

ABTECT Maintenance Part 2 Primer

June 2026

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Where We Are Today

June 1st Readout

- ABTECT Part 1 Maintenance Efficacy & Safety Topline Release

Today June 15th

- ABTECT Maintenance Part 2 Primer



End of June Readout

- ABTECT Part 2 Data Release

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Agenda

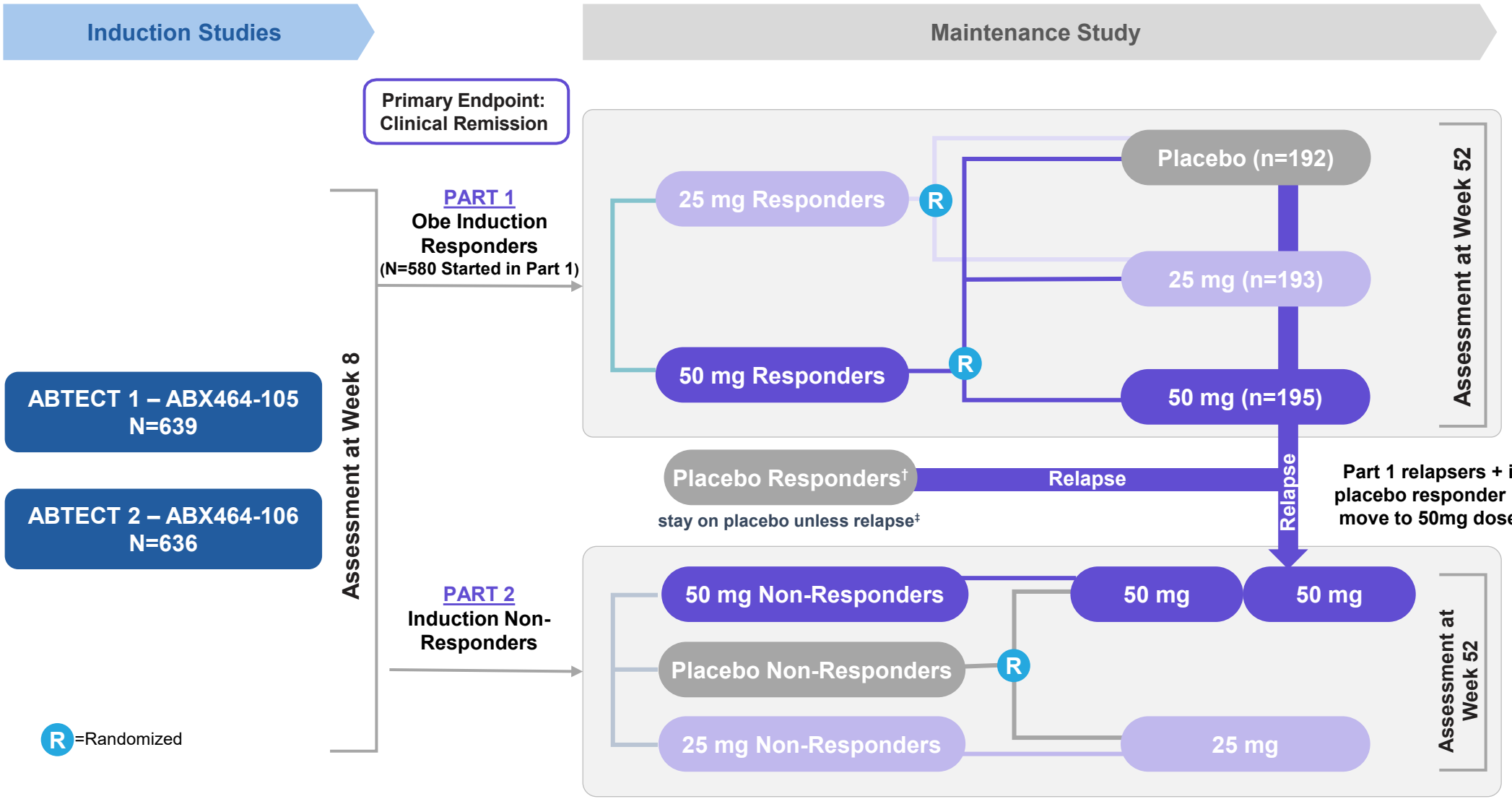
1 Part 2 Study Design Overview

2 Part 1 Readout Recap

3 Key Considerations for the Upcoming Part 2 Readout

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Next Steps: Assessing data from Part 2 safety and efficacy



Primary Endpoint: Clinical Remission

Part 1 (Registrational):

- Contributes to assessment of the primary endpoint (clinical remission)

Part 2 (Supplemental):

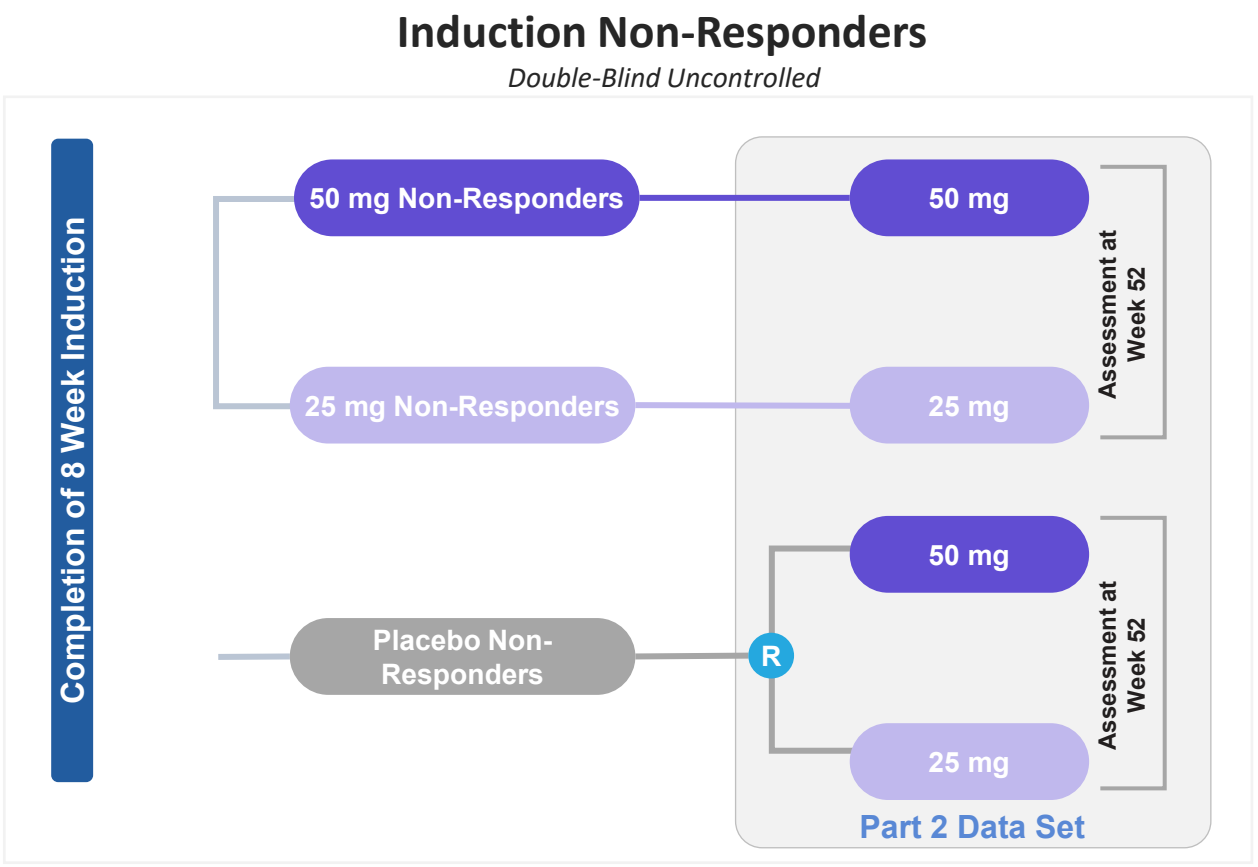
- Does not contribute to primary endpoint
- Expands the safety dataset to support NDA filing and evaluates potential delayed responders
- Only symptomatic endpoints assessed between Weeks 8–52, as endoscopy was performed only at those timepoints

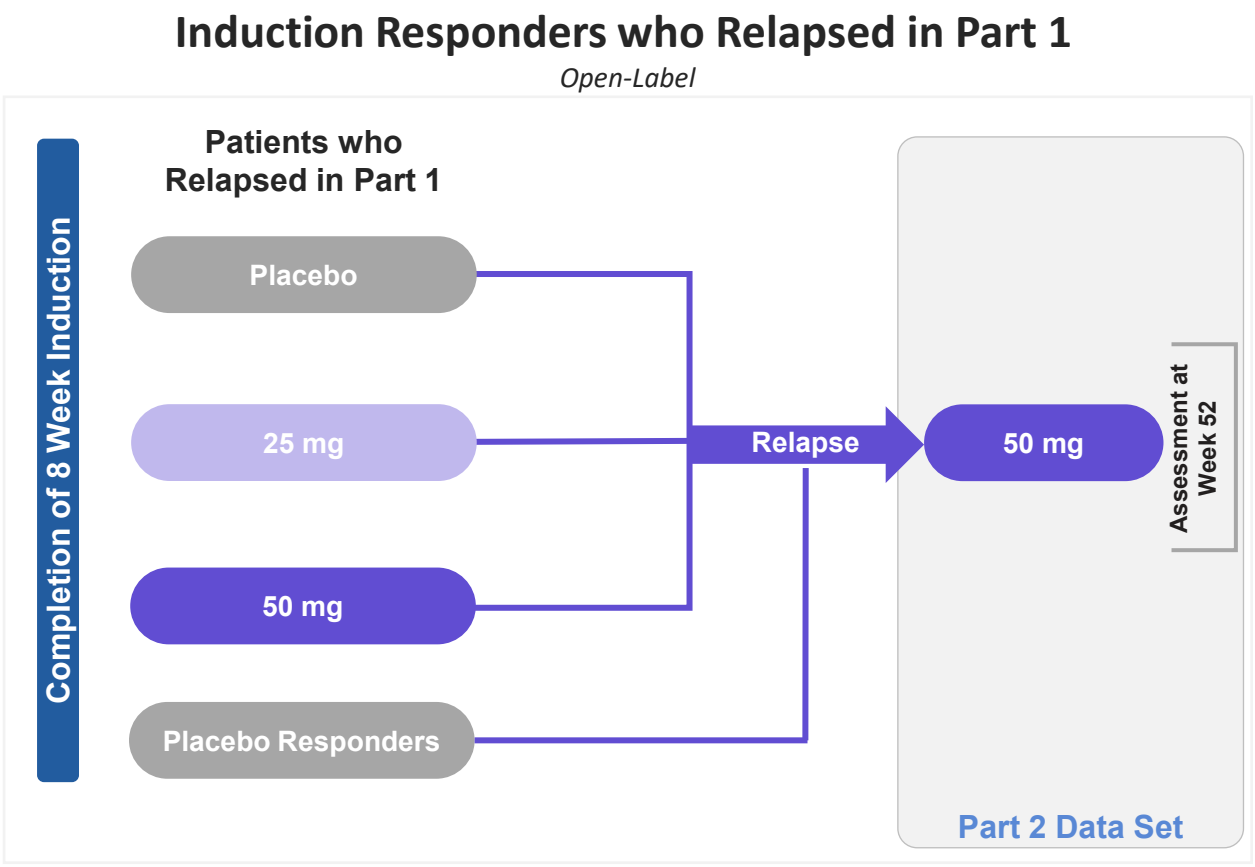
ABX464-107 Protocol

†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

Part 2 includes both induction non-responders and patients who initially responded but subsequently relapsed, creating two distinct populations within the same analysis





Part 2 integrates two clinically distinct patient populations, making subgroup context critical to interpreting overall efficacy and safety results

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ABTECT Maintenance Part 1 vs Part 2 Endpoints

Part 1 is registrational, and Part 2 provides meaningful safety data and captures potential delayed responders

Part 1 - Registrational

Primary Endpoint
- **Clinical Remission**

Key Secondary Endpoints:
- Endoscopic Improvement
- Endoscopic Remission
- Corticosteroid-free Clinical Remission
- Sustained Clinical Remission
- Histologic-Endoscopic Mucosal Improvement

Part 2 - Supplemental

Primary Endpoint
- **Safety and tolerability**

Exploratory Endpoints:
- Clinical Remission
- Endoscopic Improvement
- Endoscopic Remission
- Corticosteroid-free Clinical Remission
- Sustained Clinical Remission
- Histologic-Endoscopic Mucosal Improvement

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Agenda

1 Part 2 Study Design Overview

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Safety Results Summary – ABTECT Maintenance Part 1

Summary Safety Events, n (%)	ABTECT Maintenance Part 1		
	Placebo (N=192)	Obe 25 mg (N=193)	Obe 50 mg (N=195)
Any TEAE	96 (50.0%)	112 (58.0%)	140 (71.8%)
TEAE leading to study drug discontinuation	13 (6.8%)	5 (2.6%)	9 (4.6%)
Serious TEAE	8 (4.2%)	5 (2.6%)	11 (5.6%)
Death	0	0	0
Pregnancy	0	0	2 (1.1%)
Serious/severe (grade ≥3) infections and opportunistic infections[1]	2 (1.0%)	2 (1.0%)	1 (0.5%)
Malignancies other than Non-melanoma Skin Cancer (non-NMSC)[2]			
Breast cancer	0	0	1 (0.5%)
Prostate cancer	0	0	1 (0.5%)
Non-melanoma Skin Cancer (NMSC)			
Basal cell carcinoma	1 (0.5%)	0	2 (1.1%)
Squamous cell carcinoma	0	1 (0.5%)	2 (1.1%)
Acute Pancreatitis	0	0	0
Cardiac abnormalities suggestive of cardiac fibrosis	0	0	0

1. Serious/Severe Infections and Opportunistic Infections: Placebo = Anal abscess, bronchitis & gastroenteritis, 25 mg = 1 Lymph node tuberculosis, 1 tonsillitis, 50 mg = 1 Appendicitis, focal peritonitis; TEAE = Treatment-Emergent Adverse Event. 2. One case of colonic dysplasia was reported in the obefazimod 50mg arm.

Data on File ABX464-107

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UC is associated with increased risk for malignancies

Cancer Type	General Population	IBD / UC Population
Prostate Cancer	Common age-related malignancy in men	▪ Multiple studies and meta-analyses suggest modestly increased risk in IBD, particularly UC ▪ In one study, men with IBD were nearly 5x more likely to be diagnosed with prostate cancer than those without IBD
Breast Cancer	Common age-related malignancy in women	▪ Large-scale study reported a breast cancer prevalence of 2.3% in individuals with UC, compared with 1.1% in individuals without IBD ▪ However, other studies have found no significant difference in breast cancer rates between patients with UC and the general population

Published epidemiology data supports increased rates of NMSC in IBD populations, with emerging evidence suggesting elevated risks of breast cancer and prostate cancer

Sources: Breast and prostate cancer incidence generally not substantially different from the general population, although elevated prostate cancer risk has been reported in some cohorts; Carli E et al. *Medicina* 2020 meta-analysis: IBD associated with increased prostate cancer risk (RR 1.71; 95% CI 1.16–2.51); UC RR 1.22; Kaneko M et al. *J Clin Med* 2024: Supports accumulating evidence linking UC and elevated prostate cancer risk; Mansoor E, Abou-Saleh M, Sarmini M Gastroenterology, 158, S39-S40 P126 Epidemiology and risk factors of breast cancer in inflammatory bowel disease in the united states between 2014 and 2019: a population-based study

Part 1: Malignancies Other Than Non-Melanoma Skin Cancers

ABTECT Maintenance Trial

	Preferred Term	Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History
50 mg	**Prostate Cancer**	50+	**Induction:** 50mg (8.9 wks) **Maint-Part 1**: 50mg (28.0 wks) **Maint-Part 2:** N/A	8.5 months	Western Europe	Mesalazine, budesonide, beclomethasone dipropionate, deltacortene, beclomethasone Adalimumab, vedolizumab, infliximab, upadacitinib, ustekinumab	Unlikely Related	No	Relevant history included monoclonal gammopathy of undetermined significance (MGUS), vitamin D deficiency, and sideropenic anemia Elevated PSA was identified, leading to diagnosis of Grade 2 (Gleason 7) intermediate-risk prostate adenocarcinoma
	Breast Cancer	65+	**Induction:** 50mg (8.0 wks) **Maint-Part 1**: 50mg (21.4 wks) **Maint-Part 2:** N/A	6.8 months	Eastern Europe	Methylprednisolone	Unlikely Related	No	No reported family history of breast cancer or other identified breast cancer risk factors Breast cancer was detected on routine screening mammography and confirmed by core needle biopsy as a moderately differentiated Grade 2 invasive non-specific NST (ductal) carcinoma

Both malignancies occurred in patients with demographic and clinical characteristics consistent with background cancer risk, with no shared pattern suggestive of a treatment-related signal

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“; One case of colonic dysplasia was reported in the obefazimod 50mg arm

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UC is associated with increased risk for non-melanoma skin cancers (NMSCs)

Managing NMSCs in Patients with UC is Part of Current Clinical Practice

Skin Cancer Type	General Population	IBD / UC Population
Non-Melanoma Skin Cancers (NMSCs)	Common age-related skin cancer in men and women	▪ Ulcerative Colitis associated with increased relative risk for NMSCs (Basal Cell Carcinoma and Squamous Cell Carcinoma), with advanced age and thiopurines contributing to risk ▪ American Gastroenterological Association (AGA) guidelines recommend annual total body exams for all adult IBD patients receiving immunomodulators, anti-TNF biologics, or small molecules, and for patients with any prior thiopurine exposure

Published epidemiology data supports increased rates of NMSC in IBD populations

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; 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; Caldera F, Kane S, Long M, Hashash JG. AGA Clinical Practice Update on Noncolorectal Cancer Screening and Vaccinations in Patients With Inflammatory Bowel Disease: Expert Review. *Clin Gastroenterol Hepatol*. 2025;23(5):695–706

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Part 1: Non-Melanoma Skin Cancers

ABTECT Maintenance Trial

	Preferred Term	Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Skin Cancer	Medical History
50 mg	**Basal Cell Carcinoma**	70+	**Induction:** 50mg (8 wks) **Maint-Part 1**: 50mg (18.0 wks) **Maint-Part 2:** N/A	6.1 months	Australia	Hydrocortisone, prednisone	Unlikely Related	Yes	Basal cell carcinoma
	Basal Cell Carcinoma	45+	**Induction:** 50mg (8 wks) **Maint-Part 1**: 50mg (15.6 wks) **Maint-Part 2:** N/A	5.5 months	Eastern Europe	Methylprednisolone, budesonide, sulfasalazine, mesalamine	Not Related	No	Reportedly no family history of melanoma or other skin cancers.
	Squamous Cell Carcinoma	70+	**Induction:** 50mg (8 wks) **Maint-Part 1**: 50mg (7.0 wks) **Maint-Part 2:** N/A	3.5 months	Southern US	Prednisone, tofacitinib citrate, infliximab, adalimumab, vedolizumab , mesalamine	Possibly Related	Yes	Single squamous cell carcinoma
	Squamous Cell Carcinoma	60+	**Induction:** 50mg (8 wks) **Maint-Part 1**: 50mg (4.0 wks) **Maint-Part 2:** N/A	2.8 months	Western Europe	Prednisolone, mesalamine, budesonide	Possibly Related	No	Confounders per investigator: sun exposure, age, smoking, and others
25 mg	**Squamous Cell Carcinoma**	60+	**Induction:** 25mg (8 wks) **Maint-Part 1**: 25mg (29.0 wks) **Maint-Part 2:** N/A	8.7 months	Southern US	Mesalazine, azathioprine, prednisone methylprednisolone deucravacitinib (investigational)	Not Related	Yes	Melanoma
Placebo	**Basal Cell Carcinoma**	70+	**Induction:** 50mg (8 wks) **Maint-Part 1**: PBO (18.6wks) **Maint-Part 2:** N/A	1.9 months	Eastern Europe	Vedolizumab, infliximab, corticosteroids	Not Related	No	Reportedly no past medical history of basal cell carcinoma or pre-cancerous skin lesions. Pre-existing skin lesion at the site of the carcinoma.

5/6 NMSC cases had one or more established risk factors, including advanced age (5/6 ≥60 years), prior skin cancer history (3/6), and prior exposure to therapies associated with increased NMSC risk (5/6); 5/6 cases occurred within the first ~6 months of obefazimod 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"

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Agenda

1 Obefazimod Phase 3 UC Maintenance Results: Interpreting the Data

2 Part 2 Study Design Overview

3 Key Considerations for the Upcoming Part 2 Readout

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Part 2 population: Induction non-responders or relapsers from Part 1 of maintenance

Comparing Part 1 and Part 2 Populations

	Induction Responders – Part 1			Induction Non-Responders – Part 2	Part 1 Relapsers – Switch to Part 2
Topline Readout Timing	June 1			End of June	End of June
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**		
Baseline Induction MMS, Mean (SD)	6.9 (1.1)	6.7 (1.1)	6.9 (1.2)	TBD	TBD
Baseline Induction Fecal Calprotectin (mg/g), Median	1202	1585	1568	TBD	TBD
Prior Advanced Therapy Failure (%)	37.5%	39.4%	46.2%	TBD	TBD

The Part 2 readout should be evaluated within the context of a potentially more refractory patient population than Part 1

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ABTECT MAINTENANCE PART 2:
Expected data sets to be released

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ABTECT Maintenance Part 2 Readout

Expected safety data to be released for Part 2 malignancies

Safety

1. **ABTECT Maintenance Part 2 Safety:**
   - A. Exposure adjusted incident analysis of malignancies
   - B. Comparison to expected background rates for UC population per 100 patient years
   - C. Case background for any cases identified
2. **ABTECT Maintenance Part 1 & Part 2 Combined Safety:**
   - A. Exposure adjusted incident analysis of malignancies by dose
   - B. Comparison to expected background rates for UC
3. **ABTECT Phase 3 + Phase 2 UC Program Combined Safety**
   - A. Exposure adjusted incident analysis of malignancies by dose
   - B. Comparison to expected background rates for moderate to severely active UC

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Observed incident rate by dose vs IBD incident rates for malignancies

Phase 3 (Part 2) Maintenance Malignancy Summary

Phase 3 (Part 2)	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
Total Patient Years of Exposure	N/A	TBD	TBD	TBD	N/A
Observed Malignancies	N/A	TBD	TBD	TBD	N/A
Observed Incidence Rate per 100 PY*	N/A	TBD	TBD	TBD	0.30 - 0.70

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.

Observed incident rate by dose vs IBD incident rates for malignancies

Phase 3 (Part 1 + Part 2) Maintenance Malignancy Summary

Phase 3 (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
Total Patient Years of Exposure	TBD	TBD	TBD	TBD	N/A
Observed Malignancies	TBD	TBD	TBD	TBD	N/A
Observed Incidence Rate per 100 PY*	TBD	TBD	TBD	TBD	0.30 - 0.70

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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ABTECT Maintenance Part 2 Readout

Expected Data Sets To Be Released

Safety

1. **ABTECT Maintenance Part 2 Safety:**
   - A. Exposure adjusted incident analysis of NMSCs
   - B. Comparison to expected background rates for UC population per 100 patient years
   - C. Case background for any cases identified
2. **ABTECT Maintenance Part 1 & Part 2 Combined Safety:**
   - A. Exposure adjusted incident analysis of NMSCs by dose
   - B. Comparison to expected background rates for UC
3. **ABTECT Phase 3 + Phase 2 UC Program Combined Safety**
   - A. Exposure adjusted incident analysis of NMSC by dose
   - B. Comparison to expected background rates for moderate to severely active UC

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Observed incident rate by dose vs IBD incident rates for NMSCs

Phase 3 (Part 2) NMSC Summary

Phase 3 (Part 2)	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
Total Patient Years of Exposure	N/A	TBD	TBD	TBD	N/A
Observed NMSCs	N/A	TBD	TBD	TBD	N/A
Observed Incidence Rate per 100 PY*	N/A	TBD	TBD	TBD	0.70 – 1.40

Sources: 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.

Observed incident rate by dose vs IBD incident rates for NMSC

Phase 3 (Part 1 + Part 2) NMSC Summary

Phase 3 (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
Total Patient Years of Exposure	TBD	TBD	TBD	TBD	N/A
Observed NMSCs	TBD	TBD	TBD	TBD	N/A
Observed Incidence Rate per 100 PY*	TBD	TBD	TBD	TBD	0.70 – 1.40

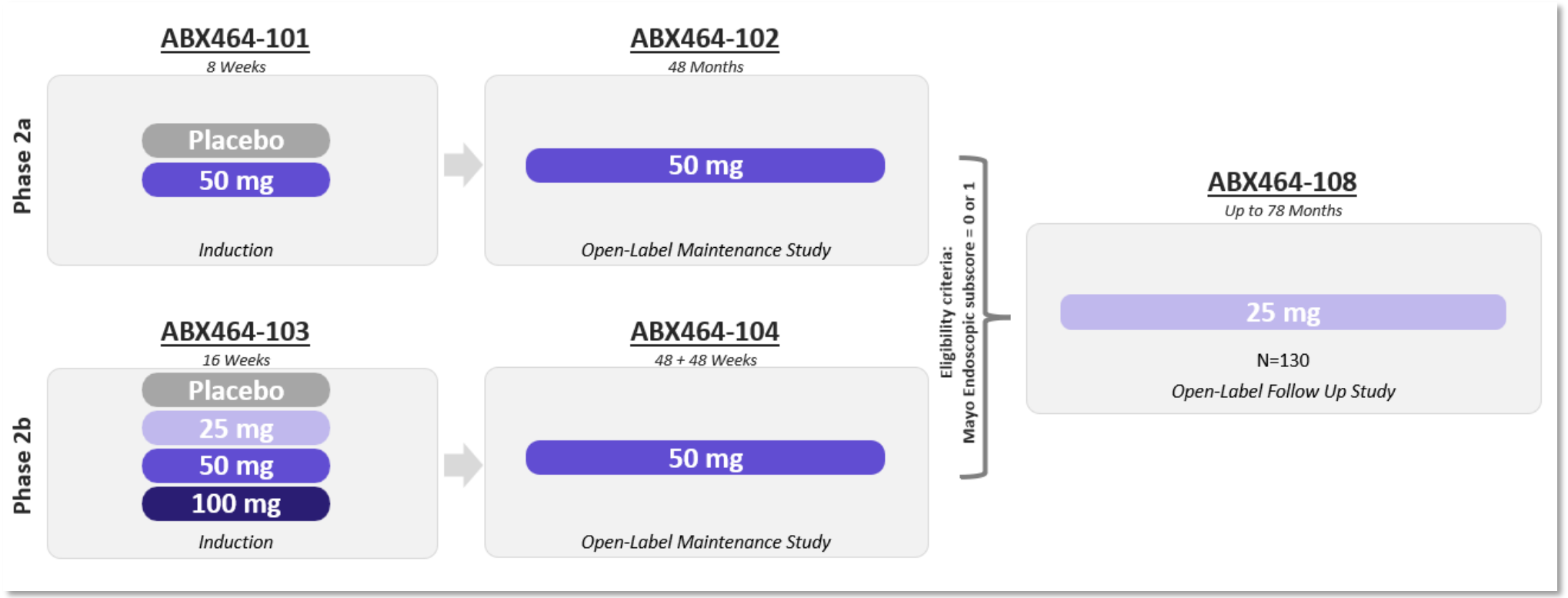
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EXAMPLE OUTPUTS:
Phase 3 (Part 1 + Part 2) Maintenance + Phase 2

Patient years of exposure across all Phase 2 programs will also be shown

Phase 2 patients have been on obefazimod for up to 7 years

TOTAL PATIENT YEARS (PYs)
~TBD



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Observed incident rate by dose vs IBD incident rates for malignancies

Phase 3 (Part 1+ Part 2) Maintenance + Phase 2 Program Malignancy Summary

Phase 3 + Phase 2	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
Total Patient Years of Exposure	TBD	TBD	TBD	TBD	N/A
Observed Malignancies	TBD	TBD	TBD	TBD	N/A
Observed Incidence Rate per 100 PY*	TBD	TBD	TBD	TBD	0.30 - 0.70

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.

Observed incident rate by dose vs IBD incident rates for NMSC

Phase 3 (Part 1+ Part 2) Maintenance + Phase 2 Program NMSC Summary

Phase 3 + Phase 2	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
Total Patient Years of Exposure	TBD	TBD	TBD	TBD	N/A
Observed NMSCs	TBD	TBD	TBD	TBD	N/A
Observed Incidence Rate per 100 PY*	TBD	TBD	TBD	TBD	0.70 - 1.40

Sources: 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.

SUMMARY

Detailed Information on Part 2 Analysis

What to expect for end of June readout

Maintenance Part 2 Safety

- Topline Safety
- If there are non-NMSC Malignancies or NMSCs, patient case histories will be provided

Combined Safety (Phase 3 + Phase 2)

- Exposure-adjusted incidence analysis of non-NMSC malignancies and NMSCs in:
  - Phase 3 Part 2 Alone
  - Phase 3 Part 1 + Part 2
  - Combined Phase 3 (Part 1 + Part 2) + Phase 2 Program

Maintenance Part 2 Efficacy

Induction Non-Responders (Treat Through)

- Week 44: Clinical Remission, Endoscopic Improvement

Induction Responders who Relapsed in Part 1

- Week 44: Endpoints for Recaptured Response

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INCIDENCE RATE METHODOLOGY

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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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)


Thank You
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