



## ABTECT Maintenance Part 2 Primer

June 2026

ABIVAX

# Where We Are Today

## June 1<sup>st</sup> Readout

- ABTECT Part 1 Maintenance Efficacy & Safety Topline Release



## Today June 15<sup>th</sup>

- ABTECT Maintenance Part 2 Primer



## End of June Readout

- ABTECT Part 2 Data Release



# Agenda

- 1 Part 2 Study Design Overview
- 2 Part 1 Readout Recap
- 3 Key Considerations for the Upcoming Part 2 Readout

# Next Steps: Assessing data from Part 2 safety and efficacy

## Induction Studies

## Maintenance Study

Primary Endpoint:  
Clinical Remission

Primary Endpoint:  
Clinical Remission

**PART 1**  
Obe Induction  
Responders  
(N=580 Started in Part 1)

### Part 1 (Registrational):

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

Assessment at Week 8

ABTECT 1 – ABX464-105  
N=639

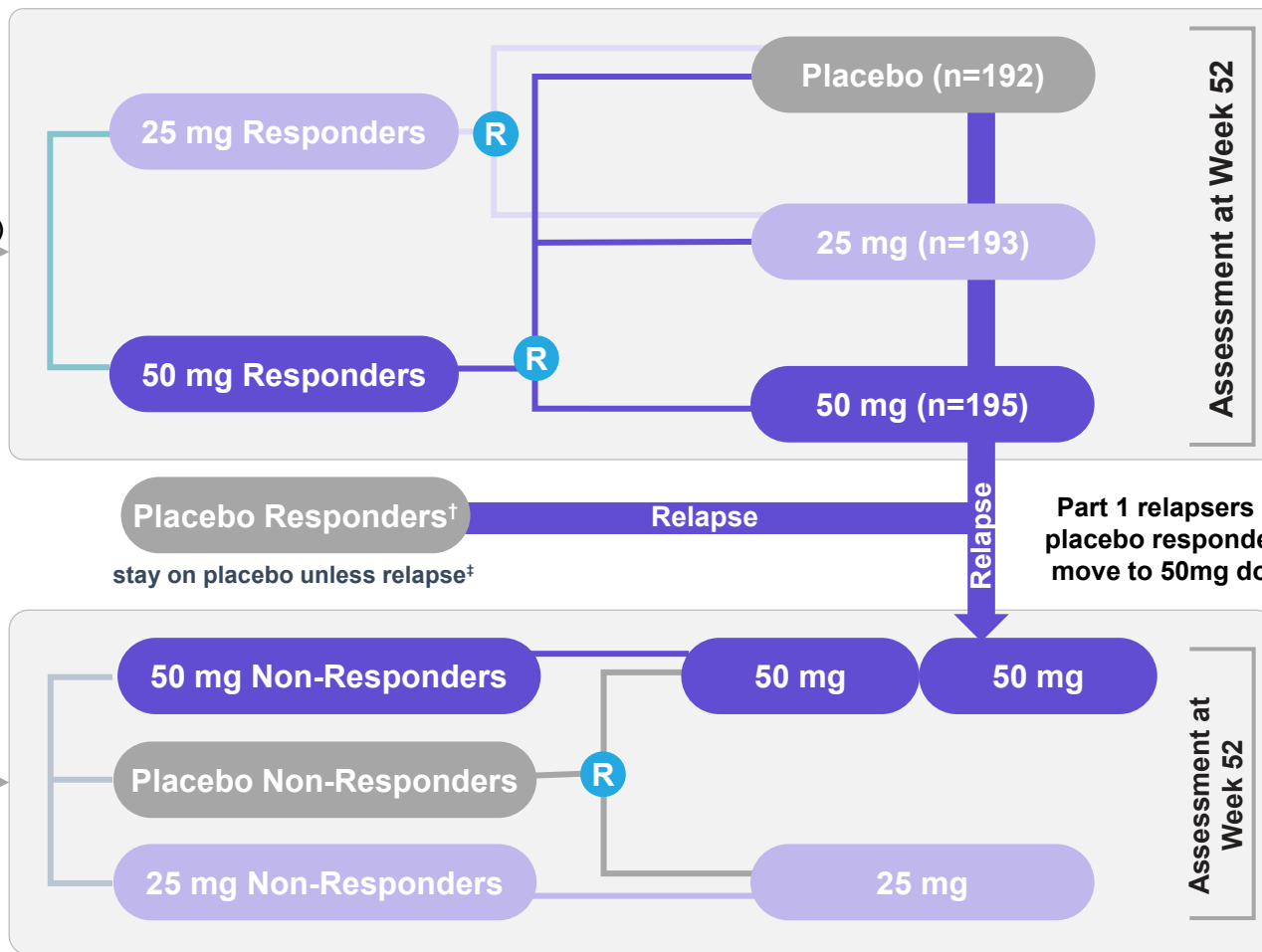
ABTECT 2 – ABX464-106  
N=636

**PART 2**  
Induction Non-  
Responders

Assessment at Week 52

Assessment at Week 52

**R**=Randomized



Part 1 relapsers + induction placebo responder relapsers‡ move to 50 mg dose in Part 2

### 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

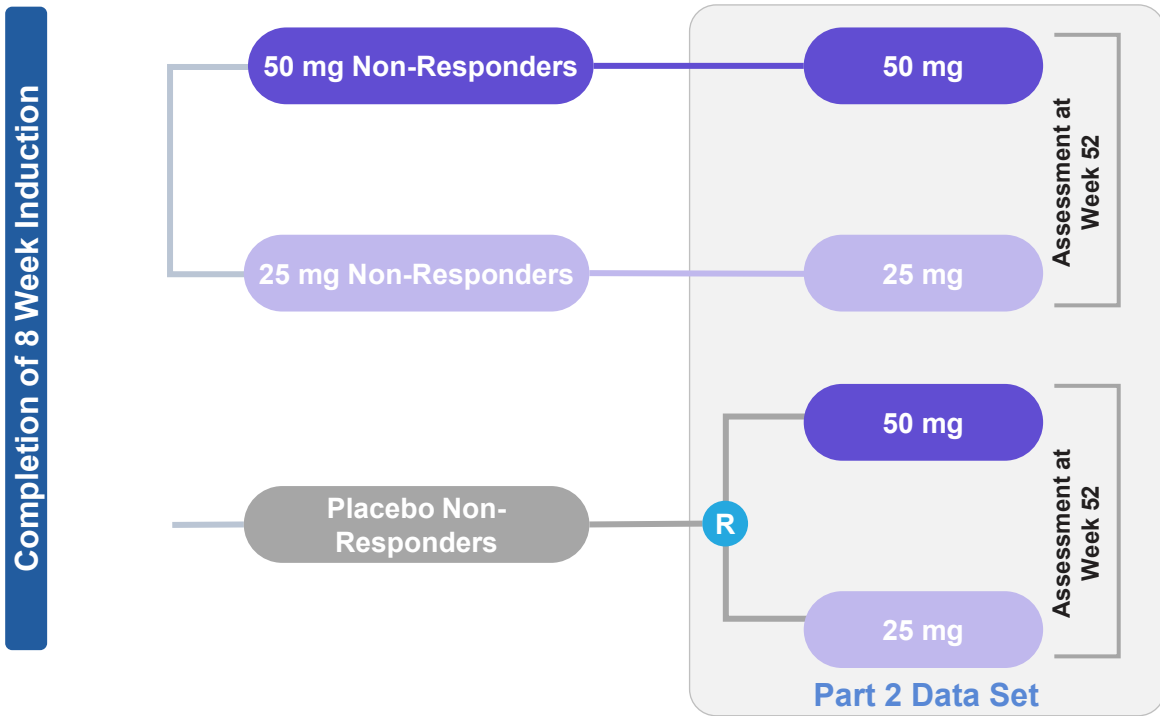
†Induction placebo responders will not be a part of the registrational efficacy dataset.

‡Relapse is assessed in two steps: symptomatic relapse during maintenance, followed by confirmation of a Mayo Endoscopic Subscore  $\geq 2$  at the Relapse Confirmation Visit endoscopy. Symptomatic relapse requires a  $\geq 2$ -point increase from maintenance baseline in the partial Modified Mayo Score, including a  $\geq 1$ -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

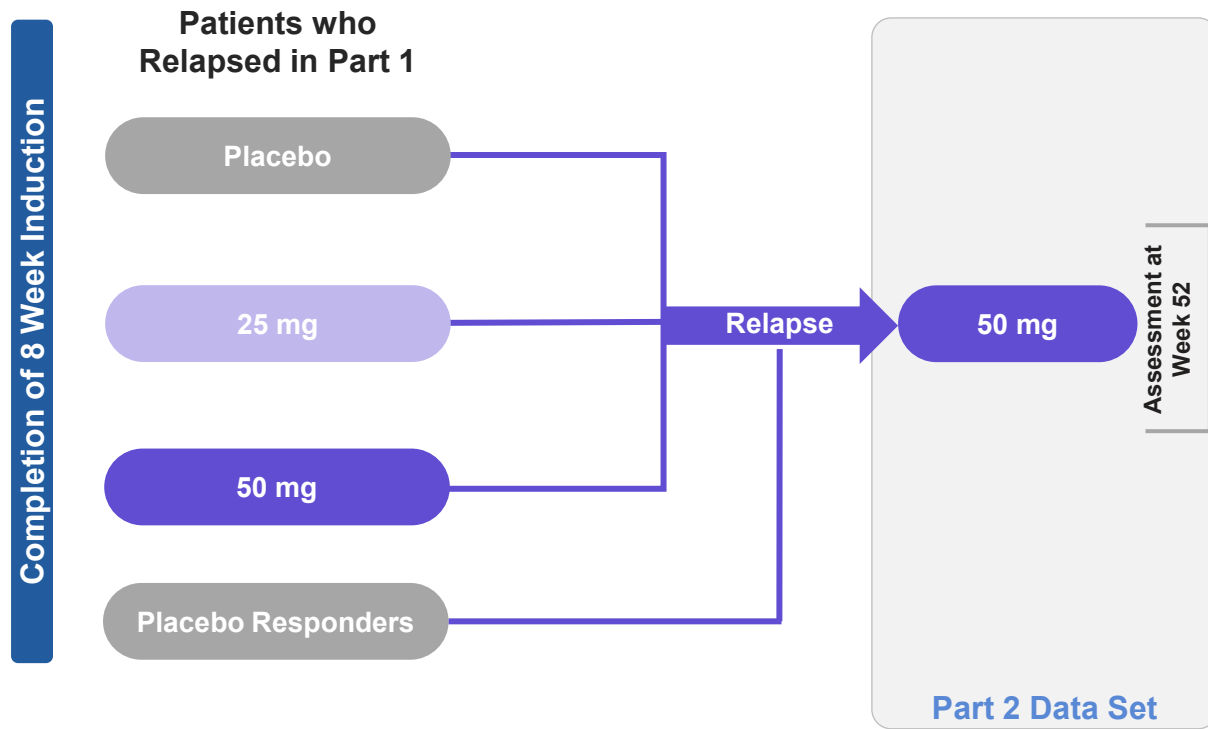
### Induction Non-Responders

*Double-Blind Uncontrolled*



### Induction Responders who Relapsed in Part 1

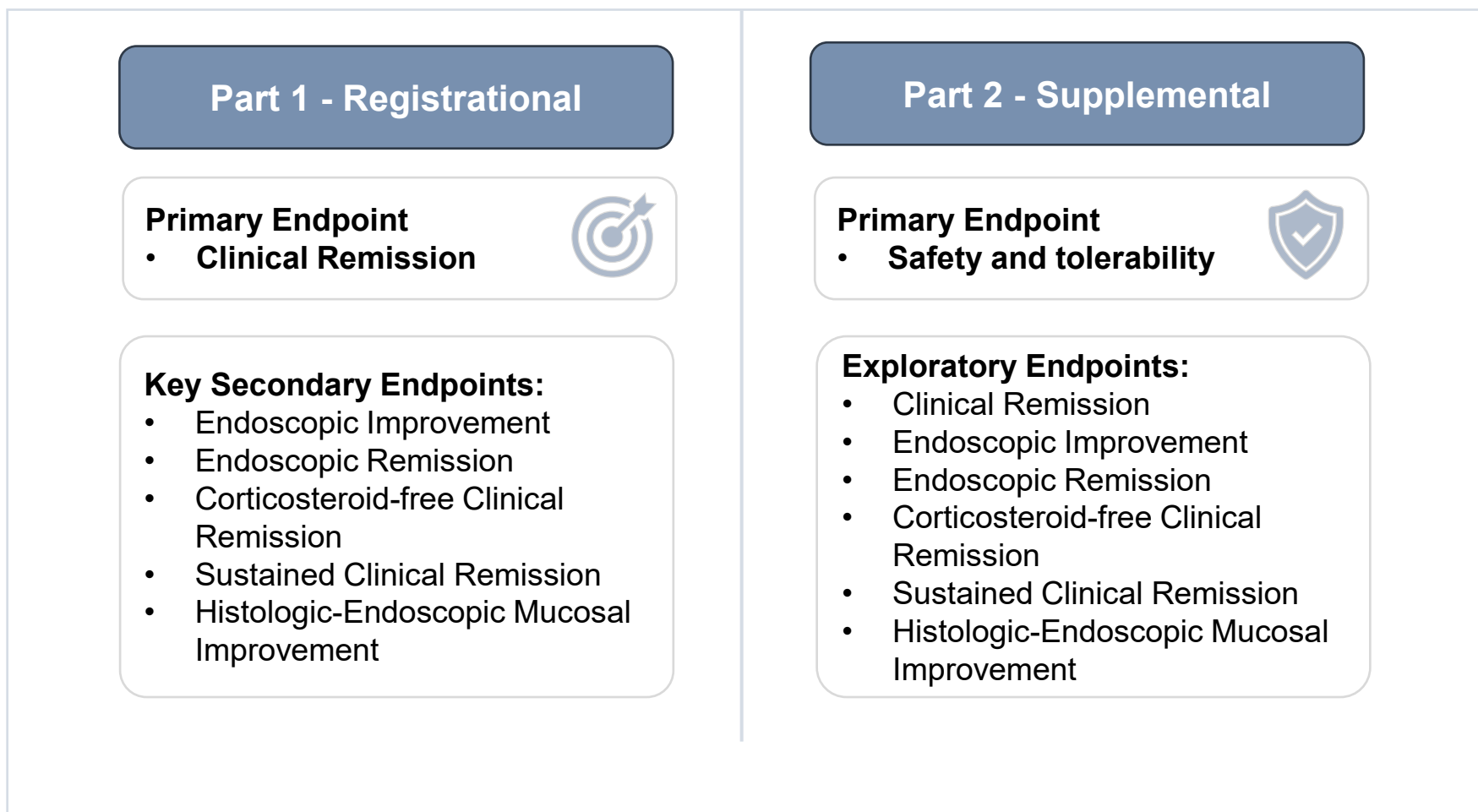
*Open-Label*



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

# ABTECT Maintenance Part 1 vs Part 2 Endpoints

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



# Agenda

- 1 Part 2 Study Design Overview
- 2 Part 1 Readout Recap
- 3 Key Considerations for the Upcoming Part 2 Readout

# 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 <sup>1</sup>	2 (1.0%)	2 (1.0%)	1 (0.5%)
Malignancies other than Non-melanoma Skin Cancer (non-NMSC) <sup>2</sup>			
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.

## UC is associated with increased risk for malignancies

Cancer Type	General Population	IBD / UC Population
<b>Prostate Cancer</b>	Common age-related malignancy in men	<ul style="list-style-type: none"> <li>Multiple studies and meta-analyses suggest modestly increased risk in IBD, particularly UC</li> <li>In one study, men with IBD were nearly 5x more likely to be diagnosed with prostate cancer than those without IBD</li> </ul>
<b>Breast Cancer</b>	Common age-related malignancy in women	<ul style="list-style-type: none"> <li>Large-scale study reported a breast cancer prevalence of 2.3% in individuals with UC, compared with 1.1% in individuals without IBD</li> <li>However, other studies have found no significant difference in breast cancer rates between patients with UC and the general population</li> </ul>

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

# 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+	<b>Induction:</b> 50mg (8.9 wks) <b>Maint-Part 1:</b> 50mg (28.0 wks) <b>Maint-Part 2:</b> N/A	8.5 months	Western Europe	Mesalazine, budesonide, beclomethasone dipropionate, dexamethasone, 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+	<b>Induction:</b> 50mg (8.0 wks) <b>Maint-Part 1:</b> 50mg (21.4 wks) <b>Maint-Part 2:</b> 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**

# 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
<p><b>Non-Melanoma Skin Cancers (NMSCs)</b></p>	<p>Common age-related skin cancer in men and women</p>	<ul style="list-style-type: none"> <li>▪ Ulcerative Colitis associated with increased relative risk for NMSCs (Basal Cell Carcinoma and Squamous Cell Carcinoma), with advanced age and thiopurines contributing to risk</li> <li>▪ American Gastroenterology and Hepatology (AGA) guidelines recommend annual skin cancer screenings for IBD patients</li> </ul>

Published epidemiology data supports increased rates of NMSC in IBD populations

Sources: Long MD, Martin CF, Pipkin CA, et al. Increased risk of nonmelanoma skin cancer in patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1; Anese V, Bonovas S, Bonovas F, et al. Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer. *Cancers (Basel)*. 2025;17(10):1710; Abbas AM, Cooper GS, Tran TT, et al. Risk of melanoma and non-melanoma skin cancer in patients with inflammatory bowel disease. *American Journal of Gastroenterology*. 2014;109(3):390–399

# 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

# 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

## 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
<b>Topline Readout Timing</b>	June 1			End of June	End of June
<b>Part of Phase 3 Program</b>	Double-Blind Placebo Controlled Trial Part 1			Double-Blind Uncontrolled Trial Part 2	Open-Label Part 2
<b>Arm</b>	<b>PBO</b>	<b>Obe 25 mg</b>	<b>Obe 50 mg</b>		
<b>Baseline Induction MMS, Mean (SD)</b>	6.9 (1.1)	6.7 (1.1)	6.9 (1.2)	TBD	TBD
<b>Baseline Induction Fecal Calprotectin (mg/g), Median</b>	1202	1585	1568	TBD	TBD
<b>Prior Advanced Therapy Failure (%)</b>	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

> ABTECT MAINTENANCE PART 2:  
Expected data sets to be released

# 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

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
<b>Total Patient Years of Exposure</b>	N/A	TBD	TBD	TBD	N/A
<b>Observed Malignancies</b>	N/A	TBD	TBD	TBD	N/A
<b>Observed Incidence Rate per 100 PY*</b>	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; Bonovas et al. Cancers 2025; Carli et al. Medical Oncology 2020; 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
<b>Total Patient Years of Exposure</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed Malignancies</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed Incidence Rate per 100 PY*</b>	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; Bonovas et al. Cancers 2025; Carli et al. Medical Oncology 2020; 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.

# 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

## 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
<b>Total Patient Years of Exposure</b>	N/A	TBD	TBD	TBD	N/A
<b>Observed NMSCs</b>	N/A	TBD	TBD	TBD	N/A
<b>Observed Incidence Rate per 100 PY*</b>	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). Anese 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

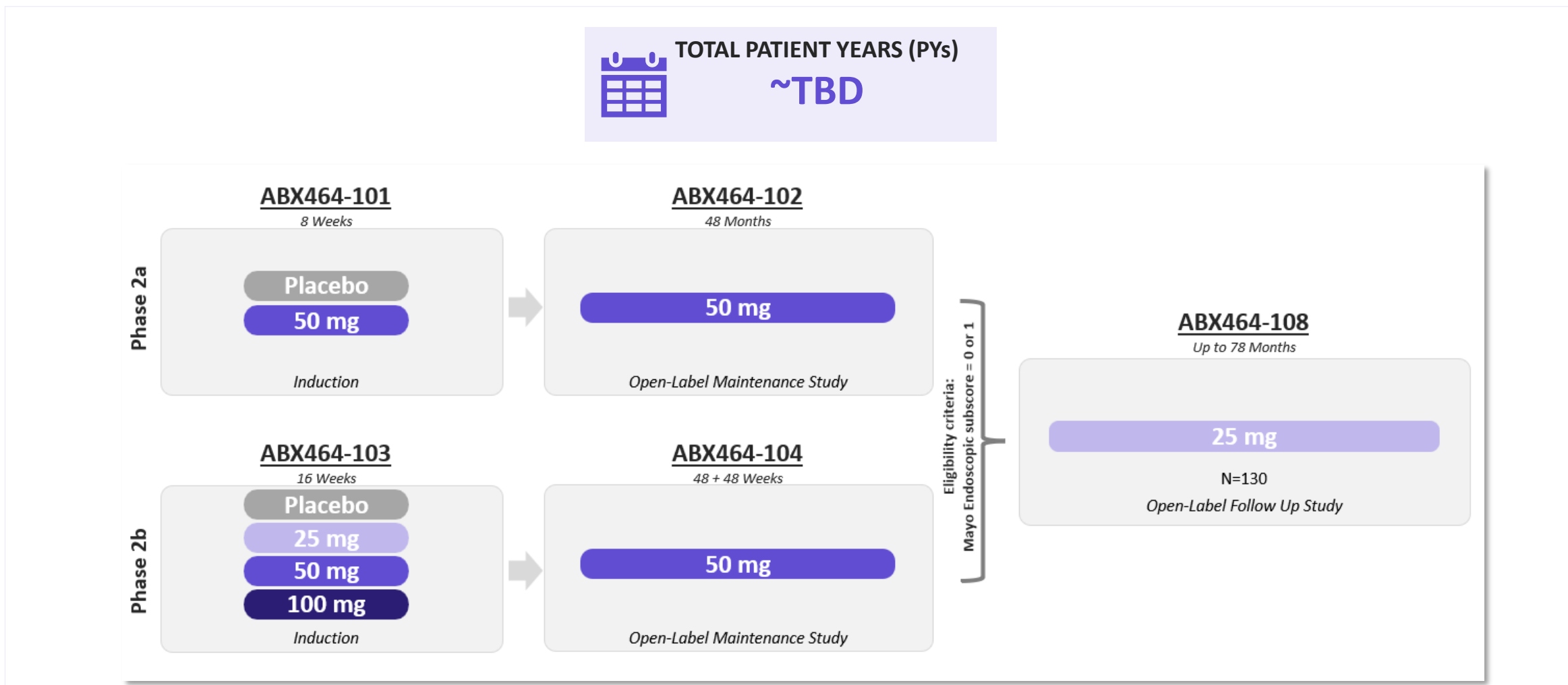
Phase 3 (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Combined	Incident Rate in IBD Patient Population Per 100 Patient Years
<b>Total Patient Years of Exposure</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed NMSCs</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed Incidence Rate per 100 PY*</b>	TBD	TBD	TBD	TBD	0.70 – 1.40

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). Anese 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.

> 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 obehazimod for up to 7 years



**Example of Potential Output –  
Phase 3 (Part 1+Part 2) + Phase 2 By Dose**

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
<b>Total Patient Years of Exposure</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed Malignancies</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed Incidence Rate per 100 PY*</b>	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, including prostate, breast, colorectal, melanoma, lymphoma, and hematologic malignancies, while excluding non-melanoma skin cancer (NMSC). Key references include Long et al. Gastroenterology 2012; Bonovas et al. Cancers 2025; Carli et al. Medical Oncology 2020; 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.

**Example of Potential Output –  
Phase 3 (Part 1+Part 2) + Phase 2 By Dose**

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
<b>Total Patient Years of Exposure</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed NMSCs</b>	TBD	TBD	TBD	TBD	N/A
<b>Observed Incidence Rate per 100 PY*</b>	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). Anese 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

## > INCIDENCE RATE METHODOLOGY

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

## 1 Published Sources

## 2 Converted to 100 Patient Years

## 3 Derived Benchmark Range

Source	Population	NMSC Incidence (as reported)
Long et al., Gastroenterology 2012 <sup>1</sup>	IBD (UC & Crohn's Disease)	912 per 100,000 patient years
Anese et al., Cancers 2025 <sup>2</sup>	IBD (Overall)	733 per 100,000 patient years
Abbas et al., Am J Gastroenterol 2014 <sup>3</sup>	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

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

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

### Sources

- Long MD, Martin CF, Pipkin CA, et al.** Increased risk of nonmelanoma skin cancer in patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1.
- Anese V, Bonovas S, Bonovas F, et al.** Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer. *Cancers (Basel)*. 2025;17(10):1710.
- Abbas AM, Cooper GS, Tran TT, et al.** Risk of melanoma and non-melanoma skin cancer in patients with inflammatory bowel disease. *American Journal of Gastroenterology*. 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

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

## 1 Published Sources

- Long MD, Martin CF, Pipkin CA, et al. Increased risk of extraintestinal cancers in patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1.
- Bewtra M, Lewis JD. How safe are biologics for IBD? Insights from systematic reviews and meta-analyses of malignancy risk. *American Journal of Gastroenterology*. 2018;113(8):1194–1205.
- Jess T, Loftus EV Jr, Velayos FS, et al. Risk of incident cancer among patients with inflammatory bowel disease: a population-based cohort study. *Gastroenterology*. 2005;129(4):1039–1046.
- Bonovas S, Bonovas F, Anese V, et al. Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer. *Cancers (Basel)*. 2025;17(10):1710.

## 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



Thank You

ABIVAX