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): March 30, 2017

CORBUS PHARMACEUTICALS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37348**	**46-4348039**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

100 River Ridge Drive, Norwood, MA	**02062**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 963-0100

Not Applicable
(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 Instruction 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))

Item 7.01. Regulation FD Disclosure.

On March 30, 2017, Corbus Pharmaceuticals Holdings, Inc. (the "Company") announced that it was hosting a conference call to provide an update on the Company's Phase 2 cystic fibrosis clinical program. A copy of the press release announcing the conference call is attached hereto as Exhibit 99.1. The Company is using the slides attached hereto as Exhibit 99.2 in connection with the conference call.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events

On March 30, 2017, the Company announced positive topline data from its Phase 2 study evaluating multiple doses of anabasum (fka JBT-101 or Resunab) compared to placebo for the treatment of patients with cystic fibrosis ("CF"). The 16-week study dosed 85 adult CF patients with baseline forced expiratory volume in 1 second (FEV1) percent predicted ≥ 40%, who were enrolled without regard to their specific CFTR mutation or infecting pathogens and continued with all baseline treatment regimens.

Anabasum successfully achieved the primary objective of the study by demonstrating an acceptable safety and tolerability profile at all doses with no serious or severe adverse events related to the study drug.

Cystic Fibrosis Foundation Therapeutics, Inc. ("CFFT"), the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation, supported the Phase 2 study.

Anabasum cohorts showed a dose-dependent reduction in a number of acute pulmonary exacerbations defined as those requiring intravenous (IV) antibiotics compared to placebo. Patients in the highest dose cohort of anabasum (20 mg orally, twice per day) had a 75% reduction in the annualized rate of pulmonary exacerbations requiring IV antibiotics compared to placebo cohort.

Additionally, anabasum caused a consistent reduction in multiple inflammatory cell types in sputum, including total leukocytes, neutrophils, eosinophils, and macrophages. Inflammatory mediators, including interleukin-8, neutrophil elastase, and immunoglobulin G, were also reduced in sputum by anabasum in a dose-dependent manner. These patient data provide evidence of biological activity of anabasum in resolving ongoing innate immune responses in lungs of CF patients and support the observed reduction in pulmonary exacerbations.

Serum concentrations of orally-administered anabasum in CF patients were similar to those previously observed in healthy volunteers. FEV1 remained stable throughout the duration of the study in all treatment cohorts.

Study Design and Results

This was an international, multi-center, double-blinded, randomized, placebo-controlled Phase 2 study supported in part by a $5 million Development Award from Cystic Fibrosis Foundation Therapeutics, Inc. The primary objective of the study was to test safety and tolerability of anabasum in adults with CF who had FEV1 ≥ 40 percent predicted and remained on background CF medications, including prophylactic antibiotics. Patients were enrolled without regard to their CFTR mutation, infecting pathogen, or baseline treatment. Acute pulmonary exacerbations requiring IV antibiotic treatment were captured as an event of special interest during the study. Secondary objectives included measurement of plasma concentrations and metabolites of anabasum and change from baseline in FEV1 percent predicted and Cystic Fibrosis Questionnaire-Revised Respiratory Symptom score. Additional outcomes included change from baseline in sputum and blood biomarkers of inflammation.

Eighty-five patients on stable standard-of-care medications were dosed with anabasum or placebo at 21 sites in the U.S. and Europe and treated for 84 days, with a follow-up period of 28 days off treatment. During the first part of the study (Weeks 1-4) patients were randomized to placebo (n = 35), 1 mg/day anabasum (n = 26) or 5 mg/day anabasum (n = 24). During the second part of the study (Weeks 5-12), anabasum patients were randomly assigned to anabasum 20 mg once per day (n = 31) or anabasum 20 mg twice per day (n = 30) with 11 patients from the placebo cohort randomly assigned to the 2 anabasum cohorts. Twenty-four patients continued to receive placebo in Weeks 5-12.

After dosing, 10 patients discontinued early from the study; 3 patients withdrew consent, 5 withdrew due to adverse events (2 on placebo, 3 on anabasum), 1 subject was lost to follow-up and 2 patients withdrew for treatment-unrelated reasons. Baseline characteristics were similar between anabasum and placebo cohorts.

Safety

During Weeks 1-4, treatment-emergent adverse events (TEAEs) occurred in 14 (54%) of patients in the anabasum 1 mg cohort, 13 (54%) of the anabasum 5 mg cohort and 15 (43%) of the placebo cohort. During Weeks 5-12, TEAEs occurred in 21 (68%) patients in the anabasum 20 mg once per day cohort, 19 (63%) of the anabasum 20 mg twice per day cohort and 14 (58%) of the placebo cohort. Six serious adverse events (SAEs) occurred the anabasum-treated patients and 6 SAEs occurred in placebo-treated patients. Three severe TEAEs occurred in the anabasum-treated patients and 4 in placebo-treated patients. None of the serious or severe TEAEs were assessed by site investigators to be related to study drug. The most common drug-related adverse event that occurred in more than 2 individuals was mild dry mouth observed in 8 (13%) of anabasum patients and no placebo patients. As expected, the respiratory system was the most common source of TEAEs overall.

Cmax values for anabasum were similar to those previously measured in healthy human volunteers after similar doses of anabasum.

Acute Pulmonary Exacerbations

Treatment with anabasum yielded a dose-dependent reduction in acute pulmonary exacerbations. The highest dose of anabasum (20 mg twice per day) was associated with a 75% reduction in the annualized rate of pulmonary exacerbations requiring treatment with IV antibiotics, compared to placebo. Similar levels of reduction were also observed in acute pulmonary exacerbations defined by new or worsening respiratory symptoms requiring treatment with any antibiotic.

Inflammatory Cells and Biomarkers

Patients treated with anabasum 20 mg twice a day showed a consistent reduction in multiple inflammatory cell types in their sputum at the end of active treatment compared to placebo, including total leukocytes, neutrophils, eosinophils, lymphocytes and macrophages. They also had a consistent reduction in inflammatory mediators in their sputum including interleukin-8, neutrophil elastase and immunoglobulin G.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 30, 2017 by Corbus Pharmaceuticals Holdings, Inc.
99.2	Presentation of Corbus Pharmaceuticals Holdings, Inc.

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 hereunto duly authorized.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Dated: March 30, 2017

By: */s/ Yuval Cohen*
Name: Yuval Cohen
Title: Chief Executive Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated March 30, 2017 by Corbus Pharmaceuticals Holdings, Inc.
99.2	Presentation of Corbus Pharmaceuticals Holdings, Inc.

Exhibit 99.1

Corbus Pharmaceuticals Reports Positive Topline Data Demonstrating Anabasum Reduces Acute Pulmonary Exacerbations and Multiple Inflammatory Biomarkers in Phase 2 Study in Patients with Cystic Fibrosis

– Anabasum achieves primary study objective of acceptable safety and tolerability –
– Management to host conference call and webcast today at 8:00 a.m. EDT –

Norwood, MA (March 30, 2017) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, today announced positive topline data from its Phase 2 study evaluating multiple doses of anabasum (fka JBT-101 or Resunab) compared to placebo for the treatment of patients with cystic fibrosis ("CF"). The 16-week study dosed 85 adult CF patients with baseline forced expiratory volume in 1 second (FEV1) percent predicted ≥ 40%, who were enrolled without regard to their specific CFTR mutation or infecting pathogens and continued with all baseline treatment regimens.

Anabasum successfully achieved the primary objective of the study by demonstrating an acceptable safety and tolerability profile at all doses with no serious or severe adverse events related to the study drug.

Cystic Fibrosis Foundation Therapeutics, Inc. ("CFFT"), the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation, supported the Phase 2 study.

Anabasum cohorts showed a dose-dependent reduction in a number of acute pulmonary exacerbations defined as those requiring intravenous (IV) antibiotics compared to placebo. Patients in the highest dose cohort of anabasum (20 mg orally, twice per day) had a 75% reduction in the annualized rate of pulmonary exacerbations requiring IV antibiotics compared to placebo cohort.

Additionally, anabasum caused a consistent reduction in multiple inflammatory cell types in sputum, including total leukocytes, neutrophils, eosinophils, and macrophages. Inflammatory mediators, including interleukin-8, neutrophil elastase, and immunoglobulin G, were also reduced in sputum by anabasum in a dose-dependent manner. These patient data provide evidence of biological activity of anabasum in resolving ongoing innate immune responses in lungs of CF patients and support the observed reduction in pulmonary exacerbations.

Serum concentrations of orally-administered anabasum in CF patients were similar to those previously observed in healthy volunteers. FEV1 remained stable throughout the duration of the study in all treatment cohorts.

"We are delighted that in this first-in-CF patient study, anabasum demonstrated an acceptable safety profile and potential clinical benefit in reducing acute pulmonary exacerbations in CF patients and that these findings are supported by biomarker data consistently showing reduction of inflammation in the lungs," stated Yuval Cohen, PhD, CEO of Corbus. "These positive results coincide with our third anniversary as a company and come on the heels of positive data from our Phase 2 study in systemic sclerosis. We are very grateful to all the patients, investigators and clinical staff who participated in this study and to Cystic Fibrosis Foundation Therapeutics for their support."

"The reduction in acute pulmonary exacerbations along with reductions in inflammatory cells and inflammatory mediators in sputum demonstrate the potential for anabasum as a new inflammation-targeting therapeutic in cystic fibrosis that can broadly target patients without regard to their specific CFTR mutations. The outcomes of this 16-week study indicate that anabasum has the potential to address the important unmet need for treatments that target inflammation in CF," commented James Chmiel, M.D., M.P.H., Professor of Pediatrics, Case Western Reserve University, Associate Director of the LeRoy W. Matthews Cystic Fibrosis Center at University Hospitals Rainbow Babies and Children's Hospital in Cleveland, and Principle Investigator of Corbus' Phase 2 cystic fibrosis clinical study.

Study Design and Results

This was an international, multi-center, double-blinded, randomized, placebo-controlled Phase 2 study supported in part by a $5 million Development Award from Cystic Fibrosis Foundation Therapeutics, Inc. The primary objective of the study was to test safety and tolerability of anabasum in adults with CF who had FEV1 ≥ 40 percent predicted and remained on background CF medications, including prophylactic antibiotics. Patients were enrolled without regard to their CFTR mutation, infecting pathogen, or baseline treatment. Acute pulmonary exacerbations requiring IV antibiotic treatment were captured as an event of special interest during the study. Secondary objectives included measurement of plasma concentrations and metabolites of anabasum and change from baseline in FEV1 percent predicted and Cystic Fibrosis Questionnaire-Revised Respiratory Symptom score. Additional outcomes included change from baseline in sputum and blood biomarkers of inflammation.

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Next steps

Barbara White, MD, Chief Medical Officer of Corbus, stated, “We are delighted that anabasum demonstrated a safety profile that was well tolerated by the CF patients in this study, especially given the challenges in safely targeting inflammation in CF. In a study of just 12-weeks of active dosing, we are especially encouraged by the consistency in data that couple clinical benefit in pulmonary exacerbations with improvement in the inflammatory response in the lungs. We believe these findings reflect the underlying mechanism of action of anabasum in activating resolution of innate immune responses without immunosuppression.”

Corbus will engage in further evaluation of the data and design of the next clinical trial in partnership with CF experts, the Cystic Fibrosis Foundation Therapeutics, Inc., Cystic Fibrosis Therapeutic Development Network and European Cystic Fibrosis Society Clinical Trials Network. Thereafter, Corbus will enter into discussions with the relevant regulatory agencies.

Anabasum was granted Orphan Drug Designation and Fast Track status for the treatment of CF by the FDA in 2015 and Orphan Drug Status from the European Medicines Agency (EMA) in 2016.

For more information on the Phase 2 study with anabasum for the treatment of CF, please visit ClinicalTrials.gov and reference Identifier NCT02465450.

Conference Call and Webcast Information

Corbus management will host a conference call for investors, analysts and other interested parties today, March 30, 2017 at 8:00 am EDT to discuss the topline data from the Phase 2 Study evaluating anabasum for the treatment of CF.

The conference call and live webcast will be accompanied by presentation slides. To participate in the call, please dial (877) 407-3978 (domestic) or (412) 902-0039 (international). The live webcast and accompanying slides will be accessible on the Events page of the Investors section of Corbus website, www.corbuspharma.com, and will be archived for 60 days.

About Cystic Fibrosis

Cystic Fibrosis ("CF") is a chronic, life-threatening, genetic disease caused by inheriting two dysfunctional CFTR genes that normally regulate salt and water movement across cells in the respiratory and digestive systems. CF affects approximately 30,000 patients in the U.S and 75,000 patients worldwide. People with CF have thick, sticky mucus that clogs their airways, with recurrent bacterial infections and chronic inflammation in their lungs. In the gastrointestinal tract, they also have mucus accumulation, bacterial overgrowth, and inflammation. The dysfunctional CFTR genes cause an exaggerated inflammatory response that compounds the damage from a coexisting infection in the lungs and gut. CF results in destruction of lung tissue, lung fibrosis, pancreatic insufficiency, CF-related diabetes, malabsorption, malnutrition, growth retardation, and liver disease, including cirrhosis. The harmful inflammation and accompanying fibrosis in CF damages multiple organs, impairs organ function, reduces health-related quality of life, and can lead to death.

About Anabasum

Anabasum is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to the CB2 receptor expressed on activated immune cells and fibroblasts. CB2 activation triggers endogenous pathways that resolve inflammation and halt fibrosis. Preclinical and Phase 1 studies have shown anabasum to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Anabasum is designed to trigger the production of "Specialized Pro-resolving Lipid Mediators" that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. Anabasum has direct effects on fibroblasts to halt tissue scarring. In effect, anabasum triggers endogenous pathways to turn "off" chronic inflammation and fibrotic processes, without causing immunosuppression.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Our lead product candidate, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Anabasum is currently in Phase 2 clinical studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis, with a fourth Phase 2 trial in systemic lupus erythematosus planned to commence during the first half of 2017.

For more information, please visit www.CorbusPharma.com and connect with the Company on Twitter, LinkedIn, Google+ and Facebook.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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Source: Corbus Pharmaceuticals Holdings, Inc.

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Exhibit 99.2


CORBUS
PHARMACEUTICALS
TOP-LINE DATA
JBT101-CF-001
PHASE 2 STUDY IN CYSTIC FIBROSIS
March 30, 2017
NASDAQ:CRBP | CORBUSPHARMA.COM

HIGHLIGHTS

- First in patient study n=85 CFTR mutation agnostic
- Primary endpoint achieved with acceptable safety and tolerability
- Reduction of multiple lung inflammatory cells and mediators
- Clinical benefit seen in acute pulmonary exacerbations
- Data support further clinical development

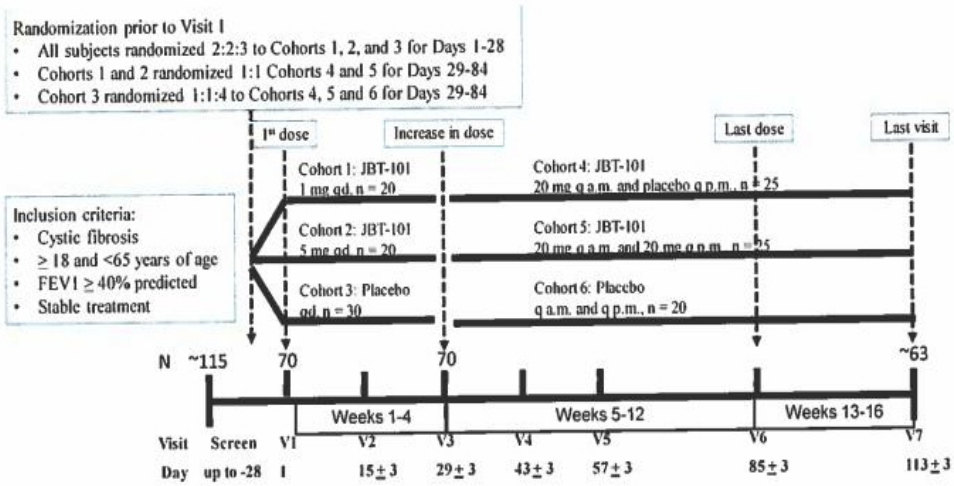
TRIAL DESIGN

JBT101-CF-001 PHASE 2 TRIAL DESIGN

- Double-blind, randomized, placebo-controlled, 16-week trial
- 21 clinical sites in the US, UK, Germany, Italy, and Poland
- Adults ages 18 to 65 with cystic fibrosis (CF)
- Eligibility criteria
  - All mutations allowed
  - FEV1 ≥ 40% predicted
  - Stable treatment for CF, with background medications including prophylactic antibiotics allowed
  - No intravenous antibiotics for 14 days prior to Day 1

- Supported by a $5MM Development Award from the Cystic Fibrosis Foundation (CFF)
- Designed with the CFF Therapeutic Development Network and European CF Society Clinical Trials Network
- Data Safety Monitoring Board members from CFF and ECFS

ANABASUM TRIAL DESIGN



- All 40 of the 1 mg and 5 mg anabasum-treated subjects in Weeks 1-4 were re-randomized to continue on anabasum in Weeks 5-12
- 10 of 30 placebo-treated subjects in Weeks 1-4 were re-randomized to receive anabasum in Weeks 5-12
- 20 of 30 placebo-treated subjects in Weeks 1-4 were continued on placebo in Weeks 5-12

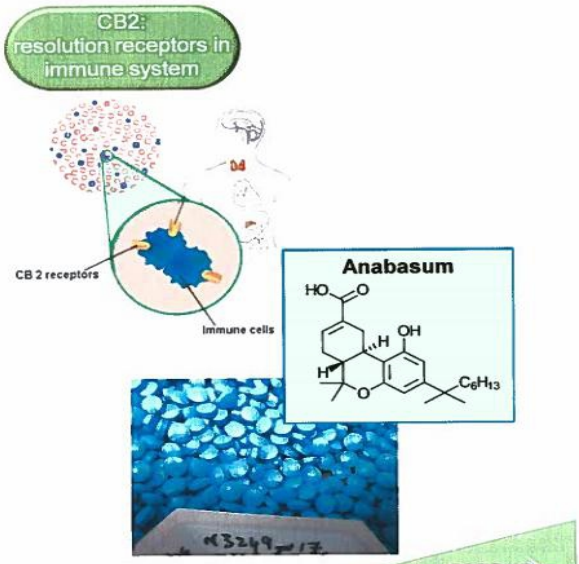
OBJECTIVES

Primary Objective

- Evaluate safety and tolerability

Secondary / Exploratory Objectives

- Evaluate plasma concentrations and metabolites
- Evaluate efficacy using FEV1, lung clearance index, and CFQ-R
- Evaluate blood and sputum biomarkers of disease activity and inflammation
- Evaluate microbiome in sputum
- Evaluate plasma metabolipidomic profile



PRIMARY ENDPOINT: SAFETY AND TOLERABILITY OUTCOMES

Safety

- Treatment-emergent adverse events
- Changes in vital signs, laboratory safety testing, electrocardiograms, Addiction Research Center Inventory – Marijuana questionnaire (ARCI-M)

Events of special interest:

- Acute pulmonary exacerbations requiring IV antibiotics
- Elevation in transaminases > 3x ULN with bilirubin > 1.5 X ULN
- QTc prolongation > 500 msec and > 60 msec from baseline

Tolerability

- Discontinuation of study product because of treatment-emergent adverse events

SAMPLE SIZE

Safety

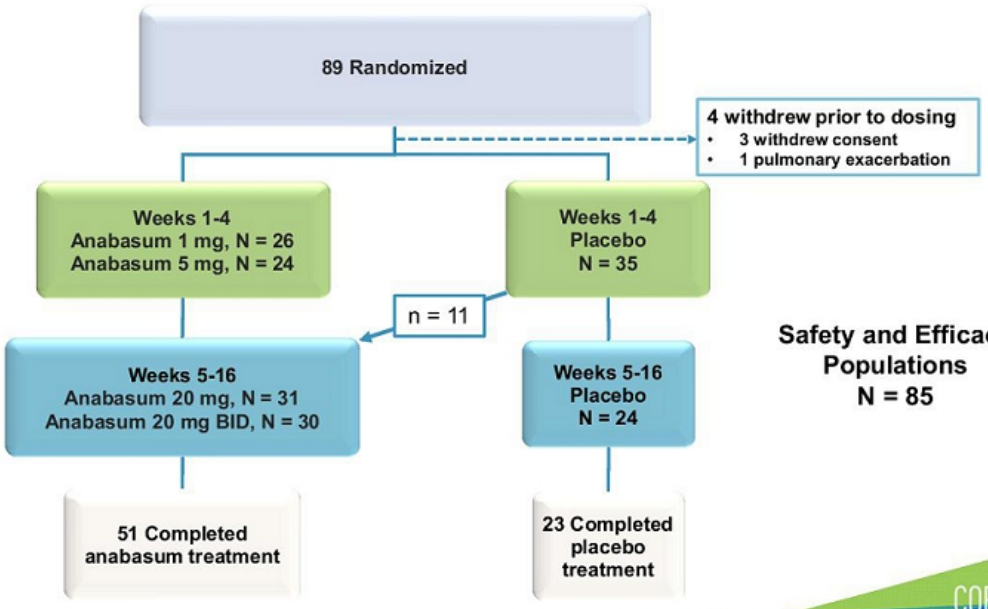
- 25 subjects in a treatment group yields ≥ 95% probability of detecting adverse events that occur at a true rate of 12% or higher

Efficacy

- 25 subjects within an active group and 20 subjects within the placebo group yields 80% power to detect a statistically significant difference in an efficacy endpoint assuming a 1-sided alpha = 0.10 and an effect size (difference in means/common standard deviation) of 0.64

SUBJECT DISPOSITION AND BASELINE CHARACTERISTICS

STUDY POPULATIONS



WITHDRAWALS FROM THE STUDY IN SAFETY POPULATION

Status	Subjects, n (%)			
	Weeks 1-4		Weeks 5-12	
	Anabasum N = 50	Placebo N = 35	Anabasum N = 61	Placebo N = 24
Withdrew consent	0	0	2 (3.3)	0
Adverse event	1 (2.0)	1 (2.9)	3 (4.9)	0
Lost to follow-up	1 (2.0)	0	0	0
Other	1 (2.0)	0	1 (1.6)	0

No withdrawals for lack of efficacy or non-compliance

BASELINE DEMOGRAPHICS OF SUBJECTS

Characteristic	Weeks 1-4			Weeks 5-12		
	Anabasum 1 mg QD N = 26	Anabasum 5 mg QD N = 24	Placebo N = 35	Anabasum 20 mg QD N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24
Male, %	65.4	50.0	48.6	51.6	50.0	62.5
Age, mean (range)	26.9 (19-52)	28.8 (18-62)	29.2 (18-59)	28.5 (18-62)	26.8 (19-46)	30.2 (18-59)
Caucasian, %	96.2	100	94.3	96.8	96.7	95.8
Not Hispanic or Latino, %	100	91.7	100	96.8	96.7	100

BASELINE DISEASE CHARACTERISTICS OF SUBJECTS

Characteristic	Weeks 1-4			Weeks 5-8		
	Anabasum 1 mg QD N = 26	Anabasum 5 mg QD N = 24	Placebo N = 35	Anabasum 20 mg QD N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24
F508D: 2 alleles/ 1 alleles/ 0 alleles	13/9/4 50%/35%/15%	14/7/3 58%/29%/13%	21/10/4 60%/29%/11%	14/12/5 45%/39%/16%	20/7/3 67%/23%/19%	14/7/3 58%/29%/13%
FEV1 % predicted, mean (range)	65.6 (31.5 – 101.8)	63.1 (29.6 – 89.3)	65.3 (39.2 – 113.3)	64.2 (26.8 – 103.2)	64.0 (31.1 – 98.4)	64.9 (25.7 – 106.8)
Lowest FEV1 % predicted last year, mean (range)	64.3 (10 – 100)	63.9 (32 – 98)	60.2 (10 – 93)	62.9 (10 – 100)	62.8 (10 – 98)	61.7 (33 – 93)
Number of exacerbations in last year, mean (range)	0.73 (0 – 2)	0.75 (0 – 3)	0.63 (0 – 3)	0.87 (0 – 2)	0.67 (0 – 3)	0.50 (0 – 3)
CRQ-R Respiratory Symptom Score, mean (range)	65.8 (33.3 – 94.4)	69.9 (16.7 – 100)	71.6 (27.8 – 88.9)	74.4 (27.8 – 100)	66.9 (22.2 – 100)	76.6 (38.9 – 94.4)
Pancreatic insufficiency, n (%)	21 (83)	20 (83)	26 (74)	24 (77)	26 (87)	17 (71)
Sinusitis, n (%)	16 (46)	11 (46)	19 (54)	16 (52)	17 (57)	13 (54)
Nasal polyps, n (%)	8 (31)	4 (17)	12 (34)	7 (23)	9 (30)	8 (33)
Diabetes mellitus, n (%)	4 (15)	3 (13)	7 (20)	3 (10)	6 (20)	5 (21)

BASELINE MEDICATIONS OF SUBJECTS

Medication	Subjects, n (%)					
	Anabasum 1 mg QD N = 26	Anabasum 5 mg QD N = 24	Placebo N = 35	Anabasum 20 mg QD N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24
Azithromycin	8 (30.1)	16 (66.7)	21 (60.0)	14 (45.2)	13 (43.3)	14 (58.3)
Inhaled or oral prophylactic antibiotics excluding azithromycin	12 (46.2) inhaled 5 (19.2) oral 13 (50.0) total	10 (41.7) inhaled 3 (12.5) oral 12 (50.0) total	16 (47.5) inhaled 0 oral 16 (45.5) total	16 (51.6) inhaled 3 (9.7) oral 18 (58.1) total	10 (33.3) inhaled 2 (6.7) oral 12 (40.0) total	11 (45.8) inhaled 0 oral 11 (45.8) total
Lumacaftor/ivacaftor	6 (23.1)	7 (29.2)	8 (22.9)	6 (19.4)	9 (30.0)	6 (25.0)
Ivacaftor	2 (7.7)	0	1 (2.9)	1 (3.2)	2 (6.7)	0
Dornase alfa	23 (88.5)	19 (79.1)	29 (82.9)	27 (87.1)	25 (83.3)	19 (79.2)

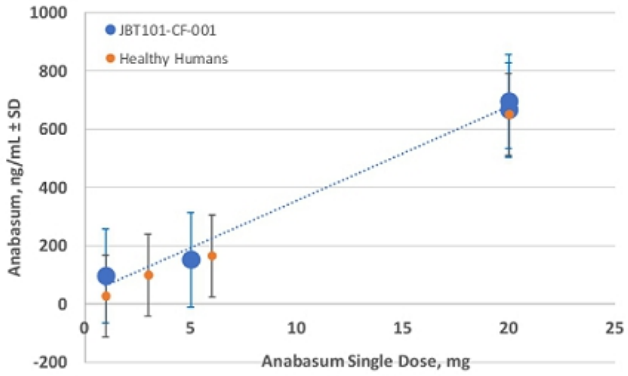
BASELINE DEMOGRAPHICS AND CHARACTERISTICS: CONCLUSIONS

- Baseline demographics and disease characteristics are similar among treatment groups
- Differences are minor among treatment groups in gender distribution, previous number of acute pulmonary exacerbations in the last year, CFQ-R Respiratory Symptoms score, and use of azithromycin

PLASMA CONCENTRATIONS

ANABASUM PLASMA CONCENTRATIONS

Anabasum C_{max} plasma concentration was measured 3 ± 0.5 hours after the first dose of 1 mg, 5 mg, or 20 mg and compared to those in healthy human volunteers



- The anabasum dose: exposure relationship is approximately linear in the therapeutic range
- The peak plasma concentrations achieved in CF patients are consistent with C_{max} plasma concentrations in healthy volunteers at the same dose

SAFETY RESULTS: TREATMENT-EMERGENT ADVERSE EVENTS

SUBJECTS WITH TREATMENT EMERGENT ADVERSE EVENTS BY DOSE

Treatment-emergent Adverse Event (TEAE)	Subjects, n (%)								
	Weeks 1-4			Weeks 5-12			Post Treatment		
	Anabasum 1 mg N = 26	Anabasum 5 mg N = 24	Placebo N = 35	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24
Any TEAE	14 (53.8)	13 (54.2)	15 (42.9)	21 (67.7)	19 (63.3)	14 (58.3)	15 (48.4)	15 (50.0)	11 (45.8)
Deaths	0	0	0	0	0	0	0	0	0
Serious Unexpected Severe Adverse Reaction	0	0	0	0	0	0	0	0	0
Serious TEAEs	1 (3.8)	0	2 (5.7)	3 (9.7)	2 (6.7)	1 (4.2)	2 (6.5)	1 (3.3)	3 (12.5)
Serious TEAEs related to study drug	0	0	0	0	0	0	0	0	0
Severe TEAEs	0	0	1 (2.9)	0	2 (6.7)	1 (4.2)	1 (3.2)	0	2 (8.3)
Severe TEAEs related to study drug	0	0	0	0	0	0	0	0	0
Any related TEAE	3 (11.5)	4 (16.7)	3 (8.6)	8 (25.8)	4 (13.3)	5 (20.8)	0	1 (3.3)	1 (4.2)
TEAEs leading to Study Discontinuation	1 (3.8)	0	1 (2.9)	1 (3.2)	2 (6.7)	0	0	0	0

SUBJECTS WITH TREATMENT-EMERGENT ADVERSE EVENTS SERIOUS ADVERSE EVENTS

Anabasum
- 6 pulmonary exacerbations

Placebo
- 7 pulmonary exacerbations
- 1 hand fracture
- 1 thrombosis in device

- No increase in pulmonary exacerbations with anabasum treatment
- No serious adverse event was assessed as related to study drug by the site investigators

SUBJECTS WITH TEAEs BY MAXIMUM SEVERITY AND WEEKS

System	Subjects with TEAEs								
	Weeks 1-4			Weeks 5-12			Post Treatment Weeks 13-16		
	Anabasum 1 mg N = 26	Anabasum 5 mg N = 24	Placebo N = 35	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Post Placebo N = 24
Total number of subjects with any TEAE	14 (53.8)	13 (54.2)	15 (42.9)	21 (67.7)	19 (63.3)	14 (58.3)	15 (48.4)	15 (50.0)	11 (45.8)
• Maximum severity = Mild	9 (34.6)	7 (29.2)	11 (31.4)	11 (35.5)	9 (30.0)	4 (16.7)	7 (22.6)	5 (16.7)	5 (20.8)
• Maximum severity = Moderate	5 (19.2)	6 (25.0)	3 (8.6)	10 (32.3)	8 (26.7)	9 (37.5)	7 (22.6)	10 (33.3)	4 (16.7)
• Maximum severity = Severe	0	0	1 (2.9)	0	2 (6.7)	1 (4.2)	1 (3.2)	0	2 (8.3)

Severe TEAEs: Anabasum

- Pulmonary exacerbation: D29
- Pulmonary exacerbation: D79
- Pulmonary exacerbation: D85
- Pulmonary exacerbation: D106

Severe TEAEs: Placebo

- Thrombosis in device: D61
- Pulmonary exacerbation: D65
- Pulmonary exacerbation: D72

No severe adverse event was assessed as related to study drug by the site investigators

NUMBER OF TEAEs BY MAXIMUM SEVERITY AND WEEKS

System	Subjects with TEAEs								
	Weeks 1-4			Weeks 5-12			Post Treatment Weeks 13-16		
	Anabasum 1 mg N = 26	Anabasum 5 mg N = 24	Placebo N = 35	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Post Placebo N = 24
Total number of subjects with any TEAE	14 (54)	13 (54)	17 (49)	21 (68)	19 (63)	14 (58)	14 (45)	15 (50)	11 (46)
Total number of TEAEs	24	27	34	54	44	21	26	20	12
• Maximum severity = Mild	18 (75)	21 (78)	25 (74)	43 (80)	30 (68)	7 (33)	14 (54)	9 (45)	7 (58)
• Maximum severity = Moderate	6(25)	6 (22)	8 (24)	10 (23)	12 (27)	12 (57)	12 (46)	11 (55)	4 (33)
• Maximum severity = Severe	0	0	1 (3)	1 (2)	2 (5)	2 (10)	0	0	1 (8)

- The number of TEAEs is slightly increased in anabasum-treated subjects compared to placebo
- The increase is in mild TEAEs, not moderate or severe TEAEs

TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO DISCONTINUATION FROM STUDY

5 Adverse Events

- 3 related to study drug as assessed by the site investigator
  - Decrease in focus for 4 hours after taking drug: Mild, intermittent, D4-15 – **placebo** discontinued D10, study discontinued D37
  - Lack of cognitive clarity: Mild, intermittent, D2-11 – **anabasum 1 mg QD** discontinued D10, study discontinued D50
  - Feeling unmotivated: Moderate, continuous, D61-74 – **anabasum 20 mg BID** discontinued Day 68, study discontinued D99

- 2 not related to study drug as assessed by the site investigator
  - Thrombosis in device: Severe, single event, D61 – **anabasum 20 mg BID** and study discontinued Day 62
  - Pulmonary exacerbation: Moderate, continuous, D37-70 – **anabasum 20 mg QD** discontinued D58, study discontinued D85

SUBJECTS WITH TEAEs BY SYSTEM

System	Subjects with TEAEs, n (%)					
	Weeks 1-4			Weeks 5-13		
	Anabasum 1 mg N = 26	Anabasum 5 mg N = 24	Placebo N = 35	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24
Total number of TEAEs	23	25	30	59	49	24
Total number of subjects with any TEAE	14 (53.8)	13 (54.2)	15 (42.9)	21 (57.7)	19 (63.3)	14 (58.3)
Cardiac disorders	0	0	0	0	1 (3.3)	0
Gastrointestinal	1 (3.8)	4 (16.7)	1 (2.9)	6 (19.4)	5 (16.7)	2 (8.3)
General disorders	1 (3.8)	2 (8.3)	1 (2.9)	7 (22.6)	4 (13.3)	0
Hepatobiliary disorders	0	0	0	0	0	1 (4.2)
Immune system disorders	0	0	2 (5.7)	0	0	0
Infections and infestations	5 (19.2)	4 (16.7)	5 (14.3)	15 (48.4)	9 (30.0)	9 (37.5)
Injury, poisoning and procedural complications	1 (3.8)	1 (4.2)	1 (2.9)	0	1 (3.3)	0
Investigations	1 (3.8)	0	0	3 (9.7)	0	1 (4.2)
Metabolism and nutrition disorders	0	1 (4.2)	1 (2.9)	1 (3.2)	3 (10.0)	0
Musculoskeletal and connective tissue diseases	2 (7.7)	0	0	1 (3.2)	0	1 (4.2)
Nervous system	3 (11.5)	0	1 (2.9)	5 (16.1)	2 (6.7)	1 (4.2)
Psychiatric disorders	0	0	2 (5.7)	2 (6.5)	1 (3.3)	1 (4.2)
Renal and urinary	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	5 (19.2)	7 (29.2)	5 (14.3)	7 (22.6)	8 (26.7)	6 (25.0)
Skin and subcutaneous	0	1 (3.8)	0	0	0	0
Vascular disorders	0	0	1 (2.9)	0	0	0

TEAEs IN ≥ 2 SUBJECTS IN ANY GROUP DURING ACTIVE TREATMENT

System	Subjects with TEAEs					
	Weeks 1-4			Weeks 5-13		
	Anabasum 1 mg N = 26	Anabasum 5 mg N = 24	Placebo N = 35	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24
Total number of TEAEs	23	25	30	59	49	24
Total number of subjects with any TEAE	14 (53.8)	13 (54.2)	15 (42.9)	21 (57.7)	19 (63.3)	14 (58.3)
Dry mouth	**0**	**2 (8.3)**	**0**	**4 (12.9)**	**2 (6.7)**	**0**
Fatigue	1 (3.8)	1 (4.2)	0	2 (6.5)	2 (6.7)	0
Malaise	1 (3.8)	0	0	2 (6.5)	2 (6.7)	0
Pyrexia	0	1 (4.2)	0	2 (6.5)	0	0
Nasopharyngitis	1 (3.8)	0	2 (5.7)	2 (6.5)	1 (3.3)	0
Upper respiratory infection	2 (7.7)	2 (8.3)	0	3 (9.7)	3 (10.0)	2 (8.3)
Decreased appetite	0	0	0	1 (3.2)	3 (10.0)	0
Headache/ migraine	0	0	1 (2.9)	2 (6.5)	0	0
Cognitive disorder	**2 (7.7)**	**0**	**1 (2.9)**	**0**	**0**	**0**
Lethargy	0	0	1 (2.9)	2 (6.5)	1 (3.3)	0
Cough	1 (3.8)	4 (16.7)	4 (11.4)	1 (3.2)	3 (10.0)	4 (16.7)
Haemoptysis	1 (3.8)	1 (4.2)	2 (5.7)	4 (12.9)	3 (10.0)	0
Dizziness	0	0	0	1 (3.2)	0	0

Bold print indicates at least 2 TEAEs were considered related to study drug

HEMATOLOGY LABORATORY INVESTIGATIONS

Data are shown for combined anabasum 20 mg QD and 20 mg BID subjects (N = 58) and placebo subjects (N = 22) from baseline at Visit 3 when subjects start on these doses

Investigation	Treatment	Baseline Mean (SD)	Change from baseline Mean (SD)	
			Week 12	Week 16
Hematocrit, %	Anabasum	43.7 (4.1)	-0.80 (2.2)	-0.22 (2.9)
	Placebo	44.1 (4.7)	0.20 (4.3)	-0.46 (4.3)
Leukocytes x 10^9/L	Anabasum	8.2 (3.1)	-0.07 (2.7)	0.03 (2.8)
	Placebo	8.4 (3.7)	0.23 (2.5)	0.66 (2.3)
Neutrophils x 10^9/L	Anabasum	5.5 (2.9)	-0.01 (2.3)	0.10 (2.9)
	Placebo	5.5 (3.4)	-0.22 (2.4)	0.53 (2.5)
Lymphocytes x 10^9/L	Anabasum	2.1 (0.7)	-0.21 (0.5)	-0.14 (0.5)
	Placebo	2.2 (0.7)	-0.09 (0.5)	-0.03 (0.4)
Platelets x 10^9/L	Anabasum	273.4 (71.3)	-2.5 (39.2)	-0.4(44.1)
	Placebo	284.5 (117.3)	-2.1 (66.4)	3.0 (59.3)

No significant difference between anabasum and placebo in hematology laboratory investigations

CLINICAL CHEMISTRY LABORATORY INVESTIGATIONS

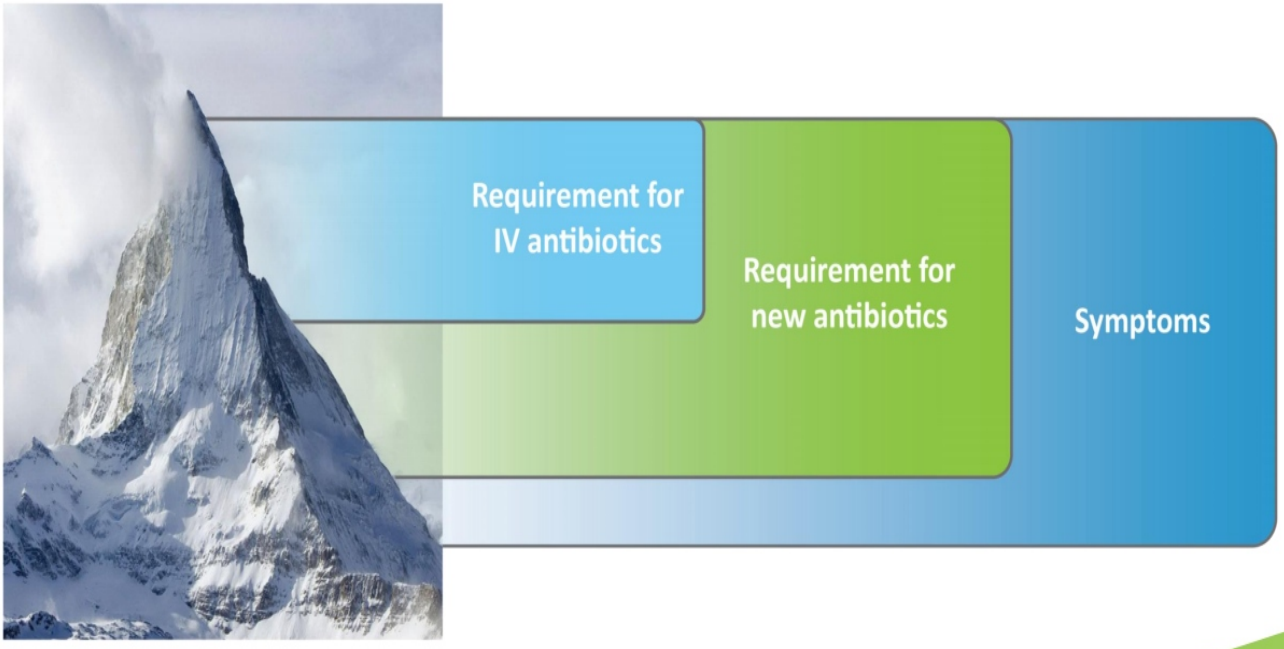
Data are shown as change from baseline for combined anabasum 20 mg QD and 20 mg BID subjects (N = 58) and placebo subjects (N = 22) from baseline when subjects start on these doses

Investigation	Treatment	Baseline Mean (SD)	Change from baseline Mean (SD)	
			Week 12	Week 16
Alanine aminotransferase, U/L	Anabasum	24.9 (20.0)	-0.9 (27.2)	-1.5 (15.6)
	Placebo	25.1 (12.8)	-0.3 (8.8)	-1.3 (9.0)
Alkaline phosphatase U/L	Anabasum	96.1(32.0)	1.7 (20.0)	6.7 (25.6)
	Placebo	97.8 (33.7)	4.9 (16.6)	4.0 (11.5)
Aspartate aminotransferase, U/L	Anabasum	28.4 (49.3)	-7.2 (51.4)	-7.0 (49.9)
	Placebo	26.0 (15.2)	-1.3 (12.3)	-1.1 (13.5)
Gamma glutamyl transferase, U/L	Anabasum	16.6 (12.2)	3.2 (13.9)	1.6 (6.6)
	Placebo	25.5 (18.4)	3.9 (15.2)	0.9 (8.1)

No significant difference between anabasum and placebo in chemistry laboratory investigations

ACUTE PULMONARY EXACERBATIONS

ACUTE PULMONARY EXACERBATIONS

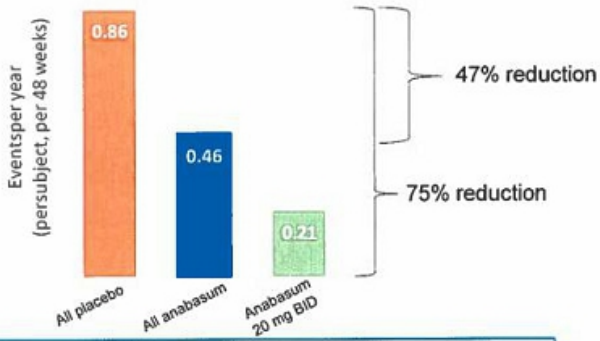


ACUTE PULMONARY EXACERBATION REQUIRING TREATMENT WITH INTRAVENOUS ANTIBIOTICS

Captured as an event of special interest. Assignment to treatment arm is by time of onset of symptoms that required intravenous antibiotic treatment

Treatment Group	Subjects, n (%)	
	Weeks 1-4	Weeks 5-12
Placebo, N = 35	3 (8.6)	
Anabasum 1 mg, N = 26	1 (7.7)	
Anabasum 5 mg, N = 24	1 (4.2)	
Placebo, N = 24		3 (16.7)
Anabasum 20 mg, N = 31		3 (6.5)
Anabasum 20 mg BID, N = 30		1 (3.3)

Acute Pulmonary Exacerbations (Intravenous Antibiotics) Per Year

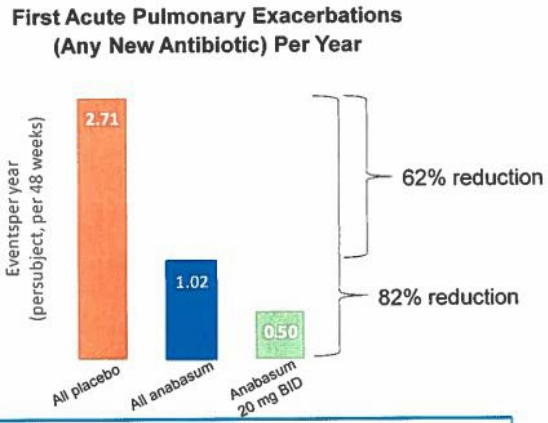


- Anabasum treatment is associated with a dose dependent-reduction in rate of acute pulmonary exacerbations requiring intravenous antibiotics per 48 weeks
- There was a 75% reduction in the 48 week rate of acute pulmonary exacerbations for anabasum at 20 mg BID

FIRST ACUTE PULMONARY EXACERBATION DEFINED AS TREATMENT WITH NEW ANTIBIOTICS

A broader look at acute pulmonary exacerbations as defined by treatment with new antibiotics for respiratory system symptoms

Treatment Group, N at risk for 1st exacerbation	Subjects n/N at risk (%)		
	Weeks 1-4	Weeks 5-12	Post-treatment
Placebo, N = 34	6 (25.0)		
Anabasum 1 mg, N = 22	3 (13.6)		
Anabasum 5 mg, N = 23	3 (13.0)		
Placebo, N= 18		9 (50.0)	
Anabasum 20 mg, N = 25		4 (16.0)	
Anabasum 20 mg BID, N = 24		2 (8.3)	
Placebo, N = 9			2 (22.2)
Anabasum 20 mg, N = 20			6 (30.0)
Anabasum 20 mg BID, N = 22			2 (9.1)



- Anabasum treatment is associated with a dose dependent-reduction in rate of acute pulmonary exacerbations treated with any new antibiotic per 48 weeks
- There was a 82% reduction in the 48 week rate of acute pulmonary exacerbations treated with any new antibiotic for anabasum at 20 mg BID

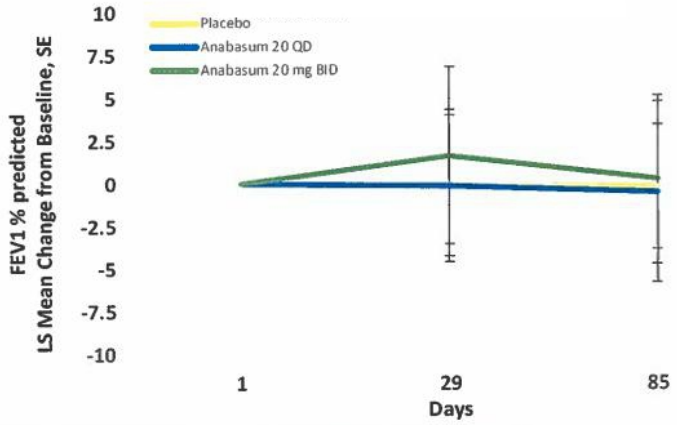
FEV1

FEV1 PERCENT PREDICTED VALUES

Weeks 1-12

Value	Treatment	Baseline Mean (range)
FEV1 % predicted	Placebo, N = 24	66.6
	Anabasum 20 mg, N = 31	64.6
	Anabasum 20 mg BID, N = 30	62.2

LS Mean Change (SE) from Baseline



Mean FEV1 values were stable throughout the study for both anabasum and placebo-treated subjects

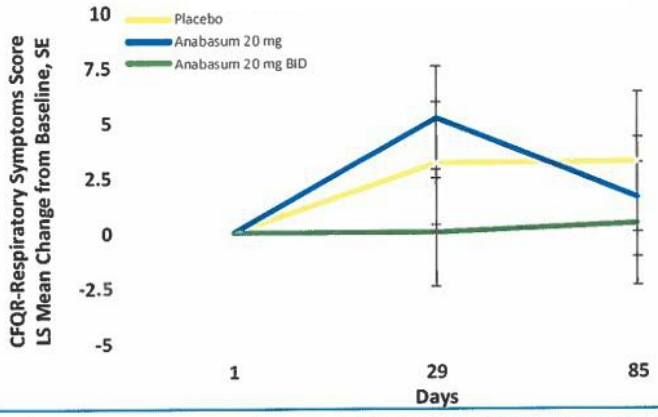
CYSTIC FIBROSIS QUESTIONNAIRE-REVISED (CFQ-R) RESPIRATORY SYMPTOMS SCORE

Weeks 1-12

Value	Treatment	Baseline Mean (range)
CFQ-R Respiratory Symptoms Score	Placebo, N = 24	74.8 (38.9 – 88.9)
	Anabasum 20 mg, N = 31	65.3 (27.8 - 94.4)
	Anabasum 20 mg BID, N = 30	69.0 (16.7 – 100.0)

LS Mean Difference (SE) from Baseline

An increase in score means fewer symptoms



In general, mean CFQ-R Respiratory Symptoms scores were not changed from baseline in any cohort

SPUTUM BIOMARKERS
INFLAMMATORY CELLS AND MEDIATORS

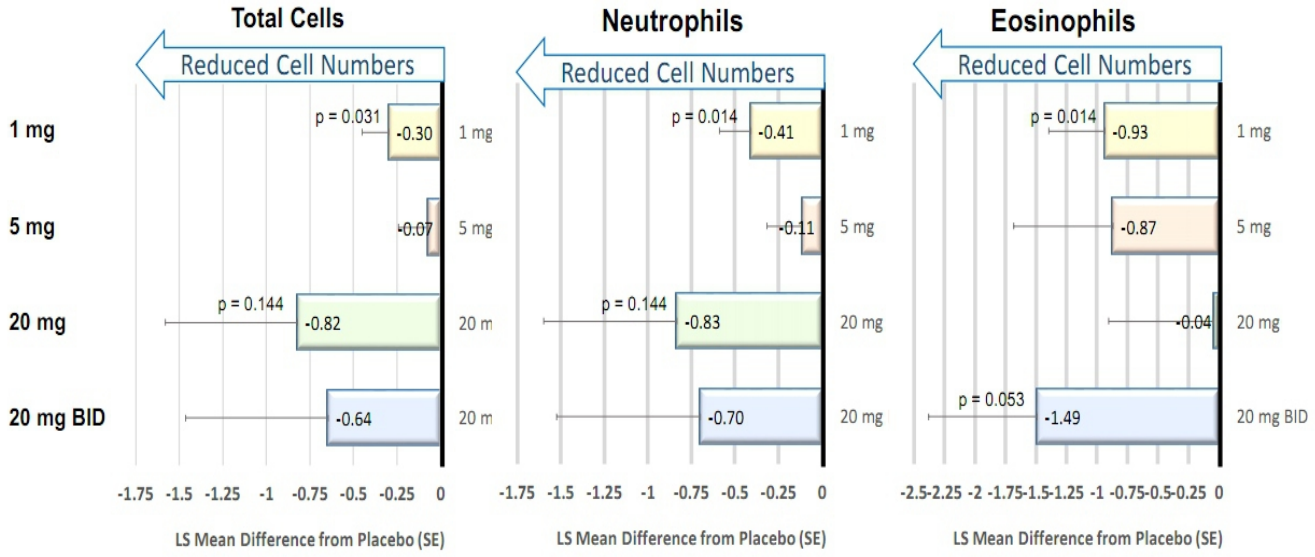
INFLAMMATORY CELLS IN CF SPUTUM AT BASELINE

Treatment, N	Baseline Value, Mean (SD), log_{10}				
	Total cells	Neutrophils	Eosinophils	Macrophages	Lymphocytes
Placebo N = 14	6.92 (0.76)	6.72 (0.88)	2.47 (2.64)	5.54 (0.76)	1.00 (1.98)
Anabasum 20 mg N = 21	6.88 (0.56)	6.66 (0.66)	4.61 (1.66)	5.42 (0.64)	1.44 (2.34)
Anabasum 20 mg BID N = 16	7.10 (0.60)	6.90 (0.80)	3.74 (2.47)	5.80 (0.84)	0.82 (1.88)

Anabasum 20 mg BID subjects have more inflammatory cells in their sputum than do placebo subjects

ANABASUM REDUCES INFLAMMATORY CELLS IN CF SPUTUM (1)

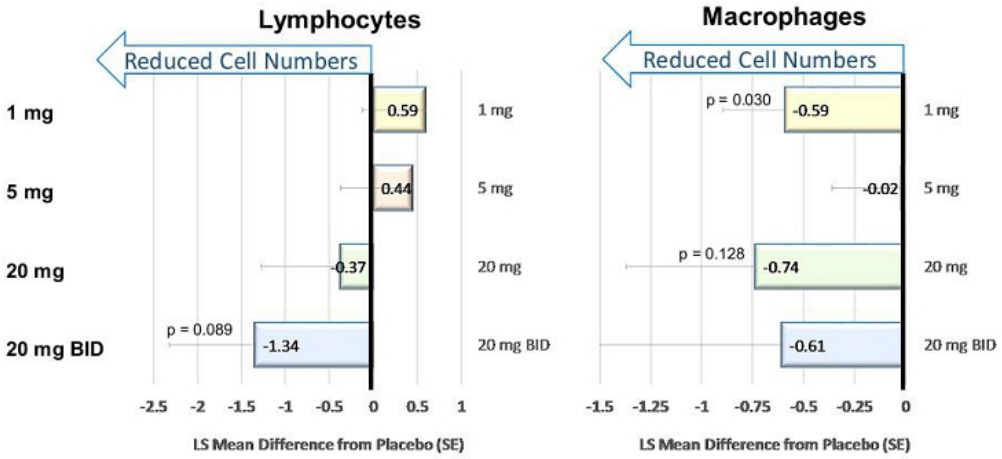
Least Squares (LS) mean difference from placebo, $\log_{10}$ (SE)



Anabasum reduces sputum total cells, neutrophils and eosinophils, with greater reduction at higher doses of anabasum

ANABASUM REDUCES INFLAMMATORY CELLS IN CF SPUTUM (2)

Least Squares (LS) mean difference from placebo, **log_{10}** (SE)



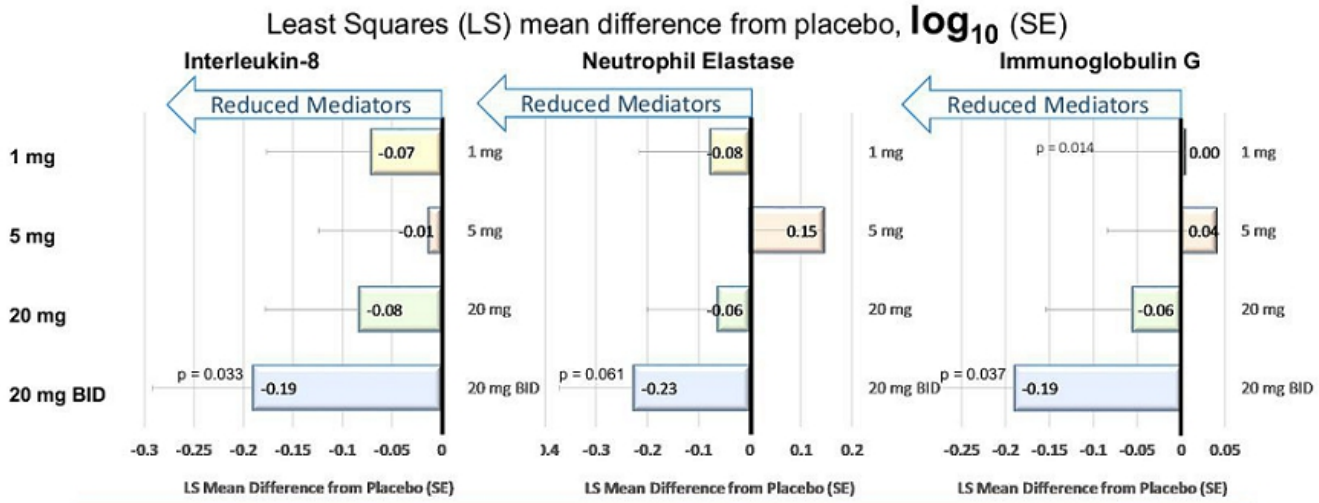
Anabasum reduces sputum lymphocytes and macrophages, with greater reduction at higher doses of anabasum

INFLAMMATORY MEDIATORS IN CF SPUTUM AT BASELINE

Treatment, N	Baseline Value Mean (SD), log_{10}		
	Interleukin-8	Neutrophil elastase	Immunoglobulin G
Placebo N = 14	5.17 (0.43)	2.02 (0.63)	1.49 (0.50)
Anabasum 20 mg N = 21	5.06 (0.48)	2.04 (0.59)	1.36 (0.60)
Anabasum 20 mg BID N = 16	5.22 (0.45)	2.19 (0.50)	1.59 (0.50)

Subjects in different treatment groups have similar levels of inflammatory mediators in their sputum

ANABASUM REDUCES INFLAMMATORY MEDIATORS IN CF SPUTUM



Anabasum 20 g BID reduces sputum interleukin-8, neutrophil elastase, and immunoglobulin G

BLOOD BIOMARKERS
INFLAMMATORY CELLS AND MEDIATORS

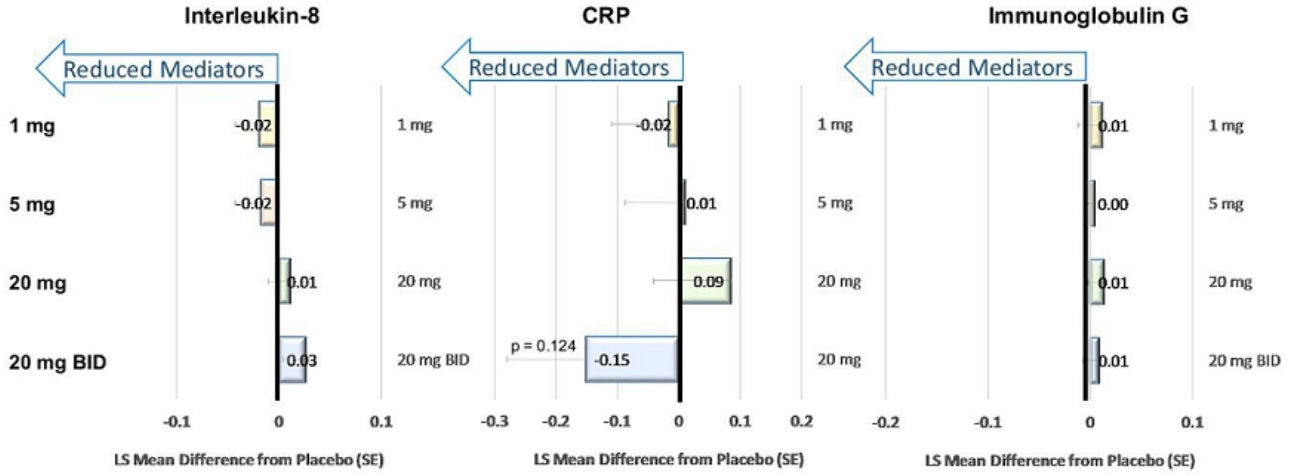
BLOOD BIOMARKERS OF INFLAMMATION AT BASELINE

Treatment, N	Baseline Value Mean (SD), log_{10}		
	Interleukin-8, pg/ml	C-reactive protein, nmol/L	Immunoglobulin G, g/L
Placebo N = 23	1.51 (0.10)	1.48 (0.60)	1.13 (0.14)
Anabasum 20 mg N = 30	1.53 (0.08)	1.47 (0.39)	1.10 (0.16)
Anabasum 20 mg BID N = 28	1.58 (0.19)	1.48 (0.56)	1.19 (0.10)

Subjects in different treatment groups have similar levels of inflammatory mediators in blood

EFFECT OF ANABASUM ON INFLAMMATORY MEDIATORS IN BLOOD

Least Squares (LS) mean difference from placebo, $\log_{10}$ (SE)



Anabasum 20 g BID reduces C-reactive protein levels in the blood

CONCLUSIONS

- Patients were exposed to anabasum at the C_{max} levels targeted
- Anabasum showed evidence of biologic activity in the lungs with reduction of multiple inflammatory cells and mediators
- Safety and tolerability profiles were acceptable
- Promising evidence of clinical benefit was seen in acute pulmonary exacerbations with greatest benefit at anabasum 20 mg BID dose
- These data support further clinical development of anabasum in CF Patients, and inform the design of the next clinical trial

Thank You!

We are Very Grateful to:

- The participants who took part in our Phase 2 clinical study of anabasum
- Our clinical investigators for their commitment to working with patients to complete the study
- Our employees for their tireless work and dedication to make this study possible
- The Cystic Fibrosis Foundation, Cystic Fibrosis Foundation Therapeutics, Inc. Development Network and European CF Society Clinical Trials Network for their support throughout the design and execution of the study

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