UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **August 23, 2021**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**001-36033**	**98-1226628**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(650) 808-6000
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Share $0.00001 Par Value	TBPH	NASDAQ Global 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 8.01. Other Events.

The information in this Current Report (including Exhibits 99.1 and 99.2) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibits 99.1 and 99.2) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

On August 23, 2021, Theravance Biopharma, Inc. issued a press release and is holding a conference call to announce top-line results from its Phase 2b dose-finding induction study of izencitinib in patients with ulcerative colitis. A copy of the press release is furnished as Exhibit 99.1 to this Current Report and a copy of materials that will accompany the call is furnished as Exhibit 99.2 to this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release dated August 23, 2021
99.2	Slide deck entitled Izencitinib (TD-1473/JNJ-8398) Top-line Results from Phase 2b Dose-Finding Induction Study in Patients with Ulcerative Colitis
104	Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

SIGNATURE

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

THERAVANCE BIOPHARMA, INC.

Date: August 23, 2021

By: /s/ Andrew Hindman
Andrew Hindman
Senior Vice President and Chief Financial Officer

Theravance Biopharma, Inc. Announces Top-line Results from Phase 2b Dose-Finding Induction Study of Izencitinib in Patients with Ulcerative Colitis

- *Randomized, double-blind, placebo-controlled study did not meet the primary endpoint: change in the total Mayo score at week eight, relative to placebo*
- *Izencitinib was well-tolerated and safety data were consistent with expectations for this gut-selective pan-JAK inhibitor*
- *Investor conference call and webcast today at 5 pm ET (2 pm PT)*

DUBLIN, IRELAND AND SOUTH SAN FRANCISCO, CALIF. – AUGUST 23, 2021 – Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH), a diversified biopharmaceutical company primarily focused on the discovery, development, and commercialization of organ-selective medicines, today announced top-line results from its Phase 2b dose-finding induction study of izencitinib, an orally administered, gut-selective pan-Janus kinase (JAK) inhibitor in development for the treatment of ulcerative colitis.

The study did not meet its primary endpoint of change in the total Mayo score or the key secondary endpoint of clinical remission at week 8, relative to placebo. There was a small dose-dependent increase in clinical response measured by the adapted Mayo score, which was driven by a reduction in rectal bleeding.

At all doses, izencitinib was well-tolerated when administered orally once daily for 8 weeks; adverse event rates were similar among patients receiving izencitinib and placebo. There were no instances of perforation, opportunistic infection, major cardiovascular or thromboembolic event, complicated zoster, or non-melanoma skin cancer in patients receiving izencitinib. There were no notable changes in lab values including creatine phosphokinase and lipids in patients receiving izencitinib relative to placebo. Plasma exposure of izencitinib was low, consistent with expectations for a gut-selective medicine.

The Company plans to present study results at a scientific forum.

"We had high expectations for the Phase 2b study after eight weeks of treatment with izencitinib in ulcerative colitis given the totality and consistency of the broad range of clinical, histologic, and biomarker data we saw in the Phase 1b study with only four weeks of treatment, albeit in a small number of patients. We plan to analyze the data to better understand the findings and the potential for optimization of a gut-selective medicine as a treatment for patients with inflammatory bowel diseases," said Rick E Winningham, Chief Executive Officer, Theravance Biopharma. "We are grateful to all those who participated in this clinical trial and to those who are still participating in the Crohn's Phase 2 study – which we expect to report top-line results in late fourth quarter 2021 or early first quarter 2022."

Regarding current plans, the Company will work to understand the complete results and implications for izencitinib. Forthcoming ulcerative colitis data will include results from the 16-week extended induction portion of the study and the 44-week maintenance study. The Company reiterates timing of the top-line results of the Crohn's Phase 2 study in late fourth quarter 2021 or early first quarter 2022. Based on the ulcerative colitis results, the Company will seek to minimize future expenses associated with the izencitinib program.

Conference Call and Live Webcast Today at 5 pm ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 5 pm ET / 2 pm PT / 10 pm IST. To participate, please dial (855) 296-9648 from the U.S. or (920) 663-6266 for international callers, using the confirmation code 3198387. Those interested in listening to the conference call live via the internet may do so by visiting Theravance.com, under the Investors section, Events and Presentations.

A replay will be available on Theravance.com under the Investors section for 30 days. An audio replay will be also available through 8:00 p.m. ET on August 30, 2021, by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 3198387.

About the Phase 2b Dose-Finding Induction Study

The study was a randomized, double-blind, placebo-controlled, multi-center Phase 2b dose-finding induction study (NCT03758443) for the treatment of adults with moderately-to-severely active ulcerative colitis with the primary endpoint at Week 8 (n=239). The safety and efficacy data of this Phase 2b study were intended to inform induction and maintenance dose regimens for a confirmatory Phase 3 induction study and the ongoing maintenance study.

About Theravance Biopharma and Janssen Strategic Collaboration

Theravance Biopharma and Janssen Biotech, Inc. have a global co-development and commercialization agreement for izencitinib, also known as TD-1473, and other compounds for inflammatory intestinal diseases. Under the terms of the agreement, Theravance Biopharma received an upfront payment of $100 million and is eligible to receive up to an additional $900 million in potential payments, if Janssen elects to remain in the collaboration following the completion of certain Phase 2 activities. In that scenario, Theravance Biopharma and Janssen will jointly develop and commercialize izencitinib in inflammatory intestinal diseases, with the two companies sharing expenses related to a potential Phase 3 program and profits in the U.S.

About Janus (JAK) Kinase Inhibition

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of immune-mediated diseases such as rheumatoid arthritis, myelofibrosis, and ulcerative colitis. However, these products are known to have adverse effects associated with their systemic exposure.

About Izencitinib

Izencitinib, also known as TD-1473, is an orally administered, once-daily, investigational, internally discovered, high affinity, reversible pan-JAK inhibitor which was designed to be gut selective. The gut-selective design provides izencitinib the potential to distribute throughout the gastrointestinal tract tissues and target inflammation at the site of gastrointestinal disease while limiting its systemic exposure. Theravance Biopharma is focused on utilizing izencitinib for the potential treatment of a range of inflammatory intestinal diseases including ulcerative colitis and Crohn's disease.

About Theravance Biopharma

Theravance Biopharma, Inc. is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Its purpose is to pioneer a new generation of small molecule drugs designed to better meet patient needs. Its research is focused in the areas of inflammation and immunology.

In pursuit of its purpose, Theravance Biopharma applies insights and innovation at each stage of its business and utilizes its internal capabilities and those of partners around the world. The Company applies organ-selective expertise to target disease biologically, to discover and develop medicines that may expand the therapeutic index with the goal of maximizing efficacy and limiting systemic side effects. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Its pipeline of internally discovered programs is targeted to address significant patient needs.

Theravance Biopharma has an economic interest in potential future payments from Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY.

For more information, please visit www.theravance.com.

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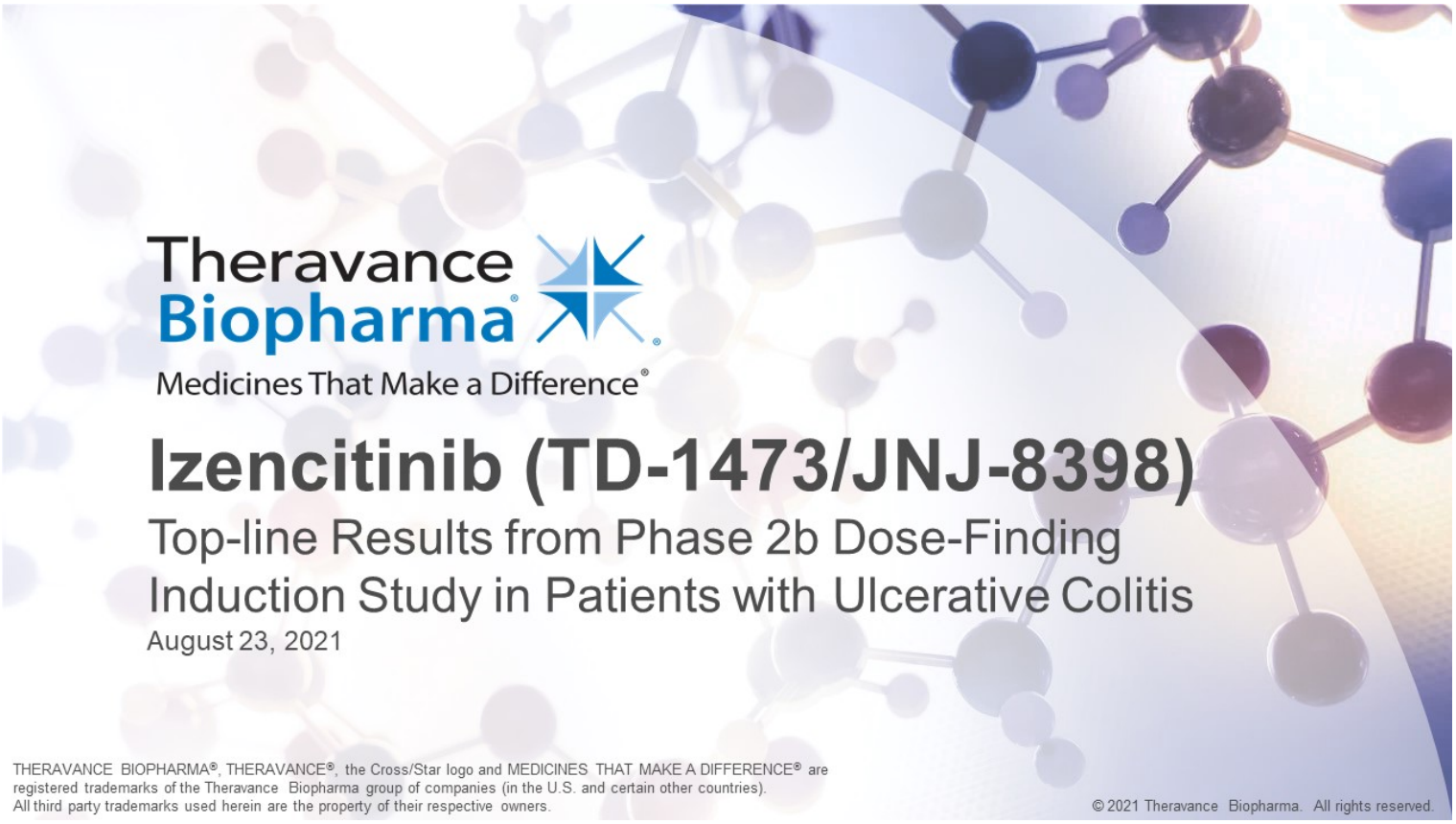
YUPELRI® is a registered trademark of Mylan Specialty L.P., a Viatris Company. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

Forward-Looking Statements

This press release contains and the conference call will contain certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, expectations and future events. Theravance Biopharma intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to: the Company's goals, designs, strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, the potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development, the Company's expectations regarding its allocation of resources, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the Company's expectations for its expenses, excluding share-based compensation and other financial results. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and the conference call and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that the results of these proceedings could be adverse to the Company, additional future analysis of the data resulting from our clinical trial(s), delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe, ineffective or not differentiated, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. In addition, while we expect the effects of COVID-19 to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI® (revefenacin), our clinical development programs (including but not limited to our later stage clinical programs for izencitinib and ampreloxetine), and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the COVID-19 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, other measures taken by us and those we work with to help protect individuals from contracting COVID-19, and the effectiveness of actions taken globally to contain and treat the disease, including vaccine availability, distribution, acceptance and effectiveness. Other risks affecting Theravance Biopharma are in the Company's Form 10-Q filed with the SEC on August 5, 2021 and other periodic reports filed with the SEC. In addition to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

Contact: Gail B. Cohen
Corporate Communications
917-214-6603

Exhibit 99.2


Theravance Biopharma
Medicines That Make a Difference®
Izencitinib (TD-1473/JNJ-8398)
Top-line Results from Phase 2b Dose-Finding Induction Study in Patients with Ulcerative Colitis
August 23, 2021
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Forward-looking statements

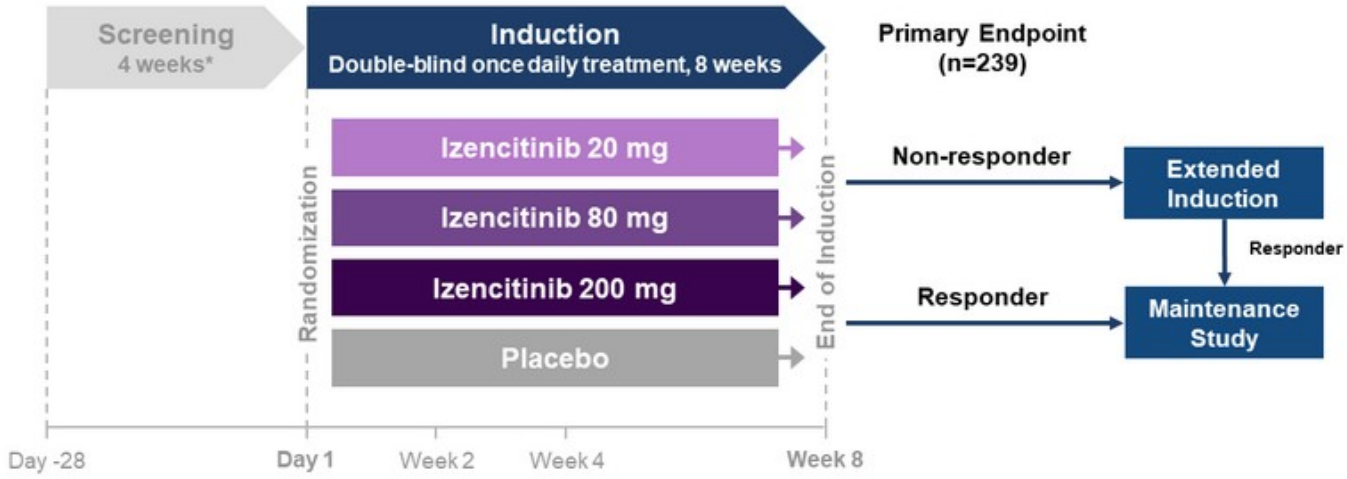
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking statements or projections.

Examples of forward-looking statements in this presentation may include the Company's goals, designs, strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, the potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development, the Company's expectations regarding its allocation of resources, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the Company's expectations for its expenses, excluding share-based compensation and other financial results.

The company's forward-looking statements are based on the estimates and assumptions of management as of the date of this presentation and are subject to risks and uncertainties that may cause the actual results to be materially different than those projected, such as risks related to the impacts on the COVID-19 global pandemic on our business, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe, ineffective or not differentiated, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result could be adverse to the Company.

Other risks affecting Theravance Biopharma are in the company's Form 10-Q filed with the SEC on August 5, 2021, and other periodic reports filed with the SEC.

Izencitinib Phase 2b induction study in ulcerative colitis



NCT03758443

*Screening was 5 weeks in Japan due to longer wait time for stool test results

Topline summary

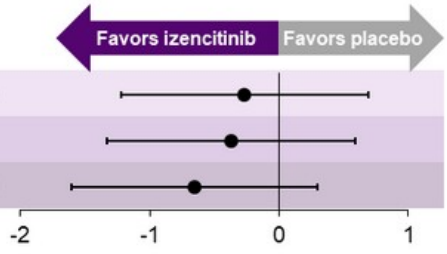
- **Primary:**
  - No statistically significant difference at any dose in the change in total Mayo score at Week 8 relative to placebo
- **Key secondary and additional efficacy endpoints at week 8 relative to placebo:**
  - No improvement in clinical remission by adapted Mayo score at any dose
  - No improvement in endoscopic healing at any dose
  - Small dose-dependent improvement in clinical response driven by reduction in rectal bleeding
  - Dose-dependent reduction from baseline in CRP
- **Safety:**
  - Izencitinib was well-tolerated as a single daily dose administered for 8 weeks at all doses
  - No safety signal and no clinically significant laboratory changes typical of systemic JAK inhibitors
- **PK:** Plasma exposure
  - Low and consistent with historical studies in UC patients and healthy participants

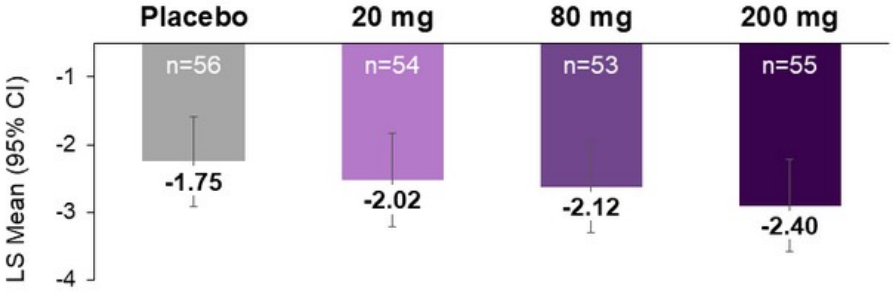
CRP, C-reactive protein; JAK, Janus kinase; UC, ulcerative colitis.

Change in total Mayo score at week 8

Observed changes appeared to be dose-dependent

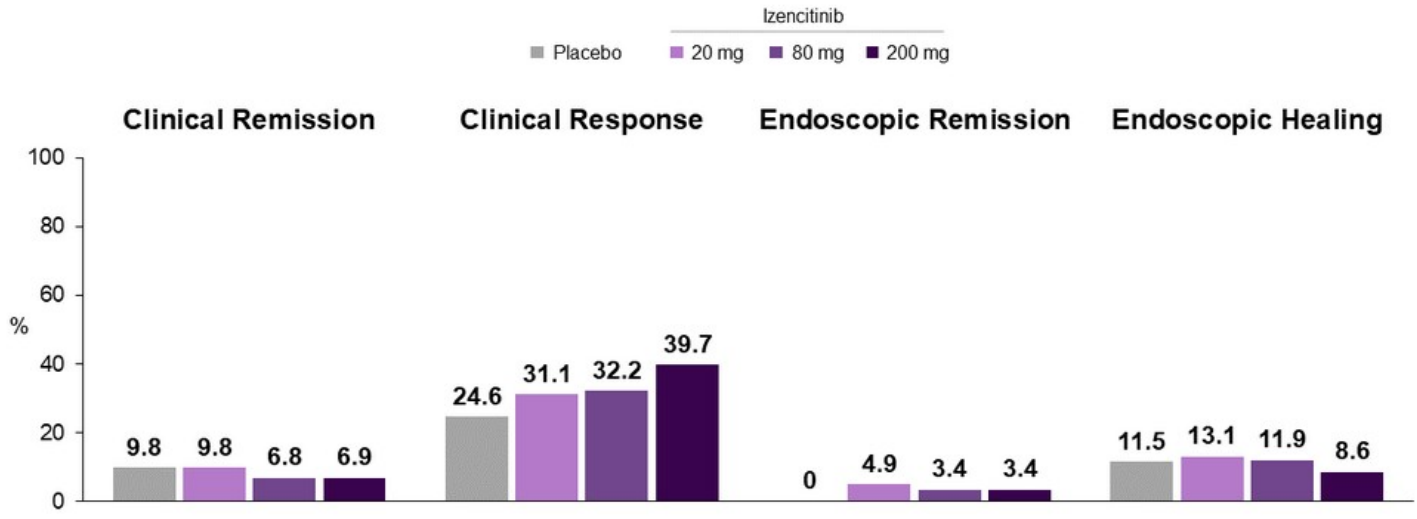
Treatment Comparison	Placebo Adj. Difference (95% CI); p-value
20 mg vs Placebo	**-0.27** (-1.22, 0.69); p=0.5809
80 mg vs Placebo	**-0.37** (-1.33, 0.59); p=0.4501
200 mg vs Placebo	**-0.65** (-1.60, 0.30); p=0.1809





n is equal to the number of subjects with data available at week 8
CI, confidence interval; LS, least-squares.

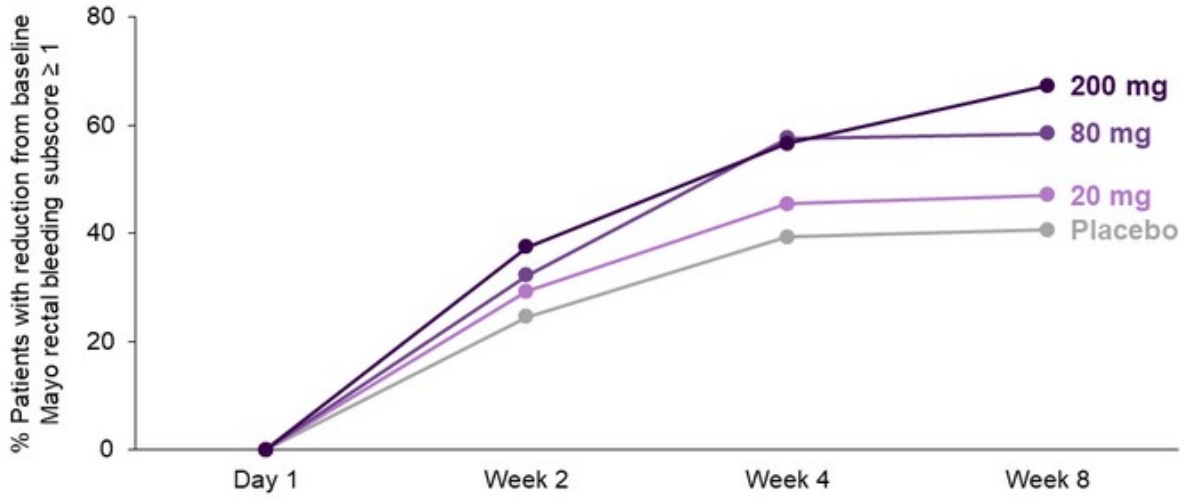
Rates of key secondary endpoints at 8 weeks



Theravance Biopharma
Medicines That Make a Difference

Clinical Remission: by adapted Mayo score components: a stool frequency score of 0 or 1, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1.
Clinical Response: by aMS: reduction in adapted Mayo score ≥ 2 and ≥ 30%, with a reduction in the rectal bleeding subscore ≥ 1 or an absolute subscore ≤ 1.
Endoscopic Remission: Mayo endoscopic subscore = 0; Endoscopic Healing: Mayo endoscopic subscore ≤ 1.
Percentages are calculated based on the number of subjects randomized in that treatment group.

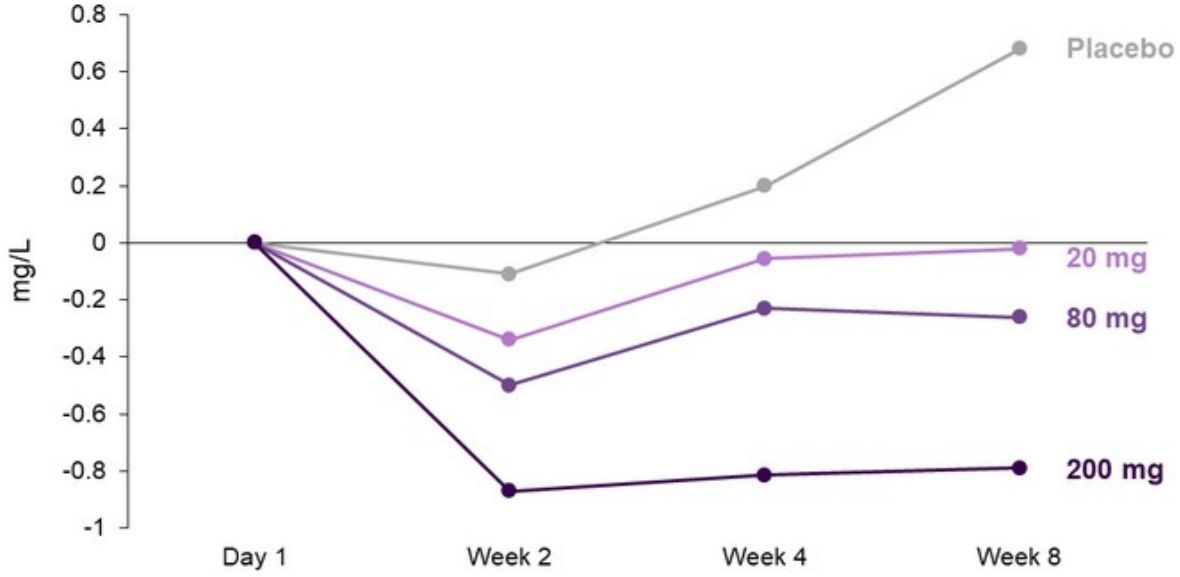
Rectal bleeding improvement (%) over time



Theravance Biopharma
Medicines That Make a Difference

% of patients with reduction from baseline is calculated based on the number of patients with data available at that visit.

Dose-dependent reduction in CRP (median change over time)



CRP, C-reactive protein.

Summary of safety results

- Izencitinib up to 200 mg daily for 8 weeks was well-tolerated
- Serious adverse events (n=13) were well balanced amongst the treatment groups and not considered related to study treatment; no deaths
- Most TEAEs were mild or moderate
  - UC exacerbation was slightly more common in izencitinib groups, but rates were consistent with other studies
  - No safety signal (including adverse events of special interest*)
- Unremarkable laboratory values, ECG parameters, and vital signs
  - Liver or kidney function
  - Creatine phosphokinase
  - Lipid parameters
  - Blood cell counts (leukocytes, lymphocytes, neutrophils, platelets, reticulocytes, hemoglobin, hematocrit)

*Includes malignancy, thromboembolic events, major cardiovascular events, opportunistic infections, serious infections, complicated zoster, and laboratory abnormalities of interest.
ECG, electrocardiogram; TEAE, treatment-emergent adverse event.

Topline summary

- **Primary:**
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- **PK:** Plasma exposure
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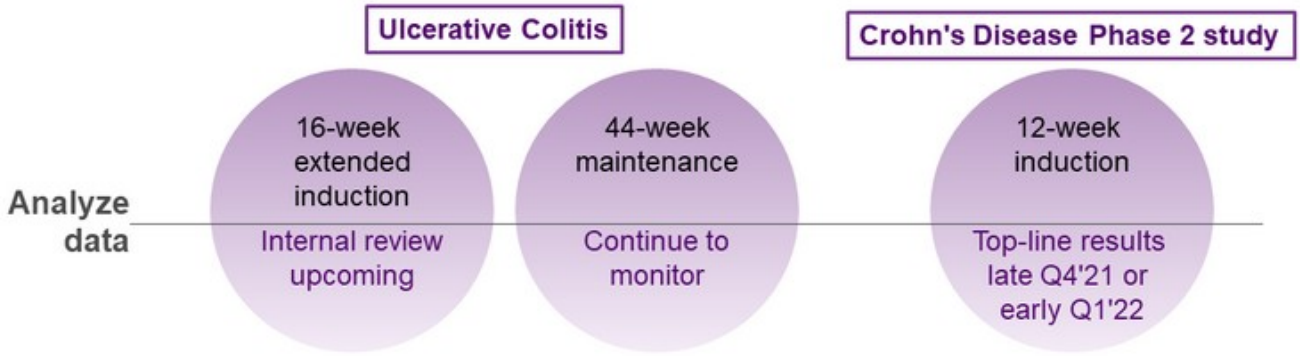
CRP, C-reactive protein; JAK, Janus kinase; UC, ulcerative colitis.

Izencitinib program current plan



Based on the ulcerative colitis results, the Company will seek to minimize future expenses associated with the izencitinib program.


Rick E Winningham
Chairman and Chief Executive Officer
Richard A. Graham
Senior Vice President, Development
Andrew A. Hindman
Senior Vice President, Chief Financial Officer
Q&A Session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