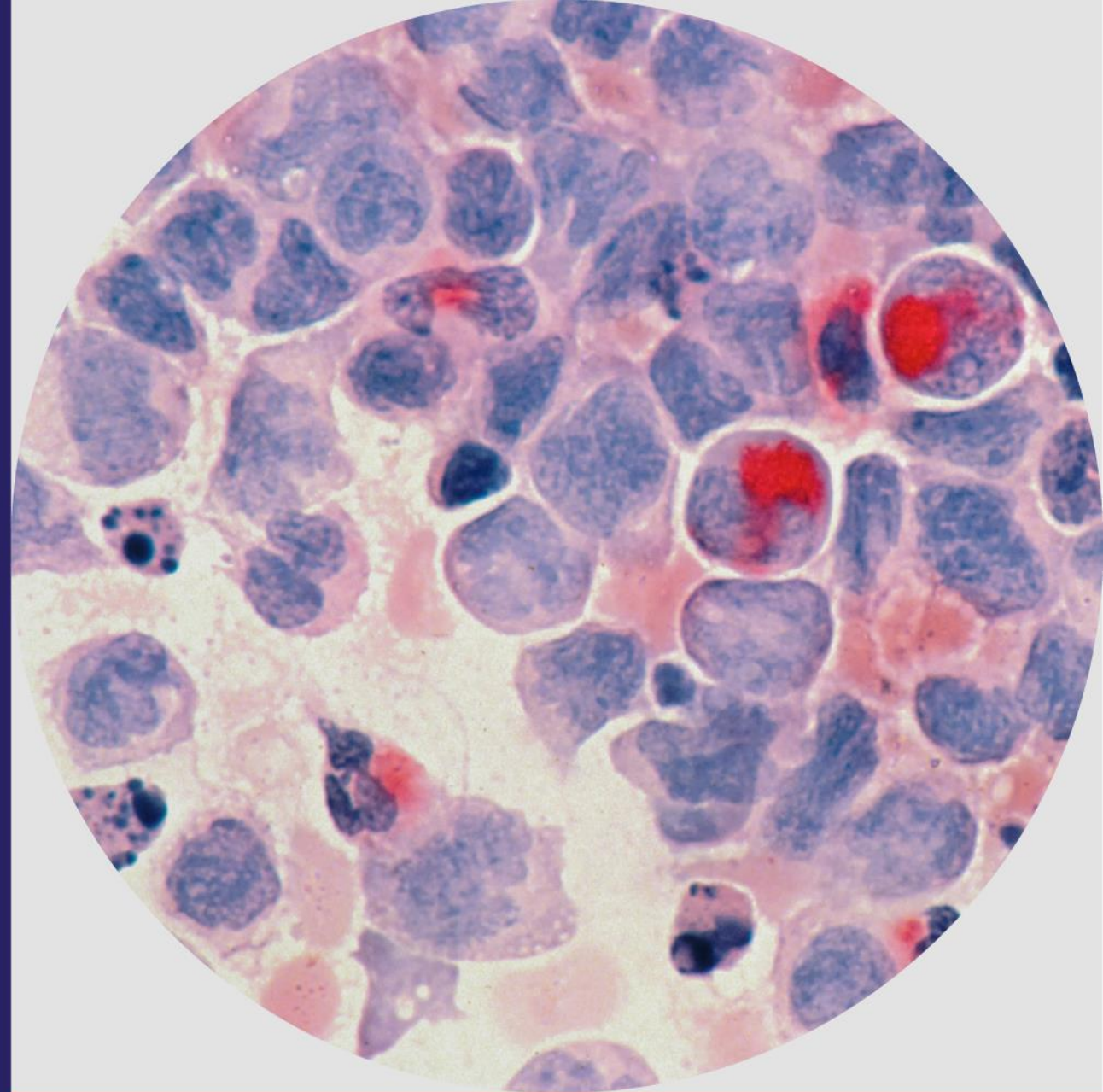


# RVT-3101 TUSCANY-2 Chronic Period Data Presentation

June 2023

roivant



# Forward-Looking Statements

This presentation includes forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and clinical trials for our products and product candidates, including the information presented in this presentation with respect to RVT-3101 and the potential for RVT-3101 to improve the treatment of Ulcerative Colitis (UC) and Crohn's Disease (CD) and to be a first-in-class agent, are forward-looking statements.

These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this presentation, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements. The data presented here is from the induction and chronic periods of the TUSCANY-2 study and is based on a preliminary analysis of key efficacy and safety data, and such data may change following completion of the clinical trial and may not accurately reflect the complete results of the TUSCANY-2 study.

These forward-looking statements will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the sections captioned "Risk Factors" and "Forward-Looking Statements" of our

filings with the U.S. Securities and Exchange Commission, available at [www.sec.gov](http://www.sec.gov) and [investor.roivant.com](http://investor.roivant.com). We operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.














This presentation includes data, results and attributes for RVT-3101 and certain other products and product candidates generated from separate, independent studies and that do not come from head-to-head analysis. Differences exist between study or trial designs and patient characteristics and caution should be exercised when comparing data across studies. Data regarding other products and product candidates is based on publicly available information.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Today's discussions and presentation are intended for the investor community only; they are not intended to promote the product candidates referenced herein, which remain subject to regulatory approval, or to otherwise influence healthcare prescribing decisions.

# Roivant Has One of the Deepest Immunology Pipelines in the Industry

Seven ongoing registrational trials in multi-billion dollar markets

	Modality	Preclinical	Phase 1	Phase 2	Phase 3	Approved
 <b>VTAMA</b> (tapinarof) cream 1% Psoriasis   <i>Dermavant</i>	Topical					▶
 <b>VTAMA</b> (tapinarof) cream 1% Atopic Dermatitis   <i>Dermavant</i>	Topical				Completed	
 <b>RVT-3101</b> Ulcerative Colitis   <i>New Vant</i>	Biologic			Completed		
 <b>RVT-3101</b> Crohn's Diseases   <i>New Vant</i>	Biologic			▶		
 <b>BREPOCITINIB</b> Dermatomyositis   <i>Priovant</i>	Small Molecule				▶	
 <b>BREPOCITINIB</b> Systemic Lupus Erythematosus   <i>Priovant</i>	Small Molecule			▶		
 <b>BREPOCITINIB</b> Other Indications   <i>Priovant</i>	Small Molecule			▶		
 <b>BATOCLIMAB</b> Myasthenia Gravis   <i>Immunovant</i>	Biologic				▶	
 <b>BATOCLIMAB</b> Thyroid Eye Disease   <i>Immunovant</i>	Biologic				▶	
 <b>BATOCLIMAB</b> Chronic Inflammatory Demyelinating Polyneuropathy   <i>Immunovant</i>	Biologic			▶		
 <b>BATOCLIMAB</b> Graves' Disease   <i>Immunovant</i>	Biologic			▶		
 <b>IMVT-1402</b> Numerous Indications   <i>Immunovant</i>	Biologic		▶			
 <b>NAMILUMAB</b> Sarcoidosis   <i>Kinevant</i>	Biologic			▶		

▶ Represents registrational or potentially registrational trials

# TL1A Blockade is a Unique Mechanism with Broad Potential Application in Both Inflammatory and Fibrotic Diseases

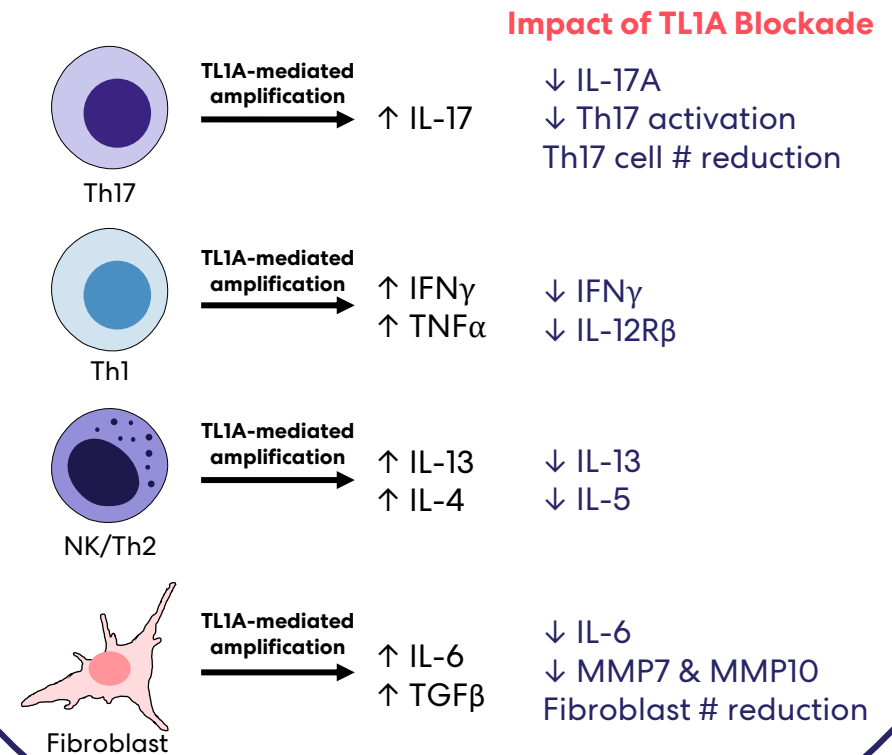
TL1A independently mediates both inflammation and fibrosis. TL1A is linked to numerous immune and fibrotic diseases:

- Multiple Inflammatory Diseases: RA, Atopic Dermatitis, SLE, Asthma, Psoriasis
- Intestinal Fibrosis
- Pulmonary Fibrosis
- Liver Fibrosis

Clinical validation in ulcerative colitis and Crohn's disease in hand, with SSc-ILD also being studied

Additional indications to be announced

Analyses of patient samples from Ph2a TUSCANY study demonstrate impact of RVT-3101 treatment across a broad range of inflammatory and fibrotic biomarkers



# Continued Treatment with RVT-3101 Improves Upon High-End Efficacy Results Observed During the Induction Period in TUSCANY-2

Safety and efficacy observed through 56 weeks confirms RVT-3101 potential for best-in-category profile

	<b>Clinical Remission</b> (Week 14 → Week 56)	<b>Endoscopic Improvement</b> (Week 14 → Week 56)
<b>Overall Population</b> (At Expected Phase 3 Dose)	<b>29% → 36%</b>	<b>36% → 50%</b>
<b>Biomarker Positive</b> (At Expected Phase 3 Dose)	<b>33% → 43%</b>	<b>47% → 64%</b>

**Well-tolerated through 56 weeks across all doses;  
No impact of immunogenicity on clinical efficacy or safety results**

# Two Robust, Positive Studies Conducted By Pfizer To Date

## TUSCANY (Phase 2a)

- 14-week induction study
- IV, single-arm study
- Biologic experienced and naïve
- Exploratory biomarkers; biomarker of interest identified
- Global study
- N = 50

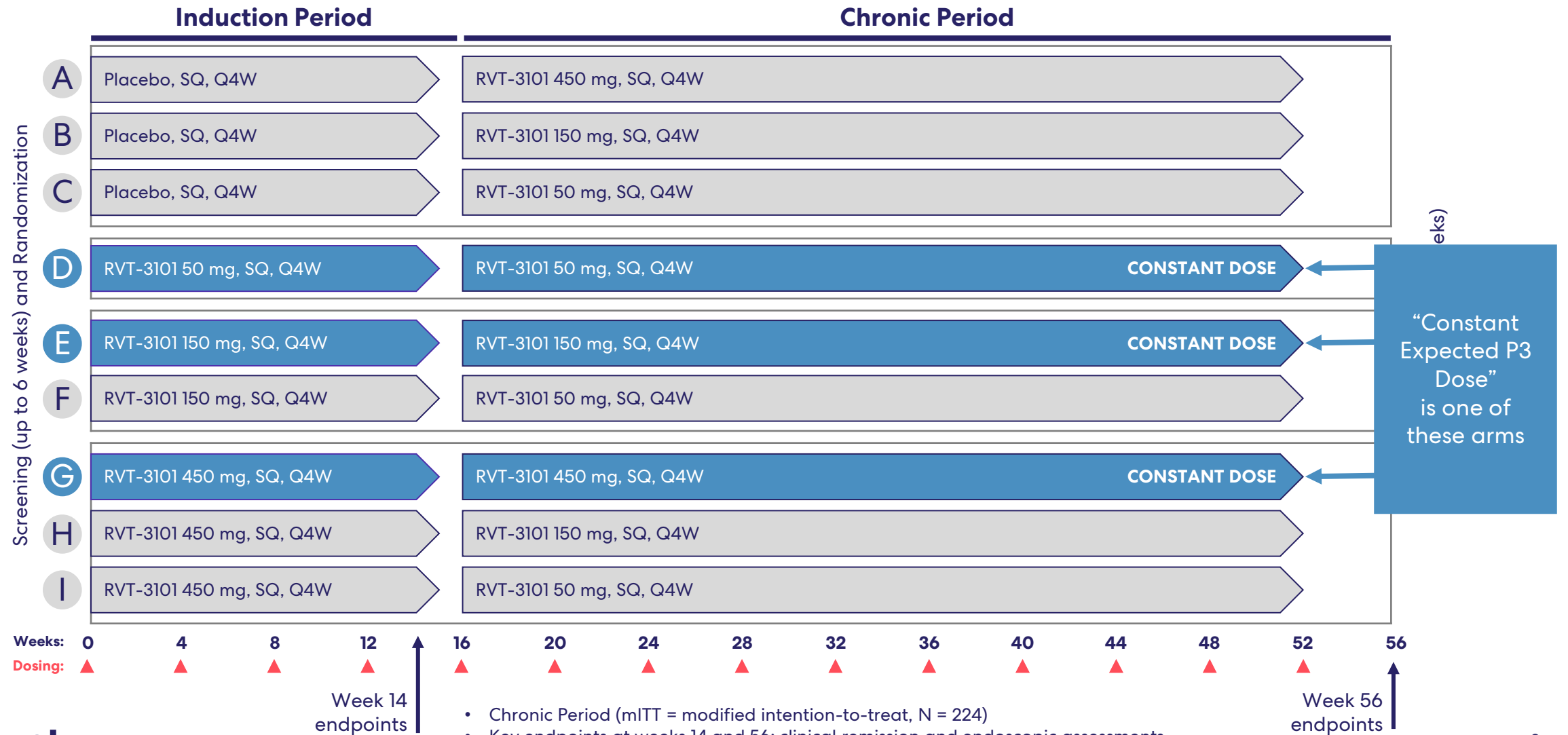
## TUSCANY-2 (Phase 2b)

- 56-week induction and chronic study
- SQ, placebo-controlled dose ranging study
- Biologic experienced and naïve
- Single, prospectively-defined biomarker used
- Global study
- N = 245
- *Among the largest Phase 2b studies conducted in ulcerative colitis*



# TUSCANY-2 Phase 2b Used a Treat-Through Study Design

Patients Randomized to One of Nine Arms at Start of Study

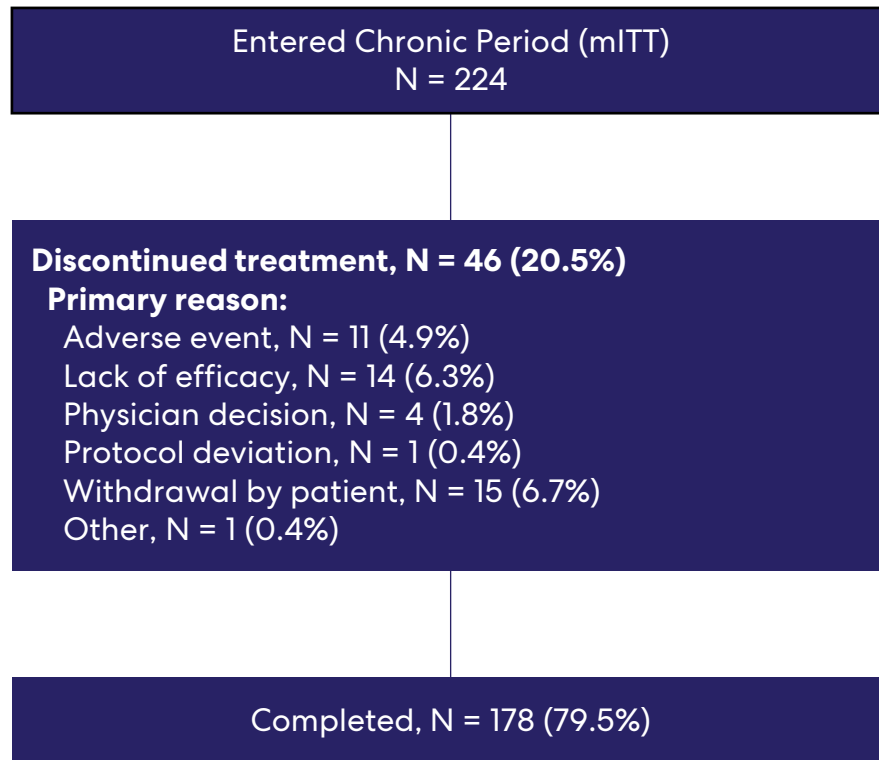


- Chronic Period (mITT = modified intention-to-treat, N = 224)
- Key endpoints at weeks 14 and 56: clinical remission and endoscopic assessments



# Data from Chronic Period of TUSCANY-2

# Patient Disposition in Chronic Period of TUSCANY-2 Phase 2b Study



*mITT is defined as patients who received at least one dose of RVT-3101 during the Chronic Period*

*Efficacy data presented here reflect Induction and Chronic Period data for this group of patients*

*mITT analysis is as prespecified in the Pfizer SAP*

# Baseline Disease Characteristics and Demographics

Baseline characteristics are consistent with the Induction Period and reflective of a refractory and difficult-to-treat patient population

	All Arms N = 224	Constant Expected Ph3 Dose Arm
<b>Age (years, mean)</b>	40.8	46.0
<b>Female</b>	40%	28%
<b>Weight (kg, mean)</b>	71.4	74.8
<b>Geographic Region</b>		
US / Canada / Australia	12%	17%
EU	64%	52%
Asia	19%	24%
Other	5%	7%
<b>Extent of Disease</b>		
Proctosigmoiditis	26%	7%
Left-sided colitis	44%	48%
Pancolitis	40%	41%
<b>Modified Mayo Score (mean)</b>	6.7	6.9
<b>Endoscopy Score</b>		
2	46%	34%
3	54%	66%
<b>Concomitant corticosteroid use</b>	38%	38%
<b>Number of prior advanced therapies exposed</b>		
Naïve	57%	55%
1 prior advanced therapy	18%	14%
2 prior advanced therapies	11%	24%
≥3 prior advanced therapies	14%	7%

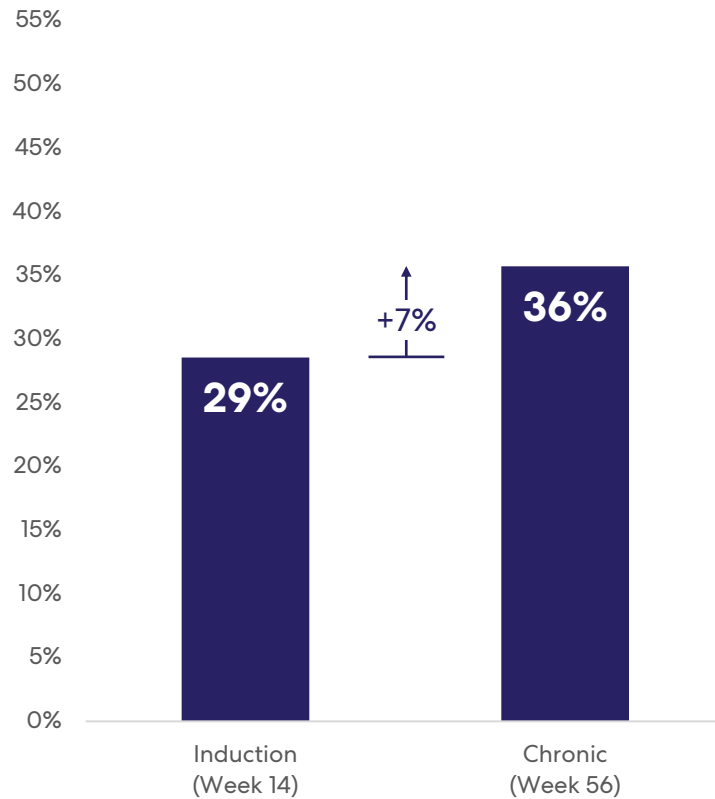
↑  
All Nine  
Arms

↑  
Either Arm  
D, E or G

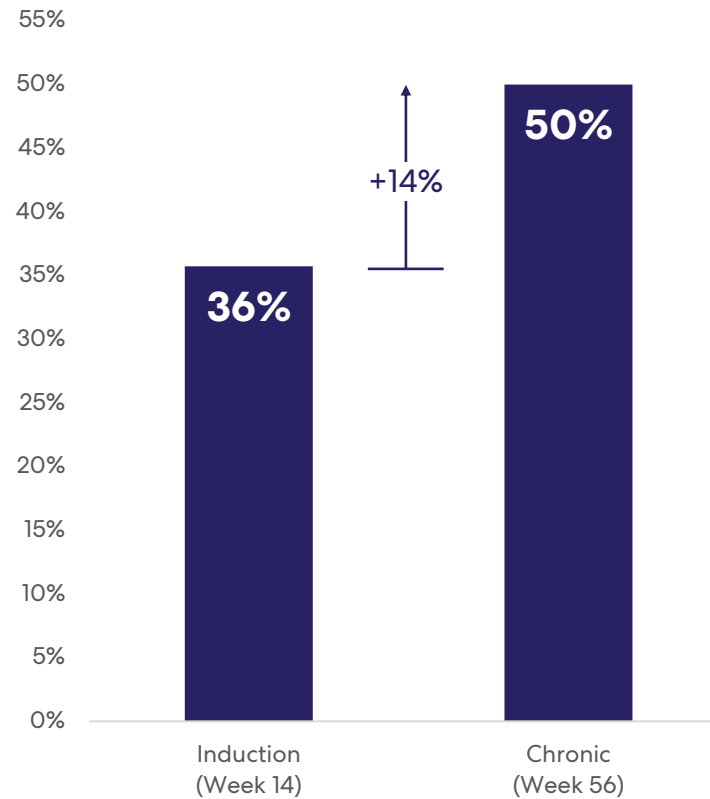
# At the Expected Phase 3 Dose, Substantial Improvements Were Observed Across All Key Efficacy Metrics with Chronic Dosing

Efficacy data from patients assigned Expected P3 Dose throughout study

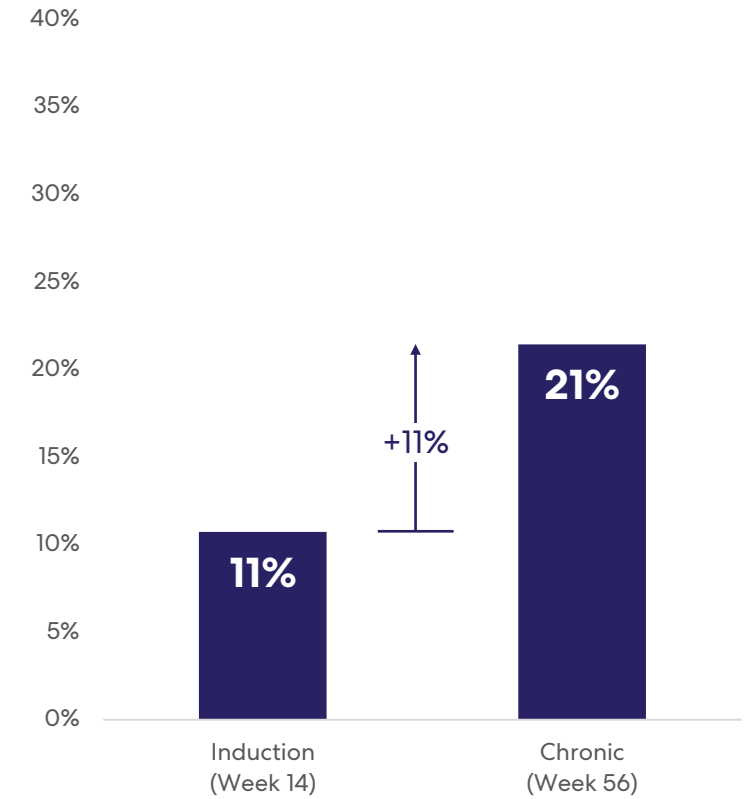
## Clinical Remission (Modified Mayo)



## Endoscopic Improvement



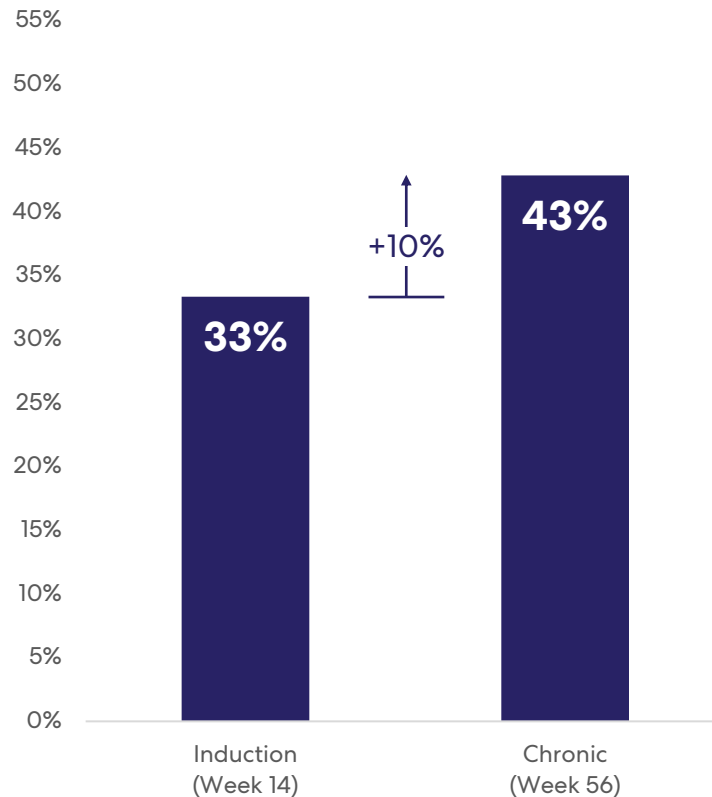
## Endoscopic Remission



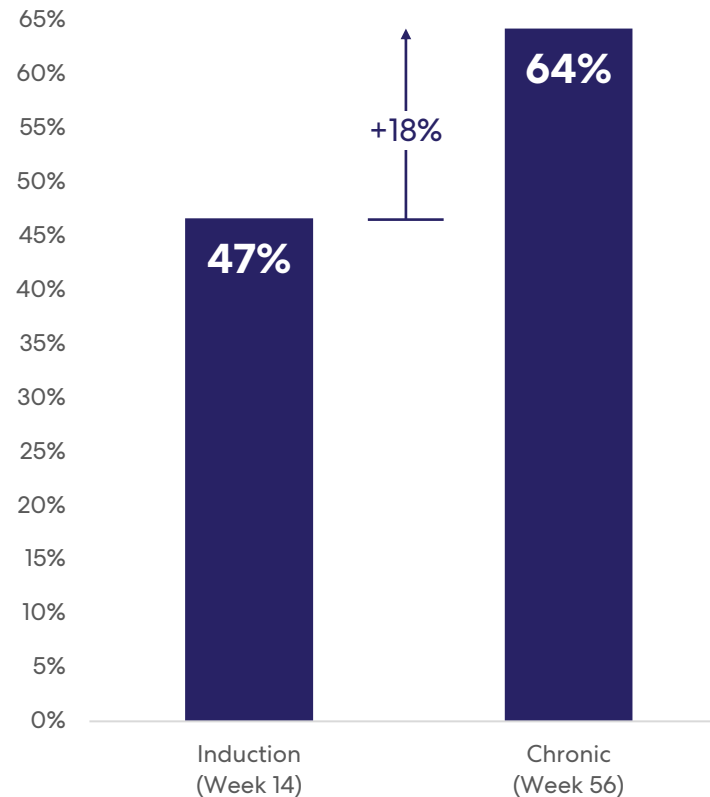
# At the Expected P3 Dose, Even Greater Improvements Were Observed with Chronic Dosing in Biomarker Positive Patients

Efficacy data from biomarker positive patients assigned Expected P3 Dose throughout study

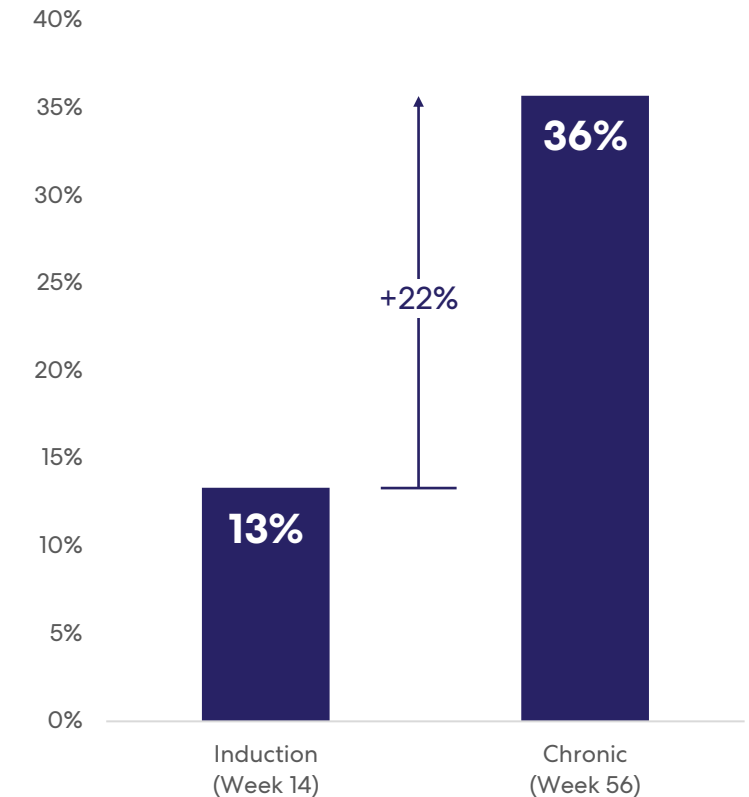
## Clinical Remission (Modified Mayo)



## Endoscopic Improvement



## Endoscopic Remission



# At the Expected Phase 3 Dose, Sustained Efficacy Rates Were Among the Highest Observed in Ulcerative Colitis

Efficacy data from patients assigned Expected P3 Dose throughout study

## Sustained Clinical Remission:

Proportion of Patients With Clinical Remission at Week 14  
Who Maintain Clinical Remission at Week 56

75%

## Sustained Endoscopic Improvement:

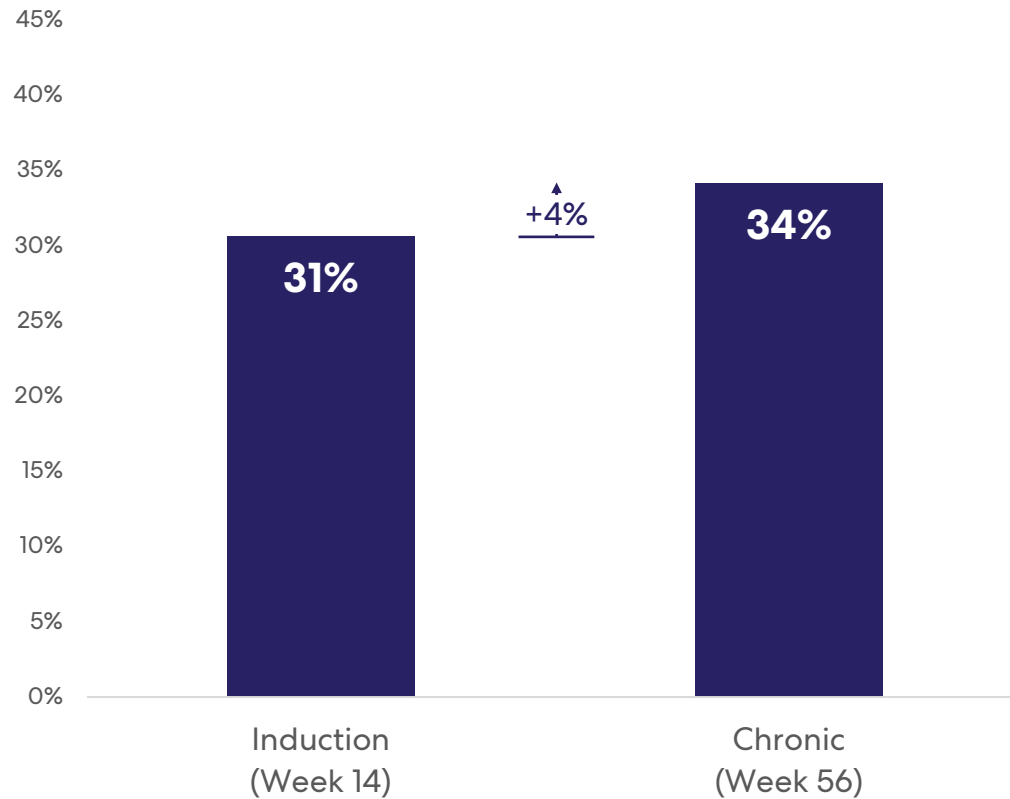
Proportion of Patients With Endoscopic Improvement at Week 14  
Who Maintain Endoscopic Improvement at Week 56

80%

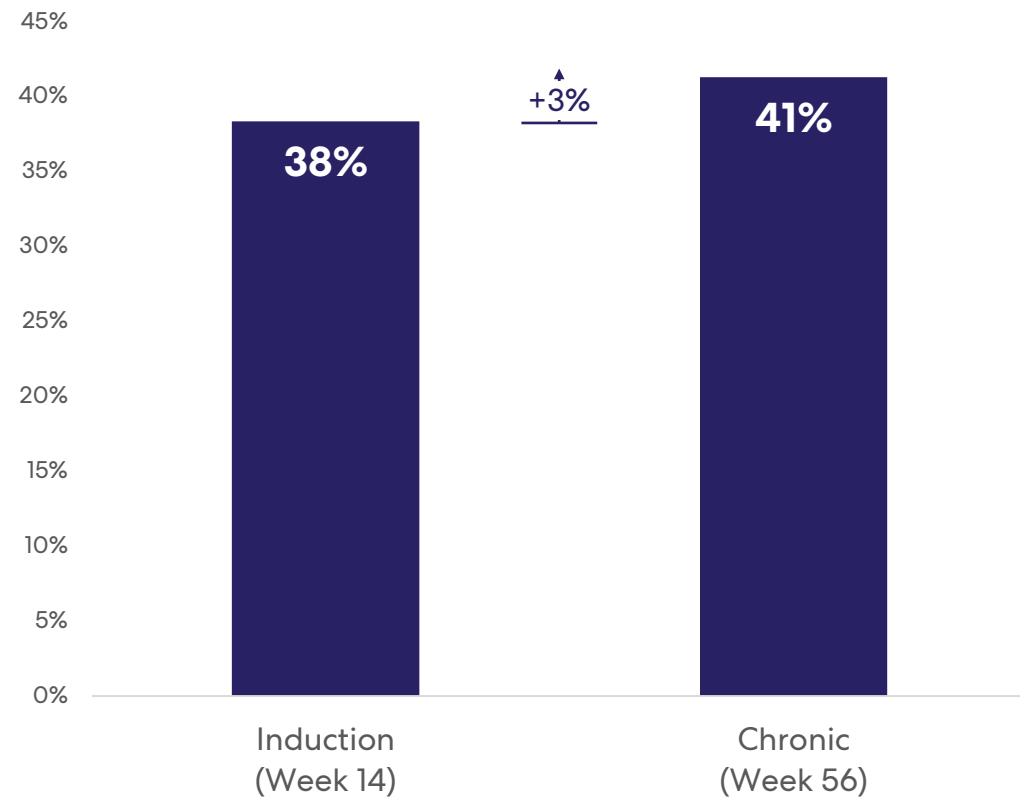
# RVT-3101 Showed Strong Results in All Comer Population that Were Maintained in the Chronic Period Across Endpoints

Efficacy data pooled across all nine arms (A through I)

## Clinical Remission (Modified Mayo)



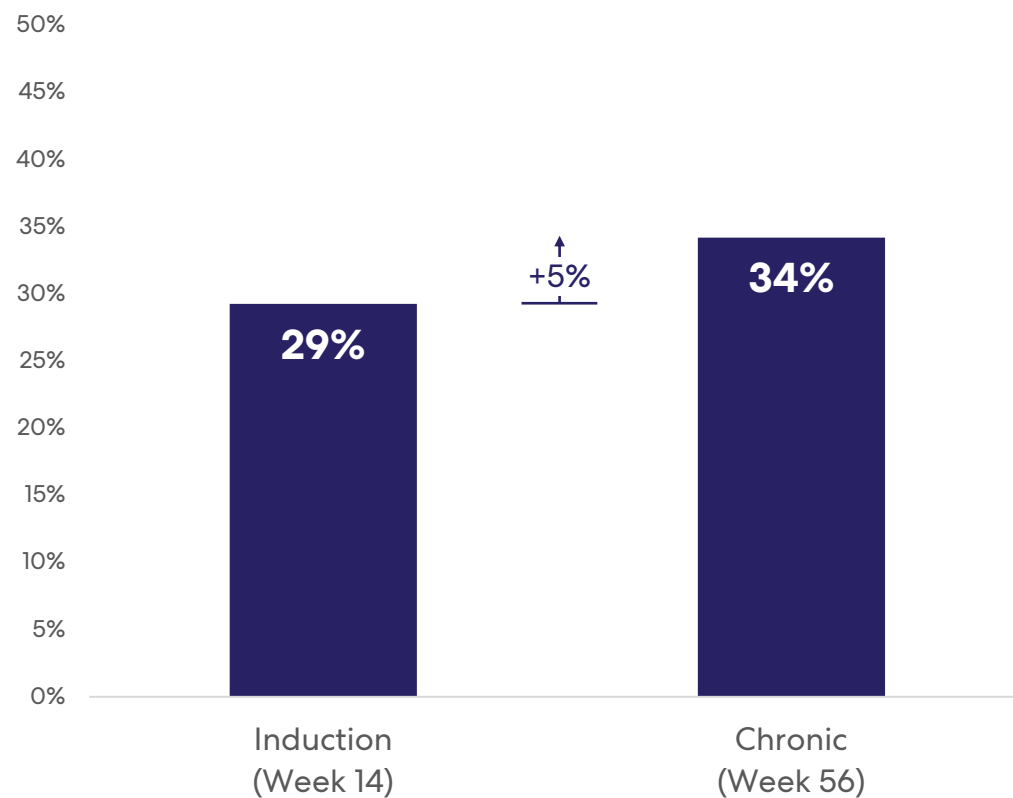
## Endoscopic Improvement



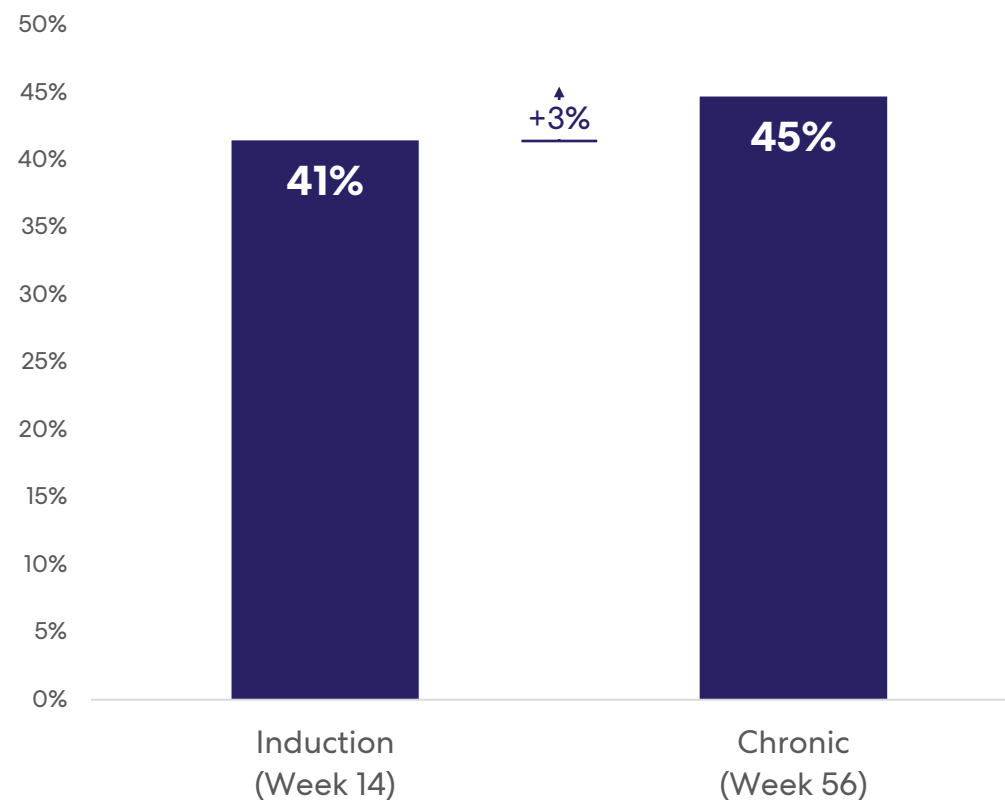
# Biologic-Experienced Patients Who Are Biomarker Positive Saw Transformative Outcomes at Completion of Chronic Period

Efficacy data pooled across all nine arms (A through I)

## Clinical Remission (Modified Mayo)



## Endoscopic Improvement





# RVT-3101 Remained Well Tolerated in the Chronic Period

**Topline Safety data:** no safety signals; favorable safety profile in Induction Period was maintained in Chronic Period

	Induction Period (Prior to Week 16)			Chronic Period (Weeks 16 to 56)		
	Placebo	All Drug Arms	Exp P3 Dose	All Arms	Constant Exp P3 Dose	Pbo → Exp P3 Dose
Participants with adverse events (AEs)	56%	47%	54%	59%	66%	64%
Participants with severe AEs	9%	2%	2%	6%	14%	0%
Participants with serious AEs	9%	4%	4%	5%	14%	0%
Participants who discontinued study due to AEs	0%	0%	0%	0%	0%	0%
Participants who discontinued study drug due to AEs	7%	3%	2%	5%	3%	0%
Participants with dose reduced or temporary discontinuation due to AEs	0%	1%	0%	2%	3%	7%
Deaths	0%	0%	0%	0%	0%	0%
<b>Treatment-Emergent AEs at ≥5% in Chronic Period</b>						
Colitis ulcerative	2%	5%	4%	10%	3%	0%
SARS-CoV-2 test positive	2%	1%	1%	8%	7%	14%
Anemia	9%	5%	2%	8%	10%	0%
Pyrexia	2%	3%	5%	5%	3%	0%
Headache	2%	6%	10%	5%	3%	7%
<b>Injection site reactions</b>	2%	3%	2%	3%	0%	7%

↑ All Nine Arms      ↑ Either Arm D, E or G      ↑ Either Arm A, B or C

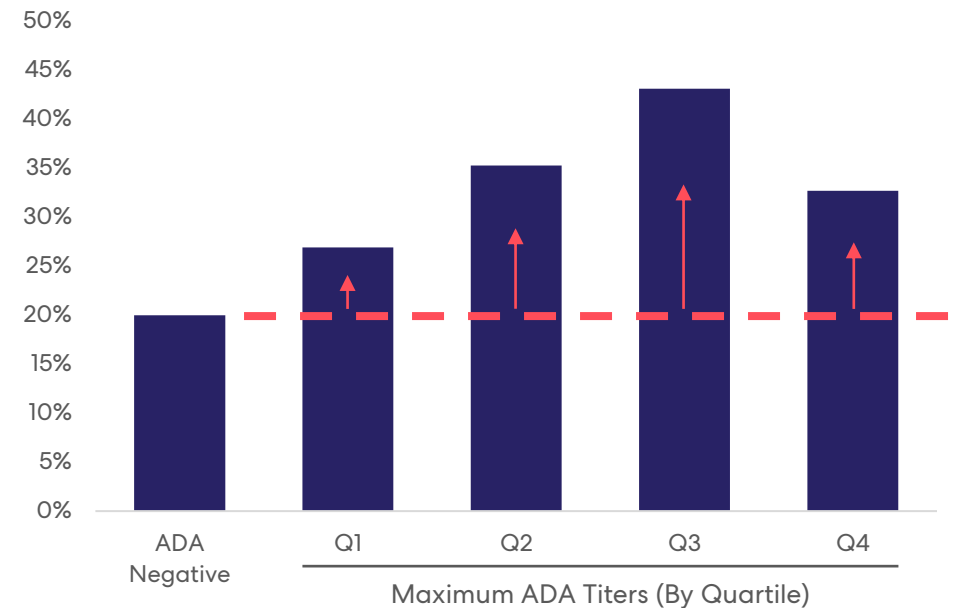
In the  
Chronic  
Period

- Well tolerated through 56 weeks at all doses
- Serious AEs were sporadic and determined not to be related to drug
- No severe infections observed; no infections observed at ≥5%
- No dose response observed for injection site reactions; all cases but one were mild

# No Negative Impact of ADAs or NAb on Either Short-Term or Long-Term Efficacy Results of RVT-3101

Efficacy data pooled across all nine arms (A through I)

## Week 56 Clinical Remission Rate by ADA levels



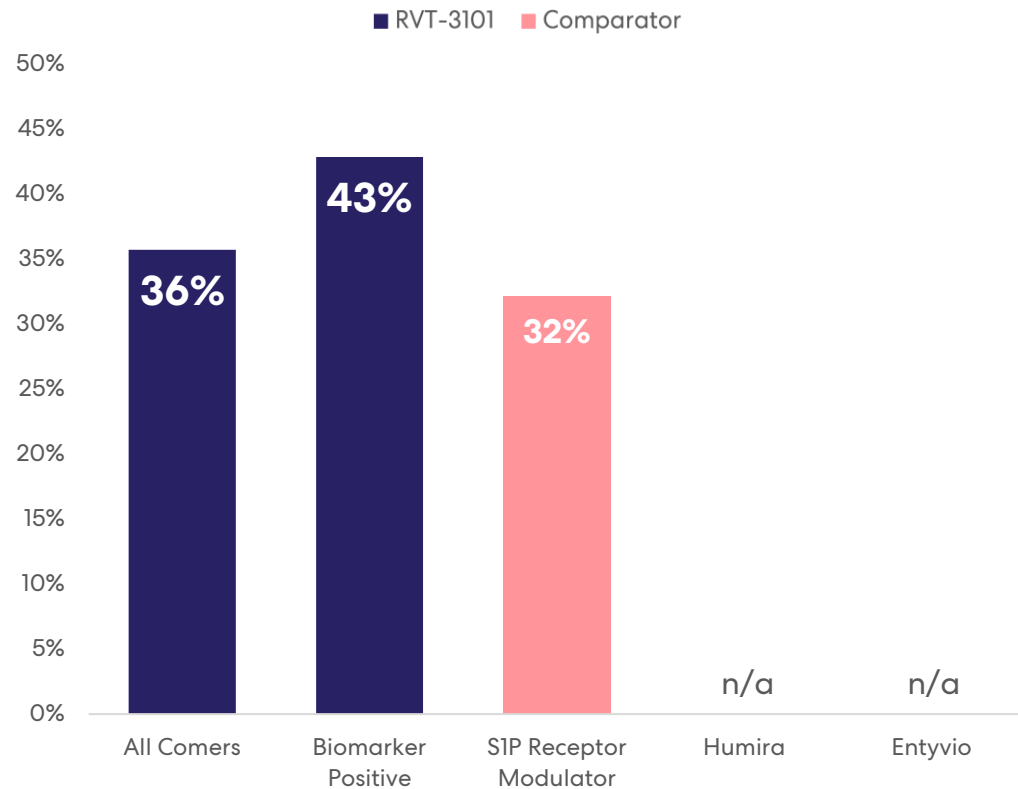
NAb rate was **0%** at Week 56 at the Constant Expected Phase 3 Dose

# RVT-3101 Results Surpass Data Recently Seen in a Treat-Through Design

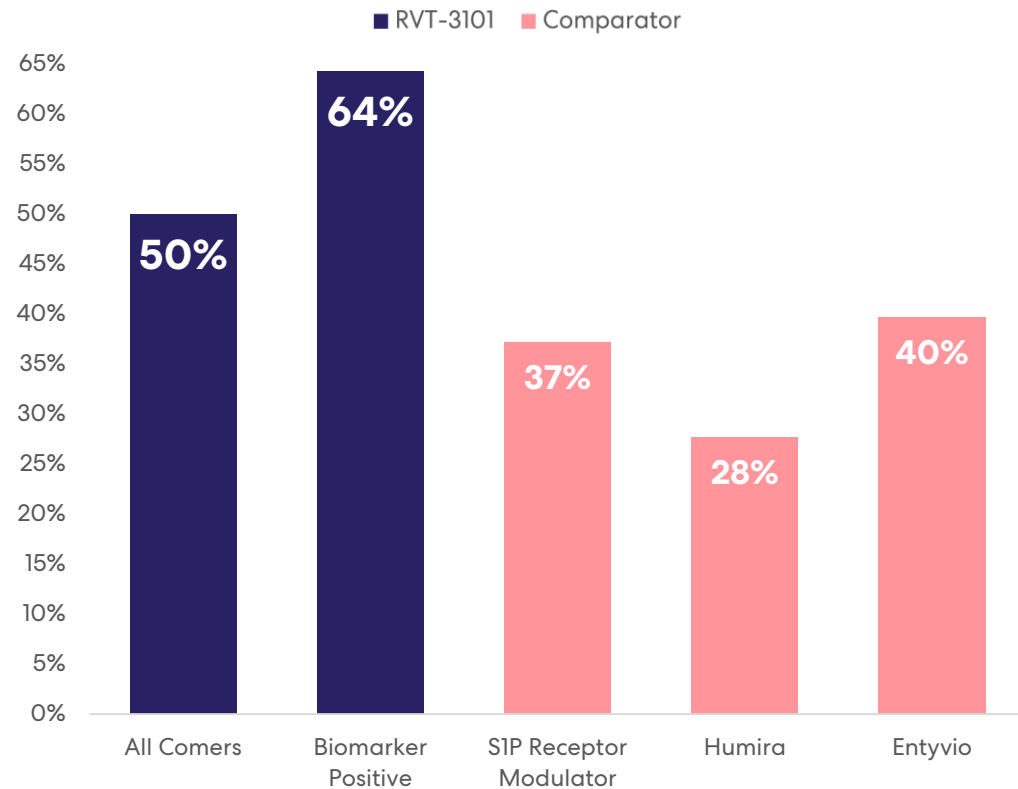
Recent UC studies have employed a treat-through design, which lacks the selection bias of a “re-randomization design” that serves to artificially increase Week 52 or Week 56 response rates

Efficacy data from patients assigned the Expected P3 Dose throughout the study

## Clinical Remission (Modified Mayo)



## Endoscopic Improvement

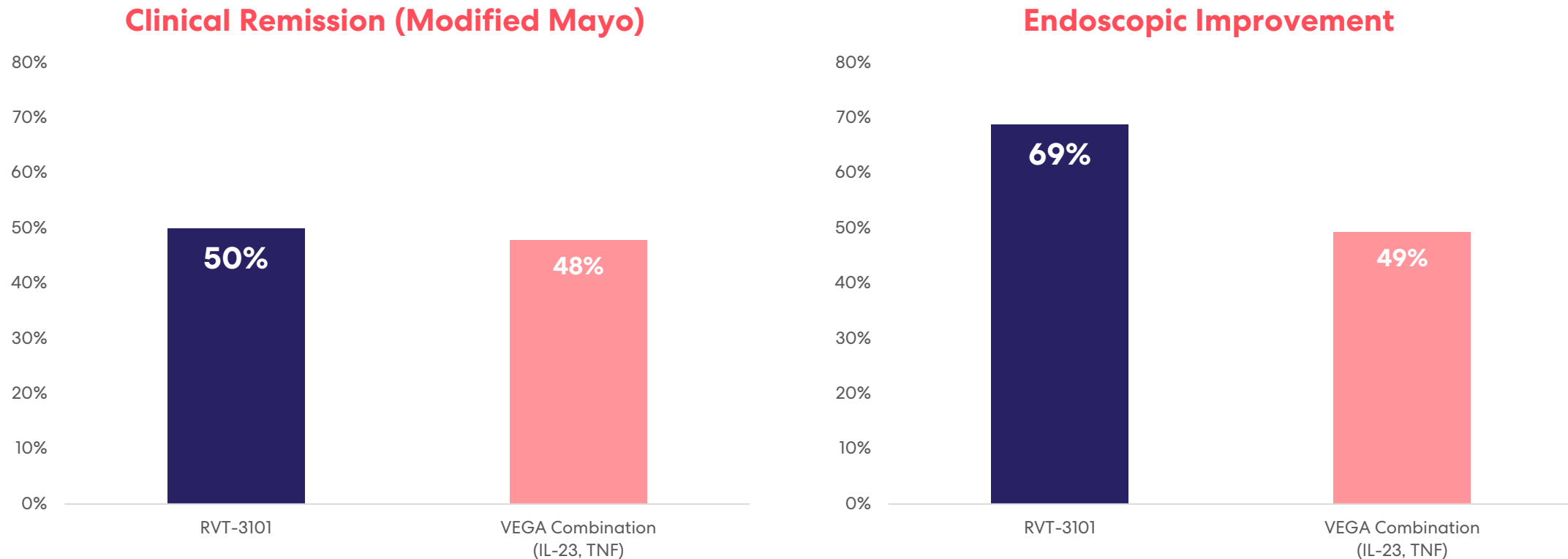


Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and patient characteristics, caution should be exercised when comparing data across studies

# RVT-3101 Breaks Through the Monotherapy Barrier

Results at Week 56 exceed that seen in recent VEGA combination study which intensively combined an anti-TNF and an anti-IL23 in biologics-naïve patients

Efficacy data from biologics-naïve patients assigned Expected P3 Dose throughout study



VEGA was a partially IV regimen; signs of broad immunosuppression were observed, such as the appearance of opportunistic infections

Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and patient characteristics, caution should be exercised when comparing data across studies

# RVT-3101: Potentially First-in-Class and Best-in-Class

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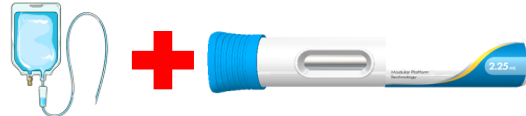

RVT-3101

Prometheus /  MERCK

PRA-023

**teva**

TEV-48574

Data Generated to Date	Total Subjects Dosed	>400	~225	<100 (none in IBD)
	Induction Data	~250 patients across one IV and three SQ doses	~70 patients at a single IV dose	X
	Maintenance Data	>200 patients across three SQ doses out to one year	X	X
	SQ Injection Efficacy Data	>200 patients across three doses	X	X
Phase 3 Readiness	Dose Ranging Data	>250 patients across one IV and three SQ doses	X	X
	Biomarker Strategy Locked	>200 patients prospectively defined >250 patients total	X	No Biomarker Data
Commercial Presentation	Expected Commercial Form Factor	QM SQ autoinjector 	Likely an IV loading dose → SQ injection 	Likely a large volume SQ infusion loading dose → Q2W SQ infusion 

# RVT-3101 Leads the Emergence of TL1A Blockade as a New Potential “Superclass” of Therapeutics

**~\$15B**

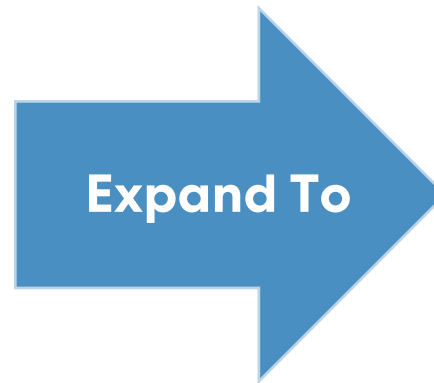
**Starts with the transformation of the US IBD market**

High-end efficacy combined with a very favorable safety profile

Positioned for all patients, regardless of line of therapy

More patients stay on drug for longer duration

Bring promise of precision immunology to IBD



*Indications for which aberrant TL1A amplification is implicated*

**Large Market Inflammation-Driven Indications**

Rheumatoid Arthritis  
Atopic Dermatitis  
SLE  
Asthma  
Psoriasis

**>\$50B**

**High Unmet Need Fibrosis-Driven Indications**

Intestinal Fibrosis  
Pulmonary Fibrosis  
Liver Fibrosis

**Largely Untapped**

# Key Highlights



## **First-in-class anti-TL1A Antibody, with an efficient, well-validated path to approval**

- Most comprehensive data set in the class enables deep understanding of dose response and molecule behavior
- De-risked and ready for Phase 3 – single dose selected, no IV to SQ translation risk, biomarker locked



## **Uniquely positioned to overcome traditional limitations of IBD therapies**

- Outstanding efficacy results regardless of line of therapy, which meaningfully improve with long-term dosing
- Sustained clinical remission and endoscopic improvement rates among the highest ever reported
- Favorable safety and tolerability profile, with no impact of immunogenicity on short- or long-term efficacy results



## **Precision immunology approach creates significant upside potential**

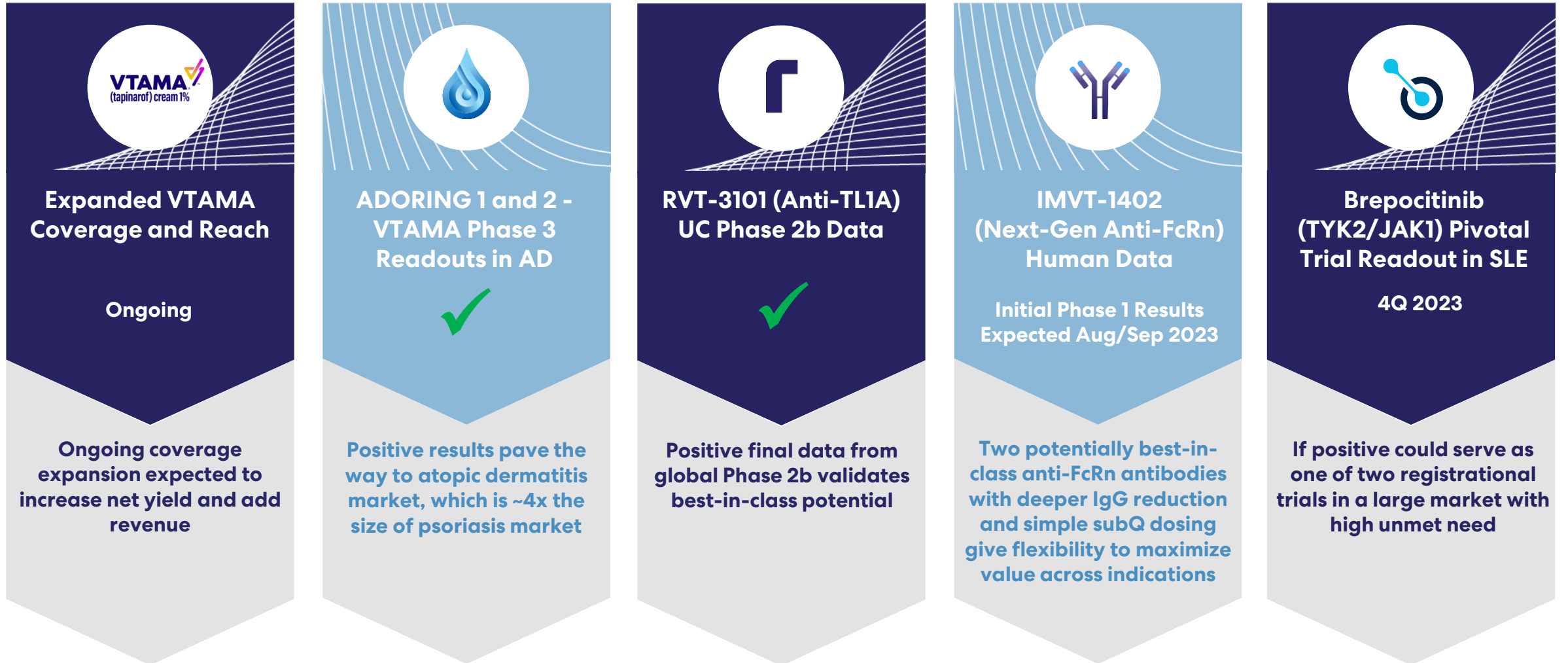
- A simple diagnostic test identifies the ~60% of patients who could see significantly improved benefit
- High-end efficacy results shown in all comorbid population allow optionality for where and how to position biomarker



## **Multiple avenues for additional growth**

- Dose-ranging Phase 2 in Crohn's disease initiated with fast path to Phase 3, in line with competition
- Dual targeting of both inflammatory and fibrotic pathways uniquely enables access to a broad range of large market and high unmet need indications

# 2023: Roivant's Biggest Year Yet





**Thank you.**

**roivant**

