



# ABTECT Phase 3 Topline Readout – Analyst and Investor Webcast

July 22<sup>nd</sup>, 2025

ABIVAX

# Agenda

**01 Welcome**

**Pat Malloy**

*Senior Vice President, Investor Relations*

**02 Opening Remarks**

**Marc de Garidel**

*Chief Executive Officer*

**03 ABTECT Phase 3 Program Overview**

**Fabio Cataldi, M.D.**

*Chief Medical Officer*

**04 Topline ABTECT Phase 3 Induction Results – Efficacy & Safety**

**Fabio Cataldi, M.D.**

*Chief Medical Officer*

**05 Summary & Next Steps**

**Marc de Garidel**

*Chief Executive Officer*

**06 Q&A**

**Abivax Leadership &**

**David Rubin, M.D.**



## David Rubin, MD

- Joseph B Kirsner Professor In Medicine
- Chief, Section of Gastroenterology, Hepatology and Nutrition
- Director, Inflammatory Bowel Disease Center

David T. Rubin, MD, is a renowned gastroenterologist whose work is focused on new clinical trial designs, novel measures and metrics for evaluating inflammation, prevention methods for poor outcomes and quality of life in IBD patients. He has published over 500 articles on managing IBD, including the 2019 (and upcoming 2025) American College of Gastroenterology (ACG) guidelines for ulcerative colitis.

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Ongoing and future clinical development, including our Phase 3 clinical programs, trial design and initiation, is subject to assessment of clinical data of obefazimod by European Medicines Agency (“EMA”), U.S. Food and Drug Administration (“FDA”) and other regulatory authorities. These authorities could request important modifications to the design of the ongoing and future clinical trials and/or request that additional studies or trials be conducted prior to their initiation. The FDA, EMA or other regulatory authorities may take decisions that would result in a delay or a clinical hold of Abivax’s clinical programs (including in particular its Phase 3 clinical trials for obefazimod in moderately to severely active ulcerative colitis).

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# Landmark Clinical Trial Results for First-in-Class, Oral, miR-124 Enhancer in Ulcerative Colitis

- **One of the largest Phase 3 UC Trials Conducted:** 1,275 patients enrolled in 30 months in 36 countries with over 600 participating clinical trial sites
- **ABTECT trials included balanced population** of participants that were advanced therapy naïve and those with an inadequate response to advanced therapy
  - ABTECT trials included **largest population** of participants with inadequate response to **prior JAK** inhibitor therapy
- **Oral, first-in class, miR-124 enhancer** demonstrated positive topline efficacy results and was generally well tolerated
- **50mg obefazimod** demonstrated highly significant and clinically meaningful efficacy results with a **pooled 16.4% placebo-adjusted remission rate** with no new safety signals observed

*ABTECT Induction Trials Delivered Clinical Results Superior to Phase 2b with a Competitive and Differentiated Profile*

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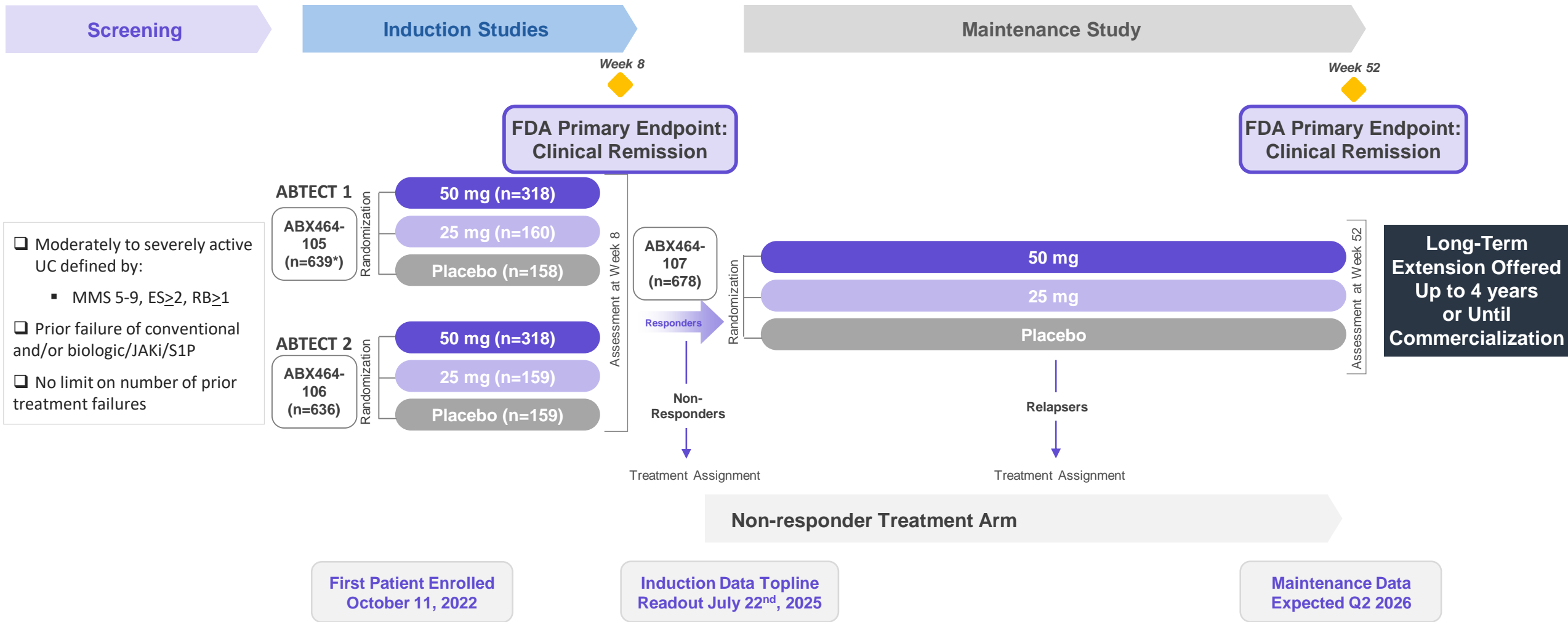
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**Abivax Leadership &  
David Rubin, M.D.**

# ABTECT Phase 3 Program Design: 2 Induction Trials and 1 Maintenance Trial

Contemporary re-randomization of induction responders

## Ulcerative Colitis Program Design



- Moderately to severely active UC defined by:
  - MMS 5-9, ES $\geq$ 2, RB $\geq$ 1
- Prior failure of conventional and/or biologic/JAKi/S1P
- No limit on number of prior treatment failures

# Key Primary and Secondary Endpoints

Endpoints for FDA and EMA differ slightly for primary endpoints and key secondary endpoints

	FDA	EMA
Primary Endpoints	<b>Clinical Remission:</b> Proportion of subjects in clinical remission at Week 8	<b>Co-Primary Endpoint:</b> Endoscopic improvement and symptomatic remission at week 8
Key Secondary Endpoints	<b>Endoscopic Improvement:</b> Proportion of subjects who achieve endoscopic improvement at Week 8 <b>Clinical Response:</b> Proportion of subjects with clinical response at Week 8 <b>HEMI:</b> Proportion of subjects with HEMI per Geboes scoring at Week 8	<b>Clinical Remission:</b> Proportion of subjects in clinical remission at Week 8 <b>Clinical Response:</b> Proportion of subjects with clinical response at Week 8 <b>HEMI:</b> Proportion of subjects with HEMI per Geboes scoring at Week 8

# Innovative study design elements, execution excellence, and a successful Phase 3 outcome



## Increased Clinical Trial Awareness and Education

- Deployed global team of medical science liaisons (MSLs) to engage and educate study sites
- Site engagement plans included R&D leadership visits with investigators and clinical research teams
- Accelerated ABTECT Phase 3 enrollment through expanded global GI congress presence



## Minimized Placebo Response

- Wide diversification of trial sites with no single region accounting for more than ~25%
- Unlike Phase 2b trial, Phase 3 protocol did not allow concurrent treatment with immunomodulators
- Concomitant corticosteroid dose limit reduced from 20 mg in Phase 2b trial to 15 mg in Phase 3 trial



## Improved Results from Phase 2 to Phase 3

- Many approved US products showed better efficacy in Phase 2 than in Phase 3, due to more refractory patients being included in Phase 3 than Phase 2
- Rinvoq's\* efficacy between Phase 2 and Phase 3 remained consistent by studying the same percentage of refractory patients in Phase 2
- Abivax successfully enrolled a Phase 3 patient population with a similar bio-naïve vs bio-experienced patient population to Phase 2b

## Table of ABTECT Phase 3 Baseline Characteristics

	ABTECT 1 (Study 105)	ABTECT 2 (Study 106)	Pooled
<b>Study Participants</b> <i>Randomized and Dosed</i>	636	636	1,272
<b>Baseline Mean MMS (SD)</b>	6.9 (1.05)	6.9 (1.06)	6.9 (1.06)
<b>Baseline MES=3 (%)</b>	59.0%	60.7%	59.8%
<b>MMS 7-9 (%)</b>	417 (65.6%)	408 (64.2%)	825 (64.9%)
<b>Mean Duration of disease (Years)</b>	7.8	7.8	7.8
<b>Fecal Calprotectin µg/g (Median)</b>	1636	1719	1666
<b>Prior Advanced Therapy Failure (%)</b>	45.3%	49.4%	47.3%
<b>% JAK Failures</b>	8.2%	11.3%	9.7%
<b>Corticosteroids</b>	39.9%	39.9%	39.9%

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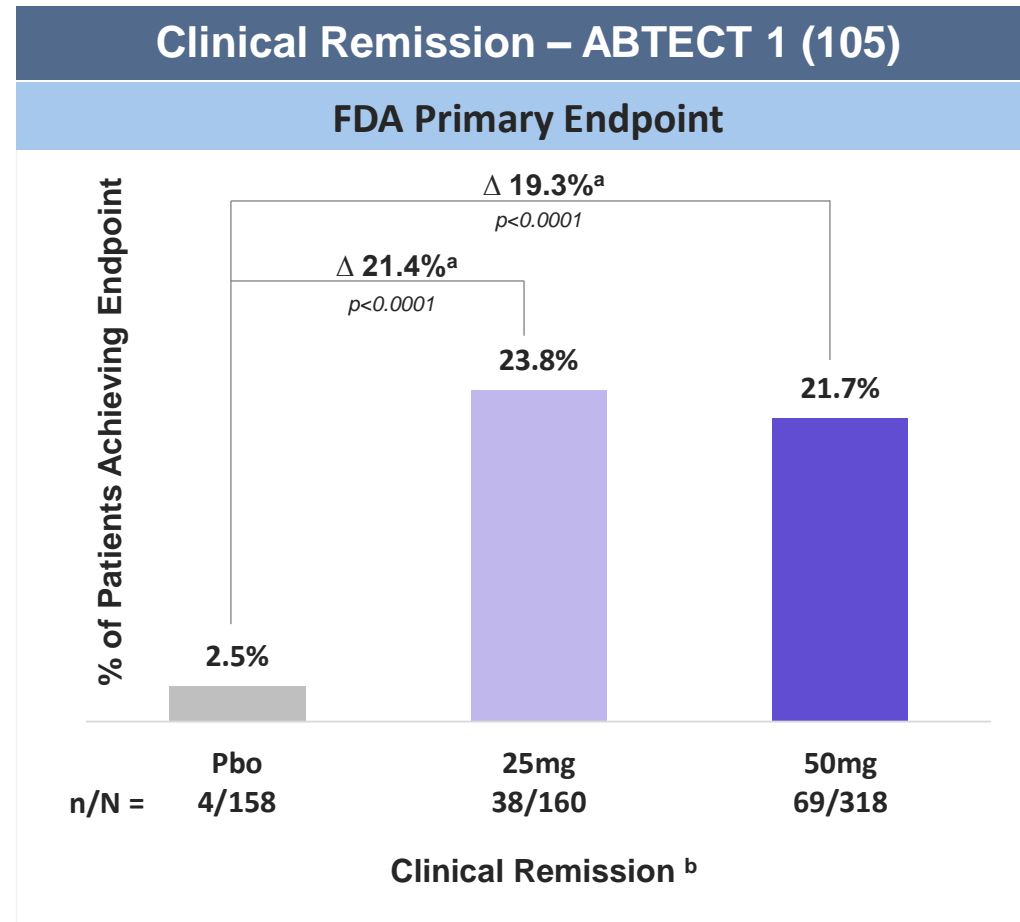
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# Obefazimod achieved statistical significance with both doses in ABTECT 1

25mg and 50mg both statistically significant and clinically meaningful



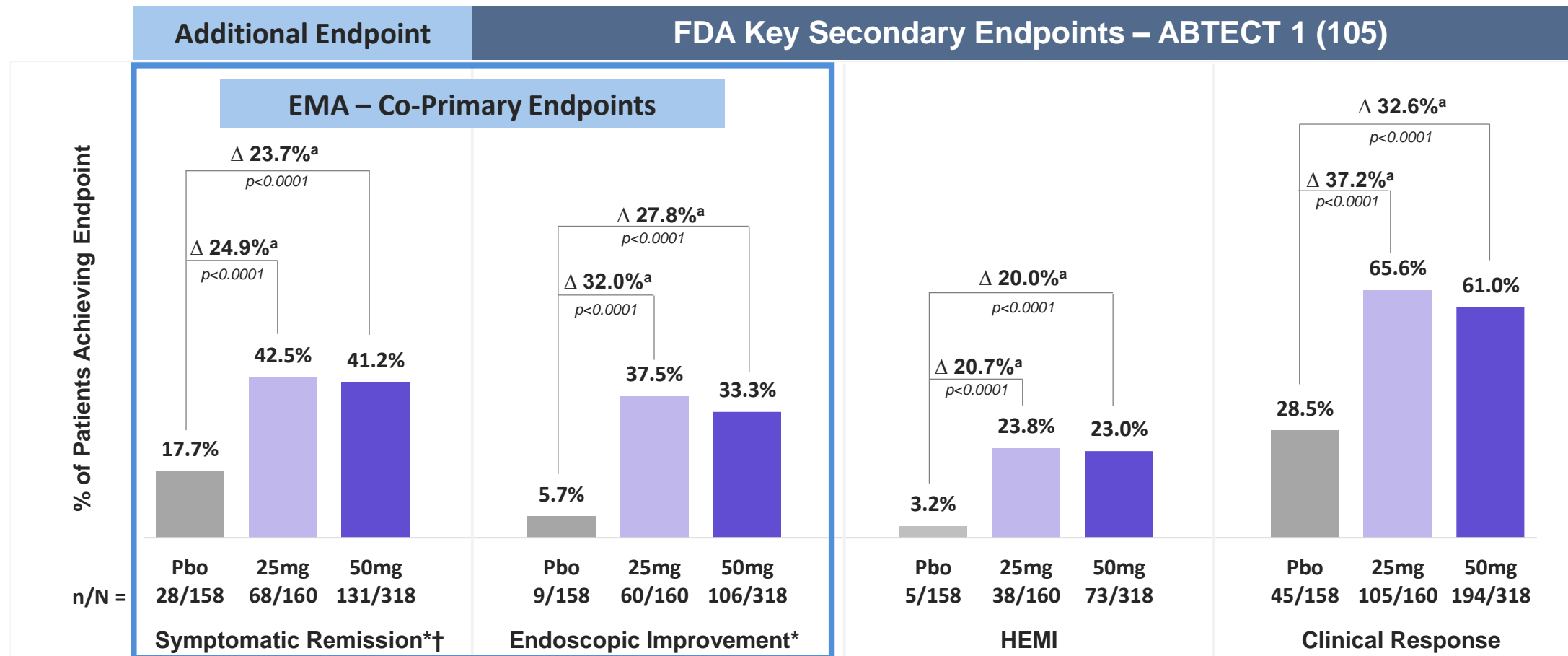
Data on File ABX464-105

[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), Baseline oral corticosteroids usage (yes/no). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

[b] Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability).

# Obefazimod achieved statistical significance on all key secondary endpoints in ABTECT 1

## EMA co-primary endpoints met for 25mg and 50mg



Data on File ABX464-105

[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), Baseline oral corticosteroids usage (yes/no). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability).

Clinical response is defined as a reduction from Baseline in MMS  $\geq$  2 points and a relative reduction from Baseline in MMS  $\geq$  30%, and a reduction from Baseline in RBS  $\geq$  1 point and/or RBS = 0 or 1.

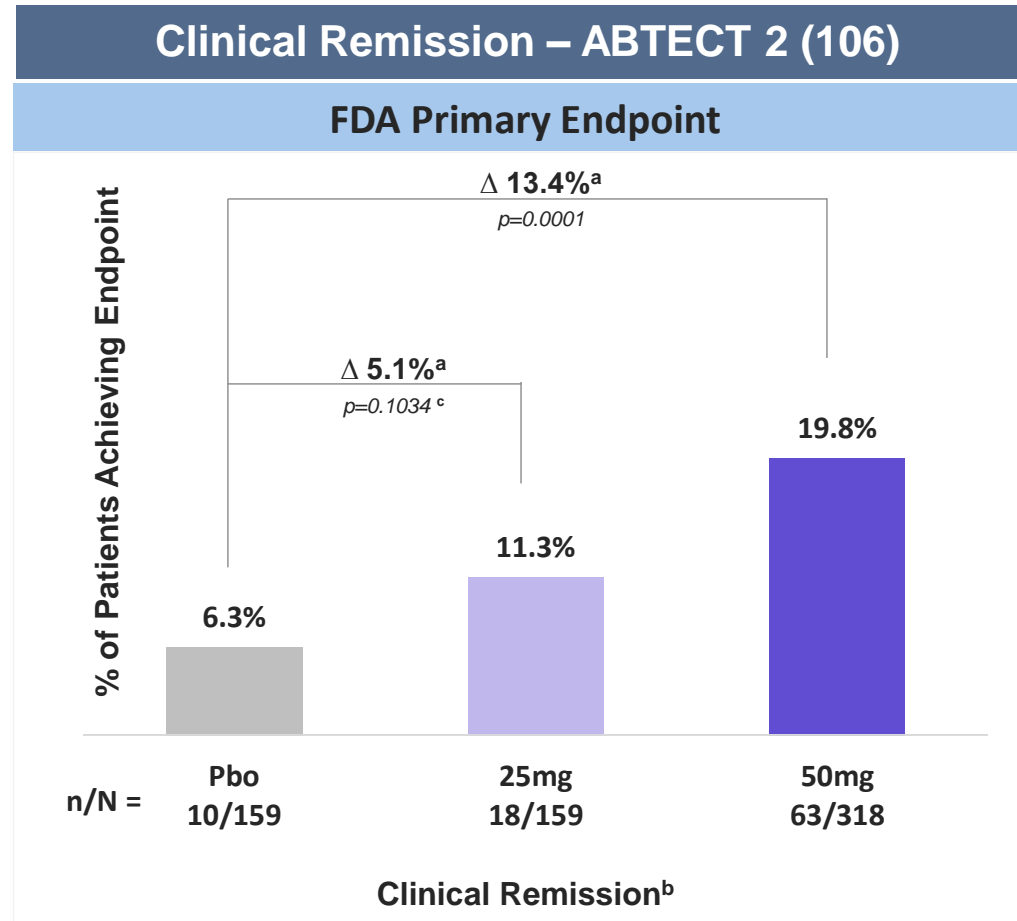
HEMI is defined as MES = 0 or 1 and Geboes Index score  $\leq$  3.1

Symptomatic remission is defined as RBS=0 and SFS= 0 or 1

\*Co-Primary Endpoints for EMA † Secondary endpoint for FDA testing procedure

# Obefazimod met the FDA primary endpoint with 50mg in ABTECT 2

Statistically significant and clinically meaningful improvement observed



Data on File ABX464-106

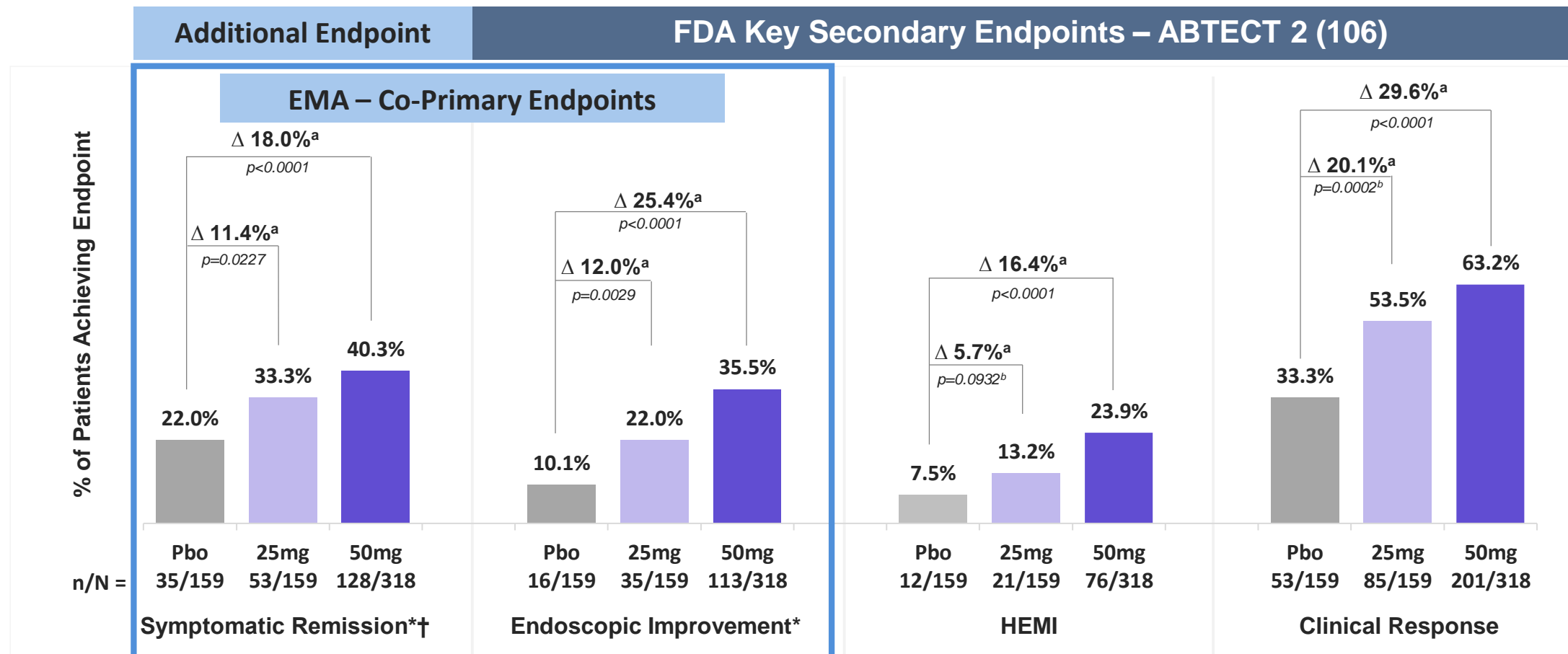
[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), Baseline oral corticosteroids usage (yes/no). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

[b] Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability).

[c] 25mg did not show statistical significance at 8 weeks

# 50mg achieved statistical significance on all key secondary endpoints in ABTECT 2

Obefazimod achieved statistical significance on EMA co-primary endpoints for 25mg and 50mg



Data on File ABX464-106

[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), Baseline oral corticosteroids usage (yes/no). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability).

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.

HEMI is defined as MES = 0 or 1 and Geboes Index score ≤ 3.1

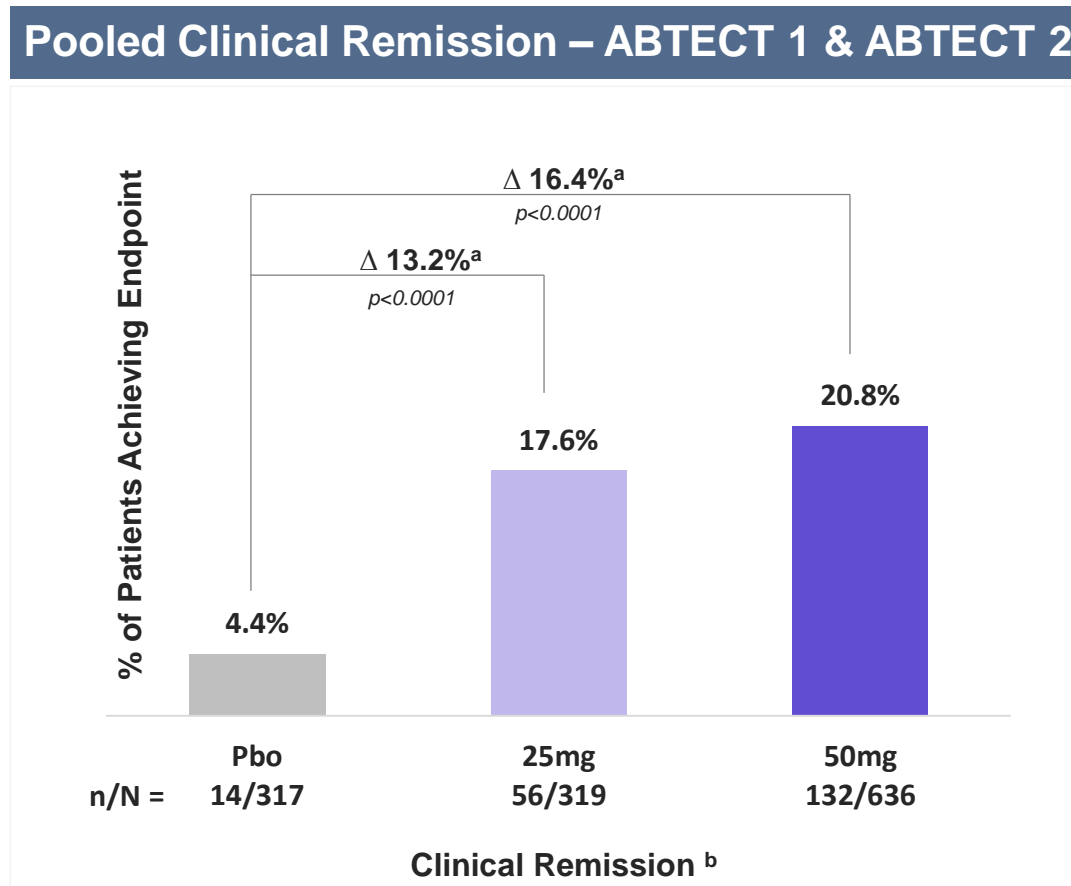
Symptomatic remission is defined as RBS=0 and SFS= 0 or 1

[b] p values for 25mg are nominal on key FDA secondary endpoints of HEMI and Clinical Response

\*Co-Primary Endpoints for EMA † Secondary endpoint for FDA testing procedure

# Obefazimod met the FDA primary endpoint with both doses in a pooled analysis

50mg exceeded previous Phase 2b results; 25mg results were comparable to Phase 2b\*



Data on File ABX464-105 & ABX464-106

[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), Baseline oral corticosteroids usage (yes/no). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

[b] Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability).

\*25mg showed a 13.7% delta vs placebo in Ph2b (26.2% vs 12.5%); 50mg dose showed a 5% delta vs placebo in Ph2B (17.5% vs 12.5%). However, clinical remission was not the primary endpoint in Ph2b and was not powered to show statistical significance. Both 25mg and 50mg met the primary endpoint in Ph2b (Change from Baseline in Modified Mayo Score at Week 8)

# 25mg met EMA co-primary endpoint in both trials and other endpoints

1

## EMA Co-Primary Endpoint Achieved

**25 mg met the EMA co-primary endpoints** (endoscopic improvement and symptomatic remission) in both ABTECT 1 and ABTECT 2

2

## Pooled Clinical Remission Statistically Significant

**Pooled clinical remission** induction results across ABTECT 1 and ABTECT 2 for 25mg were nominally **statistically significant and were consistent across Ph2b and Ph3 results** (13.7% to 13.2% placebo adjusted clinical remission rate)

3

## 25mg Arm of ABTECT 2 Had Hardest to Treat Population

**Patient population randomized to 25mg in ABTECT 2 comprised one of the more difficult to treat study arms across both ABTECT 1 & 2** (based on MES and fCal); these patients may need more than 8 weeks to achieve clinical remission

4

## Key Secondary Endpoints Demonstrate Efficacy

**Key secondary endpoints were met** in ABTECT 1, with clinical response and endoscopic improvement nominally significant\* in ABTECT 2

# Generally well tolerated with no new safety signals observed

## Summary of Adverse Events<sup>1</sup>

TEAE, n (%) #	ABTECT 1 (105)			ABTECT 2 (106)		
	Placebo (N=158)	Obe 25 mg (N=160)	Obe 50 mg (N=318)	Placebo (N=159)	Obe 25 mg (N=159)	Obe 50 mg (N=318)
<b>Any TEAE</b>	84 (53.2) 180	75 (46.9) 165	189 (59.4) 483	77 (48.4) 166	81 (50.9) 167	194 (61.0) 505
<b>TEAE leading to study drug discontinuation</b>	6 (3.8) 8	0	17 (5.3) 22	9 (5.7) 11	8 (5.0) 11	15 (4.7) 18
<b>Serious TEAE</b>	3 (1.9) 3	1 (0.6) 1	14 (4.4) 14	7 (4.4) 8	6 (3.8) 6	6 (1.9) 6
<b>Malignancy</b>	0	0	1 (0.3) 1*	0	0	0
<b>Serious/severe (grade ≥3) infections and opportunistic infections</b>	1 (0.6) 1 <sup>¥</sup>	1 (0.6) 1 <sup>‡</sup>	2 (0.6) 2 <sup>†</sup>	0	0	2 (0.6) 2 <sup>δ</sup>

Data on File ABX464-105 & ABX464-106

1. The final safety database lock will not occur until August, but is more than 95% complete; n= number of subjects experiencing event; #=number of events; \*prostate cancer, stage 1; †Covid-19, pneumonia

¥ Bronchopulmonary aspergillosis; ‡ Appendicitis; δ Anal abscess, pneumonia

# Headaches were not a barrier to treatment, as evidenced by the low discontinuation rate

## Treatment-emergent Headaches – Onset, Discontinuation, Duration

	ABTECT 1 (105)			ABTECT 2 (106)		
	Placebo (N=158)	Obe 25 mg (N=160)	Obe 50 mg (N=318)	Placebo (N=159)	Obe 25 mg (N=159)	Obe 50 mg (N=318)
Any treatment-emergent (TE) headache, n (%) #	9 (5.7) 9	25 (15.6) 37	69 (21.7) 100	10 (6.3) 15	26 (16.4) 35	84 (26.4) 136
Headache leading to study discontinuation (per subject), n (%)	0	0	2 (0.6)	0	1 (0.6)	5 (1.6)
Duration of headache for all TE headaches, days, median	2.0	3.0	2.0	4.0	3.0	2.0

*Headaches was not a barrier to treatment, as evidenced by the low discontinuation rate*

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# ABTECT Topline Results Summary

Obefazimod Achieved Statistically Significant Results in Both ABTECT 1 (105) and ABTECT 2 (106)



## Strong Clinical Trial Execution

- Enrolled 1,275 patients across 36 countries – one of the largest and fastest enrolling UC programs ever conducted
- Trials reflect a ‘real-world’ patient population including both naïve (52.7%) and refractory patients (47.3%) who have failed multiple therapies (no limit on number of prior treatment failures)



## Differentiated Clinical Profile

- Number of patients achieving clinical remission on obefazimod statistically significant for 50mg in both trials
  - Pooled (ABTECT-1 + ABTECT-2): 50mg = 20.8% ( $\Delta$ 16.4%), 25mg 17.6% ( $\Delta$ 13.2%), placebo = 4.4%
  - ABTECT 1 (Study 105): 50mg = 21.7% ( $\Delta$ 19.3%), 25mg = 23.8% ( $\Delta$ 21.4%) , placebo = 2.5%
  - ABTECT 2 (Study 106): 50mg = 19.8% ( $\Delta$ 13.4%), 25mg = 11.3% ( $\Delta$ 5.1%)\*, placebo = 6.3%
- Favorable safety and tolerability results – no new safety signals observed in Phase 3 induction trials
- Met all key secondary endpoints with 50mg in both trials



## Looking Ahead

- Additional data to be presented at a future medical congress
- 44-week maintenance data expected in Q2 2026

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