



Izencitinib (TD-1473/JNJ-8398)

Top-line Results from Phase 2b Dose-Finding
Induction Study in Patients with Ulcerative Colitis

August 23, 2021

Forward-looking statements

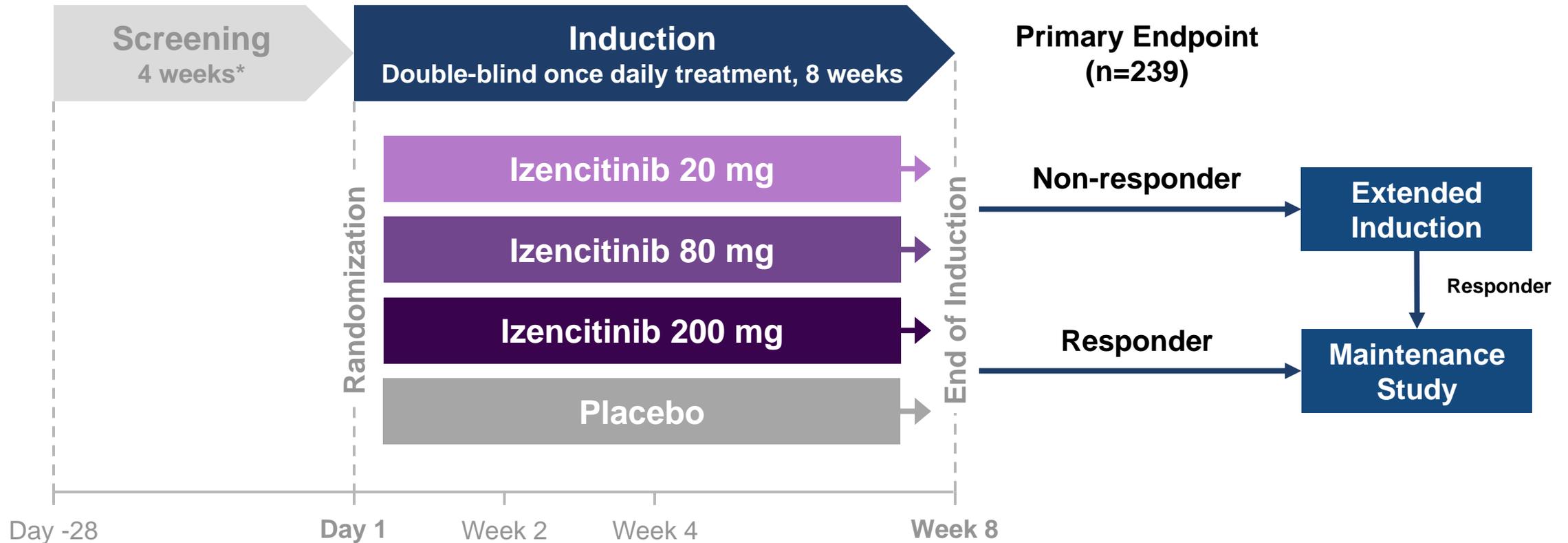
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking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



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:**

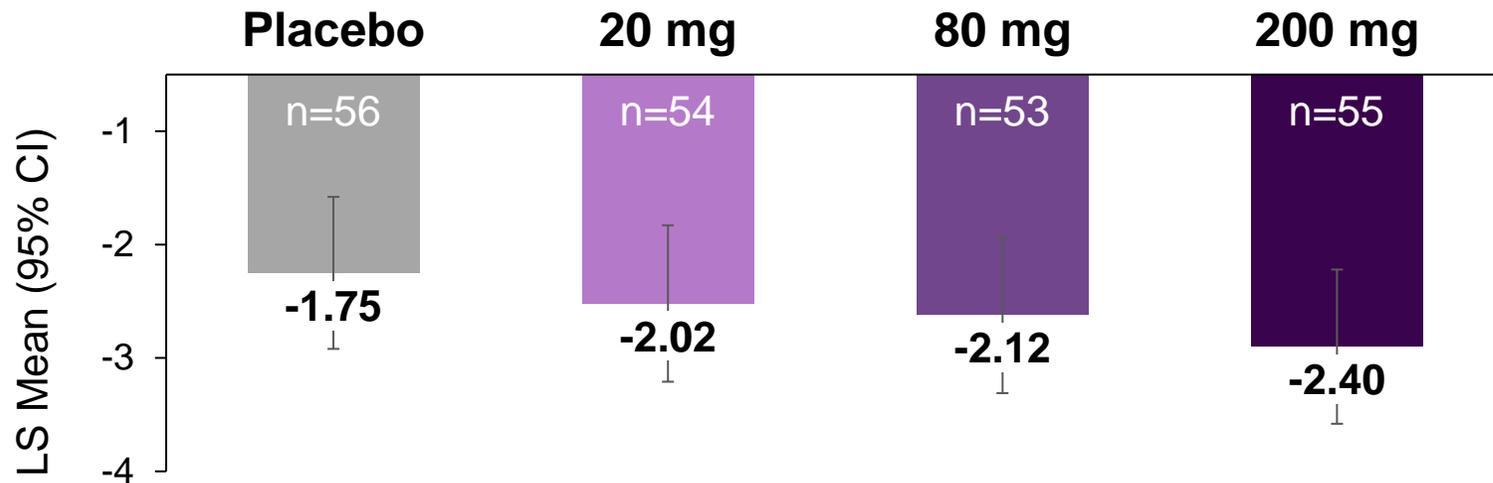
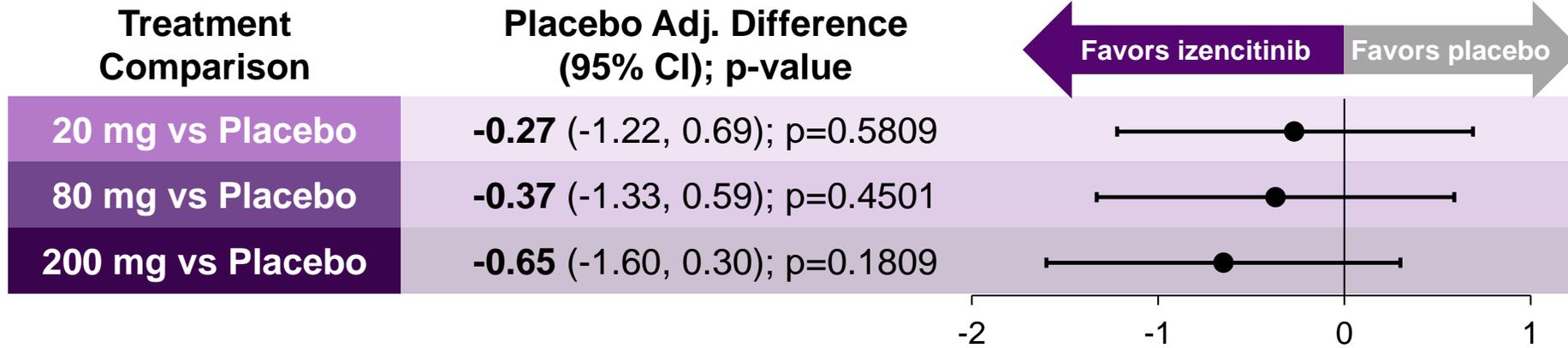
- Izencitinib was well-tolerated as a single daily dose administered for 8 weeks at all doses
- No safety signal and no clinically significant laboratory changes typical of systemic JAK inhibitors

▶ **PK: Plasma exposure**

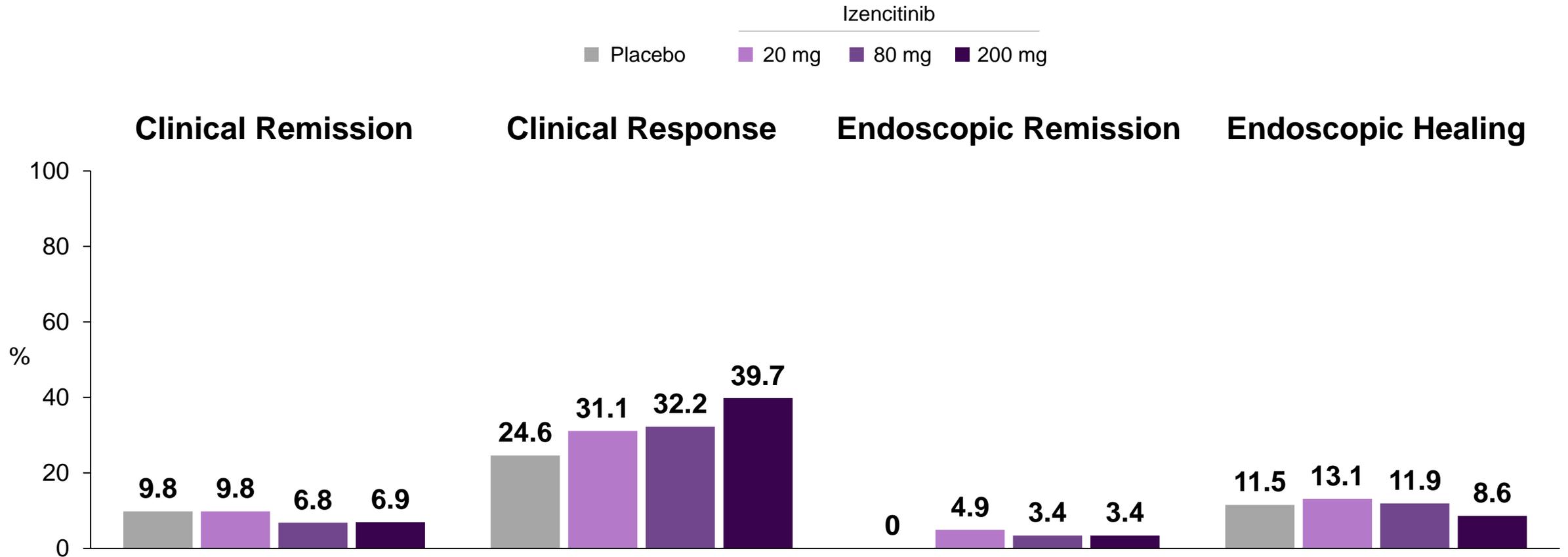
- Low and consistent with historical studies in UC patients and healthy participants

Change in total Mayo score at week 8

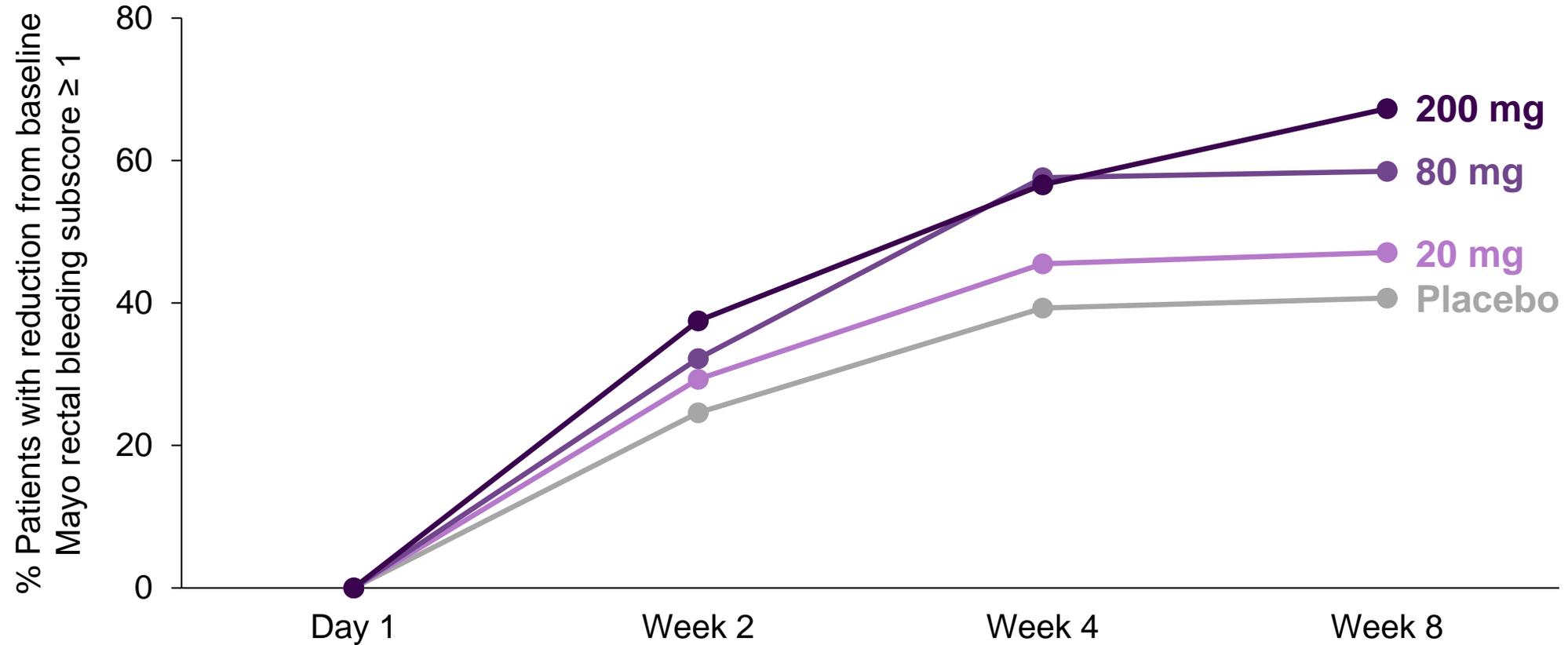
Observed changes appeared to be dose-dependent



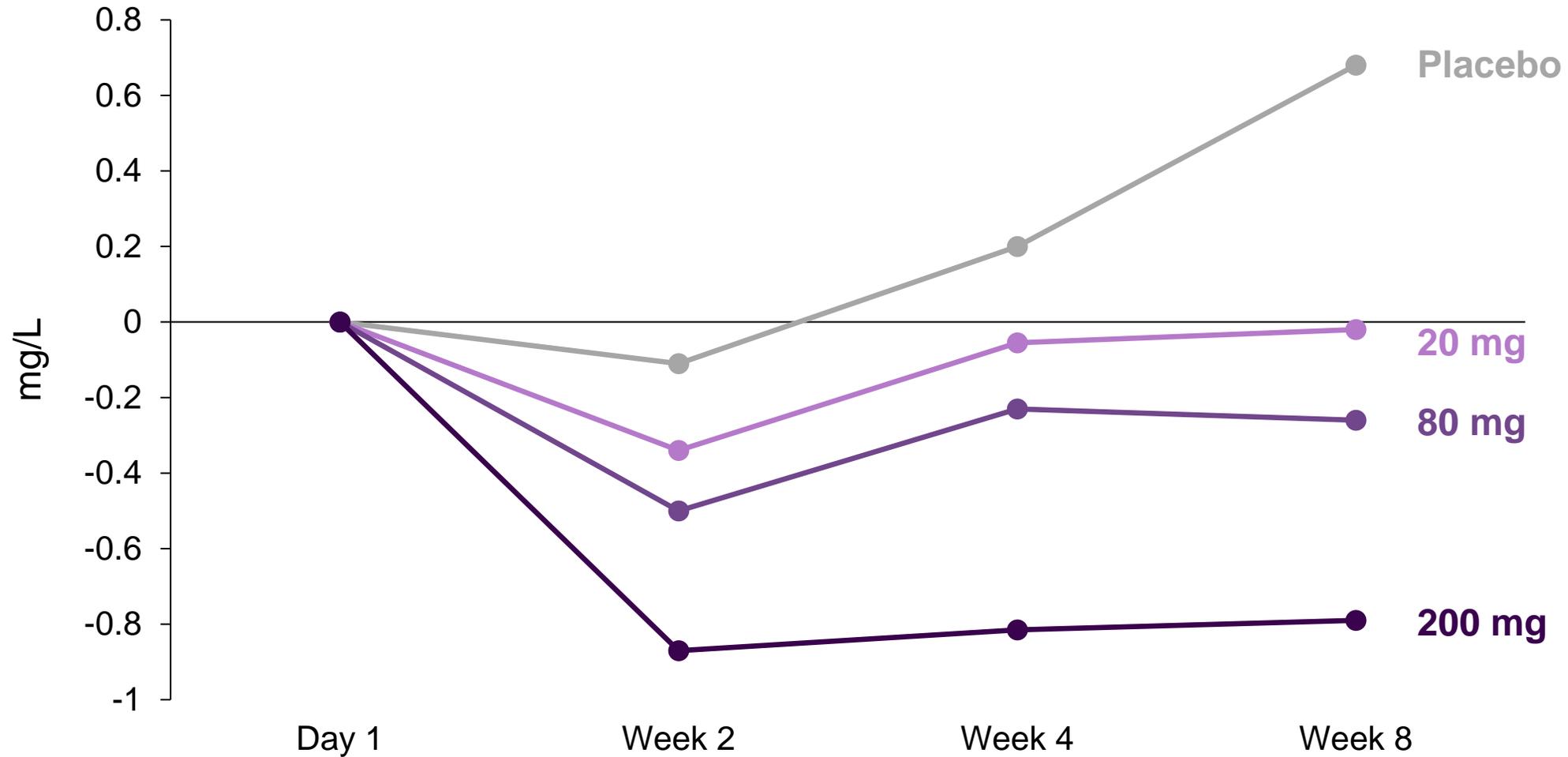
Rates of key secondary endpoints at 8 weeks



Rectal bleeding improvement (%) over time



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



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)

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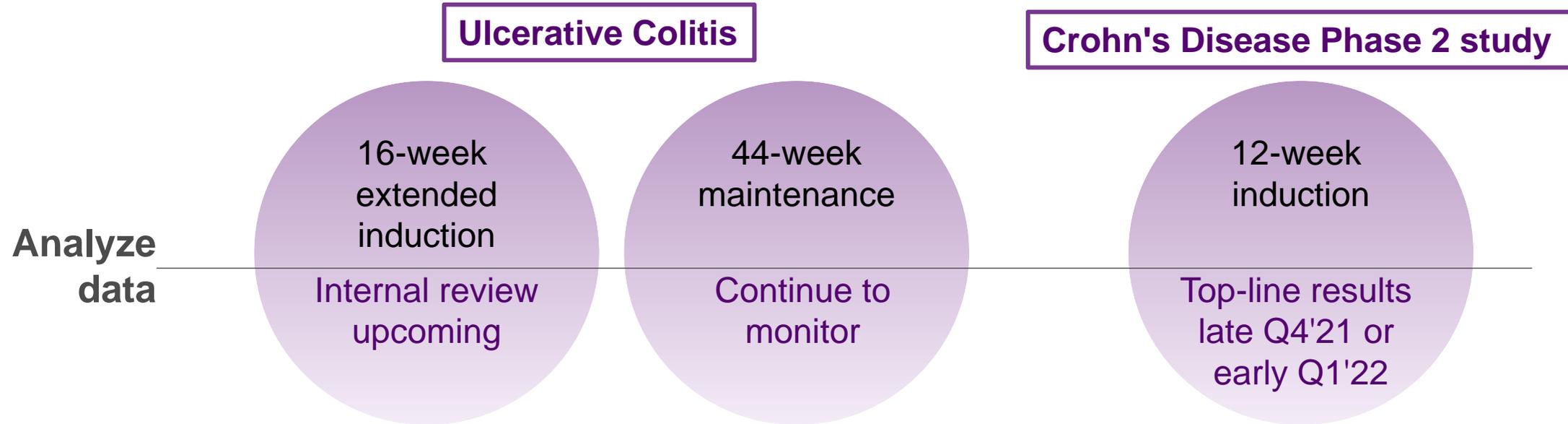
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▶ **PK: Plasma exposure**

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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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