Positive Data from Maintenance Phase of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Ulcerative Colitis

NASDAQ: IMUX | April 5, 2023

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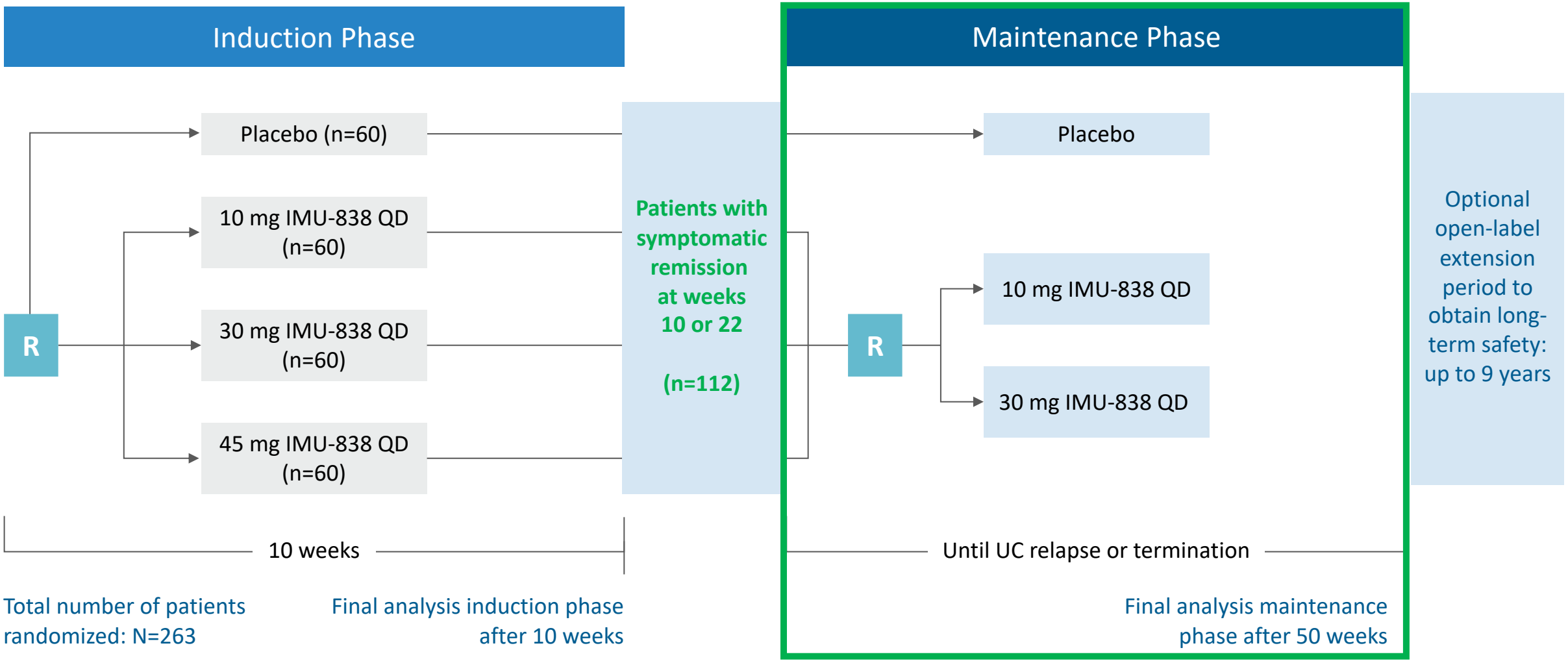
Vidofludimus Calcium in Ulcerative Colitis (UC)

CALDOSE-1: Final Week 50 Maintenance Phase Data

CALDOSE-1: Phase 2 Trial Design in UC
NCT03341962



R: randomization; QD: quaque die = once-daily

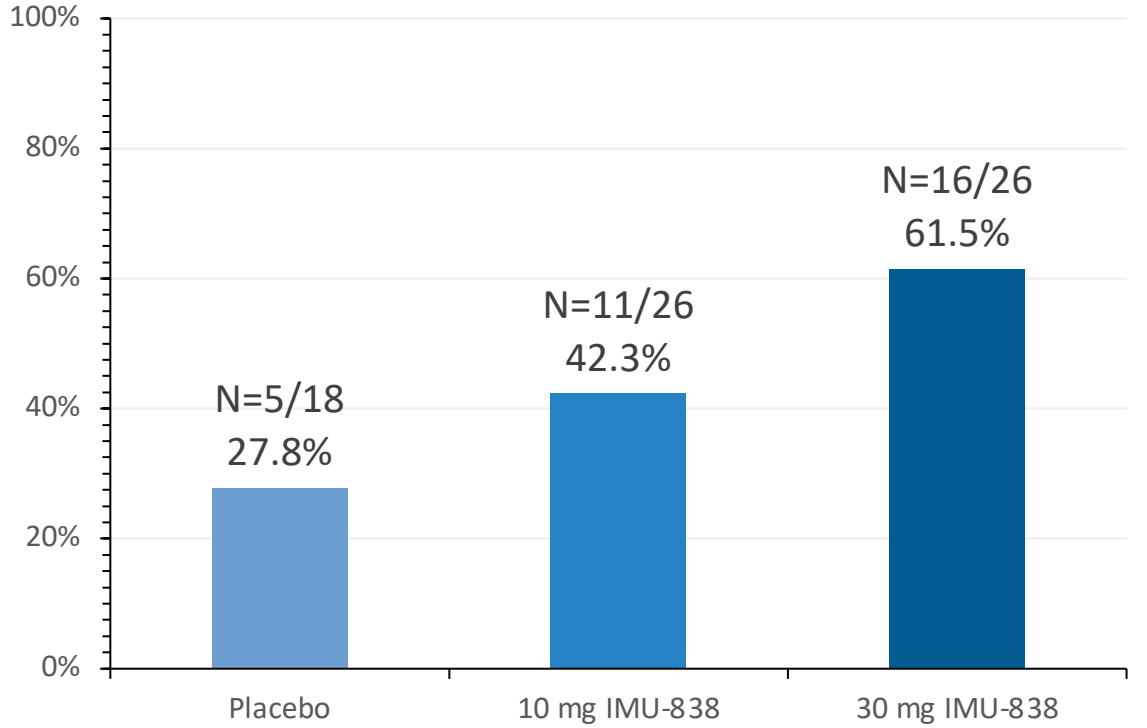
Dose-Linear Increase in Clinical Remission at Week 50 For Vidofludimus Calcium as Compared to Placebo

Clinical Remission at Week 50

Full Analysis Set$_{MP}$ (N_{PBO} = 27, N_{10} = 45, N_{30} = 40)

Data Set: (n-evaluable/n-total of group)	Placebo (N=18/21)	10 mg IMU-838 (N=26/35)	30 mg IMU-838 (N=26/29)
Number of patients with clinical remission	5	11	16
Clinical remission rate	**27.8%**	**42.3%**	**61.5%**

Clinical Remission at Week 50

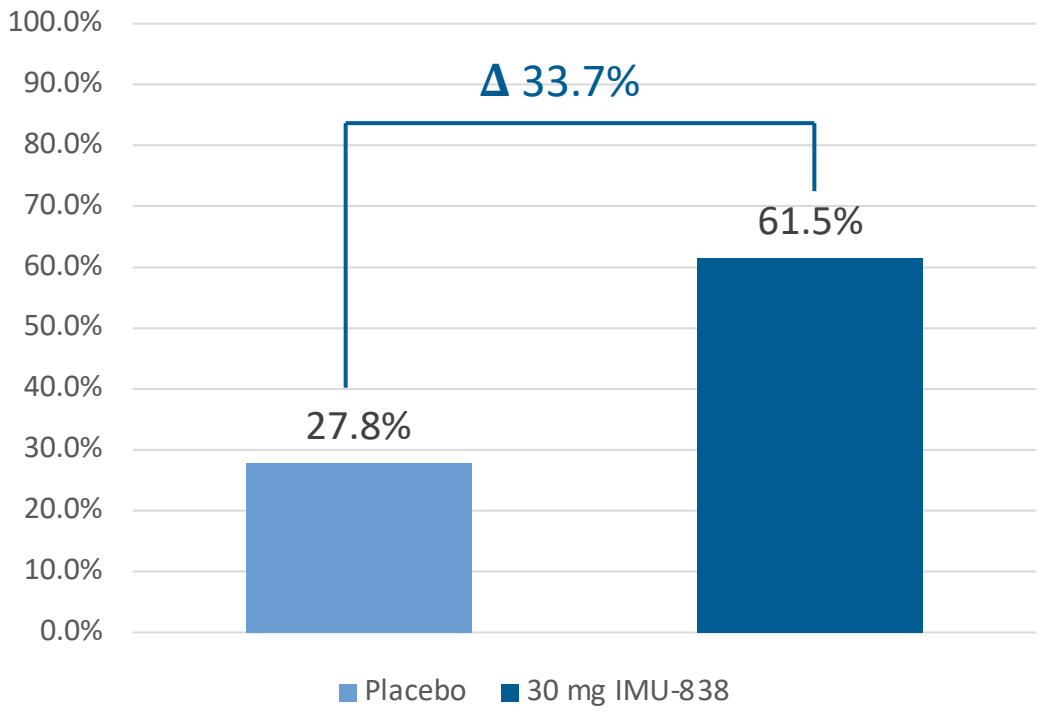


Clinical remission: composite of patient-reported symptomatic remission (stool frequency Mayo subscore of 0 or 1, rectal bleeding Mayo score of 0) and modified Mayo endoscopy subscore of 0 or 1; PBO: placebo
Full Analysis Set MP: all patients randomized into maintenance phase.

Exploratory Statistical Analysis of Clinical Remission

Statistically Significant Difference in Favor of 30 mg Vidofludimus Calcium Versus Placebo

Clinical Remission at Week 50

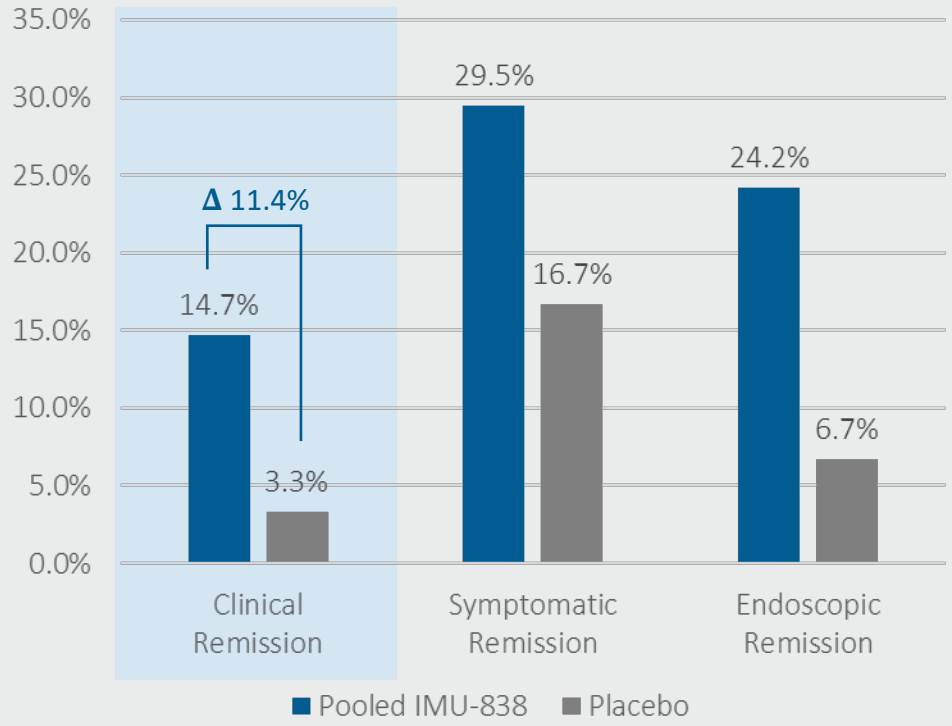


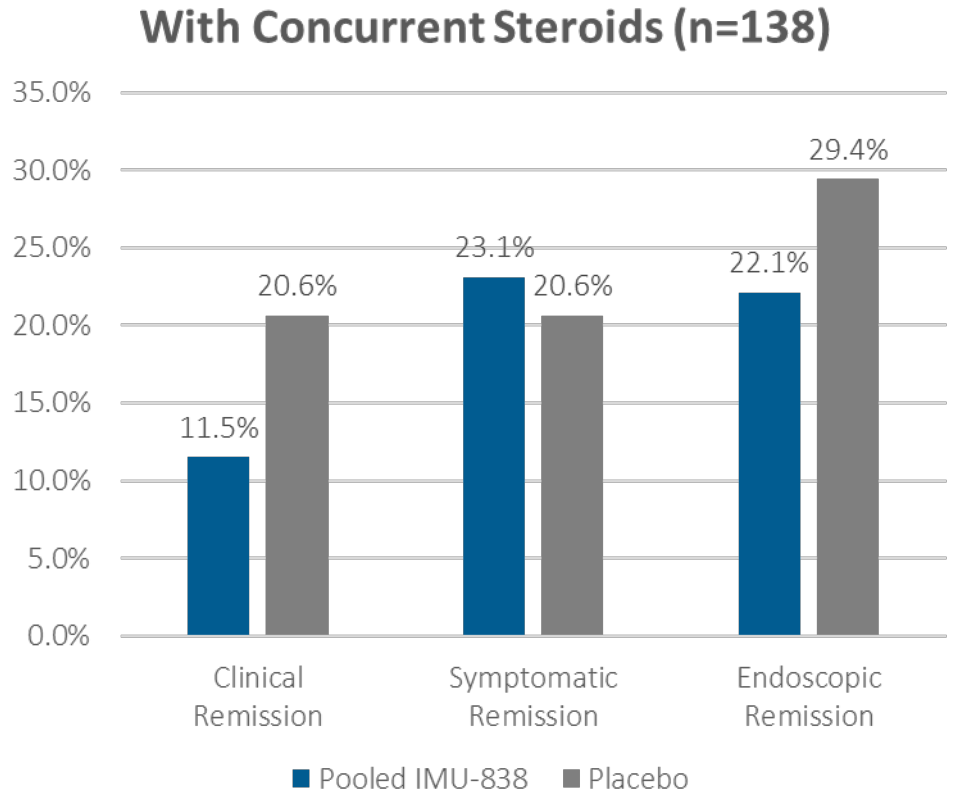
30 mg of vidofludimus calcium found to be statistically superior to achieve clinical remission during maintenance treatment at week 50 as compared to placebo

Planned treatment	Clinical remission at week 50	Number of patients (N)	Proportion of patients (%)	Statistical output (t-test)
30 mg IMU-838	Yes	16	**61.5%**	p-value (two-sided) **p=0.0358** odds ratio (30 mg IMU-838 / placebo) 4.1600
	No	10	38.5%	
Placebo	Yes	5	**27.8%**	
	No	13	72.8%	

Clinical remission: composite of patient-reported symptomatic remission (stool frequency Mayo subscore of 0 or 1, rectal bleeding Mayo score of 0) and modified Mayo endoscopy subscore of 0 or 1
Full Analysis Set of Maintenance Phase (N10 = 45, N30 = 40, NPBO = 27), Post-Hoc Unplanned Analysis: Two-sided Pearson's chi-square test (significance level alpha=0.05) for achieving clinical remission at week 50 between 30 mg IMU-838 and placebo

10-Week Induction Phase Data: UC Patients Without Concomitant Corticosteroids Responded Well (Previously Reported in June 2022)

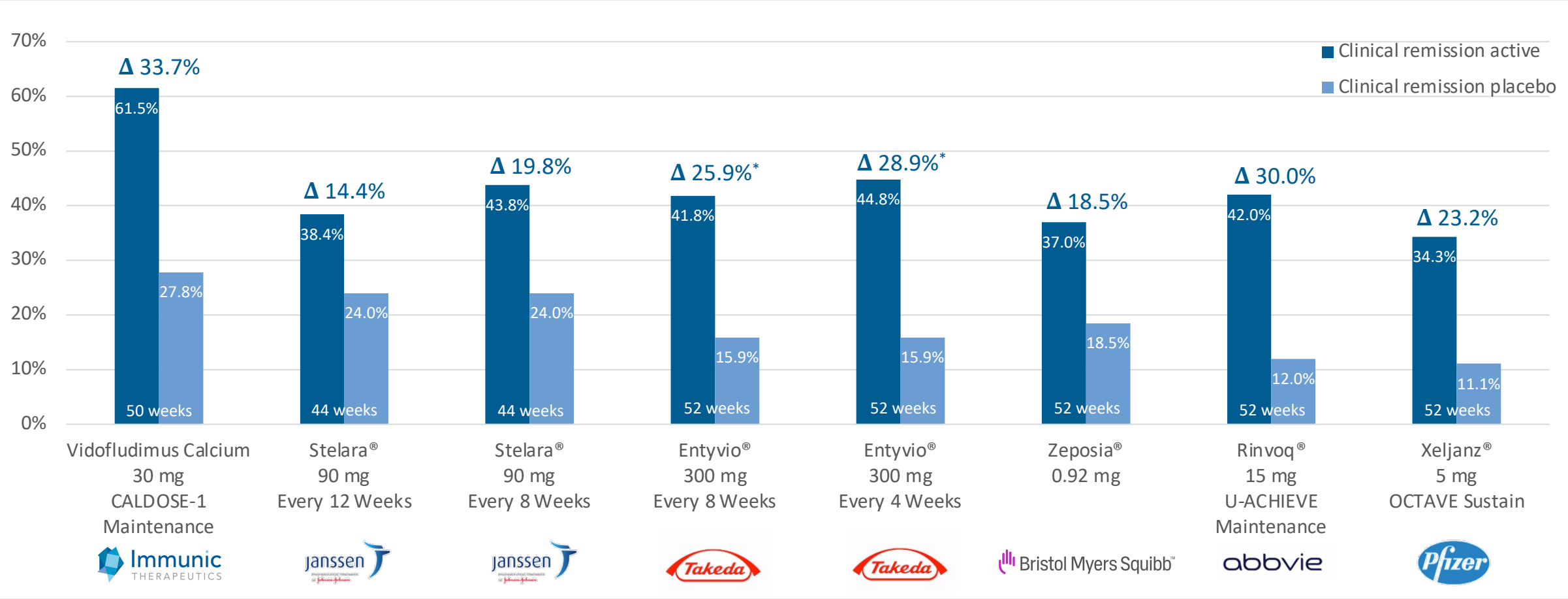




The graphs use the concurrent use of corticosteroids, as used as stratification factor for randomization provided by the investigator, not actual use of concurrent corticosteroids. However, actual steroid use does not differ substantially.
Data display ITT population of both biologic-naïve and -experienced patients. Pooled vidofludimus calcium data contain all data from 10 mg (no steroids n=33, steroids n=34), 30 mg (no steroids n=32, steroids n=34), 45 mg IMU-838 (no steroids n=30, steroids n=36). Placebo data: no steroids n=30, steroids n=34.
Clinical Remission: achieving both symptomatic remission and endoscopic remission, as defined below
Symptomatic Remission: Mayo rectal bleeding subscore of 0, and Mayo stool frequency subscore of 0 or 1
Endoscopic Remission: Modified Mayo endoscopy subscore of 0 or 1

Comparison to Other Maintenance Data

Vidofludimus Calcium Shows Competitive Maintenance Data in UC



Inter-study comparisons may be influenced by differences in studied patient populations. Difference active to placebo are absolute numbers of percentage points. Dosing is once-daily, unless otherwise indicated. Xeljanz was dosed at 5 mg twice daily (BID).

* The publication adjusted for baseline differences and reported the group differences to be 26.1% for the every 8 weeks group and 29.1% for the every 4 weeks group.

Vidofludimus calcium: Immunic data; Stelara®: N Engl J Med 2019;381:1201-1214; Entyvio®: N Engl J Med 2013;369:699-710; Zeposia®: N Engl J Med 2021;385:1280-91; Rinvoq®: Lancet. 2022; 399:2113-2128; Xeljanz®: N Engl J Med. 2017; 376(18):1723-1736

Steroid-Free Clinical Remission at Week 50

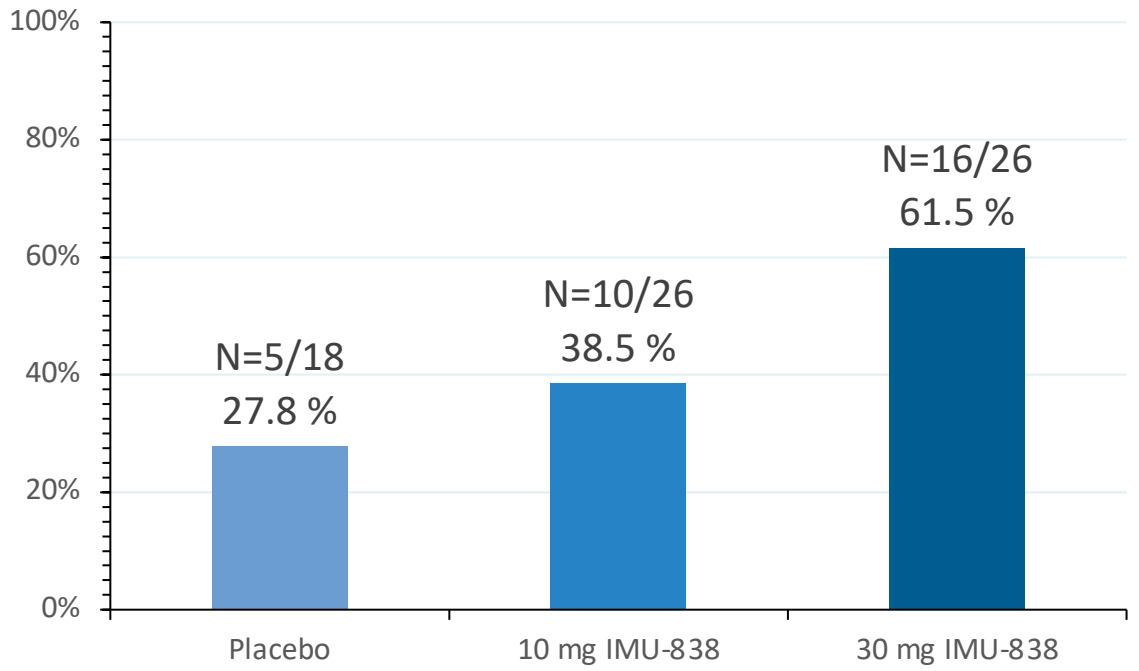
Vidofludimus Calcium Superior as Compared to Placebo

Steroid-Free Clinical Remission

Full Analysis Set$_{MP}$ (N_{PBO} = 27, N_{10} = 45, N_{30} = 40)

Data Set: (n-evaluable/n-total of group)	Placebo (N=18/21)	10 mg IMU-838 (N=26/35)	30 mg IMU-838 (N=26/29)
Number of patients with steroid-free clinical remission at week 50	5/18	10/26	16/26
Steroid-free clinical remission rate at week 50	**27.8%**	**38.5%**	**61.5%**

Steroid-Free Clinical Remission at Week 50



Full Analysis Set MP: all patients randomized into maintenance phase. PBO: placebo; MP = maintenance phase

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Steroid-Free Clinical Remission at Week 50

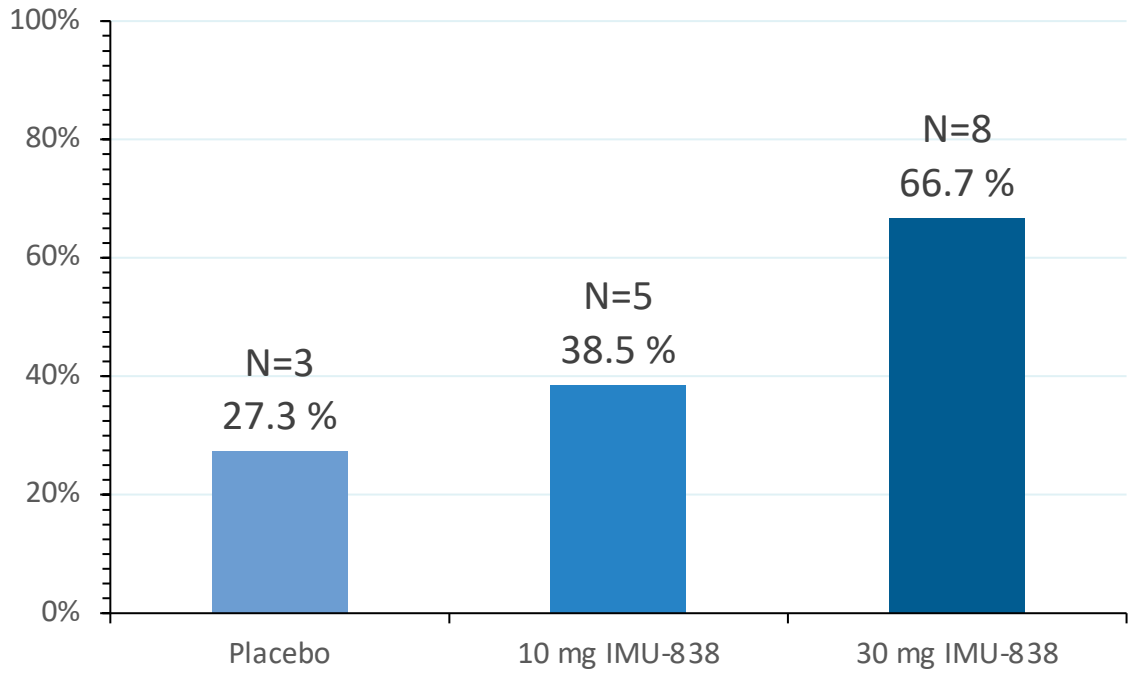
Subgroup Analysis of Patients Who Received Corticosteroids During Induction Phase

Clinical Remission

Modified Full Analysis Set$_{MP}$ (N_{PBO} = 17, N_{10} = 22, N_{30} = 22)

	Placebo		10 mg IMU-838		30 mg IMU-838	
	N	%	N	%	N	%
No	8	72.7	8	61.5	4	33.3
Yes	3	27.3	5	38.5	8	66.7
Evaluable at week 50	11		13		12	

Clinical Remission of Induction Steroid Sub-Group at Week 50



Modified Full Analysis Set: all patients that were randomized into maintenance phase who received concomitant corticosteroids during induction phase. PBO: placebo

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Endoscopic Healing at Week 50

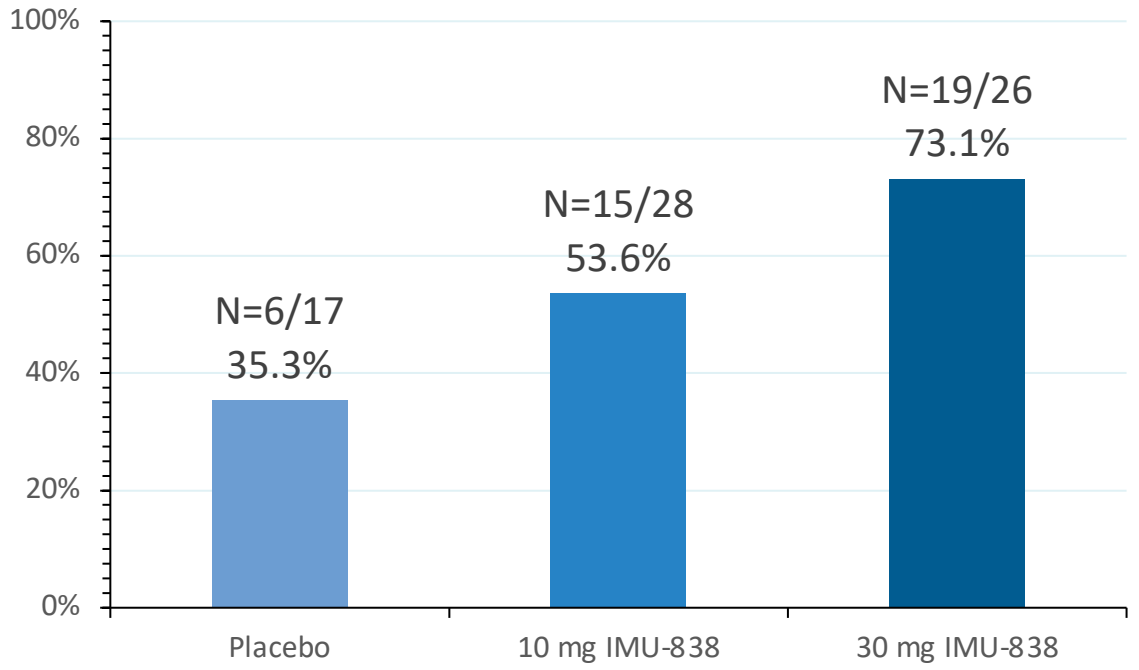
Vidofludimus Calcium Superior as Compared to Placebo

Endoscopic Healing

Full Analysis Set$_{MP}$ (N_{PBO} = 27, N_{10} = 45, N_{30} = 40)

Data Set (n-evaluated/n-total of group)	Placebo (N=17/21)	10 mg IMU-838 (N=28/35)	30 mg IMU-838 (N=26/29)
Number of patients meeting endpoint	6/17	15/28	19/26
Endoscopic healing rate at week 50	**35.3%**	**53.6%**	**73.1%**

Endoscopic Healing at Week 50



Full Analysis Set MP: all patients randomized into maintenance phase
Endoscopic healing: modified Mayo endoscopy subscore of 0 or 1; PBO: placebo; MP = Maintenance Phase

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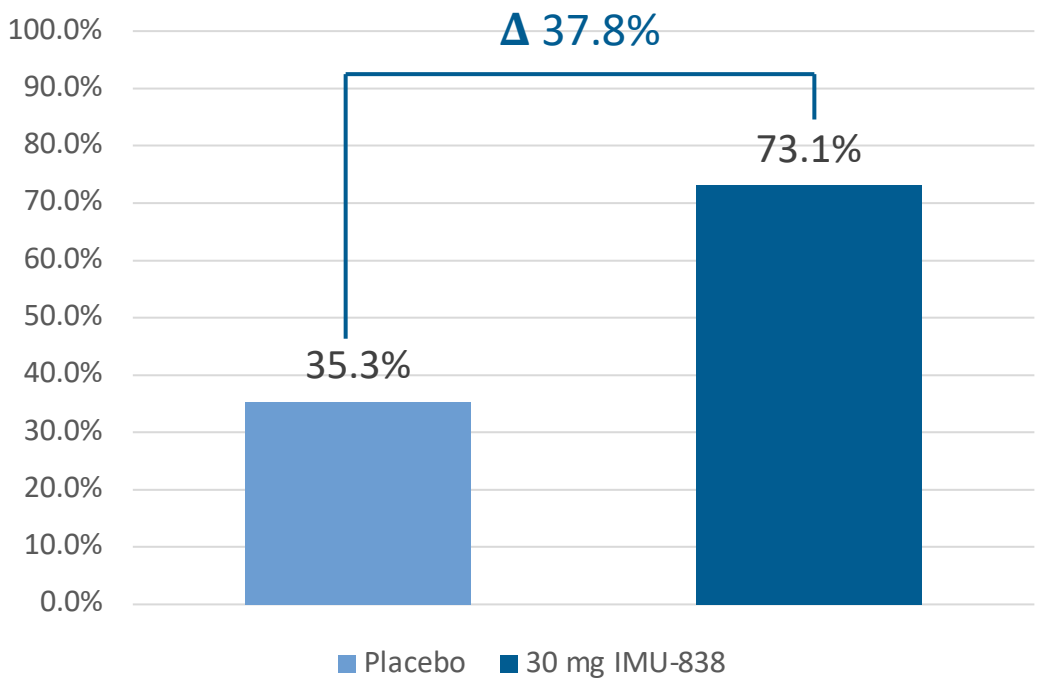
Exploratory Statistical Analysis of Endoscopic Healing

Statistically Significant Difference in Favor of 30 mg Vidofludimus Calcium Versus Placebo

Endoscopic Healing at Week 50

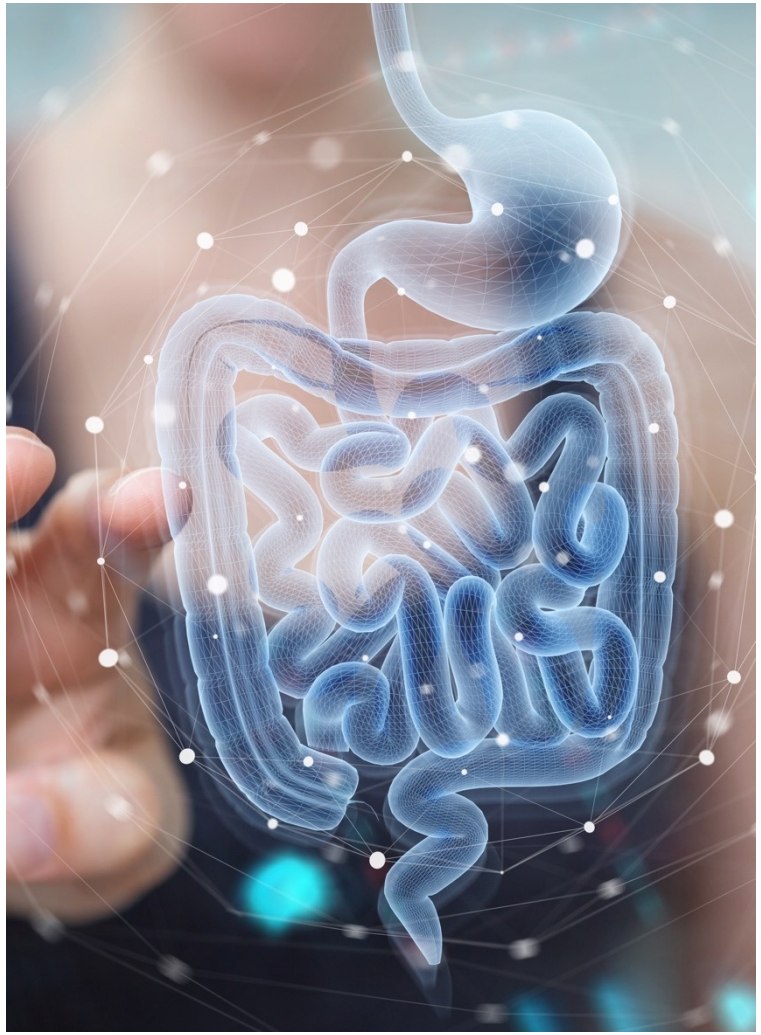


30 mg of vidofludimus calcium found to be statistically superior to achieve endoscopic healing at week 50 as compared to placebo

Planned treatment	Clinical remission at week 50	Number of patients (N)	Proportion of patients (%)	Statistical output (t-test)
30 mg IMU-838	Yes	19	**73.1%**	p-value (two-sided) **p=0.0259** odds ratio (30 mg IMU-838 / placebo) 4.9762
	No	7	26.9%	
Placebo	Yes	6	**35.3%**	
	No	11	64.7%	

Full Analysis Set maintenance phase (NPBO = 27, N10mg = 45mg, N30mg = 40), Post-Hoc Unplanned Analysis: Two-sided Pearson's chi-square test (significance level alpha=0.05) for achieving endoscopic healing at week 50 between 30 mg IMU-838 and placebo
Endoscopic healing: modified Mayo endoscopy subscore of 0 or 1; PBO = placebo

Summary Efficacy Results Maintenance Phase CALDOSE-1 Trial



- Maintenance phase results confirm the previous hypothesis *(from the analysis of patients without concomitant corticosteroid use during the induction phase)* that vidofludimus calcium provides a benefit regarding clinical remission, as compared to placebo, in UC patients without concurrent use of corticosteroids.
  - Patients who originally received concomitant corticosteroids in the induction phase respond well when corticosteroids are withdrawn during maintenance phase, indicating that steroid tapering before induction phase could have avoided the observed interference during induction.
- At week 50, the dose of 30 mg vidofludimus calcium once-daily demonstrated a statistically significant higher proportion of patients (p=0.0358) achieving clinical remission versus placebo (exploratory analysis).
- Vidofludimus calcium also demonstrated a trend to provide benefits versus placebo in other endpoints, including endoscopic healing, microscopic healing and steroid-free clinical remission.
- For most efficacy endpoints, a dose-linear response was observed for 10 mg and 30 mg vidofludimus calcium.

Incidence of TEAEs Lower in Both 10 mg and 30 mg Vidofludimus Calcium Groups Than in Placebo Group

Number of patients with TEAEs, serious TEAEs, and TEAEs of special interest
Safety Set$_{MP}$ (N_{PBO} = 27, N_{10} = 45, N_{30} = 40)

	Placebo		10 mg IMU-838		30 mg IMU-838		Total	
	TEAE N (n)	TEAE (%)	TEAE N (n)	TEAE (%)	TEAE N (n)	TEAE (%)	TEAE N (n)	TEAE (%)
TEAEs	**12(24)**	**44.4%**	**16(26)**	**35.6 %**	**16(33)**	**40%**	**44(83)**	**39.3%**
Serious TEAEs	1(1)	3.7%	3(3)	6.7%	2(2)	5%	6(6)	5.4%
TEAEs of special interest	1(1)	3.7%	0	0.0%	2(2)	5%	3(3)	2.7%
Renal TEAEs	2(2)	7.4%	1(1)	2.2%	2(5)	5%	5(8)	4.5%
Liver TEAEs	1(4)	3.7%	1(1)	2.2%	0	0.0	2(2)	1.8%

Safety set maintenance phase: all patients who were randomized into maintenance phase and received at least one dose of study drug
TEAE: treatment-emergent adverse event; PBO: placebo; N: number of patients; n: number of events
TEAE of special interest are defined as red blood cells urine positive, hematuria, or retroperitoneal pain

No Increase in Liver Events Observed as Compared to Placebo

		Placebo		10 mg IMU-838		30 mg IMU-838		Total	
		TEAE N (n)	TEAE (%)	TEAE N (n)	TEAE (%)	TEAE N (n)	TEAE (%)	TEAE N (n)	TEAE (%)
Hepatobiliary disorders	Cholecystitis	0	0	1(1)	2.2%	0	0	1(1)	0.9%
Investigations	Aspartate aminotransferase increased	1(1)	3.7%	0	0	0	0	1(1)	0.9%
	Gamma-glutamyltransferase increased	1(1)	3.7%	0	0	0	0	1(1)	0.9%
	Hepatic enzyme increased	1(2)	3.7%	0	0	0	0	1(1)	0.9%
	Total	**1(4)**	**3.7%**	**1(1)**	**2.2%**	**0**	**0**	**2(5)**	**1.8%**

Safety set maintenance phase: all patients who were randomized into maintenance phase and received at least one dose of study drug
TEAE: treatment-emergent adverse event; N: number of patients; n: number of events
Only TEAEs with predetermined preferred terms related to liver function within Investigations and Hepatobiliary Disorders (terms selected by Sponsor before unblinding of study) are displayed.

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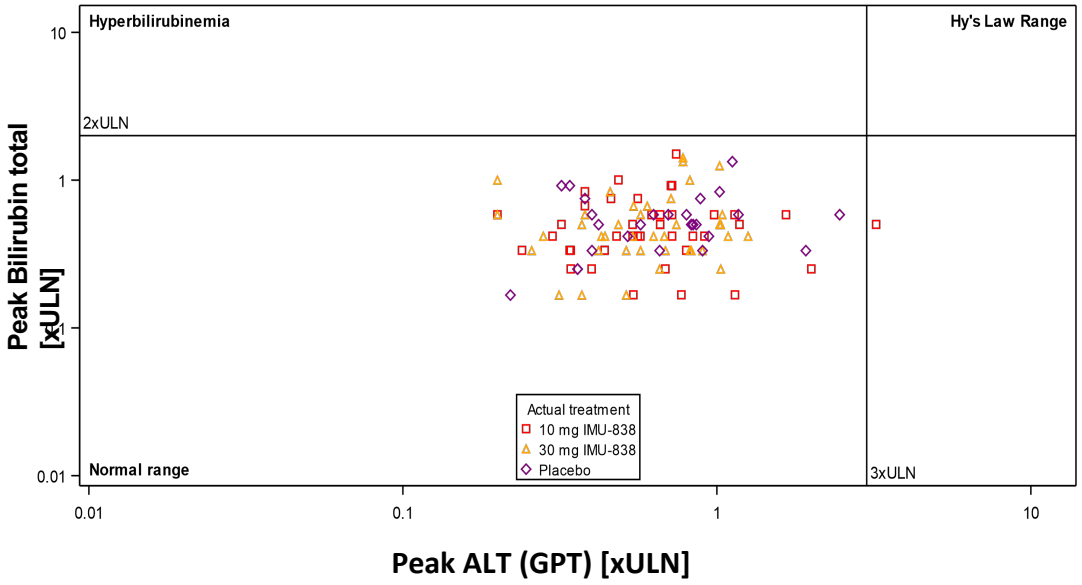
Absence of Hy's Law Cases

Indicates Low Potential for Drug-Induced Hepatotoxicity

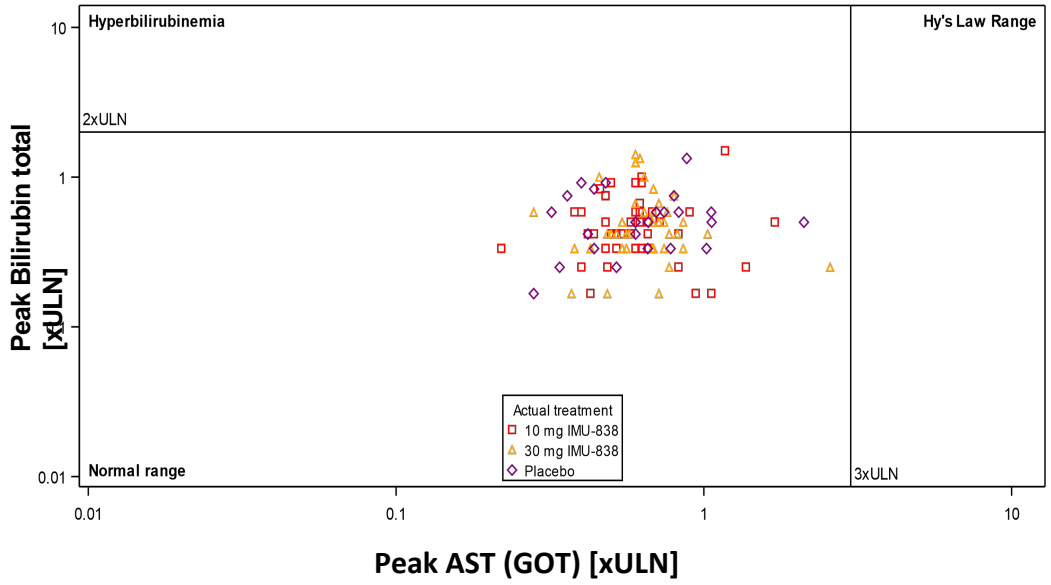
Hy's Law Plot: Alanine Aminotransferase (ALT)

Safety Analysis Set$_{MP}$ (N_{PBO} = 27, N_{10} = 45, N_{30} = 40)



Hy's Law Plot: Aspartate Aminotransferase (AST)

Safety Analysis Set$_{MP}$ (N_{PBO} = 27, N_{10} = 45, N_{30} = 40)



Safety set maintenance phase: all patients who were randomized into maintenance phase and received at least one dose of study drug
PBO: placebo; ULN: upper limit of normal

No Increase in Renal Events Observed as Compared to Placebo

		Placebo		10 mg IMU-838		30 mg IMU-838		Total	
		TEAE N(n)	TEAE (%)	TEAE N(n)	TEAE (%)	TEAE N(n)	TEAE (%)	TEAE N(n)	TEAE (%)
Investigations	Blood creatinine increased	1(1)	3.7%	0	0	0	0	1(1)	0.9%
	Blood urine present	0	0	1(1)	2.2%	0	0	1(1)	0.9%
	Red blood cells urine positive	1(1)	3.7%	0	0	0	0	1(1)	0.9%
Renal and urinary disorders	Hematuria	0	0	0	0	2(2)	5%	2(2)	1.8%
	Ketonuria	0	0	0	0	1(1)	2.5%	1(1)	0.9%
	Nephrolithiasis	0	0	0	0	1(1)	2.5%	1(1)	0.9%
	Proteinuria	0	0	0	0	1(1)	2.5%	1(1)	0.9%
	Total	**2(2)**	**7.4%**	**1(1)**	**2.2%**	**2(5)**	**5%**	**5(8)**	**4.5%**

Safety set maintenance phase: all patients who were randomized into maintenance phase and received at least one dose of study drug
TEAE: treatment-emergent adverse event; N: number of patients; n: number of events
Only TEAEs with predetermined preferred terms related to renal function within Investigations and Renal and Urinary Disorders (terms selected by Sponsor before unblinding of study) are displayed.

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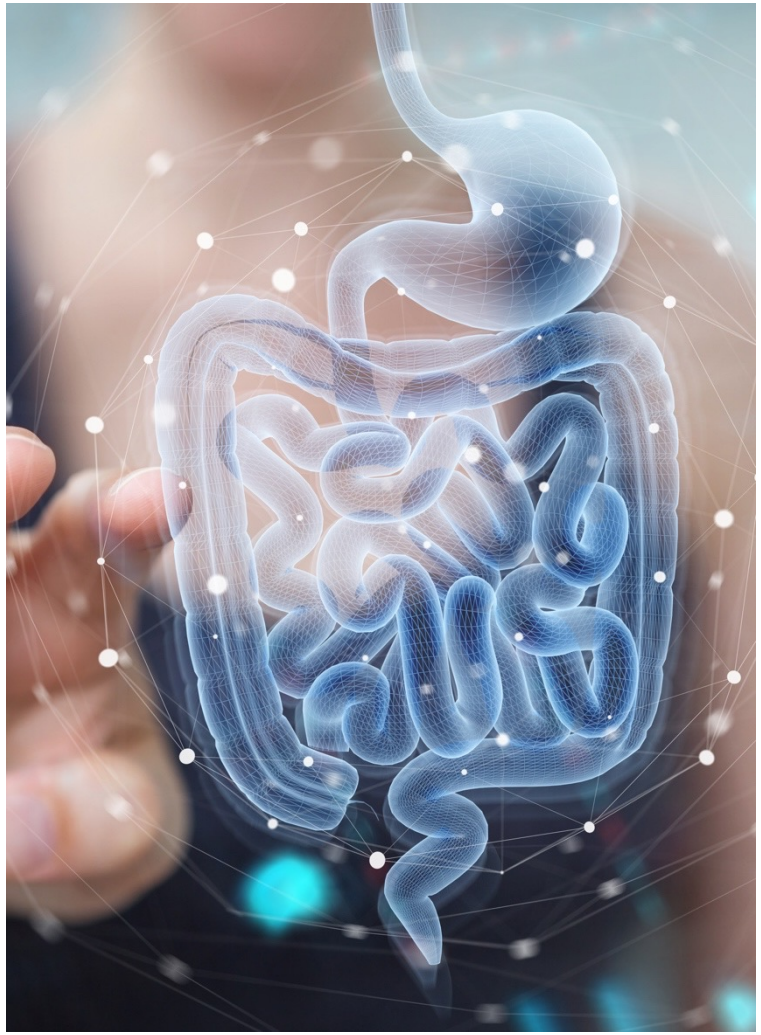
Summary Safety Results Maintenance Phase CALDOSE-1 Trial



- Administration of vidofludimus calcium during maintenance phase found to be safe and well-tolerated
- Incidence of TEAEs for vidofludimus calcium comparable to placebo
- Very few serious TEAEs observed
- As compared to placebo, the incidence in the vidofludimus calcium treatment groups showed:
  - No increased rate of liver events or liver enzyme elevations
  - No increased rate of renal events or adverse events of special interest
- Overall, the safety and tolerability profile of vidofludimus calcium in UC patients is comparable to placebo and in line with prior data sets in other patient populations

TEAE: treatment-emergent adverse event

Immunic Therapeutics

Pipeline Update and Outlook

Pipeline Focus on Vidofludimus Calcium and IMU-856

- Immunic to focus on the rapidly advancing vidofludimus calcium and IMU-856 programs
- Positive data from the CALDOSE-1 trial of vidofludimus calcium shown today support strategic focus on gastroenterology and neurology indications
- Totality of available data lead to the decision to deprioritize izumerogant (IMU-935) development program
  - Key reasons include changes in expected time to market and increased complexity of potential further development and related expected development costs
  - Immunic to explore if a backup molecule could offer a more attractive way and is worth to be further explored in the future

Summary: Several Clinical Data Readouts Expected in 2023

IMU-856	Initial phase 1b celiac disease data expected in the current quarter
IMU-856	Mode of action and molecular target to be presented in the context of an upcoming scientific GI congress
IMU-838	Interim analysis of phase 2 CALLIPER trial in progressive multiple sclerosis estimated for H2/2023

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Q&A Session

Thank You!

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Vidofludimus Calcium in Ulcerative Colitis (UC)

CALDOSE-1: Further Information

CALDOSE-1: Clinical Phase 2 Trial in Ulcerative Colitis (UC)

NCT03341962

Coordinating investigator:
Dr. Geert D'Haens
(AMC Amsterdam)

Conducted with active IND in the United States

Total number of patients randomized: 263

More than 100 sites in 19 countries: USA, Western, Central and Eastern Europe

Patient population:

- Male and female patients, aged 18 to 80 years
- Previous treatment failure with immuno-modulators, steroids or biologicals
- Active disease was defined as Mayo stool frequency score of ≥2, Mayo rectal bleeding score of ≥1 and a modified Mayo endoscopy subscore of ≥2 at the screening flexible sigmoidoscopy (independent central reader)

Primary endpoint:

Proportion of patients with clinical remission (symptomatic remission and endoscopic remission) at week 10

Primary statistical analysis:

Clinical remission of pooled 30 and 45 mg active dose groups versus placebo group

IND: investigational new drug

Reminder About Corticosteroids Use in the CALDOSE-1 Trial

A During Induction Phase

- Concomitant use of corticosteroids was allowed:
  - At doses ≤20 mg prednisolone equivalent
  - Steroid dose MUST remain stable for entire induction phase
- Approximately 50% of patients had concomitant corticosteroids and were well balanced between groups due to stratification during randomization in induction phase

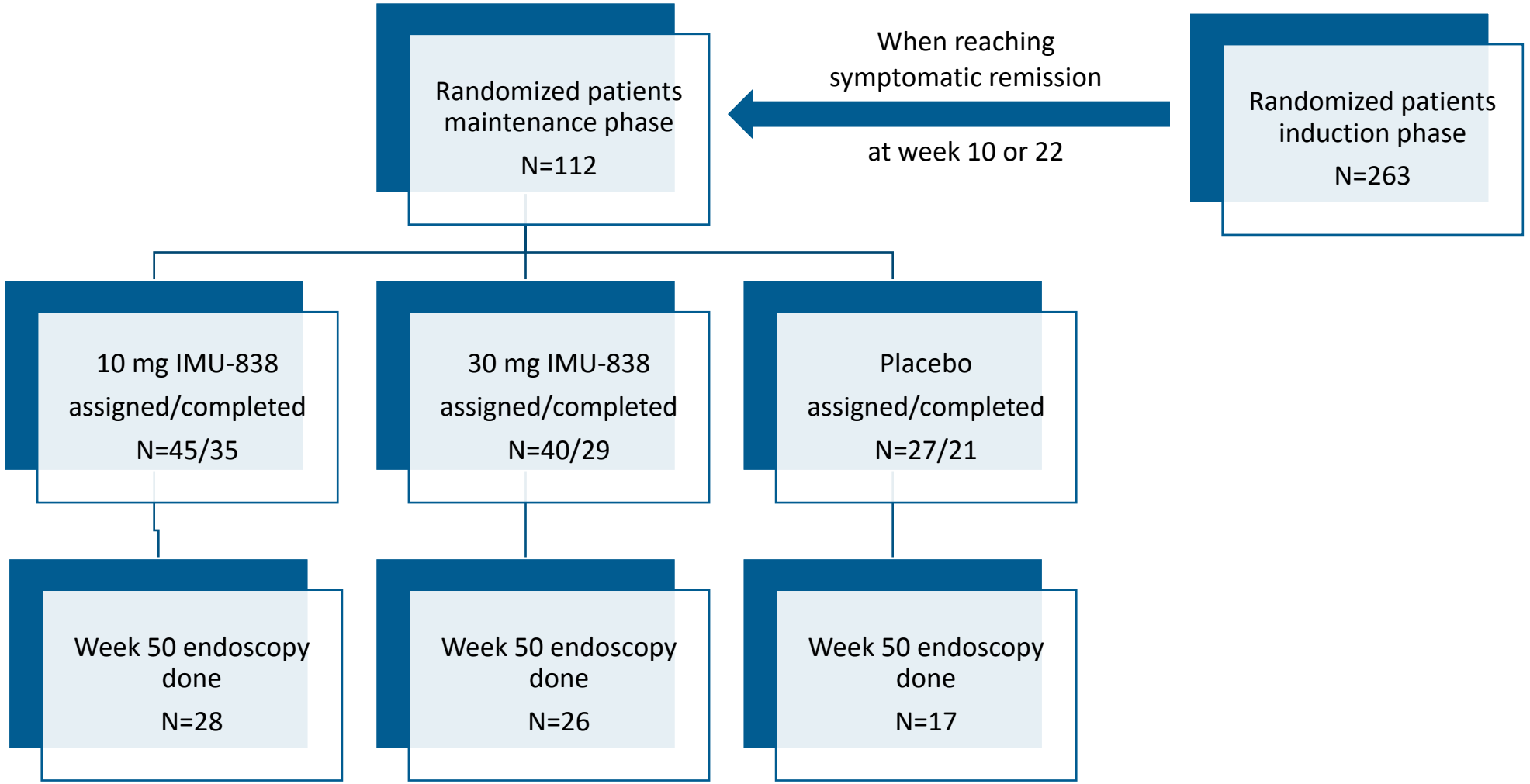
  -> interference was found between vidofludimus calcium and corticosteroids

B During Maintenance Phase

- Re-randomization of vidofludimus calcium patients to 10 and 30 mg doses (independent of their induction phase treatment assignments)
- Placebo patients who achieved symptomatic remission during induction phase were “sham randomized” to continue receiving placebo in maintenance phase
- Corticosteroids had to be tapered off at the start of the maintenance phase, if no symptoms re-appeared during tapering procedure

Patients Per Treatment Group

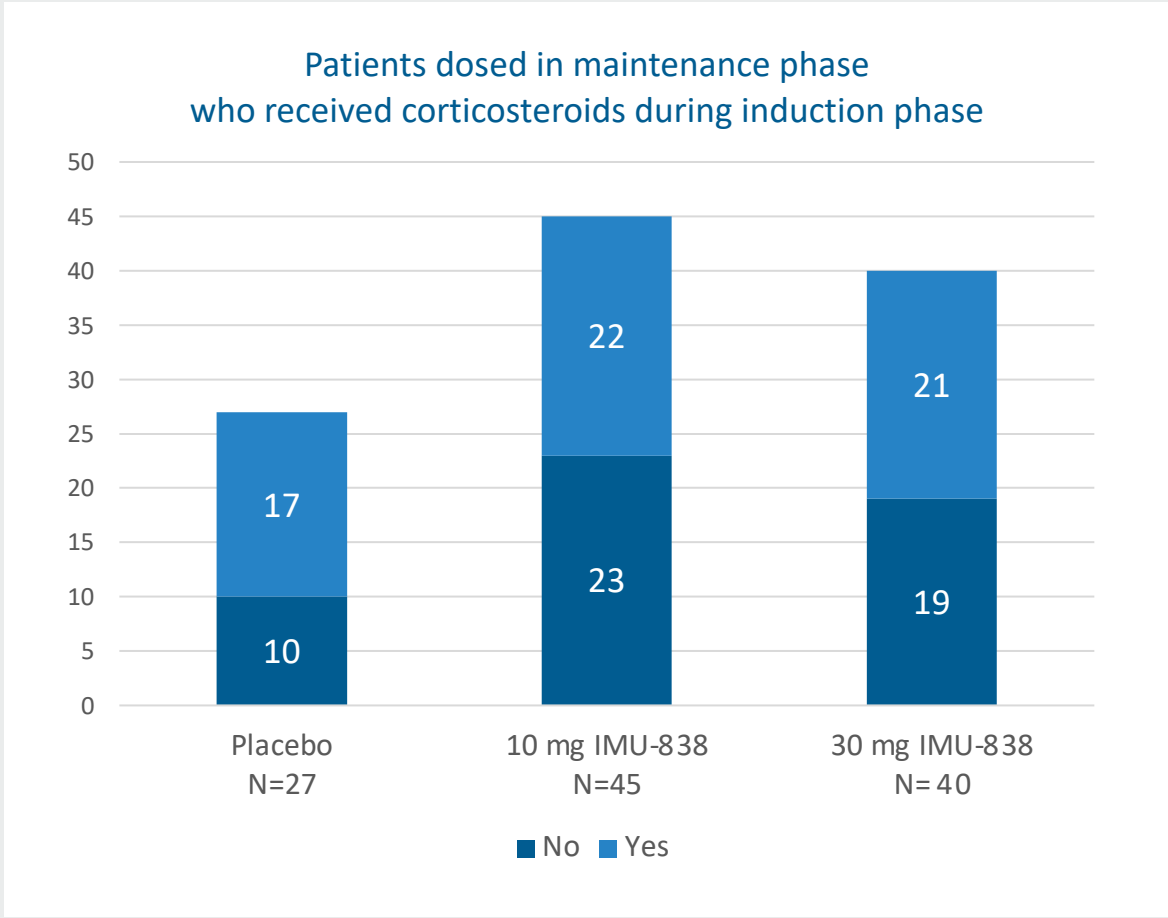
CALDOSE-1 Maintenance Phase



Patient Demographics and Prior Treatment History

CALDOSE-1 Maintenance Phase

Characteristics		Placebo N=27	10 mg IMU-838 N=45	30 mg IMU-838 N= 40
Mean age (years)		40.1 (14.1)	39.7(13.1)	43.8 (14.1)
Male (N in %)		18 (66.7)	30 (66.7)	15 (37.5)
Mean height (cm)		173.1 (10.3)	174.6 (8.2)	169.7 (10.4)
Mean weight (kg)		72.44 (13.25)	74.43 (13.08)	70.4 (16.4)
Race	White	26	45	40
	Other	1	0	0
Prior UC treatment before study: oral immunomodulator/ non-biologics	No	1	2	0
	Yes	29	43	40
Prior treatment before study: use of any biologics as previous treatment	No	23	43	38
	Yes	4	2	2
Prior treatment before study: use of any corticosteroids	No	0	3	2
	Yes	27	42	38



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Multivariate Analysis Shows Concomitant Steroid Use is Main Factor for Outcome of Clinical Remission in Induction Phase

Multivariate analysis shows that concomitant steroids have highest impact on clinical remission data

Impact

Parameter	Estimate	P-value
Concomitant use of corticosteroids	**0.59**	**0.057**
Full Mayo score at baseline	-0.29	0.097
Time from diagnosis	0.02	0.505
Prior use of biologics	-0.12	0.732

Estimation of odd ratios for vidofludimus calcium achieving clinical remission versus placebo

	Odds Ratio Estimate
Active treatment groups of 30/45 mg to achieve clinical remission versus placebo **without concomitant steroids**	**3.53**
Active treatment groups of 30/45 mg to achieve clinical remission versus placebo **with concomitant steroids**	**0.58**

Multivariate logistical regression analysis for endpoint of clinical remission; use of four dependent variables, interaction term and pooled treatment groups of 30/45mg, full analysis set (N10=67, N30=66, N45=66, NPBO=64)
PBO: placebo