
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of May 2022

Commission File Number: 001-40212

Connect Biopharma Holdings Limited
(Translation of registrant's name into English)

Science and Technology Park
East R&D Building, 3rd Floor
6 Beijing West Road, Taicang
Jiangsu Province, China 215400
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

On May 3, 2022, Connect Biopharma Holdings Limited (the "Company") announced top-line results at 12 weeks from its Phase 2 trial for CBP-307 ("CBP-307CN002"), a once-daily, orally administered, selective sphingosine 1-phosphate receptor modulator in development for the treatment of ulcerative colitis ("UC").

Administration of CBP-307 0.2 mg demonstrated a numerical reduction for the primary endpoint of least squares ("LS") mean change from baseline in adapted Mayo Score at Week 12 that did not meet statistical significance. A significantly higher proportion of patients who received CBP-307 0.2 mg dose achieved Clinical Remission as compared to placebo based on both the complete and adapted Mayo Scores. Additionally, reductions in lymphocyte counts amongst individuals receiving CBP-307 0.2 mg confirmed pharmacodynamic activity of CBP-307 in patients with active UC. The Company intends to engage in partnership discussions for the future development of CBP-307 to focus resources on its lead program CBP-201, a IL4Ra antagonist.

The primary endpoint of LS mean change from baseline in adapted Mayo Score (stool frequency, rectal bleeding, and endoscopy scores) at Week 12 for CBP-307 0.2 mg and placebo were -2.65 and -2.01, respectively ($p=0.103$).

Secondary endpoints that were met for CBP-307 0.2 mg included a significantly higher proportion of patients reaching Clinical Remission compared to placebo as measured by both adapted (28.3% vs 9.6%, difference=18.7; $p=0.016$) and complete Mayo Scores (18.9% vs 5.8%, difference=13.1; $p=0.044$), respectively. For patients receiving CBP-307 0.2 mg, significant improvements were also noted for change in complete Mayo Score (adapted Mayo Score with physician's global assessment) from baseline to Week 12 (LS Mean Change from Baseline for CBP-307 vs. placebo: -3.67 vs -2.74, $p=0.050$) and in Clinical Response as measured by complete Mayo Score (52.8% vs 30.8%, $p=0.023$). A numerical improvement in Clinical Response as measured by adapted Mayo Score (54.7% vs 36.5%, $p=0.064$) was observed in the CBP-307 0.2 mg group that did not meet statistical significance.

For CBP-307 0.1 mg, a numerically higher proportion of patients reached Clinical Remission compared to placebo as measured by both adapted (12.8% vs 9.6%, difference=3.5; $p=0.601$) and complete Mayo Scores (10.3% vs 5.8%, difference=4.8; $p=0.397$), respectively, that did not meet statistical significance. In this group, numerical improvements were noted for Clinical Response as measured by complete Mayo Score (33.3% vs 30.8%, $p=0.760$) that did not meet statistical significance. No improvement in Clinical Response as measured by adapted Mayo Score (33.3% vs 36.5%, $p=0.784$) was observed in the CBP-307 0.1 mg group.

Analysis of exploratory pharmacodynamic endpoints showed that patients receiving CBP-307 0.2 mg and 0.1 mg demonstrated a mean percent lymphocyte count reduction from baseline of 51.3% and 42.7% with mean absolute lymphocyte counts reduced to approximately 0.8 ($10^9/L$) and 1.0 ($10^9/L$), respectively, at Week 12.

Across the CBP-307 0.2 mg, CBP-307 0.1 mg, and placebo groups, the occurrence of drug-related treatment emergent adverse events ("TEAEs") was 66.0%, 59.0%, and 38.5%, respectively. In addition, CBP-307 0.2 mg and placebo groups were similar in the occurrence of Grade 3 or higher TEAEs (7.5% vs 7.7%, respectively) and Serious TEAEs (3.8% vs 5.8%, respectively). For CBP-307 0.1 mg, the rates of Grade 3 or higher TEAEs and Serious TEAEs were 25.6% and 15.4%, respectively. Across the CBP-307 0.2 mg and CBP-307 0.1 mg groups, the occurrence of drug-related Grade 3 or higher TEAEs was 5.7% and 12.8%, respectively, and the occurrence of drug-related Serious TEAEs was 1.9% and 5.1%, respectively, and no such TEAEs were observed in the placebo group. There were no cases of progressive multifocal leukoencephalopathy and no deaths. The overall safety results in this study showed CBP-307 to be generally well tolerated in patients with moderate-to-severe UC. Given the safety findings along with the efficacy results of this study, the Company believes that CBP-307 warrants further clinical development in UC.

CBP-307CN002 is an active Phase 2 study evaluating the efficacy and safety of CBP-307 as an induction and maintenance therapy in adult patients with moderate-to-severe UC. The randomized, double-blind, placebo-controlled, multi-center study enrolled a total of 145 patients in two active dose arms (CBP-307 0.1 mg [n=39]; CBP-307 0.2 mg [n=53]) and a placebo arm (n=53) from over 60 sites in 4 countries.

On May 3, 2022, the Company issued the press release attached hereto as Exhibit 99.1.

Also on May 3, 2022, the Company provided a corporate presentation by posting the presentation to the Company's website, www.connectbiopharm.com. This presentation is also attached hereto as Exhibit 99.2. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to furnish a Form 6-K report alerting investors each time the presentation is updated.

This report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3 and S-8 (Registration Nos. 333-264340 and 333-254524, respectively) of the Company and to be a part thereof from the date on which this report is furnished, to the extent not superseded by documents or reports subsequently filed or furnished. The information set forth in the attached exhibits shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

The furnishing of the attached exhibits is not an admission as to the materiality of any information therein. The information contained in the exhibits is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or furnishing of other reports or documents with the SEC, through press releases, by updating its website or through other public disclosures.

Forward-Looking Statements

The Company cautions that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "look forward," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company's plans to advance the development of its product candidates, the potential of such product candidates, including to achieve any benefit or profile, and trends within the ulcerative colitis population, and partnerships for the future development of CBP-307. The inclusion of forward-looking statements shall not be regarded as a representation by Connect Biopharma that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Connect Biopharma business and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"), including the Company's Annual Report on Form 20-F filed with the SEC on March 31, 2022, and its other reports. Investors 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 revise or update this report to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included in Connect Biopharma's filings with the SEC which are available from the SEC's website (www.sec.gov) and on Connect Biopharma's website (www.connectbiopharm.com) under the heading "Investors." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 99.1	Press release dated May 3, 2022: Connect Biopharma Announces Week 12 Top-Line Results from Phase 2 CBP-307 Trial in Patients with Moderate-to-Severe Ulcerative Colitis
Exhibit 99.2	Corporate presentation

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.

Dated: May 3, 2022

CONNECT BIOPHARMA HOLDINGS LIMITED

By /s/ Steven Chan

Name: Steven Chan

Title: Chief Financial Officer

FOR IMMEDIATE RELEASE

Connect Biopharma Announces Week 12 Top-Line Results from Phase 2 CBP-307 Trial in Patients with Moderate-to-Severe Ulcerative Colitis

- *Primary endpoint of change from baseline on adapted Mayo Score for CBP-307 0.2 mg once-daily, orally administered dose showed a numerical improvement, but did not achieve statistical significance*
- *Clinical Remission on adapted Mayo Score and other secondary endpoints achieved statistical significance with strong evidence of pharmacodynamic activity as measured by reduction in lymphocyte counts, and CBP-307 was observed to be generally well tolerated*
- *Company intends to engage in partnership discussions for future development of CBP-307 to focus on lead program CBP-201 (IL4a antagonist)*

SAN DIEGO, CA and TAICANG, China – May 3, 2022 – **Connect Biopharma Holdings Limited** (Nasdaq: CNTB) (“Connect Biopharma” or the “Company”), a global clinical-stage biopharmaceutical company dedicated to improving the lives of patients with chronic inflammatory diseases through the development of therapies derived from T cell-driven research, today announced top-line results at 12 weeks from its Phase 2 trial for CBP-307 (CBP-307CN002), a once-daily, orally administered, selective sphingosine 1-phosphate (S1P) receptor modulator in development for the treatment of ulcerative colitis (UC).

Administration of CBP-307 0.2 mg demonstrated a numerical reduction for the primary endpoint of least squares (LS) mean change from baseline in adapted Mayo Score at Week 12 that did not meet statistical significance. A significantly higher proportion of patients who received CBP-307 0.2 mg dose achieved Clinical Remission based on both the complete and adapted Mayo Scores, which has been accepted by the FDA as the primary endpoint in clinical trials that have supported prior approvals for treatments of UC. Additionally, reductions in lymphocyte counts amongst individuals receiving CBP-307 0.2 mg confirmed pharmacodynamic activity of CBP-307 in patients with active UC.

“Ulcerative colitis is a serious chronic condition with continued unmet need. The overall 12-week results for CBP-307 demonstrate the therapeutic potential to induce a significant treatment response consistent with clinical data of other S1P modulators in patients with UC,” said David T. Rubin, MD, Professor of Medicine and Chief of the Section of Gastroenterology, Hepatology, and Nutrition at The University of Chicago Medicine.

The primary endpoint of LS mean change from baseline in adapted Mayo Score (stool frequency, rectal bleeding, and endoscopy scores) at Week 12 for CBP-307 0.2 mg and placebo were -2.65 and -2.01, respectively ($p=0.103$). Secondary endpoints that were met for CBP-307 0.2 mg included a significantly higher proportion of patients reaching Clinical Remission compared to placebo as measured by both adapted (28.3% vs 9.6%, difference=18.7; $p=0.016$) and complete Mayo Scores (18.9% vs 5.8%, difference=13.1; $p=0.044$), respectively. For patients receiving CBP-307 0.2 mg, significant improvements were also noted for change in complete Mayo Score (adapted Mayo Score with physician’s global assessment) from baseline to Week 12 (LS Mean Change from Baseline for CBP-307 vs. placebo: -3.67 vs -2.74, $p=0.05$) and in Clinical Response as measured by complete Mayo Score (52.8% vs 30.8%, $p=0.023$). Analysis of exploratory pharmacodynamic endpoints showed that patients receiving CBP-307 0.2 mg demonstrated a mean percent lymphocyte count reduction from baseline of 51.2% with mean absolute lymphocyte counts reduced to approximately 0.8 (10⁹/L) at week 12.

Across the CBP-307 0.2 mg and placebo groups, the occurrence of drug-related treatment emergent adverse events (TEAEs) was 66.0% and 38.5%, respectively. In addition, CBP-307 0.2 mg and placebo groups were similar in the occurrence of Grade 3 or higher TEAEs (7.5% vs 7.7%, respectively) and Serious TEAEs (3.8% vs 5.8%, respectively). There were no cases of progressive multifocal leukoencephalopathy and no deaths. The overall safety results in this study showed CBP-307 to be generally well tolerated in patients with moderate-to-severe UC. Given the safety findings along with the efficacy results of this study, the Company believes that CBP-307 warrants further clinical development in UC.

“These top-line, induction phase data demonstrate the potential for CBP-307 to provide benefit to patients living with moderate-to-severe UC,” said Zheng Wei, Ph.D., Co-Founder and CEO of Connect Biopharma. “Together, with recent positive results from our Phase 2 study of CBP-201 in atopic dermatitis, they support our approach to T cell-driven research in immunological pathways. To focus our resources to advance CBP-201, our lead product candidate, in a global Phase 3 clinical program and the ongoing pivotal China trial for atopic dermatitis, we plan to explore strategic partnerships to progress CBP-307 into future trials.”

An accompanying deck of today’s CBP-307 data is available in the Events and Presentations section of Connect Biopharma’s Investor Relations site at <https://investors.connectbiopharm.com/presentations-events/events>.

About CBP-307CN002 Trial

CBP-307CN002 is an active Phase 2 study evaluating the efficacy and safety of CBP-307 as an induction and maintenance therapy in adult patients with moderate-to-severe UC. The randomized, double-blind, placebo-controlled, multi-center study enrolled a total of 145 patients in two active dose arms (CBP-307 0.1 mg [n=39]; CBP-307 0.2 mg [n=53]) and a placebo arm (n=53) from over 60 sites in 4 countries.

About Ulcerative Colitis

Ulcerative Colitis (UC) is an idiopathic inflammatory condition of the mucosal and submucosal colon that has a globally increasing prevalence thought to be driven by societal changes. There are approximately 600,000 to 900,000 people in the United States living with ulcerative colitis. When insufficiently controlled, UC leads to progressive organ damage that presents as functional impairment and anatomical changes such as dysplasia, which may ultimately progress to cancer. Despite the availability of new treatments that have advanced the standard of care, a “therapeutic ceiling” means that treatment options remain limited and clinical remission is still not achieved in 70–80% patients.

About CBP-307

Discovered internally using Connect Biopharma’s proprietary Immune Modulation Technology, CBP-307 is an orally administered small molecule designed to modulate sphingosine 1-phosphate receptor 1 (S1P1), which is a validated target for the treatment of several inflammatory diseases, including UC. CBP-307 was observed to be generally well tolerated and showed evidence of clinical activity in the induction period of a Phase 2 clinical trial in adults with moderate-to-severe UC, suggesting a potential for a differentiated risk–benefit profile compared with data from clinical trials of current orally administered therapies. CBP-307 is also the subject of an ongoing maintenance phase and safety follow-up in the Phase 2 UC trial and two completed and two ongoing Phase 1 trials in healthy volunteers.

About Connect Biopharma Holdings Limited

Connect Biopharma is a global, clinical-stage biopharmaceutical company dedicated to improving the lives of patients with inflammatory diseases through the development of therapies derived from T cell-driven research. It is building a rich pipeline of internally-designed, wholly-owned, small molecules and antibodies using functional cellular assays with T cells to screen and discover potent product candidates against validated immune targets. Its lead product candidate, CBP-201, is an antibody designed to target interleukin-4 receptor alpha (IL-4R α) in development for the treatment of atopic dermatitis (AD) and asthma. The Company's second most advanced product candidate, CBP-307, is a modulator of a T-cell receptor known as S1P1 in development for the treatment of UC. Clinical development has begun for its third product candidate, CBP-174, a peripherally acting antagonist of histamine receptor 3, for the treatment of pruritus associated with AD.

With operations in the United States and China, Connect Biopharma is building a rich global pipeline of molecules and antibodies targeting several aspects of T cell biology. For additional information, please visit www.connectbiopharm.com.

FORWARD-LOOKING STATEMENTS (UPDATED)

Connect Biopharma cautions that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "look forward," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company's plans to advance the development of its product candidates, the potential of such product candidates, including to achieve any benefit or profile, and trends within the ulcerative colitis population, and partnerships for the future development of CBP-307. The inclusion of forward-looking statements shall not be regarded as a representation by Connect Biopharma that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the Connect Biopharma business and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"), including the Company's Annual Report on Form 20-F filed with the SEC on March 31, 2022, and its other reports. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Connect Biopharma undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included in Connect Biopharma's filings with the SEC which are available from the SEC's website (www.sec.gov) and on Connect Biopharma's website (www.connectbiopharm.com) under the heading "Investors." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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CBP-307
Top-line
Phase 2
Results in
Ulcerative
Colitis



NEXT-GENERATION
THERAPEUTICS FOR
T CELL-DRIVEN
INFLAMMATORY DISEASES

Forward-Looking Statements

- This presentation regarding Connect Biopharma Holdings Limited ("Connect," "we," "us" or "our") has been prepared solely for informational purposes.
- Certain information contained in this presentation relates to, or is based on, studies, publications, surveys and other data obtained from third-party sources and Connect's own internal estimates, research and analyses. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research or analysis is reliable, such research or analysis has not been verified by any independent source.
- This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding the Company's plans to advance the development of its product candidates, the potential of such product candidates, including to achieve any benefit or profile, trends within the ulcerative colitis population, and partnerships for CBP-307, are forward-looking statements. Forward-looking statements can be identified by words such as: "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "look forward," "potential," "continue" or "project" or the negative of these terms or other comparable terminology. The forward-looking statements in this presentation are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are inherently subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control, including, among other things: the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results; our ability to obtain and maintain regulatory approval of our product candidates; existing regulations and regulatory developments in the United States, the PRC, Europe and other jurisdictions; uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations; risks associated with the COVID-19 outbreak, which has and may continue to materially and adversely impact our business, preclinical studies and clinical trials; our plans and ability to obtain, maintain, protect and enforce our intellectual property rights and our proprietary technologies, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; and the degree of market acceptance of our product candidates by physicians, patients, healthcare payors and others in the medical community. These risks are not exhaustive.
- The inclusion of forward-looking statements should not be regarded as a representation by Connect that any of its expectations, projections or plans will be achieved. Actual results may differ from those expectations, projections or plans due to the risks and uncertainties inherent in Connect's business and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"), including the Company's Annual Report on Form 20-F filed with the SEC on March 31, 2022, and its other reports.
- New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statement are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation.
- In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.
- We have not conducted a head-to-head study of CBP-307 versus etrasimod or ozanimod. Comparisons of CBP-307 to etrasimod and ozanimod contained herein are based on analysis of data from separate studies. Such data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative efficacy or safety of CBP-307 compared to etrasimod or ozanimod. The potential benefits of CBP-307 does not imply an expectation of regulatory approval which is solely within the authority of the FDA (or applicable foreign regulator).

Large opportunity where high unmet need remains despite treatment advances

An autoimmune disease that causes inflammation and ulceration of the inner lining of the colon and rectum (the large bowel)

Current Treatment Limitations

- Efficacy
 - Less than half of patients achieve long-term remission, and many drugs lose the initial efficacy response ¹
 - Maximal clinical remission may require up to one year of treatment
- Safety concerns with many treatment options
- Biologics can have complicated administration regimens

Key Unmet Needs

1. Improved efficacy
2. Faster onset of efficacy
3. Reduced adverse events
4. Oral therapies



3 M

IBD patients in the US in 2015 ²

6.8 M

IBD patients worldwide in 2017 ³

Majority

of IBD patients in the US had UC ⁴

1. Ulcerative Colitis. Nature Reviews. Disease Primers. 2020. 6:74. <https://doi.org/10.1038/s41572-020-0205-x>
2. Inflammatory Bowel Disease Prevalence (IBD) in the United States. Centre for Disease Control (CDC). August 2020. <https://www.cdc.gov/ibd/data-statistics.htm>
3. GBD 2017 Inflammatory Bowel Disease Collaborators. Lancet Gastroenterol Hepatol 2020; 5: 17–30. DOI: [https://doi.org/10.1016/S2468-1253\(19\)30333-4](https://doi.org/10.1016/S2468-1253(19)30333-4)
4. Betteridge, J. et al. Inflamm Bowel Dis 2013;19:1421–1427. <https://academic.oup.com/ibdjournal/article/19/7/1421/4604306>

CBP-307 has molecular design features that offer potential for differentiation

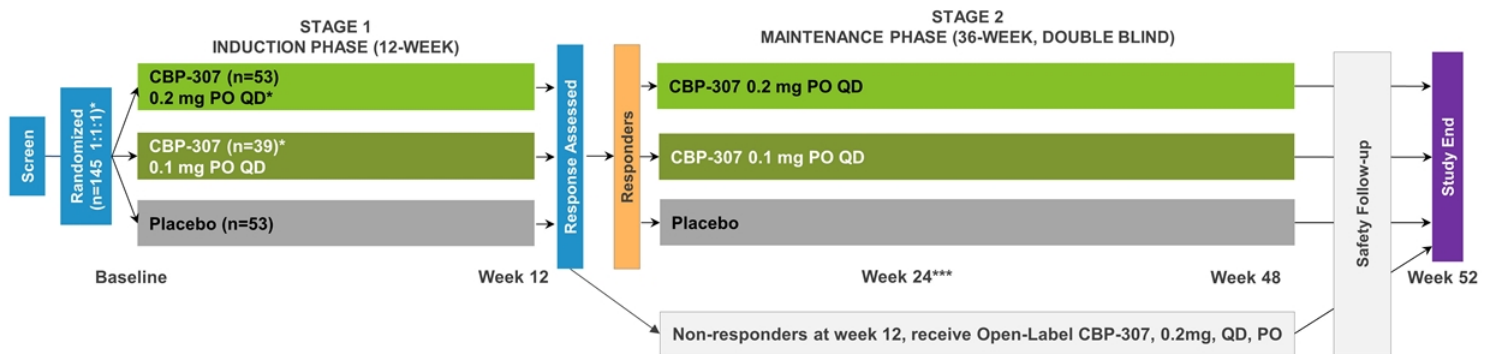
- Next-generation S1P1 modulators that are approved or have demonstrated positive proof-of-concept* in T-cell driven diseases include ozanimod (MS, IBD) and etrasimod (AD, UC)
- CBP-307 has molecular design features that offer potential for differentiation
 - High Potency & Selectivity
 - Designed to be the most potent modulator of sphingosine 1-phosphate receptor 1 (S1P1)
 - No notable activity observed for S1P3, a receptor subtype associated with known safety concerns
 - Substantially lower potency for S1P4 and S1P5 than S1P1 observed

*Efficacy demonstrated in Phase 2. Second-generation S1P1 modulators more selective for S1P1 versus other S1P receptors compared with first-generation S1P1 modulator fingolimod.
MS, multiple sclerosis; IBD, inflammatory bowel disease; AD, atopic dermatitis; UC, ulcerative colitis

Primary and all secondary endpoints were assessed at Week 12 in the induction phase

A Randomized, Double-blind, Placebo Controlled Trial to Evaluate the Efficacy and Safety of CBP-307 in Patients With Moderate to Severe Ulcerative Colitis (UC)¹

- Primary endpoint: Change from baseline in modified/adapted Mayo Score at Week 12 in 0.2 mg CBP-307 group versus placebo



Select Eligibility Criteria¹

- 8–75 years old with UC, clinically and endoscopically diagnosed ≥3 months before screening, corroborated by a histopathology report
- An adapted Mayo score of 4–9, with an endoscopic subscore of ≥2
- UC extending to the rectum, with ≥15 cm involvement on endoscopy

PO, by mouth.; QD, once daily; UC, ulcerative colitis

*For subjects in the group of CBP-307 0.2 mg once daily, a dose of 0.05 mg CBP-307 was given from day 1 to day 4; then, a dose of 0.1 mg CBP-307 was given for later 3 days; from day 8, a target dose (0.2 mg) was administered

**Study amended to modify randomization from 1:1:1 to 1:1 to 1:1 to focus patient enrolment for the 0.2 mg PO QD and placebo groups resulting n=39 patients allocated to the 0.1 mg PO QD group

***Responders at Week 12 without clinical response at Week 24 are withdrawn from treatment

CBP-307CN002 Trial - Baseline Demographics and Disease Characteristics

Baseline demographics and characteristics were generally well balanced across the treatment arms

Demographics & Characteristics	CBP-307 0.1 mg PO QD (n=39)	CBP-307 0.2 mg PO QD (n=53)	Placebo (n=53)
Mean age, years (SD)	42.9 (13.4)	42.1 (10.7)	42.2 (9.9)
Female, n (%)	14 (35.9)	20 (37.7)	20 (37.7)
Race, n (%)			
White	0	5 (9.4)	4 (7.5)
Asian	39 (100.0)	48 (90.6)	46 (86.8)
Black/African American	0	0	1 (1.9)
Not reported	0	0	2 (3.8)
Mean BMI, kg/m ² (SD)	21.4 (2.8)	22.6 (3.4)	23.1 (4.5)
Mean UC diagnosis, years, (SD)	5.0 (4.3)	5.6 (5.7)	5.9 (6.1)
Location/extent of UC, n (%)			
Proctosigmoiditis	4 (10.3)	11 (20.8)	9 (17.0)
Left sided colitis	9 (23.1)	7 (13.2)	8 (15.1)
Extensive colitis	11 (28.2)	7 (13.2)	7 (13.2)
Pancolitis	5 (12.8)	6 (11.3)	8 (15.1)
Other	4 (10.3)	3 (5.7)	7 (13.2)
Mean adapted Mayo score (SD)	5.95 (1.5)	5.91 (1.3)	5.97 (1.2)
Mean complete Mayo score (SD)	8.11 (1.6)	8.10 (1.5)	8.16 (1.3)
Failed TNF treatment, n (%)	1 (2.6)	2 (3.8)	2 (3.8)

All Randomized Set

BMI, body mass index; SD, standard deviation; TNF, tumour necrosis factor; UC ulcerative colitis

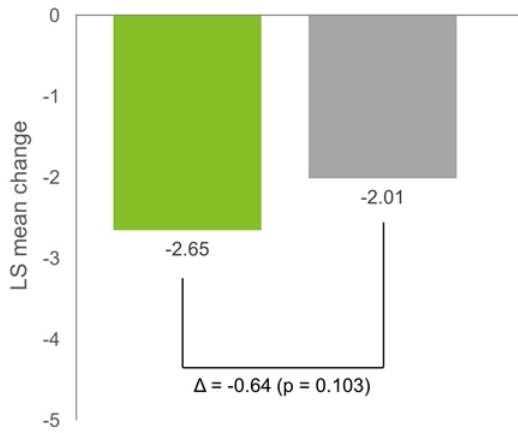
CBP-307CN002 Trial - Primary and Secondary Efficacy Endpoints

Change from baseline in **Adapted** and **Complete** Mayo score at W12 compared between CBP-307 0.2 mg PO QD and placebo

CBP-307 demonstrated a numerical, non-significant difference vs. placebo on primary efficacy endpoint

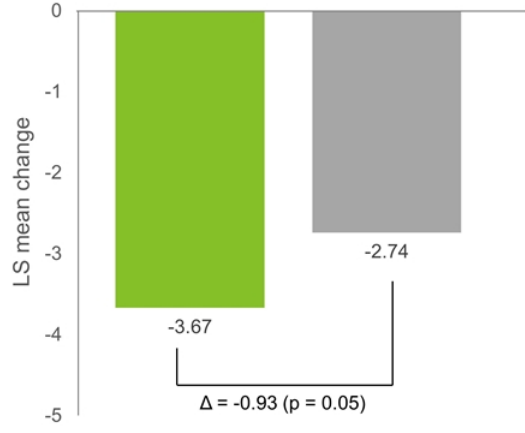
Primary Efficacy Endpoint

Change in **adapted Mayo** score at Week 12 (FAS, MI)



Secondary Efficacy Endpoint

Change in **complete Mayo** score at Week 12 (FAS, MI)



■ CBP-307 0.2mg QD PO (n=48) ■ Placebo (n=44)

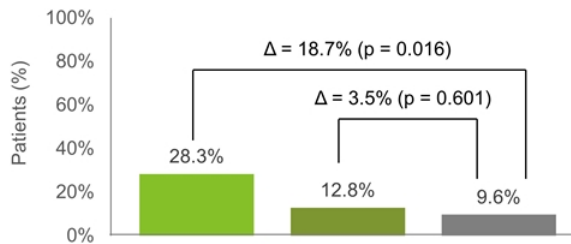
FAS, full analysis set; MI, multiple imputation; PO, by mouth; QD, once daily.
Placebo-adjusted data is the difference in score between CBP-307 and placebo.

CBP-307CN002 Trial – Secondary Efficacy Endpoints at Week 12

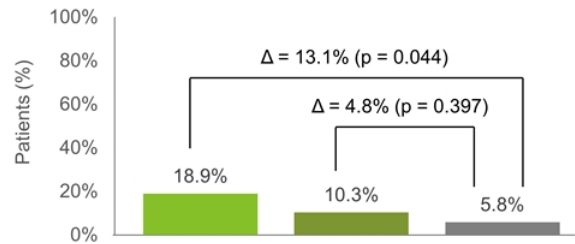
Clinical Remission based on Adapted and Complete Mayo scores

Proportion of patients achieving Clinical Remission for CBP-307 0.2 mg PO QD was significantly greater than placebo

Clinical remission rate at Week 12 (FAS, NRI) based on adapted Mayo



Clinical remission rate at Week 12 (FAS, NRI) based on complete Mayo



- CBP-307 0.2mg QD PO (N=53)
- CBP-307 0.1mg QD PO (N=39)
- Placebo (N=52)

Clinical Remission by adapted Mayo score (defined as a rectal bleeding subscore = 0 and stool frequency sub score ≤ 1, with an Endoscopy subscore ≤ 1 [excluding friability])

Clinical Remission by complete Mayo score (defined as a total Mayo score of ≤ 2 points with no individual subscore > 1 point)

FAS, full analysis set; NRI, non-responder imputation; PO, by mouth; QD, once daily. Adapted Mayo scores exclude PGA (Physician's Global Assessment) score



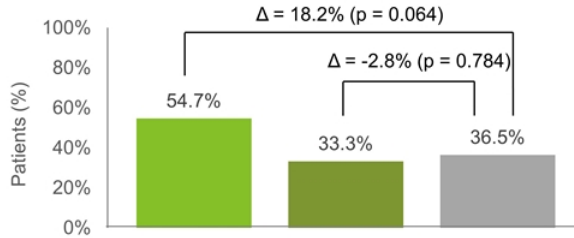
CBP-307CN002 Trial - Secondary Efficacy Endpoints at Week 12

Clinical Response based on Adapted and Complete Mayo scores

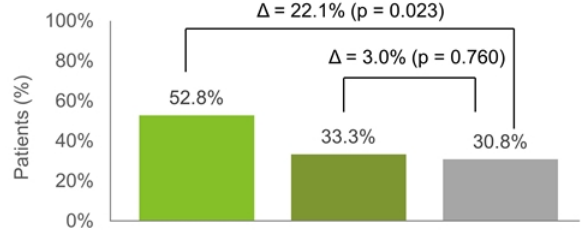
9

Clinical Response was numerically or significantly greater than placebo based on Adapted or Complete Mayo, respectively

Clinical Response rate at Week 12 (FAS, NRI) based on **adapted Mayo** numerically (but not significantly) greater than placebo



Clinical Response rate at Week 12 (FAS, NRI) based on **complete Mayo** was significantly greater than placebo



- CBP-307 0.2mg QD PO (N=53)
- CBP-307 0.1mg QD PO (N=39)
- Placebo (N=52)

Clinical Response by adapted Mayo score (decrease of ≥ 2 points and at least 30% from baseline, accompanied with a decrease of ≥ 1 point from baseline in the rectal bleeding subscore or an absolute rectal bleeding subscore of ≤ 1)
Clinical response by complete Mayo score (decrease of ≥ 3 points and at least 30% from baseline, accompanied with a decrease of ≥ 1 point from baseline in the rectal bleeding subscore or an absolute rectal bleeding subscore of ≤ 1)

FAS, full analysis set; NRI, non-responder imputation; PO, by mouth; QD, once daily.
Adapted Mayo scores exclude PGA score

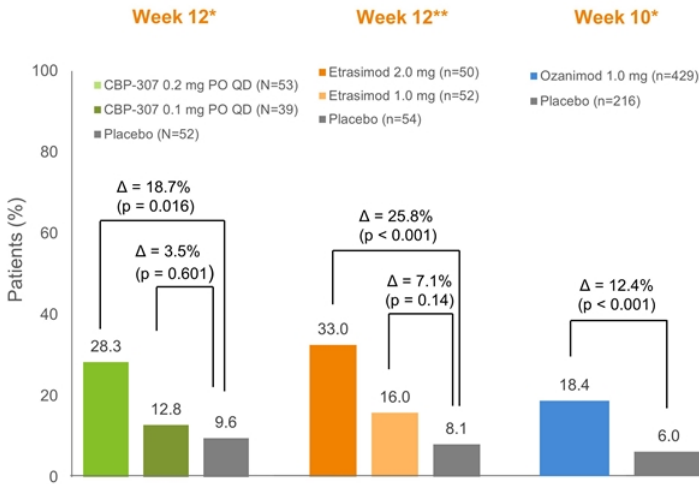
CBP-307CN002 - Secondary Endpoints

Clinical Remission rate based on Adapted and Complete Mayo score

Not head-to-head trial results. Differences exist between trial designs and subject characteristics and caution should be exercised when comparing data across trials

Phase 2 CBP-307 (FAS, NRI), Phase 2 Etrasimod¹ (ITT, MI) and Phase 3 Ozanimod²

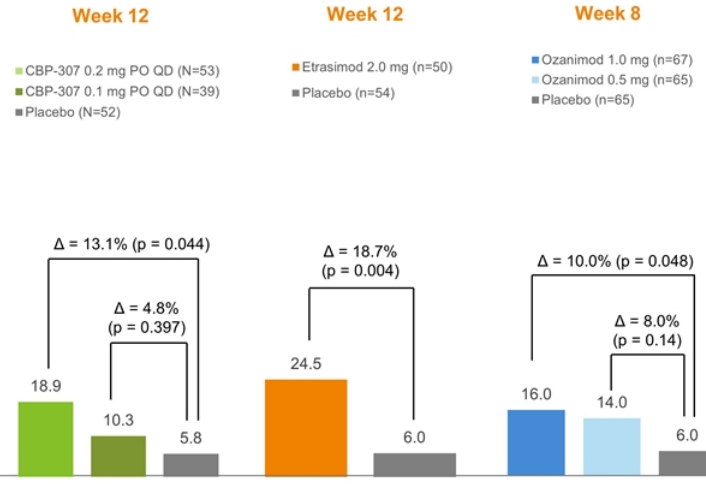
Clinical Remission rate based on adapted Mayo score



* Rectal bleeding (RB) = 0; stool frequency (SF) ≤ 1 ; endoscopy ≤ 1
 ** RB ≤ 1 ; SF ≤ 1 , endoscopy ≤ 1

Phase 2 CBP-307 (FAS, NRI), Etrasimod¹ and Ozanimod³ (ITT, MI)

Clinical Remission rate based on complete Mayo score



Total Mayo score of ≤ 2 points with no individual subscore > 1 point)

FAS, full analysis set; ITT, intention-to-treat; MI, multiple imputation; NRI, non-responder imputation; PO, by mouth; QD, once daily
 1. Sandborn et al. Gastroenterology. 2020;158:550-561 and Seeking Alpha article ("Arena Jumps On Positive Clinical Trial Results", March 20, 2018) & Arena Pharmaceuticals.
 2. Sandborn et al. NEJM 2021;385:1280-91. 3. Sandborn et al. NEJM 2016;374:1754-62

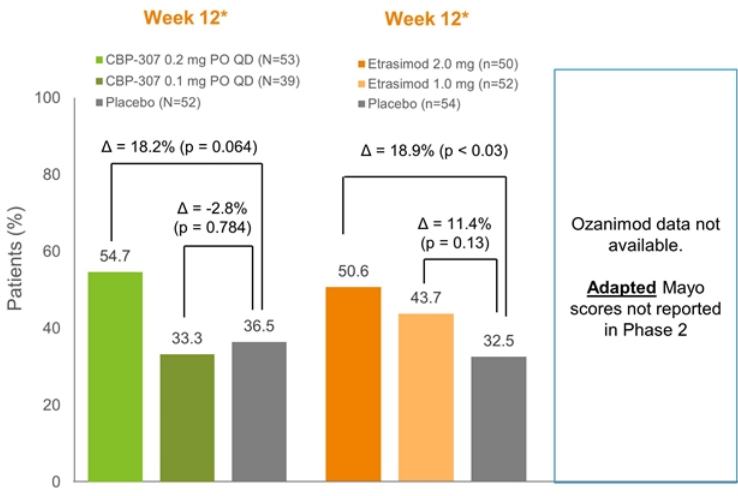


CBP-307CN002 - Secondary Endpoints

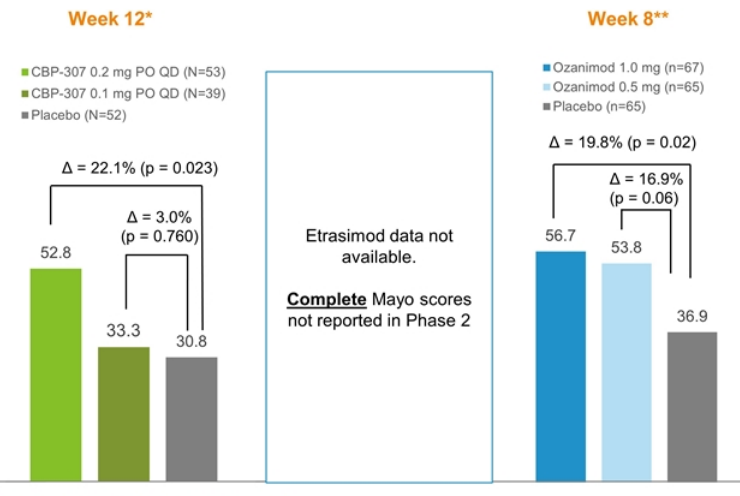
Clinical response rate at Week 12, based on **Adapted** and **Complete** Mayo

Not head-to-head trial results. Differences exist between trial designs and subject characteristics and caution should be exercised when comparing data across trials

Phase 2 CBP-307 (FAS, NRI) and Etrasimod¹ (ITT, MI) Clinical response rate based on **adapted** Mayo score



Phase 2 CBP-307 (FAS, NRI) and Ozanimod² (ITT, NRI) Clinical response rate based on **complete** Mayo score



* Mayo decrease of ≥ 2 points and $\geq 30\%$, and a decrease of ≥ 1 in RB or an absolute RB ≤ 1
 ** Mayo decrease of ≥ 3 points and $\geq 30\%$, and a decrease ≥ 1 in RB or an absolute RB ≤ 1

FAS, full analysis set; ITT, intention-to-treat; MI, multiple imputation; NRI, non-responder imputation; PO, by mouth; QD, once daily
 1. Sandborn et al. Gastroenterology. 2020;158:550-561 and Seeking Alpha article ("Arena Jumps On Positive Clinical Trial Results", March 20, 2018) & Arena Pharmaceuticals. 2. Sandborn et al. NEJM. 2016;374:1754-62

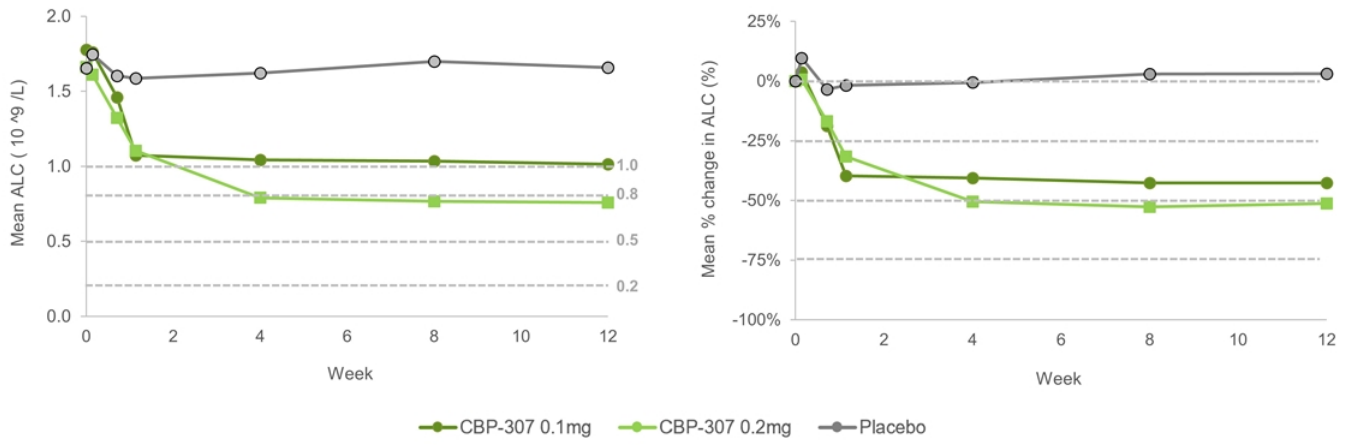


CBP-307CN002 Trial - Pharmacodynamic Endpoint

Absolute lymphocyte counts (ALC) and percentage change through Week 12 (FAS)

CBP-307 reduced the peripheral lymphocyte counts during the 12-week study period

Mean values and Percentage changes in Absolute Lymphocyte Count (ALC)



CBP-307CN002 Trial – Safety Results from 12-week Induction Period

- Overall TEAEs, including drug-related TEAEs and TEAEs of special interest, were more frequent in the CBP-307 groups
- Most TEAEs were mild and moderate in severity
- CBP-307 0.2 mg QD showed similar frequencies of SAEs and TEAEs leading to study drug withdrawal as placebo
- No cases of progressive multifocal leukoencephalopathy and no deaths were reported

Safety Parameter n (%)	CBP-307 Phase 2		
	CBP-307 0.1 mg PO QD (n=39)	CBP-307 0.2 mg PO QD (n=53)	Placebo (n=52)
Any TEAE	37 (94.9%)	47 (88.7%)	40 (76.9%)
Grade 3 or Higher TEAE	10 (25.6%)	4 (7.5%)	4 (7.7%)
Drug-Related TEAE	23 (59.0%)	35 (66.0%)	20 (38.5%)
Drug-Related Grade 3 or Higher TEAE	5 (12.8%)	3 (5.7%)	0 (0.0%)
Serious TEAE	6 (15.4%)	2 (3.8%)	3 (5.8%)
Drug-Related Serious TEAE	2 (5.1%)	1 (1.9%)	0 (0.0%)
TEAE Leading to study Drug Withdrawal	6 (15.4%)	1 (1.9%)	0 (0.0%)
TEAE Leading to Deaths	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEAE of Special Interest	6 (15.4%)	3 (5.7%)	0 (0.0%)

TEAE, treatment-emergent adverse event; UC, ulcerative colitis

Summary

- CBP-307 0.2 mg PO QD decreased disease severity based on adapted Mayo Score after 12 weeks of treatment, although the change did not reach statistical significance
- CBP-307 0.2 mg PO QD achieved statistical significance on several secondary endpoints including for Clinical Remission
- Clear dose-dependent and rapid pharmacodynamic changes were observed confirming mechanism of action
- Overall safety results showed CBP-307 to be generally well tolerated in patients with moderate-to-severe UC
- CBP-307 has the potential to be a competitive asset for further development and a welcome addition to the Gastroenterologist's treatment armamentarium to benefit patients with IBD
- Company intends to seek partnerships for CBP-307 to allow strategic focus on ongoing development plans with CBP-201 (IL4R α antagonist)