

## Roivant rises on growing hopes for novel immunology mechanism



Amy Brown

After [impressive induction results in January](#), maintenance data from the same trial of Roivant’s RVT-3101 have increased excitement about the novel TL1A-targeting mechanism. Ulcerative colitis patients showed ongoing improvements on clinical and endoscopic remission endpoints in the phase 2b [Tuscany-2](#) trial, with “compelling efficacy” across cohorts at 56 weeks; Roivant executives described the 36% endoscopic remission rate in biomarker-positive patients treated with the anticipated phase 3 dose as unparalleled. The group is keeping details on the biomarker and exact phase 3 dose under wraps for now, citing a competitive advantage over Merck & Co, [which paid \\$11bn for Prometheus's similarly acting project earlier this year](#). Roivant did confirm that its pivotal programme would recruit all-comers while stratifying for the biomarker, which it insists delivers a “clinically meaningful benefit”. These data still need close scrutiny on full presentation, of course, and confirming in phase 3, but investors saw enough today to drive Roivant’s stock 16% higher. On a call executives said the data “encourages blue sky thinking” about the potential of this asset, and with many of the questions from analysts directed at the company’s plans beyond ulcerative colitis it seems the sellside has also been convinced.

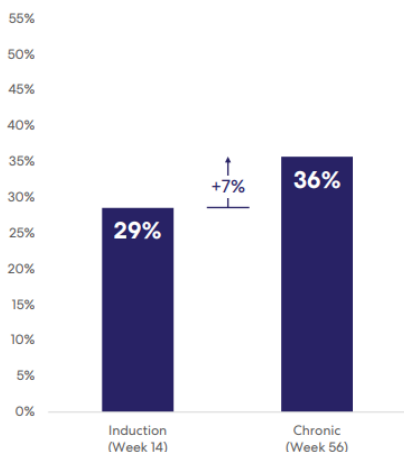
### Cohort data from Tuscany-2 trial of RVT-3101

Constant Expected P3 Dose Arm    Any Biomarker Status    Biologic Naïve and Experienced

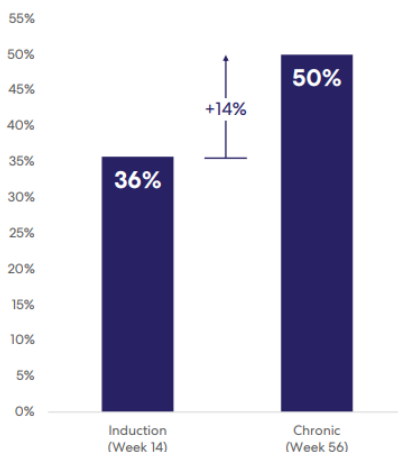
#### At the Expected Phase 3 Dose, Substantial Improvements Were Observed Across All Key Efficacy Metrics with Chronic Dosing

Efficacy data from patients assigned Expected P3 Dose throughout study

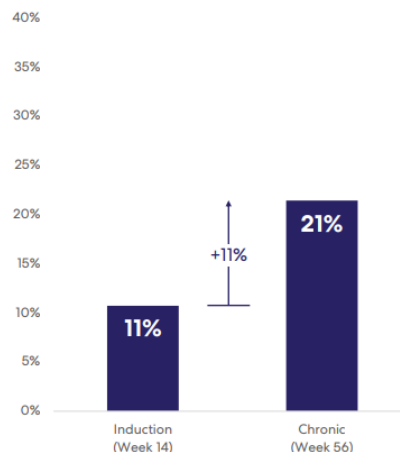
##### Clinical Remission (Modified Mayo)



##### Endoscopic Improvement



##### Endoscopic Remission



• Induction and Chronic Period data shown here and on future slides refer to mITT population at Week 14 and Week 56, where mITT is defined as patients who received at least one dose of RVT-3101 in the Chronic Period  
 • Delta values may not exactly match the difference between Week 14 and Week 56 values due to rounding

Source: Roivant presentation.

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