

# TOFACITINIB ULCERATIVE COLITIS CLINICAL TRIAL DEVELOPMENT PROGRAM OVERVIEW

*Tofacitinib is not approved for the treatment of UC and is currently under investigation.*

## About Tofacitinib

Tofacitinib is an oral Janus kinase (JAK) inhibitor being investigated for the treatment of adult patients with moderate to severe active ulcerative colitis (UC). Tofacitinib acts on specific inflammatory responses thought to play a role in the inflammation associated with UC.

## Clinical Research of Tofacitinib in UC

The safety and efficacy of tofacitinib 5 and 10 mg twice daily (BID) is currently being evaluated in clinical trials. The Phase 3 **O**ral **C**linical **T**rials for tof**A**ctinib in ulcerati**V**E colitis (OCTAVE) global clinical development program includes three Phase 3 studies, OCTAVE Induction 1, OCTAVE Induction 2 and OCTAVE Sustain, as well as a long-term extension trial, OCTAVE Open.

- **OCTAVE Induction 1 & 2:** 8-week identical, pivotal, Phase 3, placebo-controlled studies. The primary endpoint of both these studies was induction of remission\* by oral tofacitinib 10 mg BID in patients with moderate to severe active UC.<sup>1,2</sup> The studies also evaluated safety and tolerability of tofacitinib. Detailed results were presented at the 11th Congress of ECCO in March 2016.
- **OCTAVE Sustain:** 52-week pivotal, Phase 3, placebo-controlled study examined tofacitinib 5 and 10 mg BID as a maintenance treatment in patients with moderate to severe active UC who achieved clinical response or remission\* in OCTAVE Induction 1 or 2. The purpose of the study was to evaluate the efficacy, safety, and tolerability of tofacitinib.<sup>3</sup> Topline results were announced in July 2016. Detailed results were presented at the 12th Congress of ECCO in February 2017.
- **OCTAVE Open:** open-label extension study designed to assess the safety and tolerability of tofacitinib 5 and 10 mg BID in patients who completed or who had treatment failure in OCTAVE Sustain or who were non-responders in OCTAVE Induction 1 or 2. The study is currently ongoing and completion is anticipated in July 2018.<sup>4</sup>

\* Remission was defined as a Mayo score of 2 points or lower, with no individual subscore exceeding 1 point, and a rectal bleeding subscore of 0.

#### REFERENCES

1. A Study To Evaluate Both The Efficacy and Safety Profile of CP-690,550 In Patients With Moderately to Severely Active Ulcerative Colitis (OCTAVE). <https://clinicaltrials.gov/ct2/show/NCT01458951?term=OCTAVE+Induction+1+%26+2&rank=3>. Accessed January 12, 2017.
2. A Study Evaluating The Efficacy And Safety Of CP-690,550 In Patients With Moderate To Severe Ulcerative Colitis (OCTAVE). <https://clinicaltrials.gov/ct2/show/NCT01465763?term=OCTAVE+Induction+1+%26+2&rank=2>. Accessed January 12, 2017.
3. A Study Of Oral CP-690,550 As A Maintenance Therapy For Ulcerative Colitis (OCTAVE). <https://clinicaltrials.gov/ct2/show/NCT01458574?term=octave+sustain&rank=1>. Accessed January 12, 2017.
4. Long-Term Study Of CP-690,550 In Subjects With Ulcerative Colitis (OCTAVE). <https://clinicaltrials.gov/ct2/show/NCT01470612?term=octave+open&rank=1>. Accessed January 12, 2017.

