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# EMERALD-1 Topline Data

April 25, 2023

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# Agenda and Participants

**Introductory Remarks:** Praveen Tipirneni

**UC Treatment Landscape:** Dr. Bruce Sands

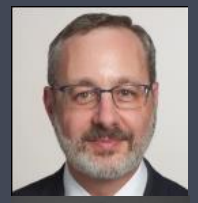
**EMERALD-1 Overview & Safety:** Brihad Abhyankar

**Clinical Data:** Bruce Rogers

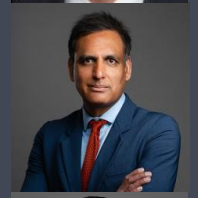
**Closing Remarks:** Praveen Tipirneni

**Q&A**

## Present for Q&A: Management and Key Opinion Leader

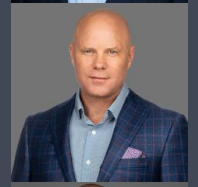


**Bruce Sands, MD**
Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai,
Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System



**Praveen Tipirneni, MD**
Chief Executive Officer

**Bruce Rogers, PhD**
President



**Marc Schegerin, MD**
Chief Operating Officer & Chief Financial Officer

**Brihad Abhyankar, MBBS, FRCS**
Senior Vice President of Clinical Development

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# The Unmet Need in IBD Treatment


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# EMERALD-1 Trial Overview

Phase 2a open-label single-arm study of MORF-057 (100mg BID) in patients with moderately to severely active ulcerative colitis (UC)

- N=35 in main cohort

- Inclusion criteria:
  - History of insufficient response, loss of response, or intolerance to conventional and/or advanced therapies
  - Modified Mayo clinical score (mMCS) of 5-9
  - Centrally read endoscopy sub-score of ≥ 2
  - Robarts Histopathology Index (RHI) score of ≥ 10
- Exclusion criteria:
  - Prior exposure to vedolizumab or other integrin inhibitors

- Primary endpoint: Change in RHI measured at 12 weeks
- Secondary endpoints: mMCS change from baseline, safety
- Pre-specified exploratory endpoints:
  - RHI remission
  - mMCS remission
  - mMCS response
  - Multiple PK/PD parameters
  - Relevant biomarkers

# Baseline Patient Demographics

*A moderately-to-severely active UC population with high disease burden*

| | N=35 |
|---|---|
| Age, years, mean (SD) | 39.2 (14.1) |
| Sex, n (%), female/male | 16 (45.7%) / 19 (54.3%) |
| Geography, n (%), Poland/US | 28 (80%) / 7 (20%) |
| Baseline RHI, mean (SD) | 22.7 (7.3) |
| mMCS, mean (SD) | 6.7 (1.1) |
| Mayo Endoscopy Score (MES), n (%), 2/ **3** | 18 (51.4%) / 17 (**48.6%**) |
| Advanced Treatment Experienced, n (%) | 13 (**37.1%**) |
| Baseline steroid use, n (%) | 9 (**25.7%**) |

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# MORF-057: Generally Well-Tolerated in EMERALD-1 No Safety Signal Observed

*Adverse Event (AE) profile consistent with underlying disease state*

| | |
|---|---|
| Patients with at least one AE | **12 (34.3%)** |
| Patients with any serious AE | **0** |
| Patients with AE leading to death | **0** |
| Patients with any grade 3 AE | **2 (5.7%)[1]** |
| Patients with treatment-related AE | **2 (5.7%)** |
| Common (>5%) AEs<br>Exacerbation of UC<br>Anemia | <br>**4 (11.4%)**<br>**3 (8.6%)[2]** |

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1. Both UC exacerbations, one led to early discontinuation
2. All anemic at baseline and continued on study with iron supplements

*As of 4/25/23 patients have been on EMERALD-1 study beyond the 12-week induction period and no other safety signals or SAEs have been reported.

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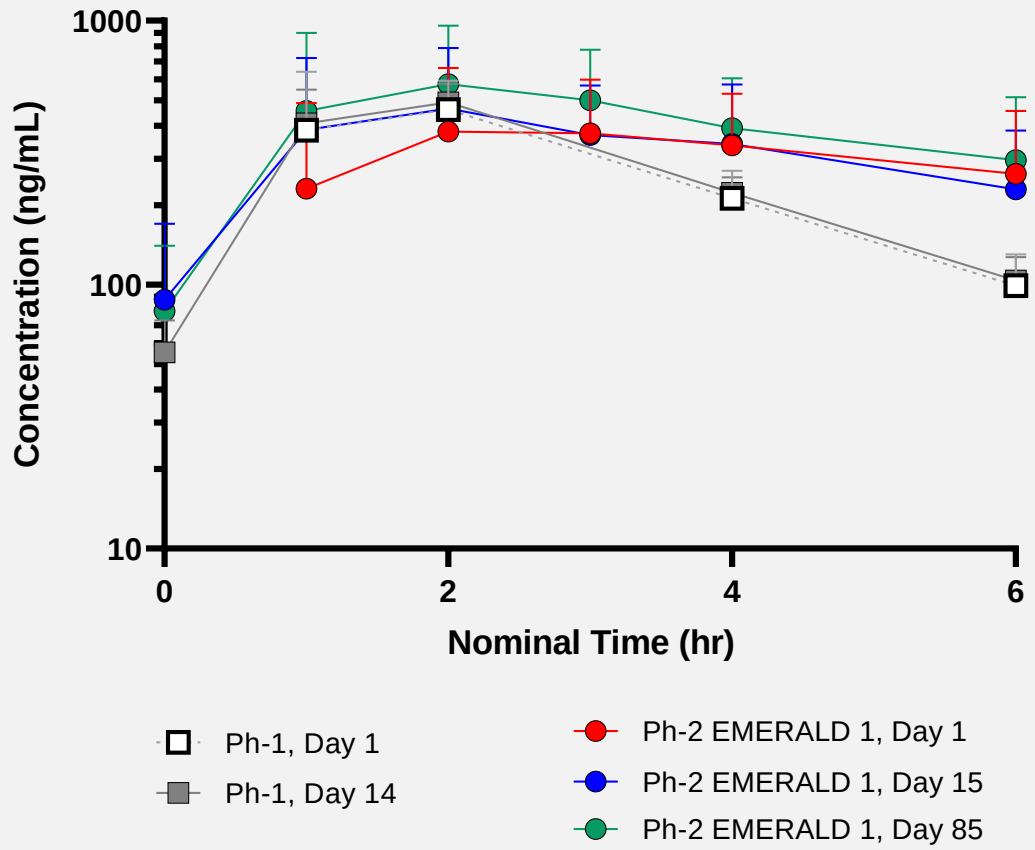
# Topline Clinical Data

# Patient PK Consistent with Healthy Volunteer PK




- Serum drug concentrations conform highly to Phase 1 healthy volunteer data
- Mean PK data demonstrate consistency from start of dosing through week 12
- MORF-057 trough concentrations sufficient for saturation of α4β7 receptor in the blood

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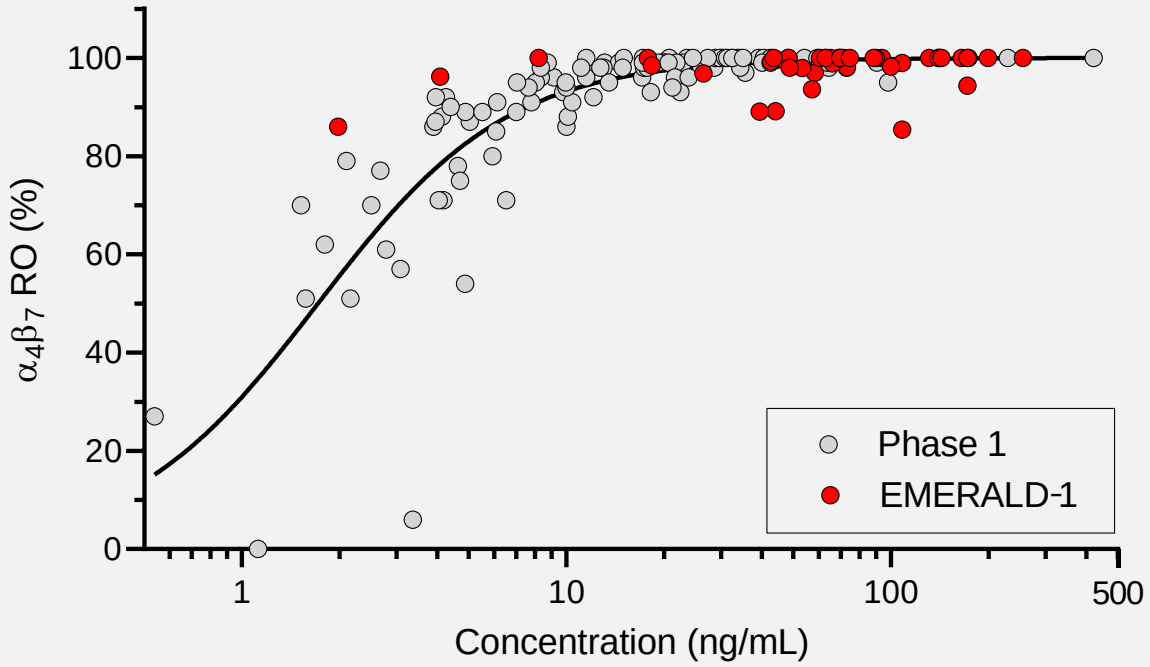
# Patient α4β7 Receptor Occupancy (RO) Consistent with Healthy Volunteer RO




α4β7 selectivity over α4β1 consistent with Phase 1 results

| RO at 12 weeks | | |
|---|---|---|
| | α4β7 | α4β1 |
| Mean | **>98%** | BLQ |
| Median | **>99%** | BLQ |

- α4β7 RO achieved early and sustained saturating levels
- α4β1 RO remained at low levels
- No lymphocytosis or changes to circulating naïve T-cells were observed
- α4β1 projected RO was below the limit of quantitation with mean trough value estimated to be <15%

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# Consistent Clinical Improvement Across Key Measures

| | |
|---|---|
| **Change in RHI from Baseline**<br>Primary Endpoint | **-6.4**<br>**(p=.0019)** |
| **mMCS Mean Change from Baseline**<br>Secondary Endpoint | **-2.3** |
| **mMCS Remission**<br>mMCS: Rectal bleeding sub-score of 0; a stool frequency sub-score of ≤1; and an MES of ≤1 without friability | **25.7%** |
| **mMCS Response**<br>Decrease from baseline in the mMCS ≥2 points and ≥30% from baseline, plus a decrease in rectal bleeding subscore ≥1 or an absolute rectal bleeding subscore ≤1 | **45.7%** |
| **RHI Remission**<br>RHI ≤ 3 | **22.9%** |

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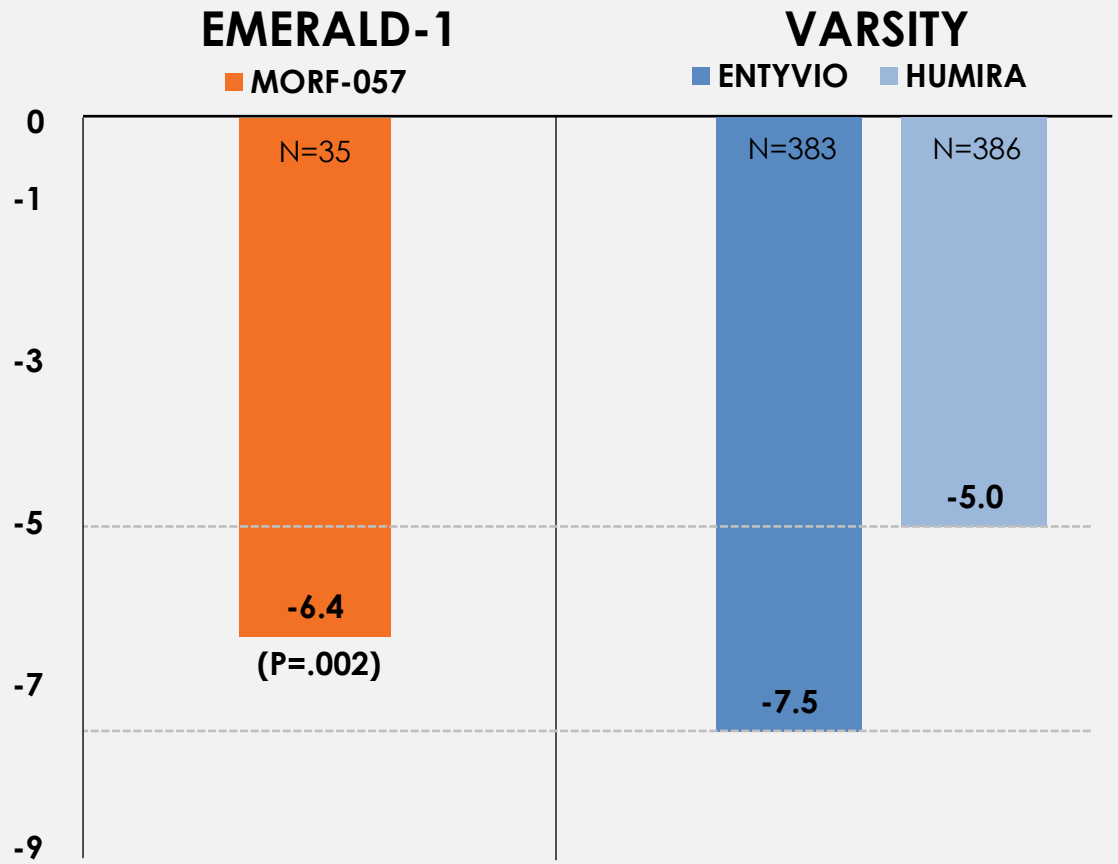
All measures at 12 weeks

# Strong RHI Results Support MORF-057

## EMERALD

- Baseline RHI:
  - 22.7 (7.32)
- 12-week timepoint
- 37% advanced therapy experienced patients
- Open-label, single arm

**Mean RHI Reduction from Baseline**




## VARSITY

- Baseline RHI:
  - ENTYVIO® - 19.5 (8.7)
  - HUMIRA® – 19.6 (8.9)
- 14-week timepoint
- 19% advanced therapy experienced patients
- Double-blind, double dummy

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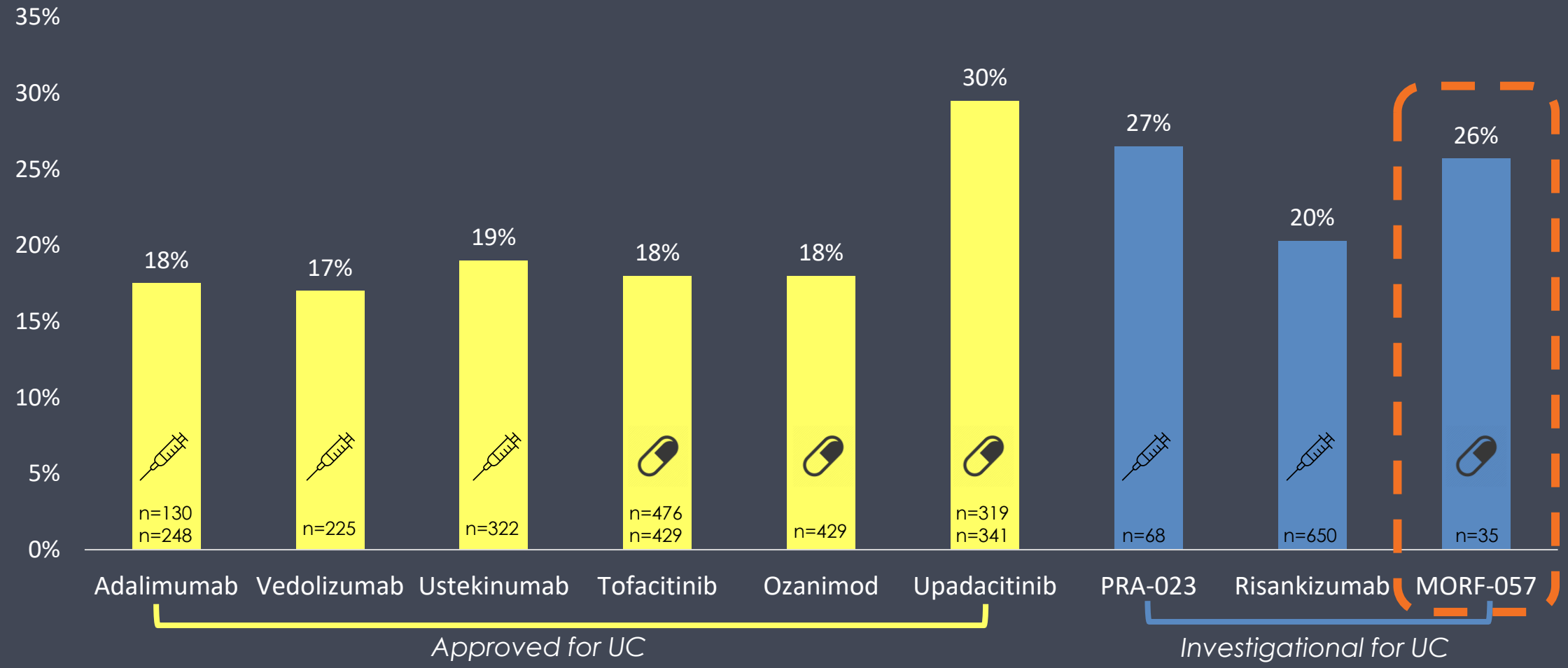
Comparing the results from different trials may be unreliable due to different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that may not be the same between trials. Therefore, cross-study comparisons provide very limited information about the efficacy or safety of a drug. Results of a head-to-head comparison may differ significantly from those set forth herein.

# UC Absolute Clinical Remission Data at Induction Selected Approved and Investigational Agents

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- PRA-023 and MORF-057 data from Phase 2 trials; all other data from RCT Phase 3 studies. Graphic is not meant to represent a head-to-head study. Comparing the results from different trials may be unreliable due to different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that may not be the same between trials. Therefore, cross-study comparisons provide very limited information about the efficacy or safety of a drug.
- Remission data is based on mMCS for all drugs except adalimumab, vedolizumab, and tofacitinib, which are based on tMCS
- MORF-057 EMERALD-1 study consisted of n=35, a significantly smaller number of patients than reflected in the other datasets represented on this slide. In larger trials of MORF-057 the clinical activity suggested by our EMERALD-1 trial may not be replicated.
- N's are from active arms only, data sourced from following trials respectively: UC-1/UC-2, Gemini-1, UC-1,/UC-1, UC-2, TRUE NORTH, , U_ACHIEVE-1/U-ACHIEVE-2, APOLLO-UC, INSPIRE and EMERALD-1

# The Unmet Need in IBD Treatment


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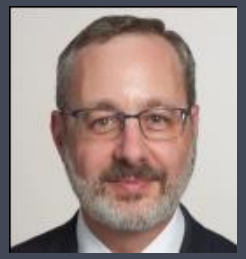
# Q&A

## Key Opinion Leader



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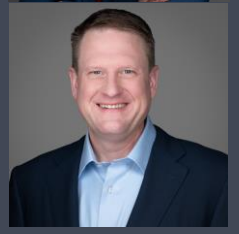
## Executive Management

**Praveen Tipirneni, MD**
Chief Executive Officer



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Thank You
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