ABTECT Maintenance – Supplemental Part 2 Update with Appendix

June 29, 2026

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Agenda

01	Welcome	**Pat Malloy** *Senior Vice President, Investor Relations*
02	Opening Remarks	**Marc de Garidel** *Chief Executive Officer*
03	Data Review: Study Context, Design & Topline Efficacy	**Fabio Cataldi, M.D.** *Chief Medical Officer*
04	Safety Review & Exposure-Adjusted Incidence Analysis	**Chris Rabbat, PhD** *Head of Global Medical Affairs*
05	Regulatory Assessment	**Keith Fournier, PhD** *Head of Regulatory Affairs*
06	KOL Perspectives	**Jordan Axelrad, M.D.** **Remo Panaccione, M.D.**
07	Q&A	**Abivax Leadership & KOLs**

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Webcast KOL Panel

Moderated Discussion and Analyst Q&A Discussion

Jordan Axelrad, M.D., M.P.H
Associate Professor of Medicine, NYU Grossman School of Medicine, Co-Director, IBD Center, NYU Langone Health

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UNIVERSITY OF CALGARY

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ABTECT Maintenance Part 2: Advancing the Treatment Paradigm in UC

Part 2 further strengthens benefit-risk profile of obefazimod and de-risks regulatory pathway

1	Obefazimod delivered **best-in-disease efficacy** in a highly refractory ulcerative colitis population
2	The Part 2 safety profile remained consistent with prior studies, with incidence rates of **NMSCs** and **malignancies** excluding NMSCs **within expected background rates**
3	Part 2 meaningfully expanded the cumulative safety data, increasing **confidence in the long-term safety assessment**
4	Long-term treatment of patients with refractory UC **further strengthens** obefazimod's favorable **benefit-risk profile** and supports our planned NDA submission by year-end

Data on File ABX464-107. UC = ulcerative colitis; NMSC = non-melanoma skin cancer; NDA = New Drug Application

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Obefazimod Demonstrated Best-in-Disease Efficacy and a Strong Benefit-Risk Profile in Difficult-to-Treat Patients

Strong Efficacy Results in Highly Refractory Patients

- **37.2%** of 50 mg **induction non-responders** achieved **clinical remission at Week 44** of maintenance
- **34.5%** of 50 mg **induction non-responders** achieved **endoscopic remission at Week 44** of maintenance
- For patients who relapsed on 25 mg in Part 1, **45.5% achieved clinical remission at Week 44** after dose-escalating to 50 mg in Part 2

Favorable Safety Profile

- **>1700 total patient years accumulated across the integrated UC Phase 3 + Phase 2 program**
  - This includes over 100 patients with more than 5 years of obefazimod treatment exposure
- Safety profile remained consistent across the clinical program
- Observed safety findings were consistent with expectations for a moderate-to-severe UC population

De-Risked Regulatory Pathway

- **Former FDA senior leaders‡** expressed **confidence in the overall safety profile of obefazimod**
- All four regulatory experts viewed a **boxed warning** as **highly unlikely**
- Suggested advancement of both 25 mg and 50 mg doses

Data on File ABX464-107. ‡ Regulatory consultant feedback meetings on ABTECT maintenance Part 1 & Part 2 data in June 2026

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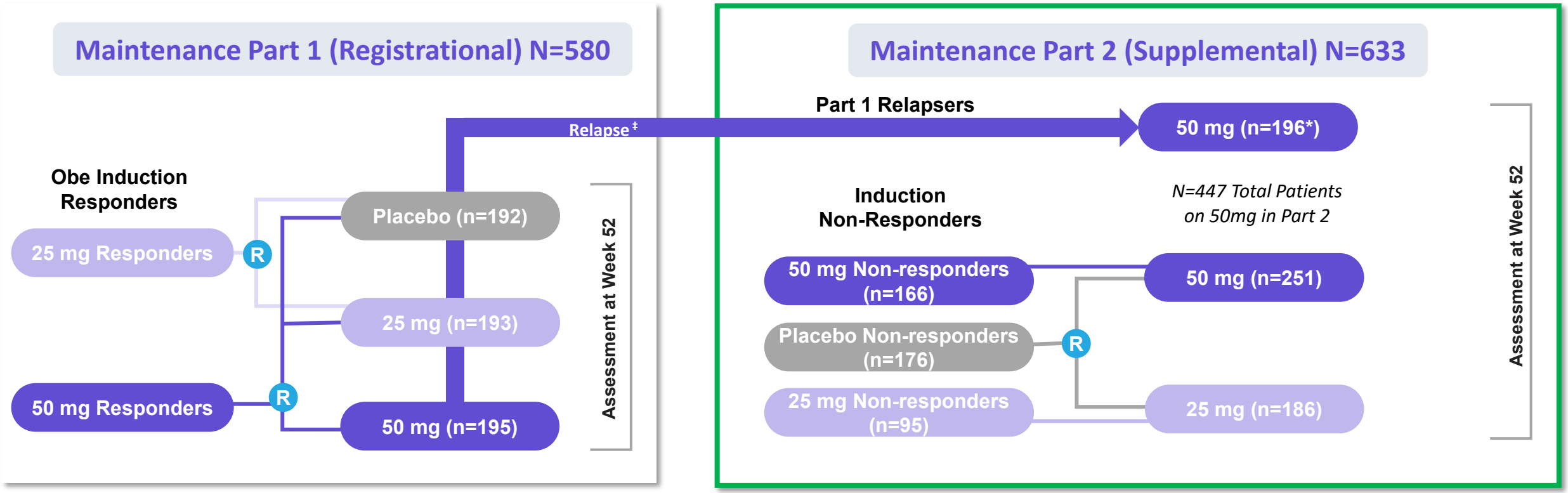
Part 2 Study Design: Difficult-to-Treat Population

Part 1 Relapsers and Induction Non-Responders

1. **Part 2 serves as a supplemental dataset to Part 1**
2. **Part 2 includes two distinct patient populations**
3. **Part 2 patients are more refractory and difficult to treat**
4. **All patients receive obefazimod**



R=Randomized

ABX464-107 Protocol

†Induction placebo responders will not be a part of the registrational efficacy dataset.

‡**Relapse is assessed in two steps: symptomatic relapse** during maintenance, followed by confirmation of a Mayo Endoscopic Subscore ≥2 at the **Relapse Confirmation Visit endoscopy**. Symptomatic relapse requires a ≥2-point increase from maintenance baseline in the partial Modified Mayo Score, including a ≥1-point increase in the Rectal Bleeding Score, at two timepoints 7–14 days apart.

*Includes Part 1 Relapsers who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1 and Placebo Responders (N=37)

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Over 55% of Part 2 Participants Previously Failed 1 or More Advanced Therapies

Comparing Maintenance Part 1 and Part 2 Patient Populations

	Part 1			Part 2		
	Induction Responders – Part 1			Induction Non-Responders‡ – Part 2		Part 1 Relapsers* – Switch to Part 2
Part of Phase 3 Program	Double-Blind Placebo Controlled Trial Part 1			Double-Blind Uncontrolled Trial Part 2		Open-Label Part 2
Arm	PBO	Obe 25 mg	Obe 50 mg	Obe 25 mg	Obe 50 mg	Relapsers (Pooled), Obe 50 mg
Study Participants (N)	192	193	195	81	148	159
Age (Years), Mean (SD)	41.3 (13.4)	43.0 (13.7)	42.3 (14.4)	42.3 (11.7)	43.5 (14.3)	40.1 (13.6)
Baseline Induction MMS, Mean (SD)	6.9 (1.1)	6.7 (1.1)	6.9 (1.2)	7.1 (0.9)	7.0 (1.0)	7.1 (1.1)
Duration of Disease (Years), Mean (SD)	8.1 (7.6)	8.1 (7.4)	7.8 (6.9)	6.9 (5.3)	7.9 (6.6)	7.9 (7.3)
Baseline Induction Fecal Calprotectin (µg/g), Median	1202	1585	1568	2102	1806	1625
Corticosteroid Use at Maintenance Baseline (%)	35.9%	41.5%	40.5%	40.7%	33.8%	42.1%
Prior Advanced Therapy Failure (%)	**37.5%**	**39.4%**	**46.2%**	**59.3%**	**58.1%**	**55.3%**
44-Week Completion Rate, n (%)	66 (34.3%)	152 (78.8%)	160 (82.1%)	57 (70.4%)	115 (77.7%)	137 (86.2%)

Despite being a more difficult-to-treat population, Part 2 patients achieved completion rates comparable to Part 1 induction responders

Data on File ABX464-107; *Includes Part 1 Relapsers who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1 and excludes placebo responders (N=37); ‡Excludes placebo non-responders who were randomized to 25 mg or 50 mg. Excludes N=32 patients who switched doses due to an early version of the ABTECT protocol and are not included in this analysis

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Part 2 Patients Entered Maintenance With A Greater Inflammatory Burden Than Part 1 Patients

Baseline Characteristics at Start of Maintenance

Post-Induction

		Focus of Today
	Part 1 **Induction Responders*** (N=678)	**Part 2** **Induction Non-responders** (N=437)
Measure	**Maintenance Baseline**	**Maintenance Baseline**
MMS, mean (SD)	**2.7 (1.4)**	**6.2 (1.2)**
Fecal Calprotectin (%) >150µg/g	**49.7%**	**82.4%**
Prior Advanced Therapy Failure (%)	**39.8%**	**57.0%**
JAK Failure **(% of Prior Advanced Therapy Failures)**	**18.9%**	**22.1%**
	Clinical Responders **Less Disease Activity**	**Clinical Non-Responders** **High Inflammatory Burden**

Data on File ABX464-107; *Includes N=98 placebo induction responders
MMS = Modified Mayo Score

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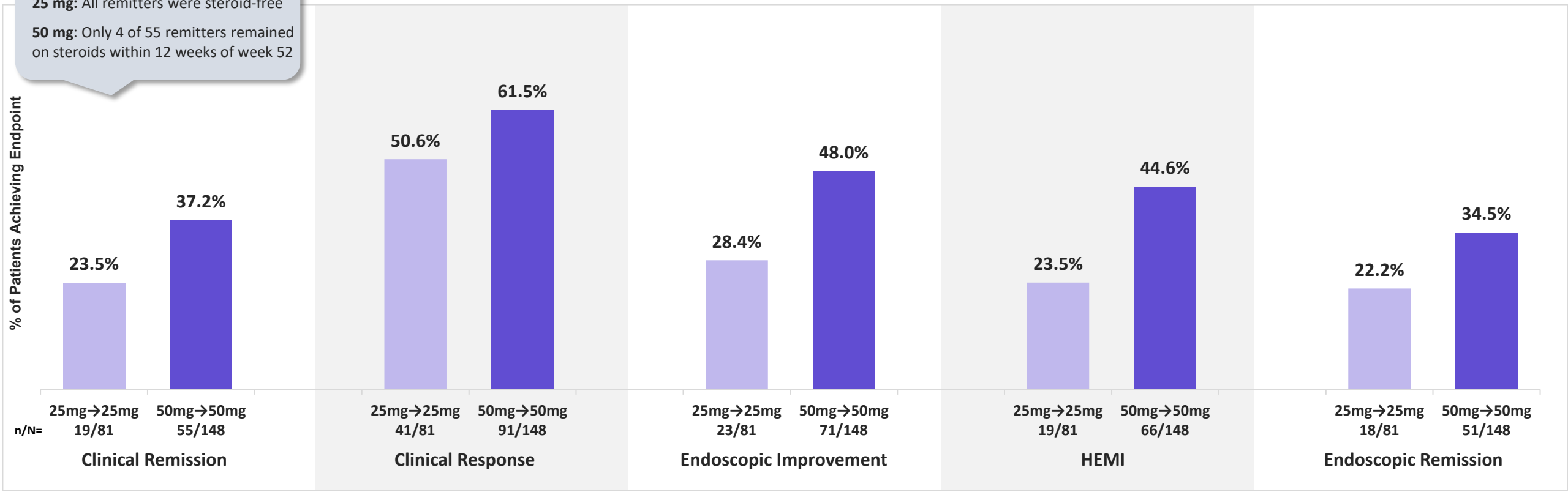
Continued Obefazimod Treatment Delivered Unprecedented Efficacy Results for Patients who Failed to Respond After 8 Weeks

Part 2: Induction Non-Responders – Exploratory Efficacy Endpoints

At Week 44 of Maintenance

25 mg: All remitters were steroid-free

50 mg: Only 4 of 55 remitters remained on steroids within 12 weeks of week 52



Compelling efficacy results were consistently observed across all key exploratory endpoints, with numerically stronger efficacy results observed in the 50 mg arm

Data on File ABX464-107; Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1; Clinical response is defined as a reduction from Baseline in MMS >= 2 points and a relative reduction from Baseline in MMS >= 30%, and a reduction from Baseline in RBS >= 1 point and/or RBS = 0 or 1; Endoscopic improvement is defined as MES = 0 or 1; HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1; Endoscopic remission is defined as MES = 0; HEMI = Histologic Endoscopic Mucosal Improvement

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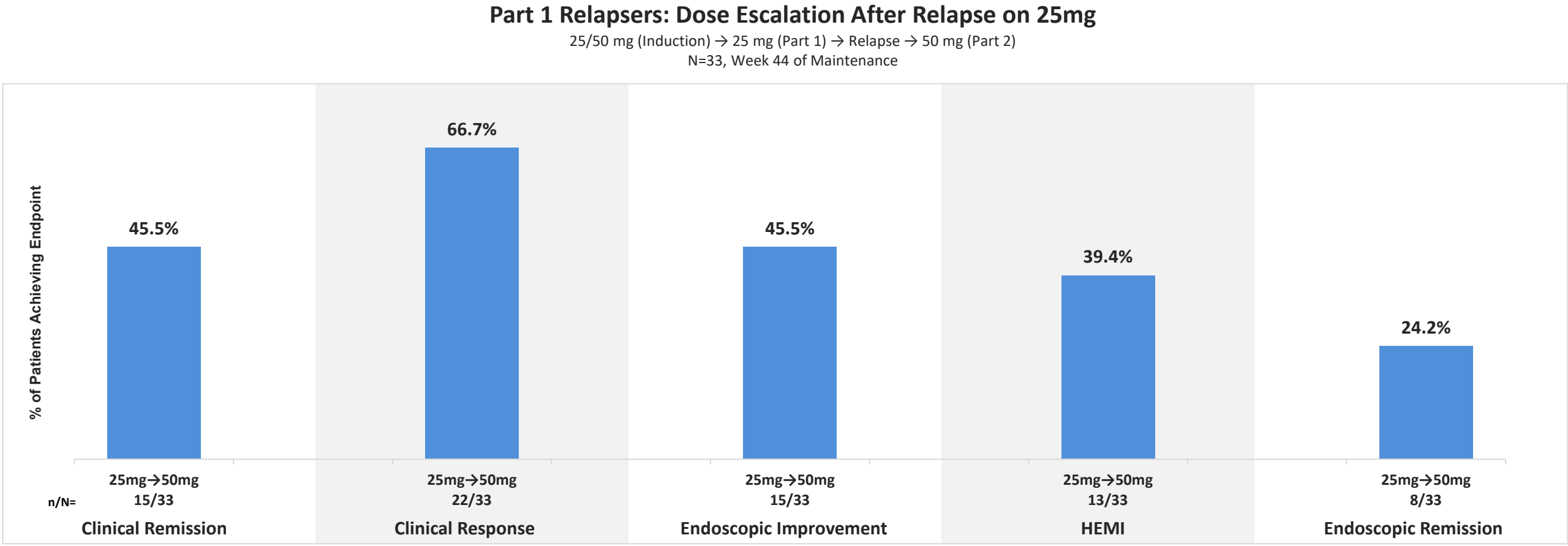
Dose Escalation From 25 mg to 50 mg Restored Disease Control in Patients Who Relapsed in Part 1, Supporting a Practical, Real-World Treatment Approach



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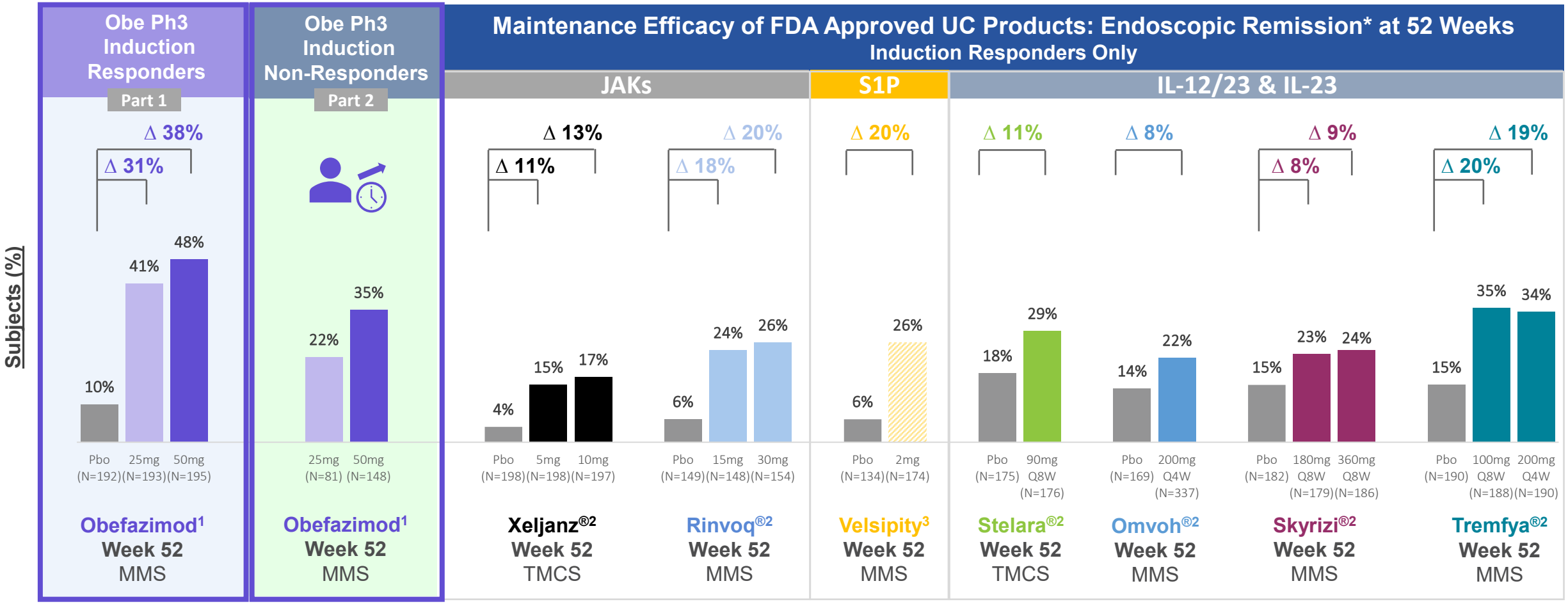
Obefazimod Achieved the Highest Endoscopic Remission Rate Among All UC Therapies

Obefazimod delivered transformational endoscopic remission, even in induction non-responders



For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

= Induction Non-Responders: Patients who did not achieve clinical response following 8-week induction with obefazimod

1. Data on File ABX464-107. 2. FDA package inserts. 3. Vermeire et. al., ECCO 2023 Poster #582. Velsipity Phase 3 was a treat-through design. Endoscopic remission is defined as MES = 0. All endoscopic remission numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts. TMCS = Total Mayo Clinic Score; MMS = Modified Mayo Score

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Contextualizing Safety Results in the Full Obefazimod Clinical Program

Part 1 Safety Review → **Part 2 and Comprehensive Safety Overview** → **Exposure-Adjusted Incidence Rate Analysis**

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Favorable Safety Profile Observed in Part 1 of the Maintenance Study

Obefazimod Part 1 Safety Results Summary

Infrequent Serious TEAEs	▪ Incidence rate of serious TEAEs similar to placebo
No Signal for Serious Infections	▪ Serious/Severe or opportunistic infection rate similar to placebo
Low Incidence of Headache AEs	▪ Headache AEs not associated with ongoing drug exposure
Strong Treatment Persistence	▪ ~80% of patients on obefazimod completed the study

Relative Regulatory and Clinical Significance of Malignancies

Malignancies Excluding NMSCs

- Primary **focus of regulatory and clinical safety** for malignancies
- Associated with boxed warning language for **JAKs** & TNFs
- Can result in **significant impact on patients**

Higher Regulatory / Clinical Focus

NMSCs

- **No precedent for boxed warnings in** IBD or other therapeutic areas
- Surveillance and sun protection are **part of standard IBD clinical practice**
- **Non-serious and treatable** when identified early

Lower Regulatory / Clinical Focus

Data on File ABX464-107.
AE = adverse event; IBD = inflammatory bowel disease; JAK = Janus kinase; NMSC = non-melanoma skin cancer; TEAE = treatment-emergent adverse event; TNF = tumor necrosis factor

Rate of Malignancies Excluding NMSCs in ABTECT Part 1 was Similar to Phase 3 Randomized Placebo-Controlled Maintenance Trials of Approved Agents

Number and Distribution of Non-NMSC Malignancies in Part 1 was Identical to Skyrizi

Malignancies Excluding NMSCs in Randomized Placebo-Controlled Maintenance Trial Cohorts

Drug (Brand)	Malignancies Excluding NMSCs % of patients in any active arm	Maintenance Trial Detail by Arm
Upadacitinib (Rinvoq)	0.99% (3/302)	High dose: 2/154, Low Dose: 1/148, Placebo: 1/149
Ustekinumab (Stelara)	0.57% (2/348)	High Dose: 1/176, Low Dose: 1/172, Placebo: 0/175
Risankizumab (Skyrizi)	0.55% (2/365)	High Dose: 2/186, Low Dose: 0/179, Placebo: 0/183
Obefazimod	**0.52% (2/388)**	**High Dose: 2/195, Low Dose: 0/193, Placebo: 0/192**
Ozanimod (Zeposia)	0.43% (1/230)	Active Dose: 1/230, Placebo: 2/227
Mirikizumab (Omvoh)	0.26% (1/389)	Active Dose: 1/389, Placebo: 0/192
Guselkumab (Tremfya)	0.27% (1/376)	High Dose: 1/190, Low Dose: 0/186, Placebo: 2/192
Vedolizumab (Entyvio)	0.16% (1/620)	Active Dose: 1/620, Placebo: 1/275
Tofacitinib (Xeljanz)	0% (0/394)	High dose: 0/198, Low dose: 0/196, Placebo: 1/198
Etrasimod (Velsipity)	0% (0/289)	Active dose: 0/289, Placebo: 0/144

Sources: Data on File ABX464-107; INSPIRE/COMMAND—Louis *JAMA* 2024; UNIFI—Sands *NEJM* 2019; QUASAR—Rubin *Lancet* 2025; OCTAVE—Sandborn *NEJM* 2017; GEMINI—Feagan *NEJM* 2013; LUCENT-1/2—D'Haens *NEJM* 2023; Data on File ABX464-107. U-ACHIEVE/U-ACCOMPLISH—Danese *Lancet* 2022; TRUE NORTH—Sandborn *NEJM* 2021; ELEVATE—Sandborn *Lancet* 2023.; Rates are percent of patients through maintenance. Not intended for cross-trial comparison.

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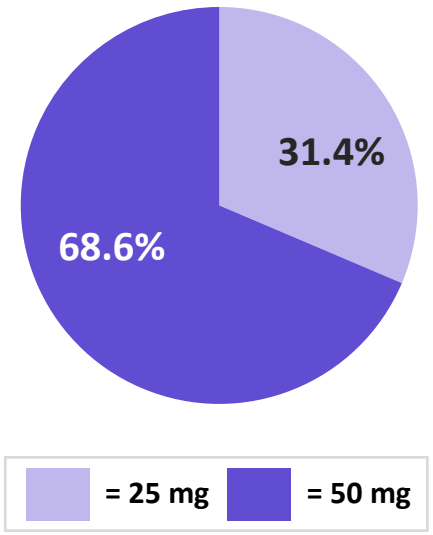
50 mg Dose Accounted for Nearly 70% of All Patient Year Exposure in Part 2

As expected, rare events are more likely to be observed in the dose group with the greatest cumulative patient-years of exposure

Patient Years Of Exposure By Dose in Part 2

Analysis Set	Dose	PYs of Exposure
Maintenance Part 2	25 mg	132
	50 mg	288
	Total	420

Exposure Distribution



How are patient-years of exposure defined?

- 1 patient treated for 1 year = 1 patient year (PY) of exposure
- 100 patients treated for 1 year = 100 PYs of exposure
- 100 patients treated for 2 years = 200 PYs of exposure

Data on File ABX464-107; PY = Patient Years

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Favorable Safety Profile Observed in Part 2, Consistent with the Overall Obefazimod Safety Experience

ABTECT Maintenance Part 2 Safety Results

Summary Safety Events, n (%)	Obe 25 mg N=186	Obe 50 mg N=447*
Any TEAE	132 (71.0%)	307 (68.7%)
TEAE leading to study drug discontinuation	21 (11.3%)	27 (6.0%)
Serious TEAE	16 (8.6%)	23 (5.1%)
Death (Non-Treatment Related)[1]	1 (0.5%)	0
Pregnancy[2]	1 (0.5%)	1 (0.2%)
Serious/severe (Grade ≥3) infections and opportunistic infections[3]	5 (2.7%)	5 (1.1%)
Malignancies (excluding NMSC)[4]	0	2 (0.4%)
Non-melanoma Skin Cancer (NMSC)[5]	2 (1.1%)	2 (0.4%)
Acute Pancreatitis	1 (0.5%)	1 (0.2%)
Cardiac Abnormalities suggestive of cardiac fibrosis	0	0

Data on File ABX464-107; 1. One death occurred in the 25 mg arm and was assessed by the investigator as unrelated to obefazimod. The suspected cause was pulmonary embolism in a 65+ patient with multiple pre-existing thromboembolic risk factors, including prior pulmonary embolism, and recent prolonged immobility. 2. Both pregnancies are currently ongoing 3. Serious/severe (grade ≥3) infections and opportunistic infections: 25 mg = Appendicitis, Bartonellosis, Cytomegalovirus gastrointestinal infection, Peritonsillar abscess, Sepsis; 50 mg (induction non-responder) = Clostridium difficile infection, pilonidal disease, Urethritis gonococcal; 50 mg Open Label (part 1 relapsers = Appendicitis (Part 1 50mg), Septic arthritis staphylococcal (Part 1 Pbo) 4. Part 1 Relapsers previous on placebo: One Case of Myoproliferative Neoplasm and one Prostate Cancer 5. Two Cases of Basal Cell Carcinoma (25mg | 50 mg) and two Cases of Squamous Cell Carcinoma (25mg | 50 mg); TEAE = Treatment-Emergent Adverse Event; *Includes combined Induction non-responders on 50mg in Part 2 (N=251) and Part 1 Relapsers (N=196) who entered Part 2

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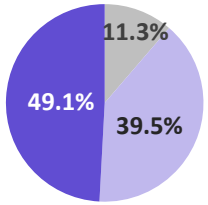
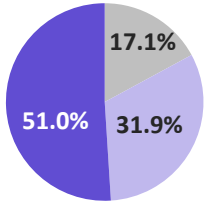
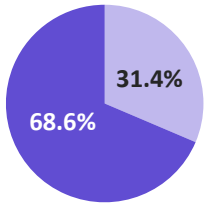
Obe 50 mg Accounts for 49% of Patient Year Exposure in Integrated UC Clinical Program

Placebo accounts for a small minority of patient-year exposure

Patient Years Overview for Exposure-Adjusted Incidence Rates

Analysis Set	Treatment Arm	Patient Years	Exposure Distribution
Integrated UC Clinical Program Phase 2 + Phase 3 Induction and Maintenance Part 1 & 2	Placebo	218	
	25 mg	760	
	50 mg	944	
	All Active	1,704	
Maintenance Part 1 + Part 2	Placebo	147	
	25 mg	274	
	50 mg	438	
	All Active	712	
Maintenance Part 2 Only	25 mg	132	
	50 mg	288	
	All Active	420	

Exposure-adjusted incidence rates provide a **meaningful comparison** across treatment groups with unequal exposure

$$\text{Incidence Rate per 100 Patient-Years} = \frac{\text{\# of events}}{\text{PYs of Exposure}} \times 100$$

Data on File ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
All Active = 25 mg & 50 mg doses only, excluding placebo; Phase 2 included 838 Patient Years of Obefazimod Exposure (50mg = 404 PY, 25mg = 434 PY) with an additional 20 PY of placebo

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All Active Combined Malignancy Other Than NMSC Rates were Consistent with the Reference Range Across All Three Datasets

Increasing Size and Relevance of Dataset

Integrated UC Clinical Program (Phase 2 + Phase 3 Induction and Maintenance)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed IR per 100 PY	0.00	0.00	0.64	0.35	0.30 - 0.70

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~147	~274	~438	~712	-
Observed IR per 100 PY	0.00	0.00	0.91	0.56	0.30 - 0.70

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed IR per 100 PY	N/A	0.00	0.69	0.48	0.30 - 0.70

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108; Patient years rounded to the largest whole number; IR = Incidence Rate; Sources: The composite malignancy benchmark range (0.3–0.7 per 100 patient-years) was derived from published ulcerative colitis (UC)- and inflammatory bowel disease (IBD)-specific malignancy epidemiology, supplemented by National Cancer Institute SEER incidence data for common malignancies where disease-specific estimates were limited. The benchmark incorporates malignancies commonly observed in UC/IBD populations, while excluding non-melanoma skin cancer (NMSC). Key references include Long et al. *Gastroenterology* 2012; Bencardino et al, *Cancers (Basel)* 2025; Carli E et al. *Medicina* 2020 meta-analysis; Kaneko et al. *J Clin Med* 2024; National Cancer Institute SEER Statistics; Beaugerie et al. *Lancet* 2009 (CESAME cohort); Lemaitre et al. *JAMA* 2017; and Scandinavian population-based registry studies evaluating malignancy risk in IBD. The benchmark range is intended for contextual comparison of observed malignancy rates and does not represent a single published incidence estimate.

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Two Malignancies Excluding NMSCs Observed in Part 2 Maintenance Trial

Multiple confounding pre-existing risk factors for both malignancy cases

Part 2 Malignancy Cases in Context

Preferred Term	Obefazimod 25 mg N=186, n	Obefazimod 50 mg N=447, n	Total in Part 2 N=633, n
Part 2 : Malignancies other than NMSC	**0**	**2**	**2**
Myeloproliferative neoplasm (MPN)	0	1	1
Prostate cancer	0	1	1

Both cases deemed unrelated to obefazimod by the study investigators

	Malignancy (Excluding NMSC)	Obefazimod Treatment Duration	Exposure to obefazimod	Pre-Existing Risk Factors for Malignancy: Age	Thiopurine History	Prior Advanced Therapies	Other Prior UC Treatment	Medical History of Cancer	Summary
50 mg	**Myeloproliferative Neoplasm (MPN)**	**Induction:** 50mg (9 wks) **Maint-Part 1:** PBO (20.1 wks) **Maint-Part 2:** 50mg (23.3 wks)	7.4 Months	40+	No	**2 (adalimumab, infliximab)**	mesalazine	N	**Thrombocythemia since 2023.** Had **elevated platelets at baseline** (909,000 per microliter)
	Prostate Cancer	**Induction:** PBO (8.7 wks) **Maint-Part 1**: PBO (6.9 wks) **Maint-Part 2:** 50mg (14.7 wks)	3.4 Months	**55+**	**Yes azathioprine**	**2 (infliximab, vedolizumab)**	**prednisolone,** mesalazine, budesonide	N	Limited adenocarcinoma of the prostate CT2 CN0 M0; Gleason score 7B

Both cases had multiple confounding factors: the MPN patient had pre-existing thrombocythemia with elevated platelets at baseline, while the prostate cancer patient was 55+, had failed two advanced therapies, and was exposed to obe for only 3.4 months

Data on File ABX464-107; **Blue** = Pre-Existing Risk Factor

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A Nonclinical Photosensitivity Finding Led to Enhanced Skin Surveillance in the ABTECT Phase 3 and Phase 2 OLE Protocols

Photosensitivity in Context

Nonclinical Photosensitivity Findings

Photosensitivity findings were observed in a nonclinical animal model

At the request of regulatory agencies, photosensitivity was incorporated into the existing skin lesion AESI

All skin lesion AESI forms, including supplementary photos, were **reviewed by a central dermatologist**

Rigorous Skin Lesion Monitoring in ABTECT and Phase 2 OLE

Phase 2 initially did not include a photosensitivity skin lesion AESI and reported no NMSCs; NMSC detection increased only after enhanced skin surveillance was added to the protocols

Most comprehensive skin lesion surveillance among historical UC Phase 3 programs

	Obefazimod ABTECT/108	Other Ph3 UC Programs*
AESI classification	✓	×
Dedicated reporting form	✓	×
Central dermatologist review	✓	×
Lesion photograph encouraged	✓	×
Lesion-specific adjudication	✓	×

*Other programs include ozanimod, etrasimod, tofacitinib, upadacitinib, risankizumab, guselkumab, and mirikizumab

Skin Lesion: No difference between obefazimod and placebo

The exposure-adjusted incidence rates (EAIR) were similar across treatment groups for ABTECT maintenance Part 1 & 2

NMSCs: Enhanced Skin Surveillance Increased Detection of NMSCs in Phase 3

NMSCs remained rare despite intensive protocol-driven surveillance

60% of NMSCs identified in Phase 3 were within the first 6 months of obefazimod exposure

No increase in NMSC detection was observed with longer treatment exposure

Clinical Study Protocols: ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
AESI = adverse event of special interest; OLE = open-label extension; NMSC = non-melanoma skin cancer; EAIR = exposure-adjusted incidence rates

No Increase in Skin Lesion Occurrence Between Placebo and Obefazimod Despite Robust Surveillance

Skin Lesion Summary – Phase 3 Maintenance Program

	Maintenance Part 1 & Part 2 Combined		
Patient Years of Exposure	**~147**	**~274**	**~438**
	Placebo	**Obe 25 mg**	**Obe 50 mg**
	n (IR per 100 PY)	n (IR per 100 PY)	N (IR per 100 PY)
Skin Lesions, All Types, *Externally Adjudicated*	**15 (10.2)**	**24 (8.8)**	**44 (10.0)**

Data on File ABX464-107; IR = Incidence Rate; PY = Patient Years

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All Active Combined NMSC Rates Were Consistent With the Reference Range Across All Three Datasets

Increasing Size and Relevance of Dataset

Integrated UC Clinical Program (Phase 2 + Phase 3 Induction and Maintenance)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed IR per 100 PY	0.46	0.53	0.64	0.59	0.70 – 1.40

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~147	~274	~438	~712	-
Observed IR per 100 PY	0.68	1.09	1.37	1.26	0.70 - 1.40

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed IR per 100 PY	N/A	1.52	0.69	0.95	0.70 - 1.40

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108; Patient years rounded to the largest whole number; IR = Incidence Rate; NMSC incidence rates were benchmarked against published IBD and UC literature. Long et al. reported an overall NMSC incidence of 912 per 100,000 patient-years in patients with IBD (0.91 per 100 patient-years). Bencardino et al. reviewed evidence demonstrating increased NMSC risk in IBD and reported an annual NMSC incidence of 733 per 100,000 patients (~0.73 per 100 patient-years). Abbas et al. reported UC-specific NMSC incidence rates ranging from 3.7 to 13.6 per 1,000 patient-years (0.37–1.36 per 100 patient-years) across thiopurine exposure strata. Based on these published estimates, a benchmark NMSC incidence range of 0.7–1.4 per 100 patient-years was used for contextual comparison. Expected cases were calculated as: (incidence rate per 100 patient-years × cumulative patient-years of exposure) ÷ 100.

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All Four Part 2 NMSC Cases Occurred in Patients with Established NMSC Risk Factors

Advanced age (3/4), thiopurine use (3/4), prior skin cancer history (2/4), failure of multiple advanced therapies (3/4)

Part 2 NMSC Cases in Context

Preferred Term	Obefazimod 25 mg N=186, n	Obefazimod 50 mg N=447, n	Total in Part 2 N=633, n
NMSC	**2**	**2**	**4**
Basal cell carcinoma	1	1	2
Squamous cell carcinoma of skin	1	1	2

	NMSC	Months of obefazimod Exposure	Pre-Existing Risk Factors for Malignancy: Age	Thiopurine History	Prior Advanced Therapies	Other Prior UC Treatment	Medical History of Skin Cancer	Summary
50 mg	**Basal Cell Carcinoma**	10.4 months	40+	Yes azathioprine	3 vedolizumab, infliximab, ustekinumab	mesalazine, prednisone	N	Thiopurine use and failure of 3 prior advanced therapies
	Squamous Cell Carcinoma	4.6 months	55+	Yes azathioprine	2 adalimumab, vedolizumab	budesonide	Y	Prior history of squamous cell carcinoma and history of multiple skin lesions
25 mg	**Basal Cell Carcinoma**	8.1 months	50+	Yes azathioprine	None	budesonide, sulfasalazine, mesalazine, prednisone, metronidazole, sodium butyrate	N	Age 50+, prior thiopurine history
	Squamous Cell Carcinoma	8.3 months	75+	No	2 adalimumab, vedolizumab	prednisone, mesalamine	Y	Age 75+ and prior history of 2x Basal cell carcinoma

Data on File ABX464-107; **Blue** = Pre-Existing Risk Factor; NMSC = non-melanoma skin cancer

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Safety Database Now Includes >1,700 Patient-Years of Exposure

Key safety observations from the expanded maintenance dataset

Safety Analysis Summary

1	**Favorable Safety Profile Maintained**	With the addition of Part 2 maintenance data, the obefazimod safety database now includes **>1,700 patient-years of exposure**, supporting a continued favorable overall safety profile
2	**Lack of Immunosuppressive Signal Consistent with MOA**	The low incidence of immunosuppression-associated AEs is consistent with obefazimod's MOA of restoring mucosal immune balance without evidence of broader immunosuppression **(no lymphomas, no melanomas, no signal of serious opportunistic infection**)
3	**Malignancy Rates Consistent with UC Background**	Exposure adjusted incidence rates for **NMSCs and malignancies excluding NMSCs** were consistent with the expected background incidence in a UC population

Data on File ABX464-107
MOA = mechanism of action; AE = adverse event; UC = ulcerative colitis; NMSC = non-melanoma skin cancer

Agenda

01	Welcome	**Pat Malloy** *Senior Vice President, Investor Relations*
02	Opening Remarks	**Marc de Garidel** *Chief Executive Officer*
03	Data Review: Study Context, Design & Topline Efficacy	**Fabio Cataldi, M.D.** *Chief Medical Officer*
04	Safety Review & Exposure-Adjusted Incidence Analysis	**Chris Rabbat, PhD** *Head of Global Medical Affairs*
05	Regulatory Assessment	**Keith Fournier, PhD** *Head of Regulatory Affairs*
06	KOL Perspectives	**Jordan Axelrad, M.D.** **Remo Panaccione, M.D.**
07	Q&A	**Abivax Leadership & KOLs**

Abivax Conducted Regulatory Assessments with Multiple Former FDA Senior Leaders Following the ABTECT Maintenance Part 1 and 2 Readouts

Feedback from Four Regulatory Consultants Regarding Part 1 and 2 Data

1 Safety & Labeling

Safety profile well within expectations

- Boxed warning considered highly unlikely
- Limited expectation for additional testing or referral requirements
- Potential warnings can likely be managed through established clinical practice guidelines (e.g. annual skin exam, sun protection)

2 Dose Strategy

Strong support for advancing both 25 mg and 50 mg

- Consensus recommendation to pursue both maintenance doses (25 mg & 50 mg)
- Preserves flexibility for patients and prescribers

3 Totality of Evidence

Maintenance strengthens the overall package

- Strong consensus that obefazimod offers a “compelling” profile in UC based on totality of evidence from Phase 2 + Phase 3
- Maintenance data strengthens the overall assessment of adverse events and provides context that rates observed are well within expected ranges

Multiple former FDA senior leaders consistently concluded that obefazimod has a favorable benefit-risk profile, that a boxed warning is highly unlikely, and that both the 25 mg and 50 mg maintenance doses should advance

Source: June 2026 regulatory consultant feedback meetings on ABTECT maintenance data

Regulatory Filing Strategy: Pursue Both 25 mg and 50 mg Doses for Maintenance

GOAL: File for BOTH 25 mg and 50 mg as maintenance treatment doses

Top Priority

Induction

8 weeks

50 mg

Maintenance

25 mg

Best-in-disease endoscopic remission results

Safety results compare favorably with approved UC therapies

50 mg

Best-in-disease endoscopic remission results

Favorable overall benefit-risk profile supported by the totality of the evidence

Flexible dosing could enable treatment optimization based on individual patient needs

Consistent feedback from former FDA senior leaders reinforces pursuing both 25 mg and 50 mg as the preferred strategy

Source: *June 2026 regulatory consultant feedback meetings on ABTECT maintenance data

ABTECT Maintenance Part 2: Advancing the Treatment Paradigm in UC

Part 2 further strengthens benefit-risk profile of obefazimod and de-risks regulatory pathway

1	Obefazimod delivered **meaningful clinical benefit** in a highly refractory ulcerative colitis population
2	The Part 2 safety profile remained consistent with prior studies, with **non-NMSC** malignancies and **NMSC** incidence rates **within expected background rates**
3	Part 2 meaningfully expanded the cumulative safety data, increasing **confidence in the long-term safety profile**
4	Long-term treatment of patients with refractory UC **further strengthens** obefazimod's **favorable benefit-risk profile** and supports our planned NDA submission by year-end

Data on File ABX464-107. UC = ulcerative colitis; NMSC = non-melanoma skin cancer; NDA = New Drug Application

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07	Q&A	**Abivax Leadership & KOLs**

Webcast KOL Panel

Moderated Discussion and Analyst Q&A Discussion

Jordan Axelrad, M.D., M.P.H
Associate Professor of Medicine, NYU Grossman School of Medicine, Co-Director, IBD Center, NYU Langone Health

NYU Langone Health

Remo Panaccione, M.D., FRCPC
Professor of Medicine,
Director, IBD Clinic
University of Calgary

UNIVERSITY OF CALGARY

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07	Q&A	**Abivax Leadership & KOLs**

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Q & A

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Thank You!
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EXPOSURE-ADJUSTED INCIDENCE RATE SUMMARY TABLES

Malignancy Exposure-Adjusted Incidence Rate Summary Tables

Phase 3 Maintenance

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed Malignancies	N/A	0	2	2	-
Observed IR per 100 PY	N/A	0.00	0.69	**0.48**	**0.30 - 0.70**

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~147	~274	~438	~712	-
Observed Malignancies	0	0	4	4	-
Observed IR per 100 PY	0.00	0.00	0.91	**0.56**	**0.30 - 0.70**

Integrated UC Clinical Program

(Phase 3 + Phase 2)

Phase 3 (Ind, Part 1 & 2) + Phase 2 Program	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed Malignancies	0	0	6	6	-
Observed IR per 100 PY	0.00	0.00	0.64	**0.35**	**0.30 - 0.70**

Phase 3 (Ind, Part 1 &2) + Phase 2 Program	UC Phase 2 (25 mg + 50 mg)	Phase 3 (Ind,1 & 2) (25 mg + 50 mg)	All Active Combined	Expected UC Background
Total PYs of Exposure	~838	~866	~1,704	-
Observed Malignancies*	1	5	6	-
Observed IR per 100 PY	0.12	0.58	**0.35**	**0.30 - 0.70**

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
~54 placebo patient-years reflect placebo induction responders in Phase 3 who remained on placebo through maintenance without transitioning to Part 2 and switching to 50 mg obefazimod. Phase 3 induction patient years were: placebo = ~51 patient years, 25 mg = ~52 patient years, 50 mg = ~102 patient years. Patient years rounded to the largest whole number; Patient years rounded to the largest whole number; IR = Incidence Rate; Sources: The composite malignancy benchmark range (0.3–0.7 per 100 patient-years) was derived from published ulcerative colitis (UC) and inflammatory bowel disease (IBD)-specific malignancy epidemiology, supplemented by National Cancer Institute SEER incidence data for common malignancies where disease-specific estimates were limited. The benchmark incorporates malignancies commonly observed in UC/IBD populations, while excluding non-melanoma skin cancer (NMSC). Key references include Long et al. *Gastroenterology* 2012; Bencardino et al, *Cancers (Basel)* 2025; Carli E et al. *Medicina* 2020 meta-analysis; Kaneko et al. *J Clin Med* 2024; National Cancer Institute SEER Statistics; Beaugerie et al. *Lancet* 2009 (CESAME cohort); Lemaitre et al. *JAMA* 2017; and Scandinavian population-based registry studies evaluating malignancy risk in IBD. The benchmark range is intended for contextual comparison of observed malignancy rates and does not represent a single published incidence estimate.
*Phase 2b: malignant meningioma; Phase 3 induction: prostate; Phase 3 Maintenance Part 1: breast, prostate; Phase 3 Maintenance Part 2: myeloproliferative neoplasm, prostate.

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NMSC Exposure-Adjusted Incidence Rate Summary Tables

Phase 3 Maintenance

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed NMSCs	N/A	2	2	4	-
Observed IR per 100 PY	N/A	1.52	0.69	**0.95**	**0.70 - 1.40**

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~147	~274	~438	~712	-
Observed NMSCs	1	3	6	9	-
Observed IR per 100 PY	0.68	1.09	1.37	**1.26**	**0.70 - 1.40**

Integrated UC Clinical Program

(Phase 3 + Phase 2)

Phase 3 (Ind, Part 1 & 2) + Phase 2 Program	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed NMSCs	1	4	6	10	-
Observed IR per 100 PY	0.46	0.53	0.64	**0.59**	**0.70 - 1.40**

Phase 3 (Ind, Part 1 &2) + Phase 2 Program	UC Phase 2 (25 mg + 50 mg)	Phase 3 (Ind,1 & 2) (25 mg + 50 mg)	All Active Combined	Expected UC Background
Total PYs of Exposure	~838	~866	~1,704	-
Observed NMSCs*	1	9	10	-
Observed IR per 100 PY	0.12	1.04	**0.59**	**0.70 - 1.40**

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
~54 placebo patient-years reflect placebo induction responders in Phase 3 who remained on placebo through maintenance without transitioning to Part 2 and switching to 50 mg obefazimod. Phase 3 induction patient years were: placebo = ~51 patient years, 25 mg = ~52 patient years, 50 mg = ~102 patient years. Patient years rounded to the largest whole number; Patient years rounded to the largest whole number; IR = Incidence Rate; NMSC incidence rates were benchmarked against published IBD and UC literature. Long et al. reported an overall NMSC incidence of 912 per 100,000 patient-years in patients with IBD (0.91 per 100 patient-years). Bencardino et al. reviewed evidence demonstrating increased NMSC risk in IBD and reported an annual NMSC incidence of 733 per 100,000 patients (~0.73 per 100 patient-years). Abbas et al. reported UC-specific NMSC incidence rates ranging from 3.7 to 13.6 per 1,000 patient-years (0.37–1.36 per 100 patient-years) across thiopurine exposure strata. Based on these published estimates, a benchmark NMSC incidence range of 0.7–1.4 per 100 patient-years was used for contextual comparison. Expected cases were calculated as: (incidence rate per 100 patient-years × cumulative patient-years of exposure) ÷ 100. *Phase 2b: squamous cell carcinoma (n=1); Phase 3 Maintenance Part 1: basal cell carcinoma (n=2), squamous cell carcinoma (n=3); Phase 3 Maintenance Part 2: basal cell carcinoma (n=2), squamous cell carcinoma (n=2)

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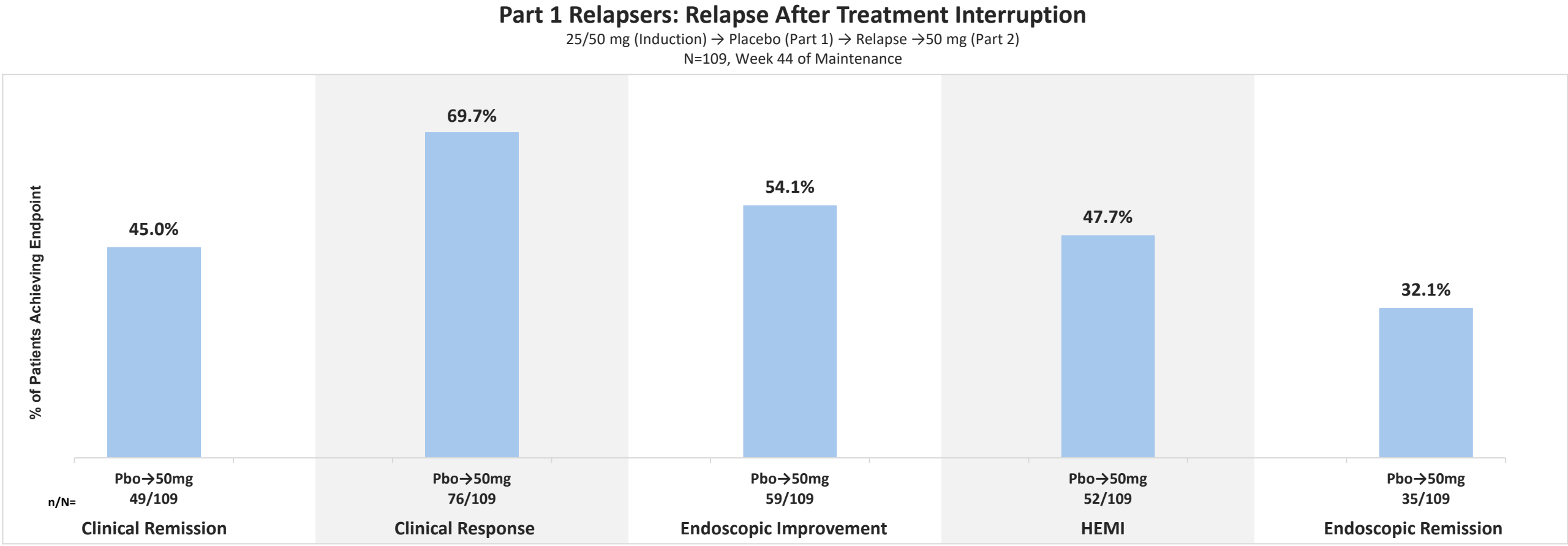
ADDITIONAL EFFICACY

Obefazimod Also Recaptured Response in Patients who Relapsed After Being Randomized to Placebo in Part 1 and Switched to 50 mg in Part 2



Data on File ABX464-107; Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1; Clinical response is defined as a reduction from Baseline in MMS >= 2 points and a relative reduction from Baseline in MMS >= 30%, and a reduction from Baseline in RBS >= 1 point and/or RBS = 0 or 1; Endoscopic improvement is defined as MES = 0 or 1; HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1; Endoscopic remission is defined as MES = 0; HEMI = Histologic Endoscopic Mucosal Improvement; Part 1 Relapsers are patients who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1

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PHASE 3 INDUCTION AND PHASE 3 PART 2 PATIENT CASES

Malignancy in Phase 3 Induction

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History & Summary
50 mg	**Prostate Cancer**	60+	**Induction:** 50mg (2.1 wks)	0.5 months	Eastern Europe	Mesalazine, budesonide, prednisolone	Not Related	N	Prostatic hyperplasia (benign prostatic hyperplasia) the year prior to enrolling in ABTECT Elevated PSA (4.52 ng/mL) was identified; early-stage, acinar adenocarcinoma of the prostate, Stage I, Grade Group 2 was reported

Data on File ABX464-105; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

Part 2: Malignancies other than non-melanoma skin cancers (non-NMSC)

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History & Summary
50 mg	**Myeloproliferative Neoplasm (MPN)**	40+	**Induction:** 50mg (9 wks) **Maint-Part 1**: PBO (20.1 wks) **Maint-Part 2:** 50mg (23.3 wks)	7.4 months	Eastern Europe	Adalimumab, infliximab, mesalazine	Not Related	N	MH of thrombocythemia since 2023. Had elevated platelets (909,000 per microliter; N: 140-450) at screening. The subject started treatment with hydroxycarbamide and ruxolitinib after diagnosis
	Prostate Cancer	55+	**Induction:** PBO (8.7 wks) **Maint-Part 1**: PBO (6.9 wks) **Maint-Part 2:** 50mg (14.7 wks)	3.4 months	Western Europe	Prednisolone, mesalazine, budesonide, azathioprine, infliximab, vedolizumab	Not Related	N	Limited adenocarcinoma of the prostate CT2 CN0 M0; Gleason score 7B

The MPN patient had pre-existing thrombocythemia and elevated platelets at baseline, while the prostate cancer case emerged after only 3.4 months of exposure

Data on File ABX464-107; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

All four Part 2 NMSC cases occurred in patients with established NMSC risk factors

Advanced age (3/4), thiopurine use (3/4), prior skin cancer history (2/4), failure of multiple advanced therapies (3/4)

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Skin Cancer	Medical History & Summary
50 mg	**Basal Cell Carcinoma**	40+	**Induction:** 50mg (8.7 wks) **Maint-Part 1**: PBO (5.0 wks) **Maint-Part 2:** 50mg (36.7 wks)	10.4 months	Western Europe	Mesalazine, prednisone, azathioprine, vedolizumab, infliximab, ustekinumab	Probably Related	N	None reported
	Squamous Cell Carcinoma	55+	**Induction:** 50mg (8.7 wks) **Maint-Part 1**: N/A **Maint-Part 2:** 50mg (11.4 wks)	4.6 months	North America	adalimumab, budesonide, vedolizumab, azathioprine for 5 years	Not Related	Y	Squamous cell carcinoma and history of multiple skin lesions
25 mg	**Basal Cell Carcinoma**	50+	**Induction:** 25mg (8.9 wks) **Maint-Part 1**: N/A **Maint-Part 2:** 25mg (26.3 wks)	8.1 months	Eastern Europe	Budesonide, sulfasalazine, mesalazine, prednisone, azathioprine, metranidazole, sodium butyrate	Unlikely Related	N	None reported
	Squamous Cell Carcinoma	75+	**Induction:** PBO (9.0 wks) **Maint-Part 1**: N/A **Maint-Part 2:** 25mg (36.0 wks)	8.3 months	North America	Prednisone, adalimumab, vedolizumab, mesalamine	Probably Related	Y	2x Basal cell carcinoma

All four Part 2 NMSC cases occurred in patients with established NMSC risk factors, including prior azathioprine exposure (3/4), prior skin cancer history (2/4), and exposure to multiple advanced therapies including TNF inhibitors, Entyvio, and Stelara

Data on File ABX464-107; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

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Reported Part 2 acute pancreatitis events occurred in patients with medical history and relevant clinical context

Case 1: 25 mg

Age: 50+

Location: Central Europe

Induction: PBO (8 wks)
Maint Part 2: 25 mg (6.9 wks)

Treatment duration: 1.6 months

Prior UC treatment:
Azathioprine, adalimumab, etrolizumab (investigational), tofacitinib

Medical History of Pancreatitis: Yes

- **Prior acute pancreatitis in 2007** attributed to azathioprine
- Immunosuppressant and steroid exposure
- **Pancreatic enzyme elevations first noted at maintenance baseline prior to any obefazimod exposure** (Placebo Induction Non-Responder)

Prior history of acute pancreatitis; pancreatic enzyme elevations first noted at maintenance baseline prior to obefazimod exposure

Case 2: 50 mg

Age: 35+

Location: Eastern Europe

Induction: 50 mg (8 wks)
Maint Part 2: 50 mg (12 wks)

Treatment duration: 4.6 months

Prior UC treatment:
Methylprednisolone, azathioprine, vedolizumab, mesalazine

Medical History of Pancreatitis: No

- Prior history of gastritis and arthralgia
- Multiple prior immunosuppressant exposures
- Abdominal pain was associated with **transient elevations in amylase (120 U/L) and lipase (130 U/L)** and CT-confirmed pancreatic edema; enzymes normalized a couple months later

Mild/transient enzyme elevations below the typical acute pancreatitis threshold

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Deaths Reported in Competitor Phase 3 Trials for Context

Obefazimod: One Non-Treatment Related Death in ABTECT Maintenance Part 2

Drug (Brand)	Phase 3 UC Program (Induction + Maintenance) Active Drug – *52 weeks*
	Death (n)
Risankizumab (Skyrizi)	2
Ustekinumab (Stelara)	2
Guselkumab (Tremfya)	1
Tofacitinib (Xeljanz)	1
Vedolizumab (Entyvio)	1
Mirikizumab (Omvoh)	1
Ozanimod (Zeposia)	1
Obefazimod	**1**
Upadacitinib (Rinvoq)	0
Etrasimod (Velsipity)	0

Details of Non-Treatment Related Death in ABTECT Part 2

Treatment Arm	**25 mg**
Age	65+
Obefazimod Treatment Duration	**Induction:** 25 mg (8 wks) **Maintenance Part 2**: 25 mg (28.6 wks)
Months of Obefazimod Exposure	8.5 months
Location	Eastern Europe
Prior UC Treatment	Mesalazine, methylprednisolone
Investigator Assessment	**Not Related**
Suspected Cause of Death	Pulmonary Embolism (Prior History)

Relevant Medical History

Prior history of pulmonary embolism in 2021

- Recent hospitalization with prolonged immobility
- Atrial fibrillation
- Type 2 diabetes
- Hypertension
- Hyperlipidemia

Other Comorbidities

- Osteoporosis
- Hepatic steatosis
- Iron deficiency anemia
- GERD
- Prostatic hyperplasia
- Recent/recurrent pneumonia
- Active UC history

Incident Details

- Fatal pulmonary embolism was suspected but unconfirmed
- Patient had substantial baseline thromboembolic and cardiometabolic risk factors plus recent infection and prolonged immobility

Sources: Data on File ABX464-107; INSPIRE/COMMAND—Louis *JAMA* 2024; UNIFI—Sands *NEJM* 2019; QUASAR—Rubin *Lancet* 2025; OCTAVE—Sandborn *NEJM* 2017; GEMINI—Feagan *NEJM* 2013; LUCENT-1/2—D'Haens *NEJM* 2023; Data on File ABX464-107. U-ACHIEVE/U-ACCOMPLISH—Danese *Lancet* 2022; TRUE NORTH—Sandborn *NEJM* 2021; ELEVATE—Sandborn *Lancet* 2023.

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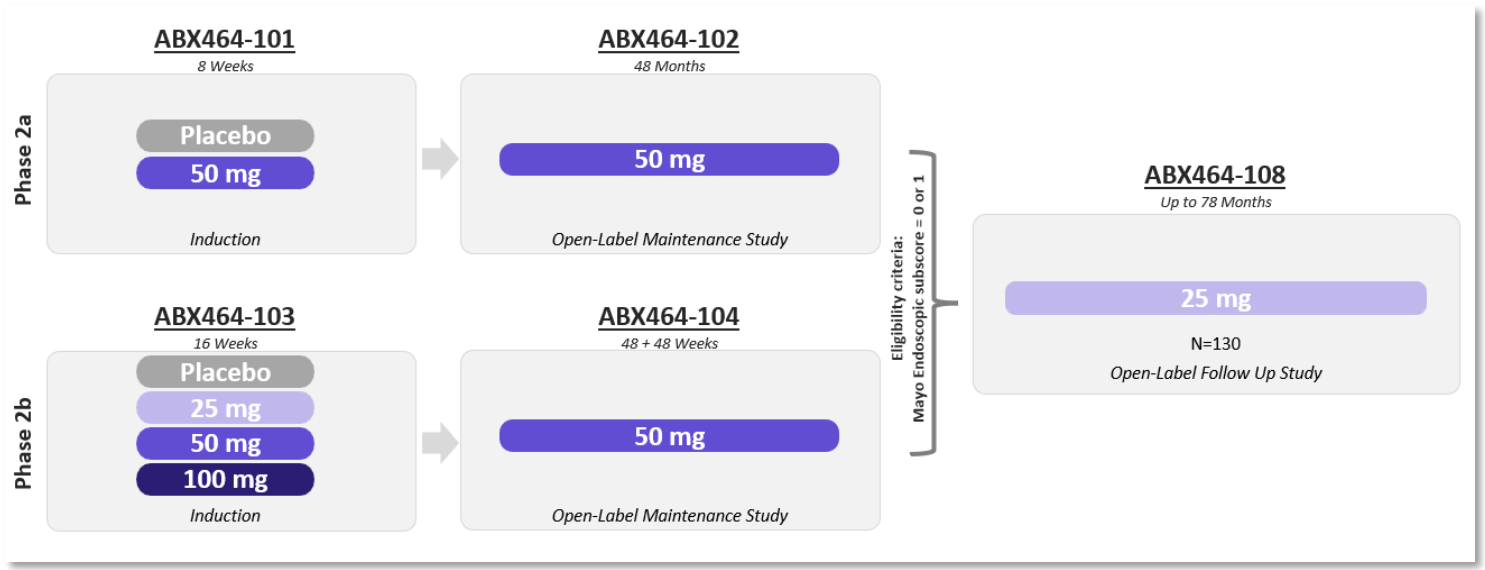
PHASE 2 PATIENT YEARS AND CASES

Long-term Phase 2 experience included ~858 patient years of exposure

TOTAL PHASE 2 PATIENT YEARS (PYs)*

~858 PY of Obe Exposure

50 mg = ~404 PY, 25 mg = ~434 PY, PBO = ~20PY



MH = Medical History; Patient Years for this analysis included obefazimod exposure only; *As of May 2026
Data on File ABX464-104 and ABX464-108. Vermeire et al. *JCC* May 2025.

Malignancy / NMSC in Phase 2 Studies

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History & Summary
50 mg	**Meningioma Malignant**	65+	**ABX464-104:** 50mg (60.7 wks)	14.0 months	Eastern Europe	Budesonide, mesalazine	Not Related	N	Approximately 14 months after treatment initiation, the subject was hospitalized for neurological symptoms and treated with carbamazepine and sulpiride; MRI subsequently identified a Grade III malignant meningioma
	Squamous Cell Carcinoma	55+	**ABX464-103:** 100mg (15.6 wks) **ABX464-104:** 50mg (96.1 wks) **ABX464-108:** 25mg (14.0 wks)	28.9 months	Eastern Europe	Infliximab, vedolizumab, prednisolone	Unlikely Related	Y	Basal cell carcinoma

Data on File ABX464-103, ABX464-104, ABX464-108; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

PROTOCOL

ABTECT Phase 3 and Phase 2b OLE protocols incorporated enhanced skin lesion surveillance following pre-clinical photosensitivity findings

Initial Protocol

ABX464-108 CSP, v1.0, released 01-Sep-2021

9.1.2. Adverse Events of Special Interest

The following events will be considered AESI and must be reported to (same procedure as SAE).

Skin Lesions (regardless of its severity)

A dermatologist consultation should be scheduled to evaluate the type of lesion, its severity and etiology. An anonymized medical report shall be provided.

Updated Protocol

ABX464-108 CSP, v3.0, released 13-Jul-2022

9.1.2. Adverse Events of Special Interest (AESIs)

The following events will be considered AESI and must be reported to (same procedure as SAE).

Skin Lesions (regardless of its severity)

The AESI "skin lesion" should be broadly captured by the site physician. Subjects are informed via the ICF that oral administration of ABX464-N-Glu was phototoxic in a nonclinical model at clinically relevant exposure levels. To mitigate this risk, subjects must comply with usual public recommendations for sun protection, such as: use shade wisely, wear protective clothing (hat, sunglasses), use sunscreen (with a sun protective factor [SPF] of 15 or higher), and limit time spent in mid-day sun or strong sunlight. Subjects experiencing skin lesion(s) will be instructed to contact the site study coordinator or investigator and to take a picture of the skin lesion for medical assessment. The site investigator will complete a specific skin lesion form as provided in Appendix 14.4. Additionally, the skin lesion form may be supplemented by pictures of the affected skin region(s) taken by the subject, at their discretion. The pseudonymized skin lesion form will be reviewed by a central dermatologist, to investigate a potential for photosensitivity. A pseudonymized medical report will be provided by the central dermatologist. In addition, the site should report the skin lesion to using the standard AESI/SAE form.

Protocol Feature	Obefazimod Initial (ABX-484-108 v1.0)	Obefazimod Updated (ABTECT/108 v3.0)
Skin lesions specifically classified as AESIs	✓	✓
Dedicated skin-lesion reporting form	✗	✓
Lesion photography permitted/encouraged	✗	✓
Central dermatologist review	✗	✓
Skin lesion adjudication pathway	✗	✓
NMSC reported through lesion-specific pathway	✗	✓
All NMSCs treated as AESIs	✗	✓
Explicit protocol for skin-lesion surveillance	✓	✓
Routine Scheduled Skin Examination	✗	✗
Dermatologist consultation if skin effect identified	✓	✓

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INCIDENCE RATES CALCULATIONS

How Malignancy Incidence Rates (per 100 Patient-Years) Were Derived

1 Published Sources

- **Long MD, Martin CF, Pipkin CA, et al.** Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1
- **Bencardino S, Bernardi F, Allocca M, et al**. Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer: What's New? *Cancers (Basel).* 2025;17(10):1710
- **Beaugerie L, Brousse N, Bouvier AM, et al**. Lymphoproliferative Disorders in Patients Receiving Thiopurines for Inflammatory Bowel Disease: A Prospective Observational Cohort Study. *Lancet*. 2009;374(9701):1617-1625
- **Kaneko M, Kantani Y, Sato H, et al**. Prognostic Factors in Prostate Cancer Associated with Ulcerative Colitis. *Journal of Clinical Medicine*. 2024;13(5):1392
- **Lemaitre M, Kirchgesner J, Rudnichi A, et al.** Association Between Use of Thiopurines or Tumor Necrosis Factor Antagonists Alone or in Combination and Risk of Lymphoma in Patients With Inflammatory Bowel Disease. *JAMA*. 2017;318(17):1679-1686
- **National Cancer Institute SEER Statistics** - Population-based U.S. cancer incidence data used to contextualize expected rates of common malignancies where UC/IBD-specific incidence estimates were limited

2 Converted to 100 Patient Years

Common UC Malignancies

Includes malignancies most commonly reported in a UC/IBD population:

- ✓ Prostate cancer
- ✓ Breast Cancer
- ✓ Other malignancies associated with IBD

3 Derived Benchmark Range

Published malignancy incidence in IBD/UC population is generally on the order of:

0.3 – 0.7

per 100 patient years

Lower bound reflects conservative estimates from population-based IBD cohorts

Upper bound reflects higher estimate observed in older, longer disease duration and more heavily treated UC populations

Key Assumptions

- Published malignancy incidence in IBD/UC varies by patient demographics, disease characteristics, treatment history, and surveillance intensity
- A composite benchmark range of 0.3 – 0.7 cases per 100 patient-years was derived from published IBD/UC epidemiology and population-based cancer incidence data
- The range is intended for contextual comparison of observed malignancy rates and does not represent a single published incidence estimate

Note: Common UC Malignancies excludes non-melanoma skin cancers (NMSCs)

How NMSC Incidence Rates (per 100 Patient-Years) Were Derived

1 Published Sources

Source	Population	NMSC Incidence (as reported)
Long et al., Gastroenterolgy 2012[1]	IBD (UC & Crohn's Disease)	912 per 100,000 patient years
Bencardino et al., Cancers 2025[2]	IBD (Overall)	733 per 100,000 patient years
Abbas et al., Am J Gastroenterol 2014[3]	UC (thiopurine exposure strata)	3.7 to 13.6 per 1,000 patient years

NMSC = non-melanoma skin cancer, IBD = inflammatory bowel disease, UC = ulcerative colitis

2 Converted to 100 Patient Years

Calculation	Incidence (per 100 patient years)
912 per 100,000 PY ÷ 1,000	0.91
733 per 100,000 ÷ 1,000	0.73
(3.7 to 13.6 per 1,000 PY) ÷ 10	0.37 to 1.36

Note = Incidence rates are expressed per person-year in the original publications and converted above to cases per 100 patient years for comparability

3 Derived Benchmark Range

Published NMSC incidence in IBD/UC population is generally on the order of:

0.7 – 1.4

NMSC Cases per 100 patient years

Lower bound anchored by Bencardino et al. (0.73)
Upper bound anchored by Abbas et al. (1.36)
Long et al. (0.91) supports the mid range

Sources

1. Long MD, Martin CF, Pipkin CA, et al. Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1
2. Bencardino S, Bernardi F, Allocca M, et al. Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer: What's New? *Cancers (Basel)*. 2025;17(10):1710
3. Abbas AM, Almukhtar RM, Loftus EV, et al. Risk of melanoma and non-melanoma skin cancer in patients treated with thiopurines: a nationwide retrospective cohort. *Am J Gastroenterol* 2014;109(3):390–399

Key Assumption

Published NMSC incidence estimates vary by patient characteristics, immunosuppressive exposure, age, and surveillance intensity; therefore, a benchmark range of 0.7–1.4 cases per 100 patient-years was selected to bracket published IBD/UC incidence estimates and provide context for safety comparisons

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