compared to placebo were seen for each GB001 group (GB001 20 mg: 20%; 40 mg: 25%; 60 mg: 11%), although the reductions were not statistically significant.

Numeric improvements in lung function, as measured by morning peak expiratory flow and pre-bronchodilator FEV1, and asthma control, as measured by the Asthma Control Questionnaire were also observed for all three GB001 groups compared to placebo.

The trial also provided the opportunity to investigate subgroups based on clinical characteristics and biomarkers. In a post-hoc analysis, a subgroup of patients was preliminarily identified with enhanced treatment response that could allow for the enrollment of an enriched patient population in future studies. We will continue to analyze the clinical data collected in the study, including further characterization of this subgroup.

Overall, the Phase 2b LEDA Study informed on the Phase 3 registrational endpoint, the optimal patient population and dose selection for future studies. We look forward to discussing our findings with global regulatory authorities and continuing our discussions with potential strategic partners.

LEDA Safety and Tolerability Results

The incidence of adverse events was generally comparable across treatment groups: 65.8% placebo, 65.8% GB001 20 mg, 69.5% GB001 40 mg, and 68.0% GB001 60 mg.

Adverse events of interest (liver chemistry elevations leading to study drug discontinuation) occurred more frequently in GB001 60 mg (4.1%, n=5) than placebo (0.8%, n=1), GB001 20 mg (0.8%, n=1), or GB001 40 mg (1.7%, n=2). One adverse event of interest was a serious adverse event of liver chemistry elevations meeting Hy’s Law criteria in the GB001 60 mg group. The patient was asymptomatic during the event, which was reversible and resolved without sequelae.

Full results from LEDA will be submitted for future presentation at an upcoming scientific meeting.

TITAN Phase 2a Trial in Chronic Rhinosinusitis with and without Nasal Polyps

The proof-of-concept TITAN trial enrolled 97 patients with chronic rhinosinusitis with and without nasal polyps and assessed treatment with GB001 40 mg vs. placebo over 16 weeks. Neither the primary nor the secondary endpoints of the trial were met. The safety and tolerability of GB001 40 mg was generally consistent with that observed in the LEDA study. We do not plan to continue further development of GB001 in chronic rhinosinusitis.

Conference Call and Webcast

Gossamer's management team will host a conference call and live audio webcast at 8:00am EDT today, Tuesday, October 13, to discuss its GB001 Phase 2 clinical trial results.

The live audio webcast may be accessed through the Events/Presentations page in the Investors section of the Company's website at www.gossamerbio.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 1333166
Domestic Dial-in Number: (833) 640-7726
International Dial-in Number: (602) 585-9912
Live Webcast: https://edge.media-server.com/mmc/p/6yqpwnxf

A replay of the audio webcast will be available for 30 days on the Investors section of the Company's website, www.gossamerbio.com.

About GB001

GB001 is a potent and highly selective oral antagonist of the DP2 pathway, a potentially important modulator of the inflammatory cascade in asthma. GB001 is an investigational, once-daily tablet being developed as an add-on maintenance treatment for moderate-to-severe uncontrolled asthma.

About the GB001 Phase 2b LEDA Study

LEDA (GB001-2001, NCT03683576) was a 24-week, randomized, double-blind, placebo-controlled, dose-ranging, multi-center Phase 2b trial in patients with moderate-to-severe eosinophilic asthma. The patient population included 480 adult patients, randomized equally to placebo, GB001 20 mg, GB001 40 mg, and GB001 60 mg, who were receiving Global Initiative for Asthma (GINA) Step 4 or 5 standard of care treatment with inhaled medium or high dose corticosteroids and at least one additional asthma controller medication. The objective of the trial was to evaluate the efficacy and safety of GB001 relative to placebo when added to standard of care treatment.

The primary endpoint was the proportion of patients who experienced asthma worsening by Week 24. Asthma worsening was a composite outcome defined as the occurrence of any one of the following at any time by Week 24: deterioration of morning peak expiratory flow, pre-bronchodilator forced expiratory volume in 1 second (FEV1), or asthma control as measured by the Asthma Control Questionnaire 5, relative to baseline; an increase in rescue medication use relative to baseline; or the occurrence of a severe asthma exacerbation, defined as deterioration of asthma that led to the use of systemic corticosteroids for at least 3 days, hospitalization, or an Emergency Department visit.

Secondary endpoints included time to first asthma worsening and the annualized rate of severe asthma exacerbations.

The safety of GB001 was assessed by adverse events, clinical laboratory tests, electrocardiograms, and vital signs.

About the GB001 Phase 2 TITAN Study

TITAN (GB001-2101, NCT03956862) was a 16-week, randomized, double-blind, placebo-controlled, dose-ranging, multi-center Phase 2 trial in patients with chronic rhinosinusitis with and without nasal polyps. The patient population included 97 adult patients, randomized equally to placebo and GB001 40 mg, stratified by nasal polyp status. The objective of the trial was to evaluate the efficacy and safety of GB001 40 mg relative to placebo when added to standard of care treatment of intranasal corticosteroids.

The primary endpoint was the change from baseline to Week 16 in SNOT-22, a patient-reported, quality of life instrument that assesses the impact of chronic rhinosinusitis. A key secondary endpoint in subjects with nasal polyps was the change from baseline to Week 16 in nasal polyp score.

The safety of GB001 was assessed by adverse events, clinical laboratory tests, electrocardiograms, and vital signs.

About Gossamer Bio

Gossamer Bio is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. Its goal is to be an industry leader in each of these therapeutic areas and to enhance and extend the lives of patients suffering from such diseases.

Forward-Looking Statements

Gossamer cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential for the LEDA Study results to allow for the design of a well-powered Phase 3 program for GB001 and our plans to discuss such results with global regulatory authorities to inform potential partnerships or strategic alternatives; potential plans to advance GB001; and the potential of GB001 to serve asthma patients. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of our plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Gossamer's business, including, without limitation: Gossamer may not proceed into Phase 3 clinical trials for GB001, including because the LEDA Study results may not support continued clinical development of GB001; topline results Gossamer reports is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory

authorities may not agree with Gossamer's interpretation of such results; disruption to our operations from the recent global outbreak of the COVID-19 pandemic, including clinical trial and regulatory meeting delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; potential delays in the commencement, enrollment and completion of any future clinical trials of GB001 and the success of any such trials; Gossamer may not be successful in establishing strategic partnerships or collaborations and may not realize the benefits of such arrangements; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Gossamer may use its capital resources sooner than it expects; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Gossamer undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

For Investors and Media:
Bryan Giraudo, Chief Financial Officer
Gossamer Bio Investor Relations
ir@gossamerbio.com

Exhibit 99.2

gossamerbio

GB001 Phase 2 Clinical Trial Topline Results

October 13, 2020

gossamerbio

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 GB001 and our plans to discuss such results with global regulatory authorities to inform potential partnerships or strategic alternatives; potential plans to advance GB001; the potential of GB001 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.

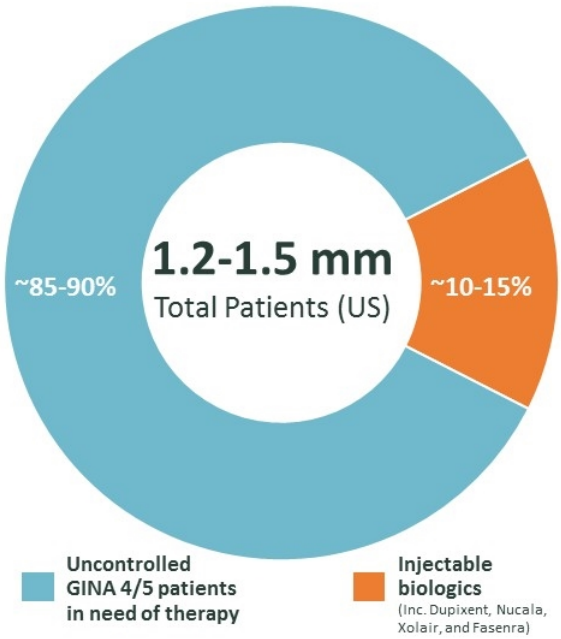
In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These known risks and uncertainties include: the potential for the LEDA Study results to allow for the design of a well-powered Phase 3 program for GB001 and our plans to discuss such results with global regulatory authorities to inform potential partnerships or strategic alternatives; topline results Gossamer reports are based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of the clinical trial, and the FDA and other regulatory authorities may not agree with Gossamer's interpretation of such results; disruption to our operations from the recent global outbreak of the COVID-19 pandemic, including clinical trial and regulatory meeting delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; potential delays in the commencement, enrollment and completion of any future clinical trials of GB001 and the success of any such trials, including any Phase 3 trials; Gossamer may not be successful in establishing strategic partnership or collaborations and may not realize the benefits of such arrangements; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Gossamer may use its capital resources sooner than it expects; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and we undertake no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

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.



3 Datamonitor, open source medical claims, internal analysis.

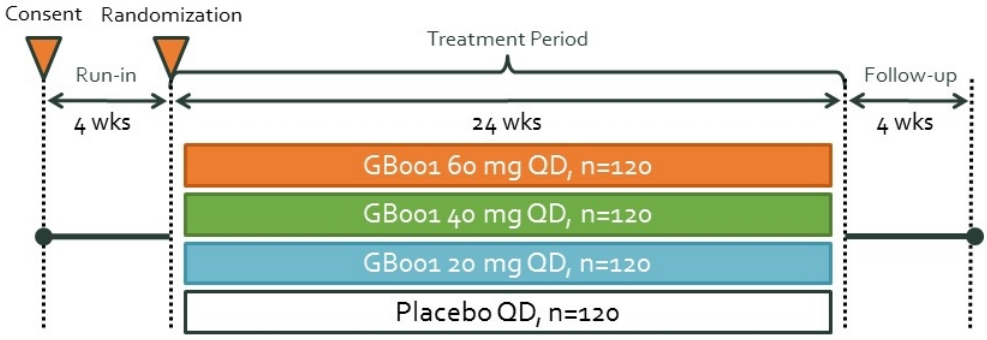
GB001: Oral DP2 Antagonist for the Treatment of Severe Asthma

- GB001 is a potent, insurmountable antagonist of the DP2 receptor
- DP2 antagonism has shown the potential to inhibit recruitment of airway eosinophils and reduce airway inflammation
- GB001 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

LEDASTUDY



Patient Population	480 adult moderate-to-severe eosinophilic asthma patients on SOC therapy (ICS + additional controller)
Endpoints	**Primary:** Proportion of Patients Who Experience Asthma Worsening by Week 24 **Secondary:** Time to First Asthma Worsening, Annualized Severe Exacerbation Rate, AM PEF, FEV_1, Asthma Control

QD = once daily dosing; wks = weeks; SOC = standard of care; ICS = inhaled corticosteroids; AM PEF = morning peak expiratory flow; FEV_1 = forced expiratory volume in 1 second.

Goals for LEDA Study

1. Evaluate whether once-daily, oral GB001 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 ≤ 75% of mean baseline AM PEF on 2 consecutive days
  2. FEV1 < 80% of baseline
  3. Increase in rescue medication use from baseline of ≥ 6 puffs/day on 2 consecutive days
  4. Increase in ACQ-5 score of ≥ 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 GB001[1])

AM PEF = morning peak expiratory flow; FEV1 = forced expiratory volume in 1 second; ACQ-5 = Asthma Control Questionnaire-5.

1) Asano, 2020.

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 ≥ 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 FEV1 (L) – mean (SD)	1.918 (0.608)
Percent predicted (%) – mean (SD)	60.32 (12.191)
FEV1/FVC (ratio) – mean (SD)	0.624 (0.111)
Post-bronchodilator FEV1 (L) – mean (SD)	2.269 (0.719)
FEV1 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.

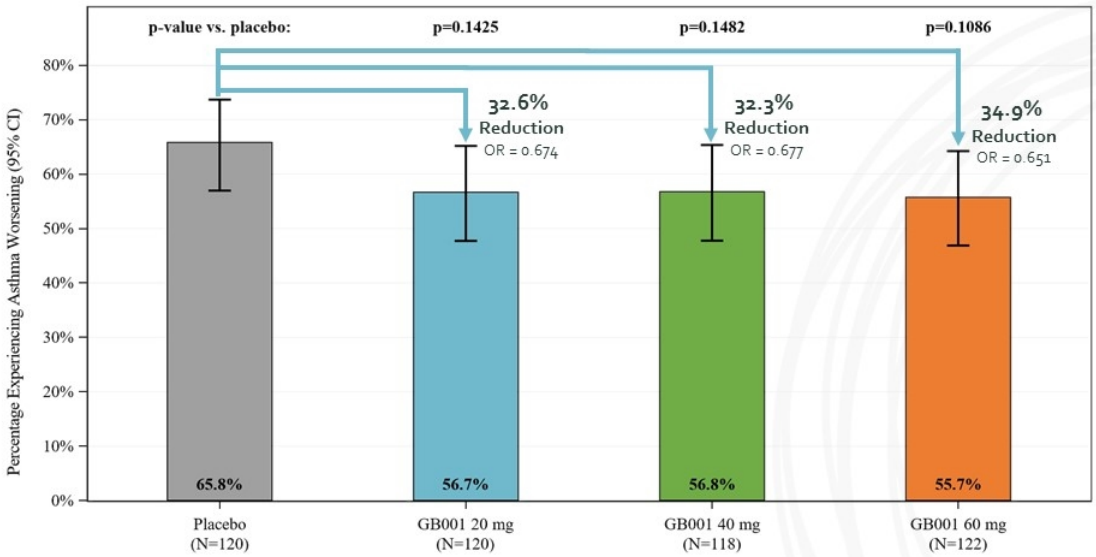
ICS = inhaled corticosteroids; FeNO = fractional exhaled nitric oxide; FEV1 = forced expiratory volume in 1 second; AM PEF = morning peak expiratory flow; ACQ-5 = Asthma Control Questionnaire-5

Summary of Phase 2b LEDA Primary and Secondary Endpoints

- GB001 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 GB001 groups**
- **GB001 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 GB001 40 mg also demonstrating a numeric effect (*23%, p=0.1222*)
- Numeric improvements in annualized severe exacerbation rate, lung function (morning peak flow and FEV1), and asthma control (ACQ-5) observed
- Consistent treatment effect in all GB001 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

FEV1 = forced expiratory volume in 1 second; ACQ-5 = Asthma Control Questionnaire-5.

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



GB001 Achieved Consistent Numeric Reductions on Primary Endpoint

10 OR = odds ratio

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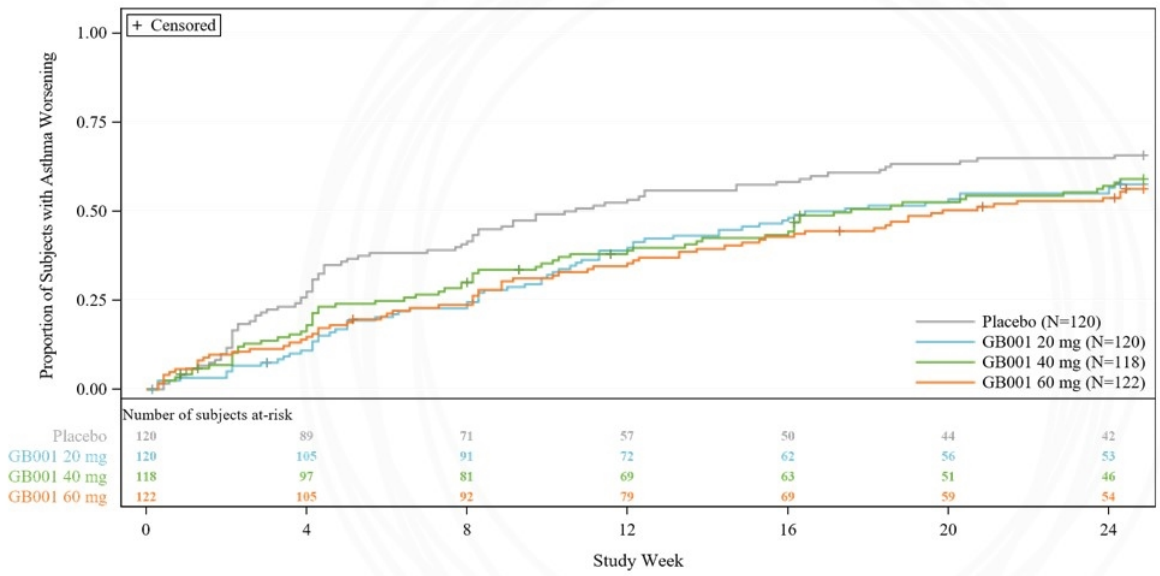
LEDA Key Secondary Endpoint:
Time to First Asthma Worsening



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

HR = Hazard Ratio

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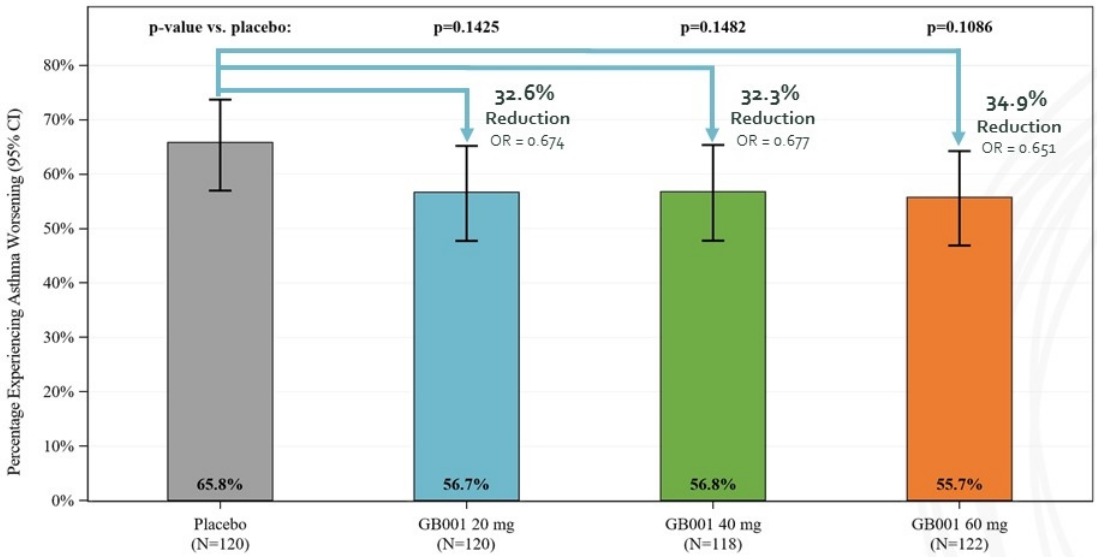
LEDA Primary Endpoint:
Proportion of Patients who Experience Asthma Worsening by Week 24



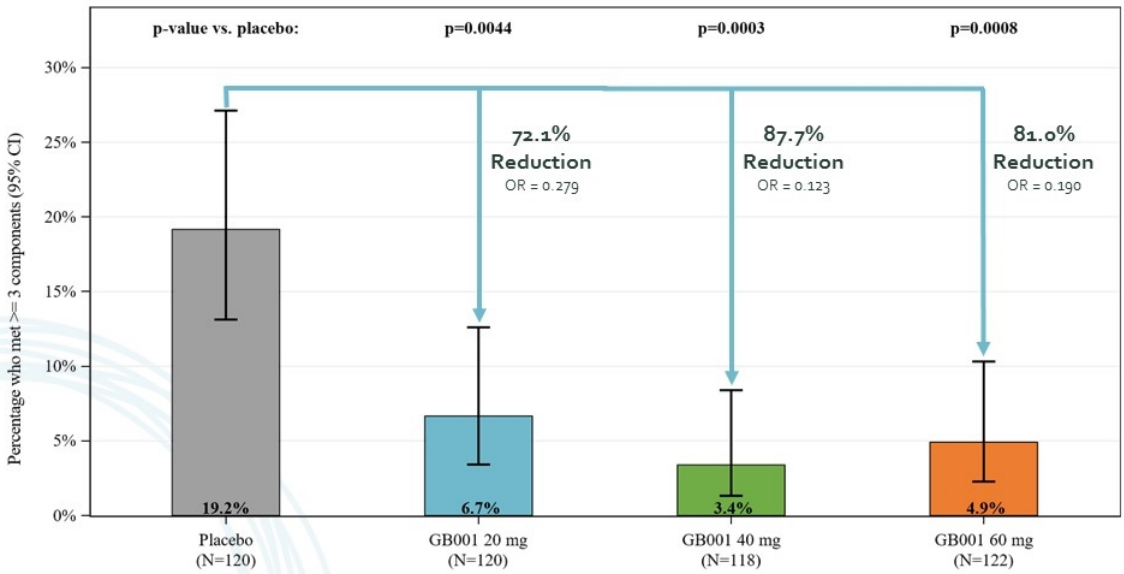
Post-Hoc Pooled GB001 Analysis

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

OR = odds ratio.

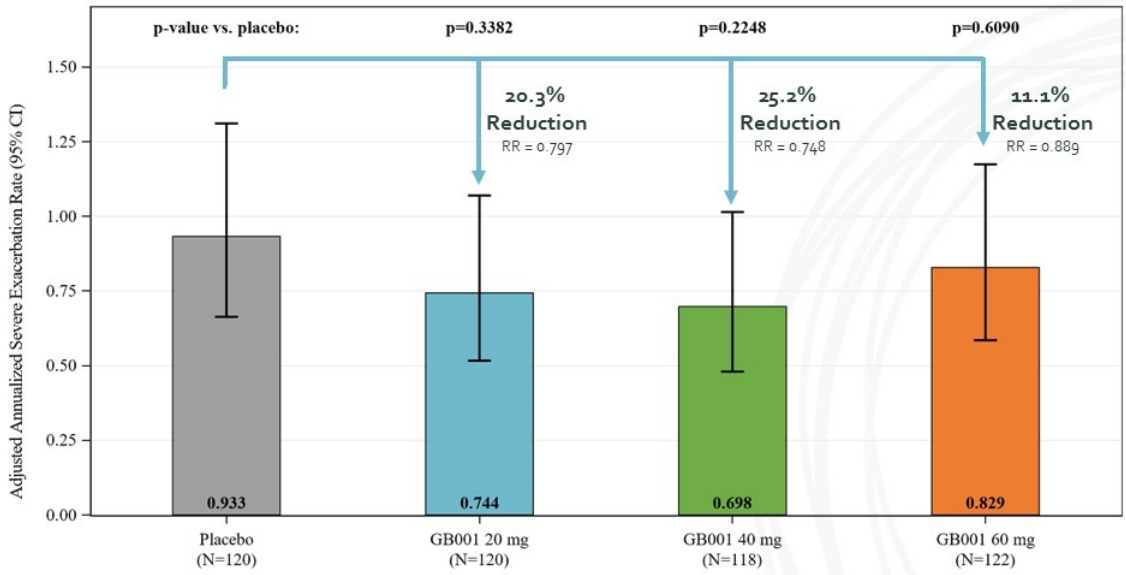
LEDA Post Hoc Analysis:
Proportion of Patients who Experience Severe Asthma Worsening by Week 24



GB001 significantly reduced the proportion of patients with severe asthma worsening, defined as meeting ≥ 3 components of the primary endpoint

OR = odds ratio.

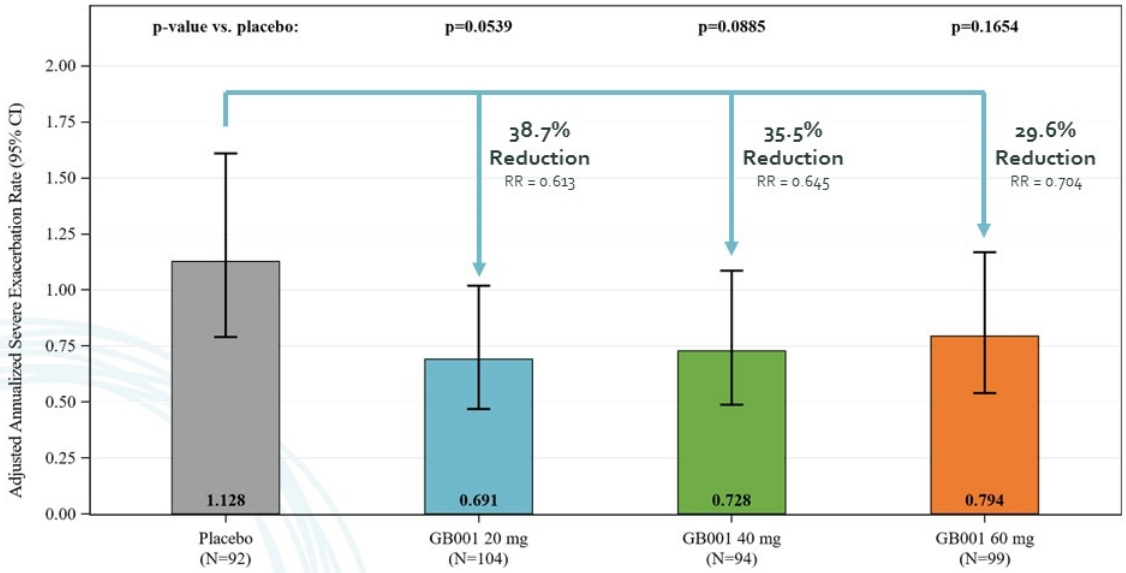
LEDA Secondary Endpoint:
Annualized Severe Asthma Exacerbation Rate (AER)



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

RR = rate ratio

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

AER = Annualized Severe Exacerbation Rate; RR = rate ratio

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Summary of LEDA Safety Profile

- Incidence of adverse events was generally comparable across treatment groups:
  - 65.8% Placebo, 65.8% GB001 20 mg, 69.5% GB001 40 mg, 68.0% GB001 60 mg
- Adverse events of interest (liver chemistry elevations leading to study drug discontinuation) occurred more frequently in GB001 60 mg (4.1%, n=5) than placebo (0.8%, n=1), GB001 20 mg (0.8%, n=1), or GB001 40 mg (1.7%, n=2)
- One adverse event of interest was an SAE of liver chemistry elevations meeting Hy's Law criteria in GB001 60 mg. The patient was asymptomatic during the event, which was reversible and resolved without sequelae

SAE = serious adverse event

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

Preferred Term – n (%)	Placebo (N=120)	GB001 20 mg (N=120)	GB001 40 mg (N=118)	GB001 60 mg (N=122)	Total GB001 (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

- GB001 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 GB001 groups**
- **GB001 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 GB001 40 mg also demonstrating a numeric effect (*23%, p=0.1222*)
- Consistent treatment effect in all GB001 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 GB001'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[1]

Efficacy Threshold for Surveyed Physicians to Find an Oral Asthma Therapeutic to be Compelling[2]

1 (N=200) Survey of allergists and pulmonologists; 2019
2 (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 GB001 40 mg or placebo
- Study failed to meet primary endpoint of change from baseline in SNOT-22 score and secondary endpoints
- GB001 40 mg was generally well tolerated with a similar safety profile as LEDA

Next Steps

- LEDA Phase 2b suggests potential of oral DP2 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-1α 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!

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