



## **Odyssey Therapeutics Presents Completed Phase 2a OD-001 Induction Results Strengthening Clinical Proof of Concept at UEG Week 2026**

*Correlation between clinical efficacy and changes in inflammatory biomarkers, mucosal transcriptomic signatures, and histologic disease activity strengthens the previously shown clinical proof of concept for OD-001*

*Favorable tolerability profile and oral administration underscore the potential of OD-001 as a monotherapy and backbone for combination regimens in inflammatory bowel disease*

*Company to host conference call and webcast at 8:00 a.m. EDT*

**BOSTON, October 20, 2026 (GLOBE NEWSWIRE)** — [Odyssey Therapeutics, Inc.](#) (Nasdaq: ODTX) (“Odyssey” or the “Company”), a clinical-stage biopharmaceutical company seeking to transform the standard of care for patients suffering from autoimmune and inflammatory diseases by developing medicines that precisely target disease pathology, today announced results from the completed induction period of its Phase 2a clinical trial evaluating OD-001, an oral, selective RIPK2 scaffolding inhibitor, in patients with moderate-to-severe ulcerative colitis (UC). The results were presented earlier today at United European Gastroenterology (UEG) Week in Barcelona, Spain, and will be discussed alongside additional analyses during a conference call and webcast to be hosted by Odyssey.

The completed OD-001 induction analysis comprises all 56 efficacy-evaluable patients. The high correlation between treatment outcomes and changes in inflammatory biomarkers, mucosal transcriptomic signatures, and histologic disease activity strengthens the previously established clinical proof of concept for OD-001 and provides biological evidence consistent with RIPK2 scaffolding inhibition. Combined with Phase 1 pharmacology data, these findings support 20 mg twice daily (BID) as the projected lowest maximally efficacious dose.

“These new analyses provide compelling evidence of pharmacologic activity at 20 mg BID, including clinical efficacy in patients with severe endoscopic disease and improvements across markers of intestinal and systemic inflammation,” said Gary D. Glick, Ph.D., founder and chief executive officer of Odyssey Therapeutics. “Transcriptomic findings that align with clinical activity and are consistent with RIPK2 scaffolding inhibition reinforce the mechanistic rationale for this approach in inflammatory bowel disease, strengthen our confidence in the treatment activity of OD-001, and support its continued clinical development.”

### **Key highlights from the induction period data**

- **Induction (Week 12) efficacy:** OD-001 met the trial's primary endpoint of change from baseline in modified Mayo score at the end of induction at Week 12 (mean reduction of 2.4 points across the evaluable population;  $p < 0.001$ ). At this time point, clinical remission, clinical response, and symptomatic remission were 27%, 61%, and 49%, respectively, in the pooled 20 mg BID group ( $n=41$ ) and 20%, 40%, and 27%, respectively, at 10 mg BID ( $n=15$ ).
- **Improvement in validated biomarkers of intestinal and systemic inflammation:** In patients treated with 20 mg BID, fecal calprotectin trended lower, hsCRP and circulating neutrophils were significantly decreased, and serum albumin significantly increased—all changes consistent with reduced intestinal and systemic inflammation. The reduction in neutrophils, a RIPK2-expressing cell type implicated in IBD pathogenesis, provides additional mechanistic support.
- **Rapid onset and deepening symptomatic benefit:** Symptomatic remission at 20 mg BID reached 21% at Week 2, increasing throughout the induction period with no plateau observed through Week 12.
- **Comparable efficacy across prior treatment exposure:** After 12 weeks of treatment with OD-001, clinical remission at 20 mg BID was 29% in advanced therapy-naïve ( $n=28$ ) and 23% in advanced therapy-experienced ( $n=13$ ) patients.
- **Clinical activity in patients with most severe endoscopic disease:** Clinical remission at Week 12 for patients taking OD-001 at 20 mg BID was 16% in patients with a Mayo Endoscopic Score (MES) of 3 ( $n=19$ ).

## Transcriptomic analyses reinforce OD-001 treatment activity

- **On-target activity indicative of RIPK2 inhibition:** Exploratory analyses of paired colonic biopsies from baseline and Week 12 showed reductions in RIPK2-responsive and downstream inflammatory gene signatures, including IL-23, TNF/NF- $\kappa$ B, TL1A, AP-1 and T-cell-associated pathways, supporting the proposed mechanism of action.
- **Modulation of fibrosis-associated and epithelial gene signatures:** Reductions in fibrosis-associated signatures and increased expression of genes linked to epithelial homeostasis and mucosal healing aligned with clinical outcomes.
- **Distinct pharmacology relative to approved mechanisms:** Exploratory patient-level comparisons with published datasets of approved therapies suggest OD-001 modulates RIPK2-associated pathways beyond general mucosal improvement achieved with other agents, supporting a differentiated mechanism of action and pharmacodynamic profile.

## Safety and tolerability

OD-001 was generally well tolerated during the 12-week induction period, with no serious adverse events, serious infections, treatment-related discontinuations, or treatment-emergent liver function abnormalities. As previously reported, three adverse events in the 20 mg BID group were considered drug-related (two fevers and one headache). One Grade 3 anemia event in the 10 mg BID group occurred in a patient with pre-existing anemia, was considered unrelated to treatment, and resolved with iron supplementation without discontinuing OD-001.

## Phase 2a clinical trial overview

The Phase 2a trial ([NCT06850727](#)) evaluated the efficacy, safety and tolerability of oral OD-001 in patients with moderate-to-severe ulcerative colitis using an open-label, dose-ranging design. The 12-week induction period included 10 mg and 20 mg BID dosing, with change from baseline in the three-component modified Mayo score as the primary endpoint. This open-label trial had no concurrent placebo control, and the data remain subject to change until database lock.

## **OD-001 advancing into Phase 2b monotherapy and Phase 2a combination trials**

Odyssey plans to advance OD-001 into a randomized, placebo-controlled Phase 2b monotherapy trial and a randomized, active-controlled Phase 2a trial evaluating OD-001 plus vedolizumab versus vedolizumab plus placebo. Both studies will be double-blind, with topline induction results expected in the second half of 2027.

### **Conference call and webcast**

Odyssey will host a conference call and webcast today at 8:00 a.m. EDT to discuss the completed Phase 2a induction results, including additional analyses beyond those presented at UEG. The live webcast and accompanying presentation will be available through the Investors section of Odyssey Therapeutics' website at [www.odysseytx.com](http://www.odysseytx.com). A replay will be available following the event.

### **About Odyssey Therapeutics**

Odyssey Therapeutics is a clinical-stage biopharmaceutical company seeking to transform the standard of care for patients suffering from autoimmune and inflammatory diseases by developing medicines that are designed to precisely target disease pathology. Since its founding in 2021, Odyssey has built a portfolio of internally discovered and developed medicines with its first program advancing through multiple clinical milestones. Odyssey's portfolio leverages the scientific expertise of its team of experienced drug hunters and a comprehensive suite of tools to efficiently advance product candidates that the Company believes have the potential to induce deep and durable remission for patients across several inflammatory diseases with unmet need.

For more information, please visit <http://www.odysseytx.com> and follow Odyssey on [LinkedIn](#) or [X](#).

### **Forward-looking statements**

This press release includes certain disclosures that contain "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of

1995, including, without limitation, statements regarding the interpretation and potential implications of OD-001's Phase 2a clinical, safety and exploratory transcriptomic results; evidence of treatment activity and RIPK2 inhibition; selection of 20 mg BID for further development; OD-001's potential efficacy, safety and use as an oral monotherapy, in combination with vedolizumab or for maintenance treatment; and the design, timing and anticipated results of planned Phase 2b monotherapy and Phase 2a combination trials, including expected topline induction results in the second half of 2027.

Forward-looking statements may be identified by words such as "anticipate," "believe," "could," "expect," "intend," "goal," "may," "plan," "potential," "will," "would" and variations of these words or similar expressions, although not all forward-looking statements contain these identifying words. Forward-looking statements reflect Odyssey's current expectations and involve risks and uncertainties that could cause actual results to differ materially. These include the inherent limitations of an open-label trial without a concurrent placebo control; potential uncertainty about exploratory transcriptomic findings; the possibility of different outcomes in future trials; clinical, regulatory, competitive and third-party risks; and other factors described under "Risk Factors" in Odyssey's most recent Form 10-Q and other SEC filings. Forward-looking statements contained in this press release are made as of this date, and Odyssey undertakes no obligation to update these statements except as required by law.

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