



# Jefferies Global Healthcare Conference

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*June 8, 2022*

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# Product Portfolio

## Addressing Unmet Needs in Multiple Indications with Multi-Billion Dollar Market Potential

Programs	Candidates	Study	Phase 1	Phase 2	Phase 3	Key Milestones
<b>HEMATOLOGY &amp; BLOOD DISORDERS</b>						
<b>POLYCYTHEMIA VERA (PV)</b>						
Hepcidin Mimetic	Rusfertide (PTG-300)	VERIFY	PV Ph3 trial			<ul style="list-style-type: none"> <li>~250 patient, randomized, double-blind, placebo-controlled study</li> <li>Patient screening underway</li> </ul>
		REVIVE	PV Ph2 PoC trial			<ul style="list-style-type: none"> <li>60+ patient enrollment completed</li> <li>Updates at 2022 ASCO &amp; EHA</li> </ul>
		PACIFIC	PV Ph2 elevated HcT (>48%) trial			<ul style="list-style-type: none"> <li>16 patients completed 16-week study and continuing in OLE</li> </ul>
		<b>HEREDITARY HEMOCHROMATOSIS (HH)</b>				
		300-06	HH Ph2 PoC trial			<ul style="list-style-type: none"> <li>16 patient study completed</li> <li>Clinical PoC established</li> </ul>
<b>INFLAMMATORY &amp; IMMUNOMODULATORY DISEASES</b>						
Oral GI Restricted $\alpha$ 4 $\beta$ 7-Integrin Antagonist	PN-943	IDEAL	Ulcerative Colitis (UC) Ph2 trial			<ul style="list-style-type: none"> <li>159 patient study; topline data announced 4/2022</li> <li>Efficacy signals with 150 mg bid dosing</li> <li>Ph3 planning &amp; partnership efforts underway</li> </ul>
Oral IL-23R Antagonist	PN-235 JNJ-77242113	FRONTIER-1	Psoriasis Ph2b PoC trial			<ul style="list-style-type: none"> <li>240 patient FRONTIER-1 psoriasis study</li> <li>80 patient SUMMIT study with new formulation</li> <li>Phase 1 NHV study (Japanese &amp; Chinese)</li> <li>IBD Ph2 Initiation expected in 2023</li> </ul>
		SUMMIT	Psoriasis Ph2b PoC trial			



# Rusfertide for Polycythemia Vera

## Continued Progress with Three Clinical Studies

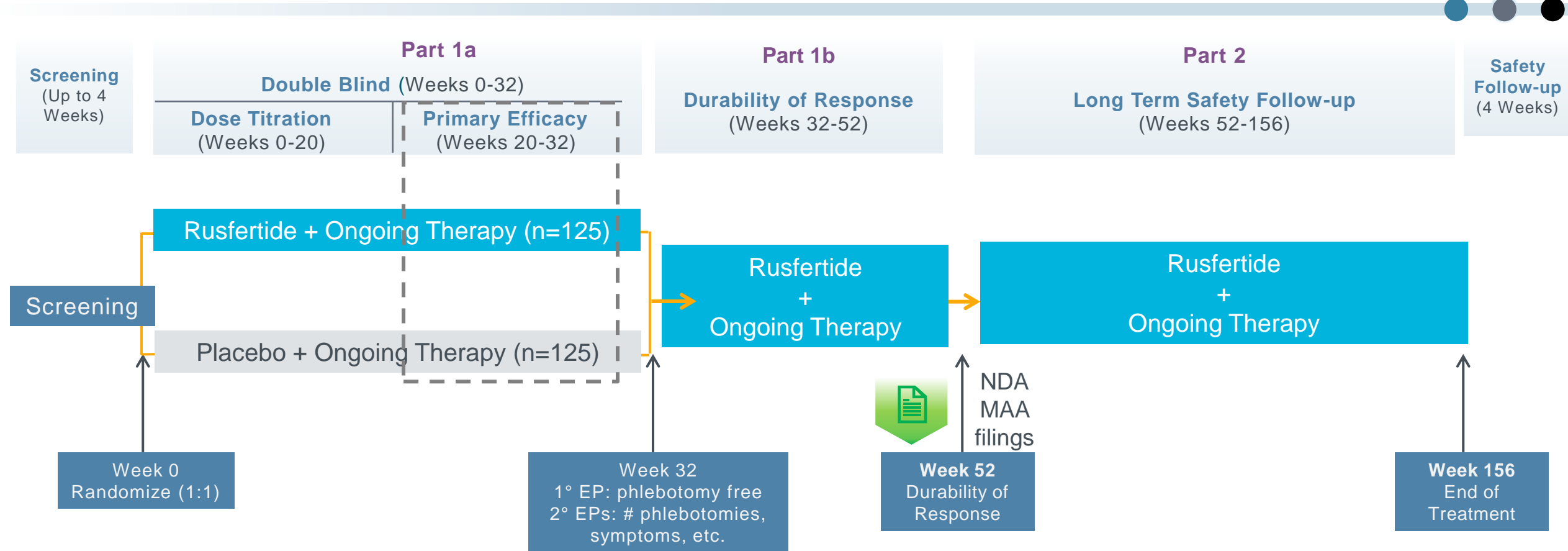
### Ph3 VERIFY, Ph2 REVIVE, Ph2 PACIFIC

- Phase 3 **VERIFY** Study:
  - FDA and CHMP (EU) have approved the Phase 3 VERIFY study design
  - Major agreements in place for US NDA
    - Non-clinical studies including two-year rat carcinogenicity study
    - Non-clinical and clinical pharmacology studies
    - Chemistry, Manufacturing and Controls plan
- Phase 2 **REVIVE** Study:
  - Clinical updates presented at ASH 2021, ASCO 2022, and EHA 2022
    - Most recent Phase 2 data, presented at ASCO 2022, demonstrates the effects of dosing interruption and resumption
  - Enrollment complete; post-hold re-enrollment rate of >85%
- Phase 2 **PACIFIC** Study:
  - High hematocrit (HcT >48%) 16-week study completed; subjects in OLE
- Orphan Drug designation, Fast Track status\*

\*The Company voluntarily withdrew its Breakthrough Therapy Designation in June 2022 following correspondence with FDA. Protagonist retains its Fast Track status for rusfertide in PV. All clinical studies in PV are proceeding as planned, with no further changes.

# Randomized, Double-blind, Placebo-Controlled Phase 3 PV Study (VERIFY)

## VERIFY Study of N~250 subjects



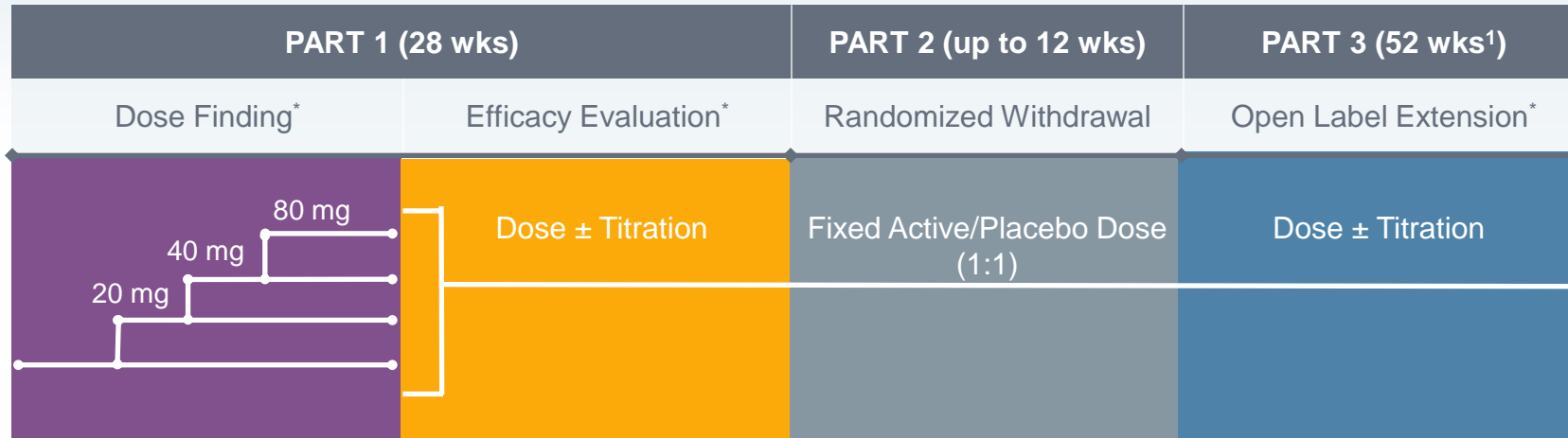
The Phase 3 study design capitalizes on the successful outcome to date of the 60-plus patient open-label Phase 2 REVIVE Study

*In consultation with the U.S. Food and Drug Administration, Protagonist has implemented a set of rigorous safety monitoring procedures in all ongoing clinical studies, including cancer surveillance measures (augmented dermatological examinations) and stopping rules.*

# Phase 2 Study of Rusfertide in PV Patients (REVIVE)

**GOAL: Maintain Hematocrit <45%**

## Clinical 'Proof-of-Concept' Study with Add-On



- \*Titrate every 4 weeks to maintain hematocrit < 45%
- <sup>1</sup>OLE increased from 52 weeks to 3 years

### ELIGIBILITY REQUIREMENTS:

- Phlebotomy dependent PV patients diagnosed as per 2016 WHO criteria
- ≥3 phlebotomies in 6 months with or without concurrent cytoreductive therapy
- Rusfertide (PTG-300) doses of 10-80 mg administered subcutaneously weekly added to prior standard therapy

### KEY ENDPOINTS:

- Safety
- Maintain Hematocrit <45%
- Reduction in Phlebotomies
- Symptom Scores: MPN-SAF TSS, PGI-C

# Baseline Characteristics of Study Participants in REVIVE Study

Characteristics (n = 70)

## AGE

Range	27-77 years (Mean = 57.3 yrs)
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## GENDER

Females	21 (30.0%)
Males	49 (70.0%)

## RISK

Low	29 (41.4%)
High	41 (58.6%) [Age based – 37.1%, Thrombotic events – 21.4%]

## DURATION SINCE PV DIAGNOSIS

<1 yr	14 (20.0%)
1 - <3 yrs	24 (34.3%)
3 - <5 yrs	11 (15.7%)
≥5 yrs	21 (30.0%)

## THERAPIES

PHL only	34 (48.6%)
PHL + HU	21 (30.0%)
PHL + IFN	8 (11.4%)
PHL + RUX	3 (4.3%)
PHL +Multiple Agents	4 (5.7%)

## NUMBER OF PHL IN 28 WEEKS PRIOR

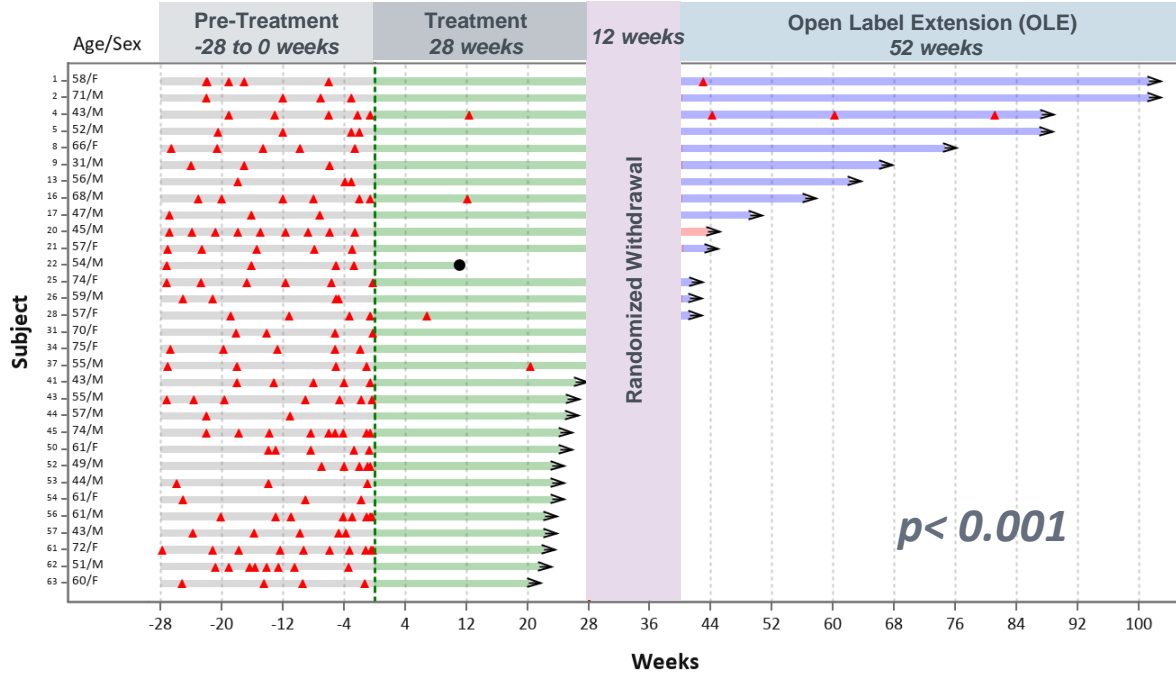
2-3	14 (20.0%)
4-5	38 (54.3%)
≥6	18 (25.7%)
Median	4.79

## DAYS BETWEEN PHLEBOTOMIES

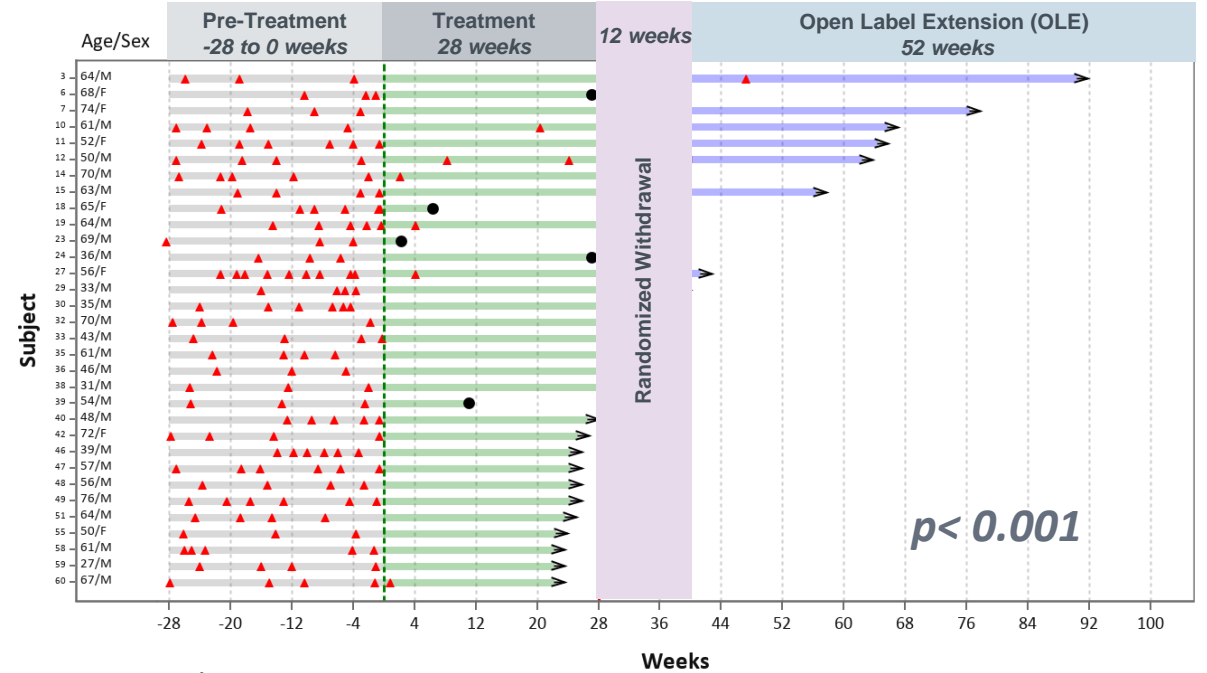
Median	34
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# Effect of Rusfertide on Phlebotomy Frequency in REVIVE Study

## Phlebotomy only (N=31, 49%)

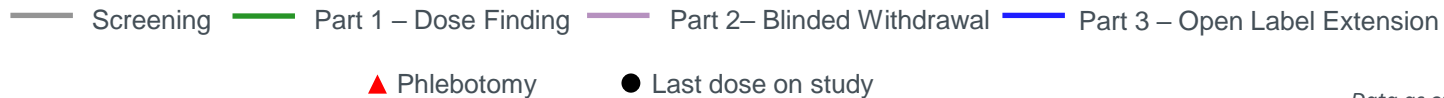


## Phlebotomy + cytoreductive (N=32, 51%)



Median Dose 40-60 mg/week

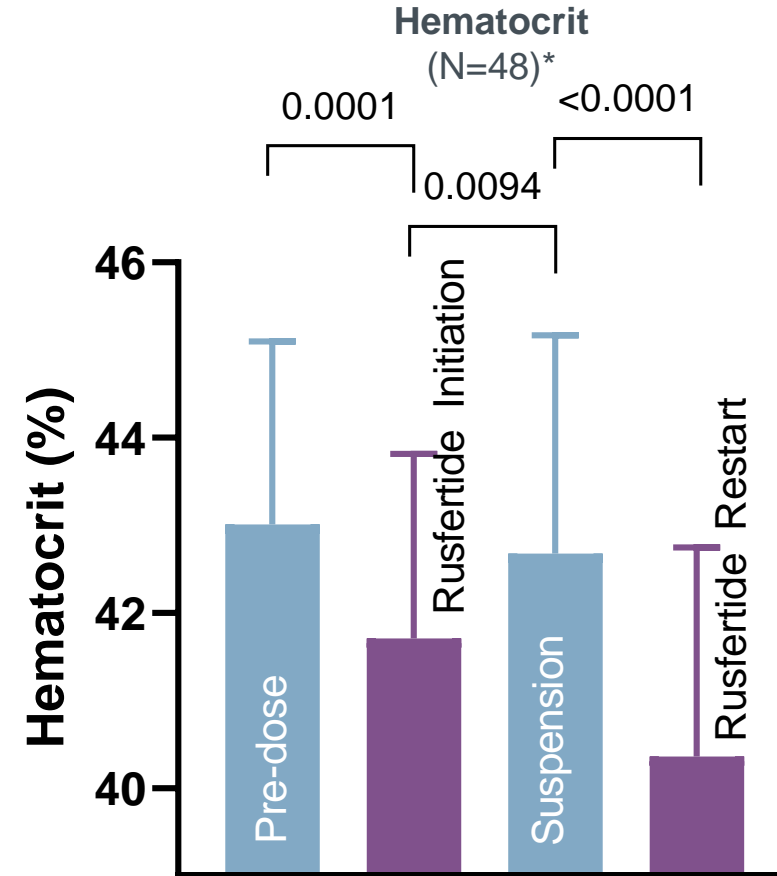
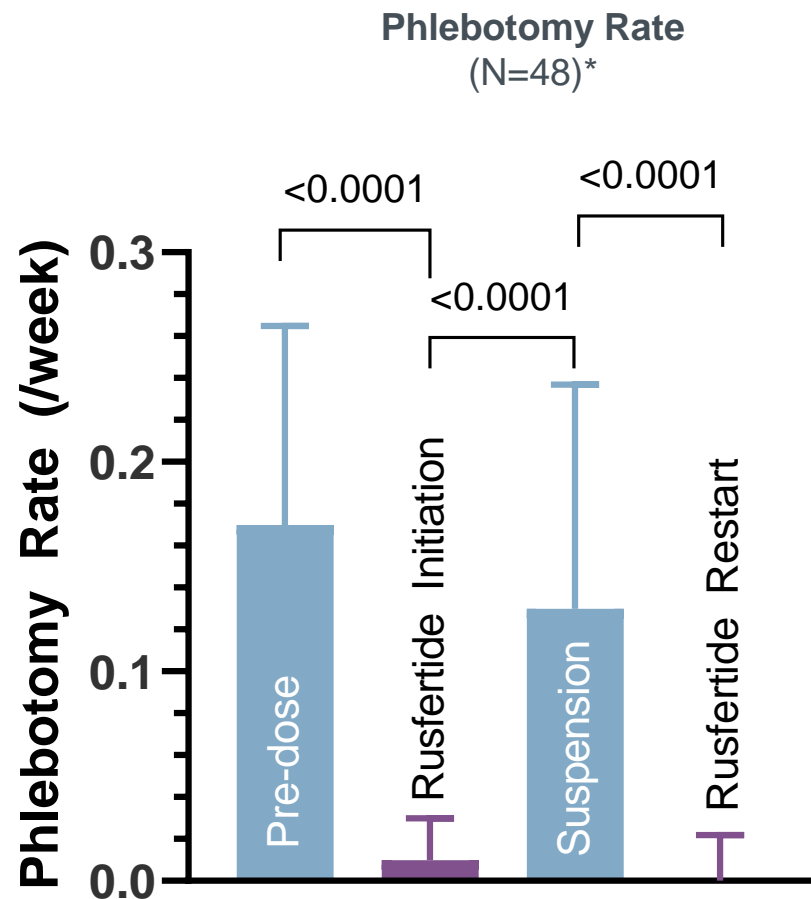
During the first 28 weeks of treatment, **84% of patients did not require a phlebotomy**  
 14% required one and 2% required two phlebotomies.





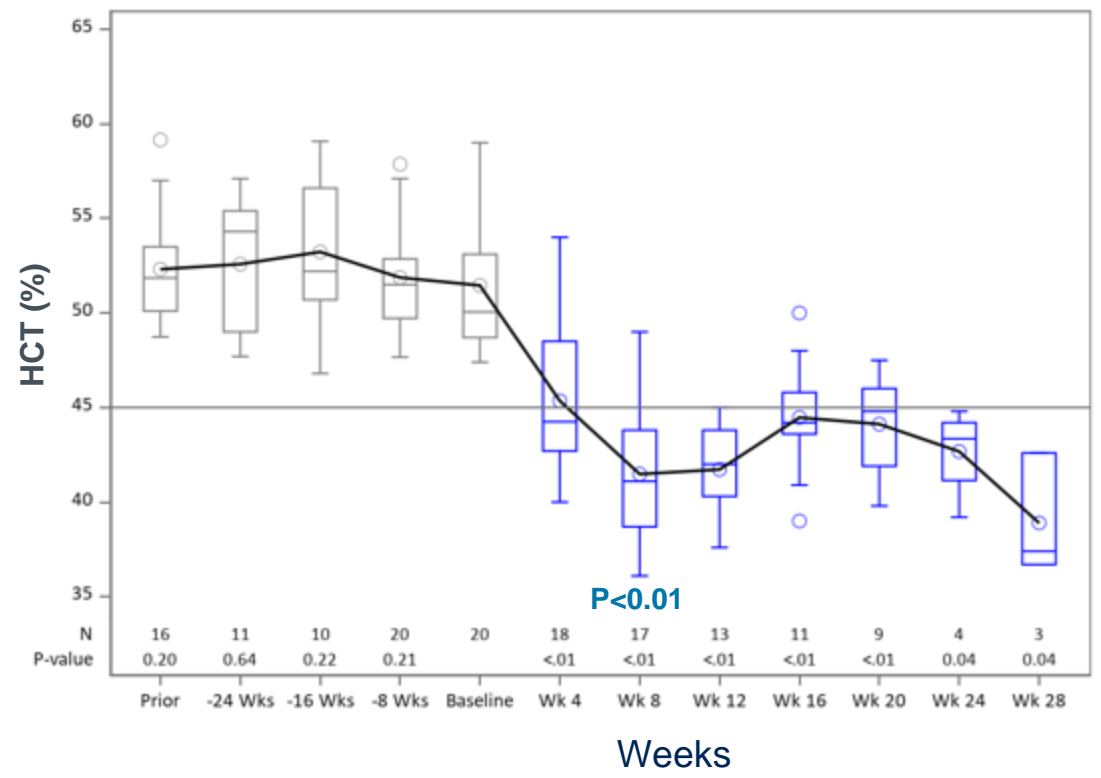
# Rusfertide Treatment Suspension Leads to Loss of Effect

## Restarting Rusfertide Treatment Restores Therapeutic Benefits

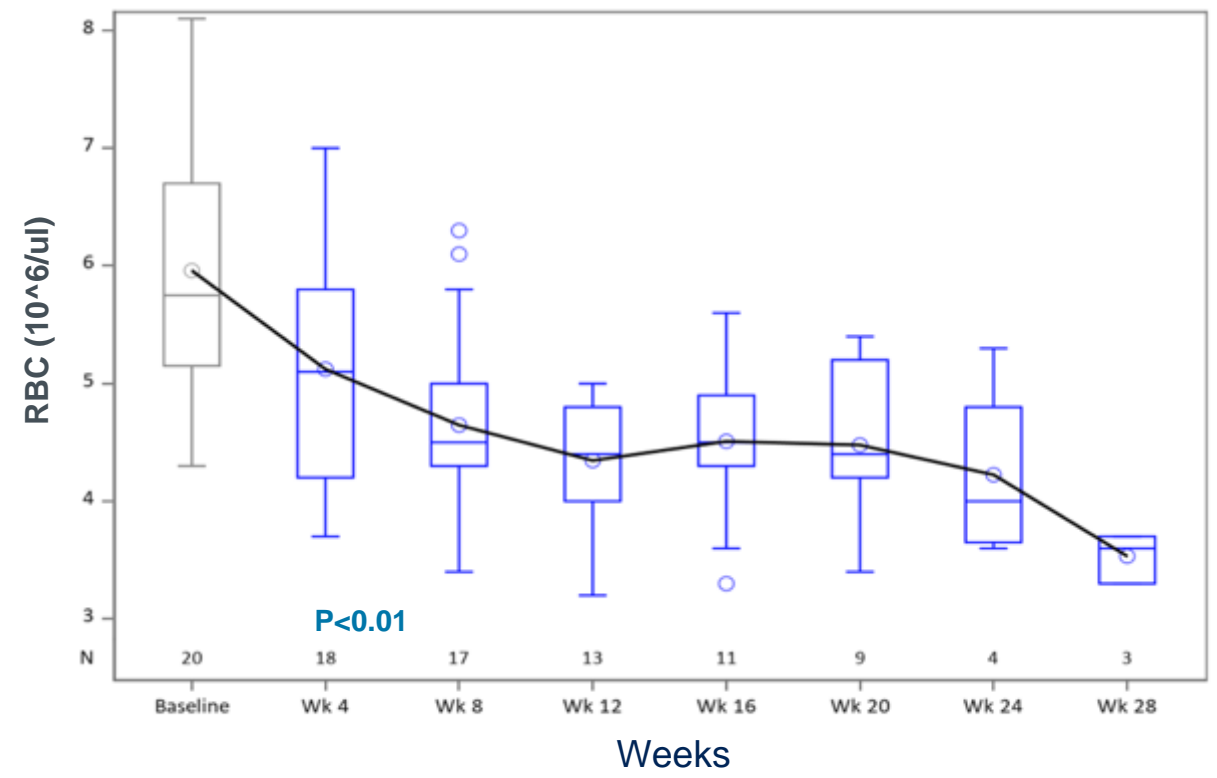


# PACIFIC Study in PV Patients with High (>48%) Baseline Hematocrit (n=20)

### Rapid HCT Control with Rusfertide



### Rapid RBC count reduction with Rusfertide



— Screening — Rusfertide — MEAN

# Adverse Events Following Rusfertide in Patients with PV

## Combined Summary of Events: REVIVE and PACIFIC Studies

System Organ Class Preferred term	AE n (%)
Total number of Subjects	90
General disorders and administrative site conditions	77 (85.6)
Fatigue	19 ( 21.1)
Skin and subcutaneous tissue disorders	37 (41.1)
Pruritis	19 (21.1)
Hyperhidrosis	9 (10.0)
Nervous system disorders	35 (38.9)
Headache	18 (20.0)
Dizziness	14 (15.6)
Gastrointestinal disorders	32 (35.6)
Nausea	13 (14.4)
Diarrhea	11 (12.2)
Musculoskeletal and connective tissue disorders	32 (35.6)
Arthralgia	17 (18.9)
Infections and infestations	23 (25.6)
Investigations	22 (24.4)
Blood and Lymphatic Disorders	20 (22.2)
Anemia	11 (12.2)
Metabolism and nutrition disorders	17 (18.9)
Respiratory, thoracic and mediastinal disorders	16 (17.8)
Injury, poisoning and procedural complications	13 (14.4)
Psychiatric disorders	11 (12.2)
Vascular disorders	9 (10.0)

*Treatment-emergent AEs with more than 10% incidence*

### Most treatment related AEs were Grade 1 or 2

- Injection site reaction (ISRs) were most common and associated with 33% of injections. All ISRs were transient, and no patient discontinued due to an ISR
- **SAEs** include aneurysm of popliteal artery, atrial fibrillation, chest pain, hydrocephalus, gastroenteritis, syncope
  - 5 subjects with cancer events (basal cell carcinoma, squamous cell carcinoma, melanoma, AML)
- No grade 3 events related to rusfertide; one grade 4 event possibly related to rusfertide (asymptomatic and fluctuating thrombocytosis)
- 2 withdrawals due to possibly related AE - both asymptomatic thrombocytosis
- No clinically significant laboratory abnormalities
- No Anti Drug Antibody (ADA) response was noted in any patient

# Clinical Studies of Rusfertide in Polycythemia Vera

## Summary of VERIFY, REVIVE and PACIFIC Studies

- Patient screening has been initiated in Phase 3 VERIFY study with enrollment completion expected in 1H 2023
- Enrollment completed in Phase 2 REVIVE and PACIFIC studies, dosing ongoing
- PV patients requiring frequent phlebotomy  $\pm$  cytoreductives have been treated with rusfertide for >18 months, with subjects remaining essentially phlebotomy free
  - Rapid, sustained and durable hematocrit control without clinically meaningful increase in WBC or platelet counts
  - Robust efficacy in all categories of patients, independent of the PV patient risk category or concurrent therapy with hydroxyurea, interferon or ruxolitinib
  - In high hematocrit PACIFIC study, rusfertide induction therapy with twice weekly dosing achieves rapid hematocrit control (<45%) without phlebotomy
  - Rusfertide dosing was interrupted and led to loss of effect (increased phlebotomy rate, increase in HCT and RBC). Rusfertide restart restored therapeutic benefits
    - Following the re-activation of all sites, >85% of patients returned to the study after dosing interruption
- Rusfertide treatment with or without cytoreductives appears to be well tolerated
  - Randomized, placebo-controlled Phase 3 VERIFY study to refine understanding of the safety profile.

# Hereditary Hemochromatosis (HH)

## Disease Prevalence and Treatment

- HH is an inherited iron overload disorder characterized by excessive iron absorption, due to deficiency of hepcidin
  - Hepcidin deficiency leads to increased circulating transferrin saturation (TSAT) and toxic non-transferrin bound iron (NTBI), and ultimately, iron accumulation in organs such as the liver, pancreas, heart, and bone
  - Therapeutic phlebotomy to reduce iron loading is standard treatment for HH. While phlebotomy is effective, it does not target the biological mechanism, and may actually exacerbate the underlying issue
- If untreated, iron overload can cause hepatomegaly, diabetes mellitus, skin hyperpigmentation, cardiomyopathy, diastolic dysfunction, heart failure, cirrhosis, etc.

**Prevalence in  
million+ patients  
in US; clinical  
disease in ~100K  
subjects**

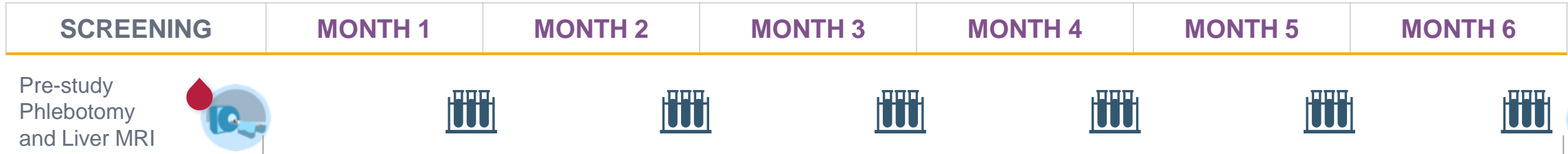
**Excessive iron  
accumulation in  
heart, liver,  
pancreas, skin,  
joint tissues &  
joint pain**

**Phlebotomy is the  
only therapeutic  
option; no  
approved drugs**

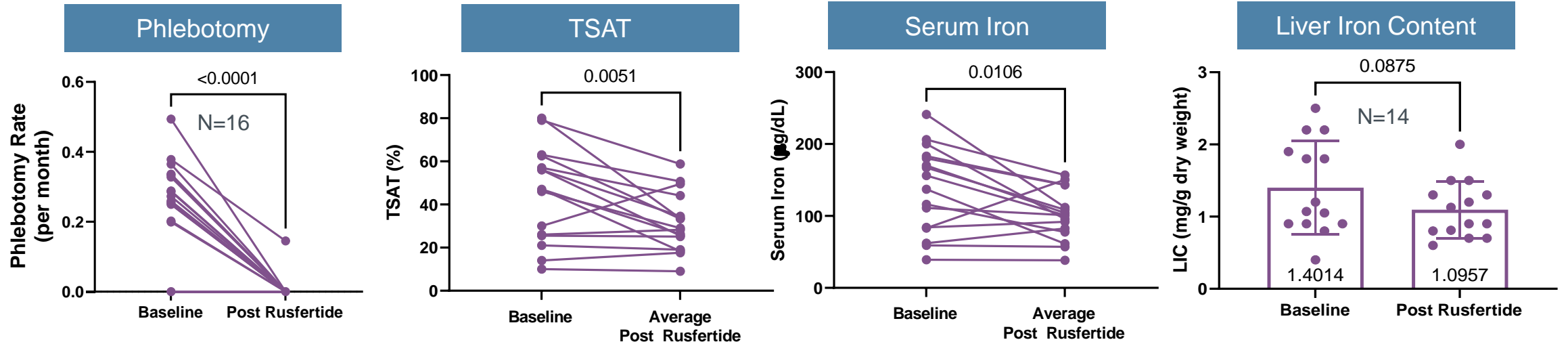
**Unmet need in  
specific sub-  
populations**

# Phase 2 Study in Hereditary Hemochromatosis

## Clinical PoC Achieved



- Six-month, open-label study in 16 HH patients in maintenance phase of iron depletion
- Stable pre-study phlebotomy for  $\geq 6$  months; requiring  $\geq 3$  phlebotomies/12 months or  $\geq 4$  phlebotomies/15 months
- Study endpoints included safety, reduction in phlebotomies, serum iron, TSAT, transferrin, ferritin, liver iron content by MRI, adverse events



# Potential Utility of Rusfertide in Hereditary Hemochromatosis (HH)

## HH Arthropathy (joint pain) is a Common and Persistent Phlebotomy Resistant<sup>1</sup> Symptom

- Chronic arthropathy occurs in 24-81% of patients with HH <sup>2,3,4</sup>
  - Joint pain is an early manifestation of the disease and in many is the cause for first diagnosis of HH
  - X-ray/MRI imaging combined with validated joint pain and function scoring instruments
- Persistent arthropathy can diminish QoL and yield high healthcare utilization and costs <sup>4,7</sup>
  - Up to 16% of HH patients undergo joint replacement surgery
- Iron accumulation in joints may be associated with increased oxidative stress, disrupted matrix metabolism, and cartilage degeneration, which contribute to the development of arthropathy <sup>3,5,6</sup>

**• Arthropathy correlates with iron overload and is associated with elevated age, ferritin, and TSAT <sup>2,3</sup>**

<sup>1</sup> Richette, P. "Musculoskeletal Complications of Hereditary Hemochromatosis: A Case-Control Study", *J Rheumatology*, 2010

<sup>2</sup> Whalen, N. "Association of Transferrin Saturation with the Arthropathy of Hereditary Hemochromatosis", *Clinical Gastroenterology Hepatology*, 2017

<sup>3</sup> Carroll, GJ. "Hereditary Hemochromatosis is characterized by a clinically definable arthropathy that correlates with iron load", *Arthritis & Rheumatism*, 2011

<sup>4</sup> Nguyen, C. "Bone and joint complications in patients with hereditary hemochromatosis: a cross-sectional study of 93 patients," *Ther Adv Musculoskel Dis*, 2020

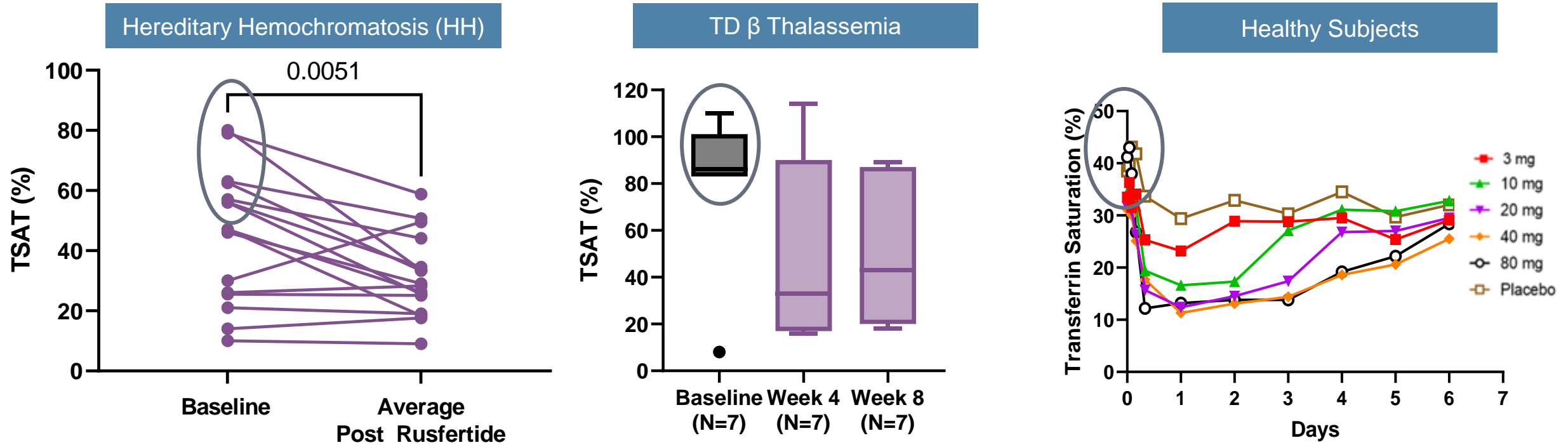
<sup>5</sup> Carroll, GJ. "Characteristics of the Arthropathy Described in Hereditary Hemochromatosis", *Arthritis Care & Research*, 2012

<sup>6</sup> Karim, A. "The role of disrupted iron homeostasis in the development and progression of arthropathy", 2022

<sup>7</sup> Sahinbegovic, E. "Musculoskeletal Disease Burden of Hereditary Hemochromatosis", *Arthritis & Rheum*, 2010

# Potential Utility of Rusfertide in Treating HH Arthropathy

## Rusfertide Treatment Leads to Rapid and Persistent Control of TSAT



### • Next Steps

- Design a Phase 2 clinical PoC study to demonstrate potential utility of Rusfertide in treating iron overload and reducing joint pain in phlebotomy resistant, HH arthropathy patients



# IBD: Paradigm Shift Toward Targeted Oral and Combination Therapy

## A Growing Multi-Billion Dollar Market

2019: ~ \$14B sales<sup>1</sup>

2029: projected ~ \$24B sales<sup>1</sup>

### Historical IBD Treatment Paradigm

#### *TNF mAbs dominated IBD Therapy*

- Injectable TNF mAbs – Blockbusters
  - Humira® & Remicade®
- Significant room for improvement
  - Low response rates / loss of response
  - Safety concerns - black box warnings

### Emerging IBD Treatment Paradigm

#### Injectable mAbs with safer MOAs

- $\alpha 4\beta 7$  integrin: Entyvio® (~ \$4B sales 2020)
- IL-12/IL-23: e.g., Stelara®

#### Oral Targeted Therapy for IBD

##### Protagonist: *mAb Validated Pathways*

- PN-943<sup>2</sup> ( $\alpha 4\beta 7$  integrin)
- IL-23Rs

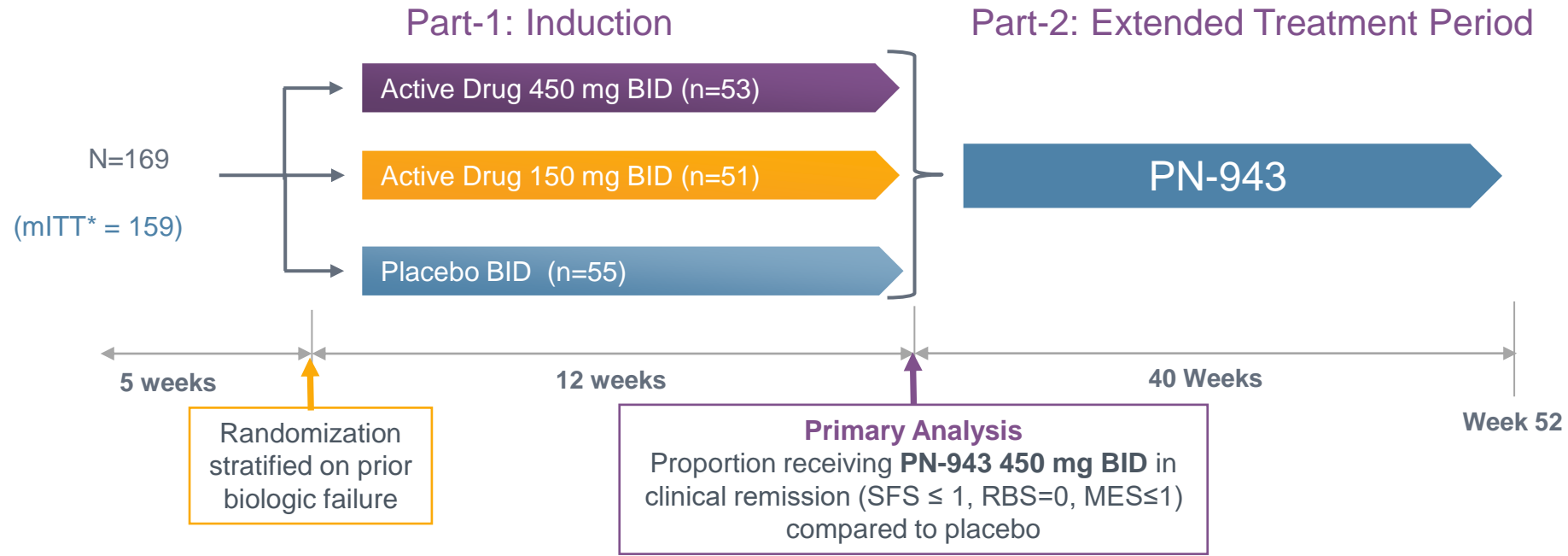
#### Other Oral Approaches: *New Targets*

- S1P1: e.g., Zeposia®
- JAK\*: e.g., Xeljanz®, Rinvoq®

*\*black box warnings*

Potential  
Future of  
IBD  
Oral Combo  
Therapy

# IDEAL: PN-943 Phase 2 UC Study Design



## Eligibility:

- Adults with moderate-severe UC: 3-Component Mayo Score 5-9 points
- Failed at least 1 UC medication (5-ASA, steroids, immunomodulators or one biologic)
- Stable dose steroids, prednisone equivalent ≤ 20 mg/day
- Stable dose immunomodulators
- One prior biologic exposure (anti-TNF or anti-IL-12/23) allowed; prior vedolizumab excluded

\*All ITT patients excluding 10 from Russia and Ukraine who did not complete Week 12 assessments prior to March 3, 2022

# The Outcome of Phase 2 IDEAL Study Will Inform Phase 3 decisions

- **Phase 2 data in UC with various candidates spanning different mechanism of actions**
  - Large confidence intervals, influenced by study design, duration, size, demographics, & criteria
  - Phase 2 outcomes (10-20% delta) has generally predicted efficacy in Phase 3

Historical Ph2, Ph3, and Approval Data in UC				
Candidate	MoA	Clinical Remission Delta		Approval
		Phase 2	Phase 3	
Vedolizumab (Entyvio®) <sup>1</sup>	α4β7 integrin	19%	11.5%	✓
Ozanimod (Zeposia®) <sup>2</sup>	S1P	10%	12.4%	✓
Upadacitinib (Rinvoq®) <sup>3</sup>	JAK	19.6%	21/29.5%	✓ (black box)

\*Cross trial comparisons complicated by different inclusion criteria, patient populations, primary endpoint definitions, timing of primary endpoint, phase of clinical development

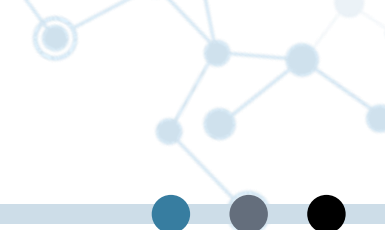
- **Phase 2 data will provide specific guidance for Phase 3 program on:**
  - Go/No-go decision ✓
  - Dose selection ✓
  - Powering of registrational primary and secondary endpoints ✓

1. Feagan, B. G., Greenberg, G. R., Wild, G., Fedorak, R. N., Paré, P., McDonald, J. W., ... & Vandervoort, M. K. (2005). Treatment of ulcerative colitis with a humanized antibody to the α4β7 integrin. *New England Journal of Medicine*, 352(24), 2499-2507; Feagan, B. G., Rutgeerts, P., Sands, B. E., Hanauer, S., Colombel, J. F., Sandborn, W. J., ... & Parikh, A. (2013). Vedolizumab as induction and maintenance therapy for ulcerative colitis. *New England Journal of Medicine*, 369(8), 699-710.

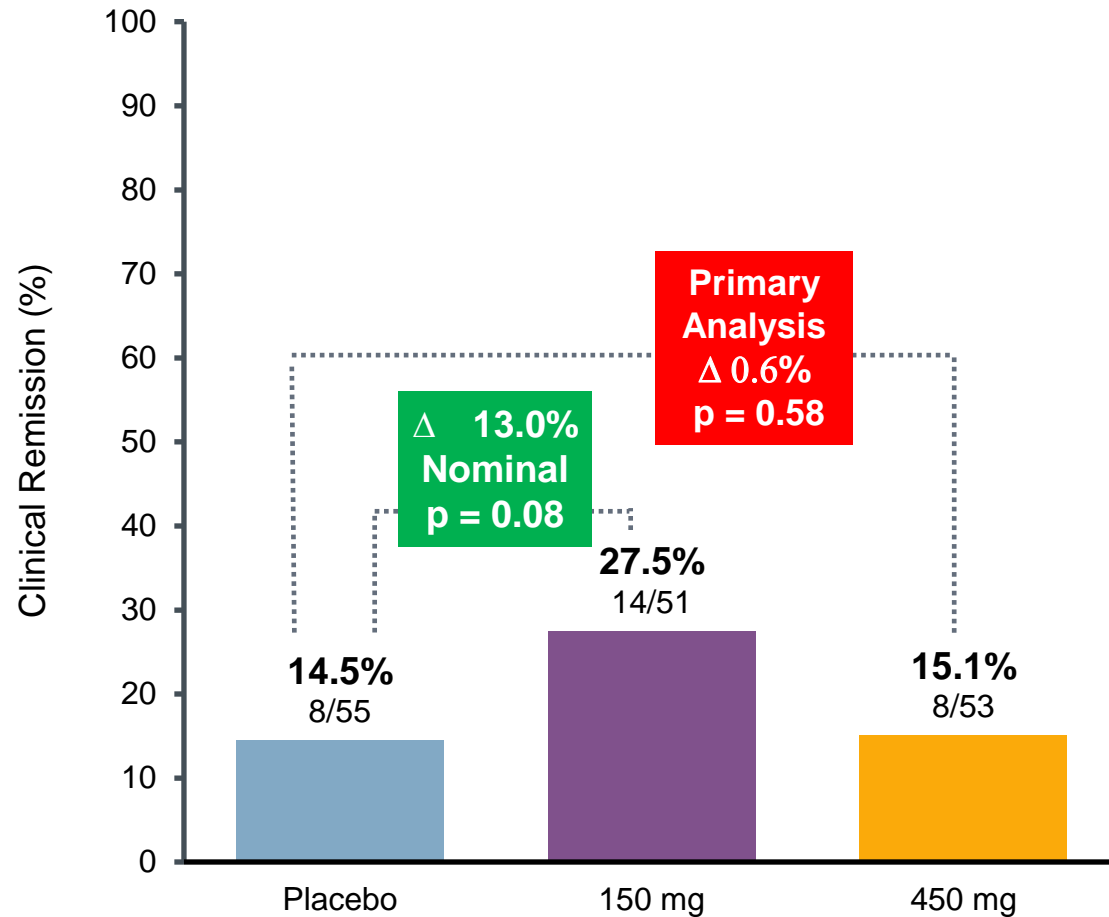
2. Sandborn, W. J., Feagan, B. G., Wolf, D. C., D'Haens, G., Vermeire, S., Hanauer, S. B., ... & Olson, A. (2016). Ozanimod induction and maintenance treatment for ulcerative colitis. *New England Journal of Medicine*, 374(18), 1754-1762; Sandborn, W. J., Feagan, B. G., D'Haens, G., Wolf, D. C., Jovanovic, I., Hanauer, S. B., ... & Danese, S. (2021). Ozanimod as induction and maintenance therapy for ulcerative colitis. *New England Journal of Medicine*, 385(14), 1280-1291.

3. Danese, S., Vermeire, S., Zhou, W., Pangan, A., Siffledeen, J., Hébuterne, X., ... & Pannaccione, R. (2021). OP24 Efficacy and safety of upadacitinib induction therapy in patients with Moderately to Severely Active Ulcerative Colitis: Results from the phase 3 U-ACHIEVE study. *Journal of Crohn's and Colitis*, 15(Supplement\_1), S022-S024.; Vermeire, S., Danese, S., Zhou, W., Pangan, A., Greenbloom, S., D'Haens, G., ... & Pannaccione, R. (2021). OP23 Efficacy and safety of upadacitinib as induction therapy in patients with Moderately to Severely Active Ulcerative Colitis: Results from phase 3 U-ACCOMPLISH study. *Journal of Crohn's & Colitis*, 15(Suppl 1), S021.

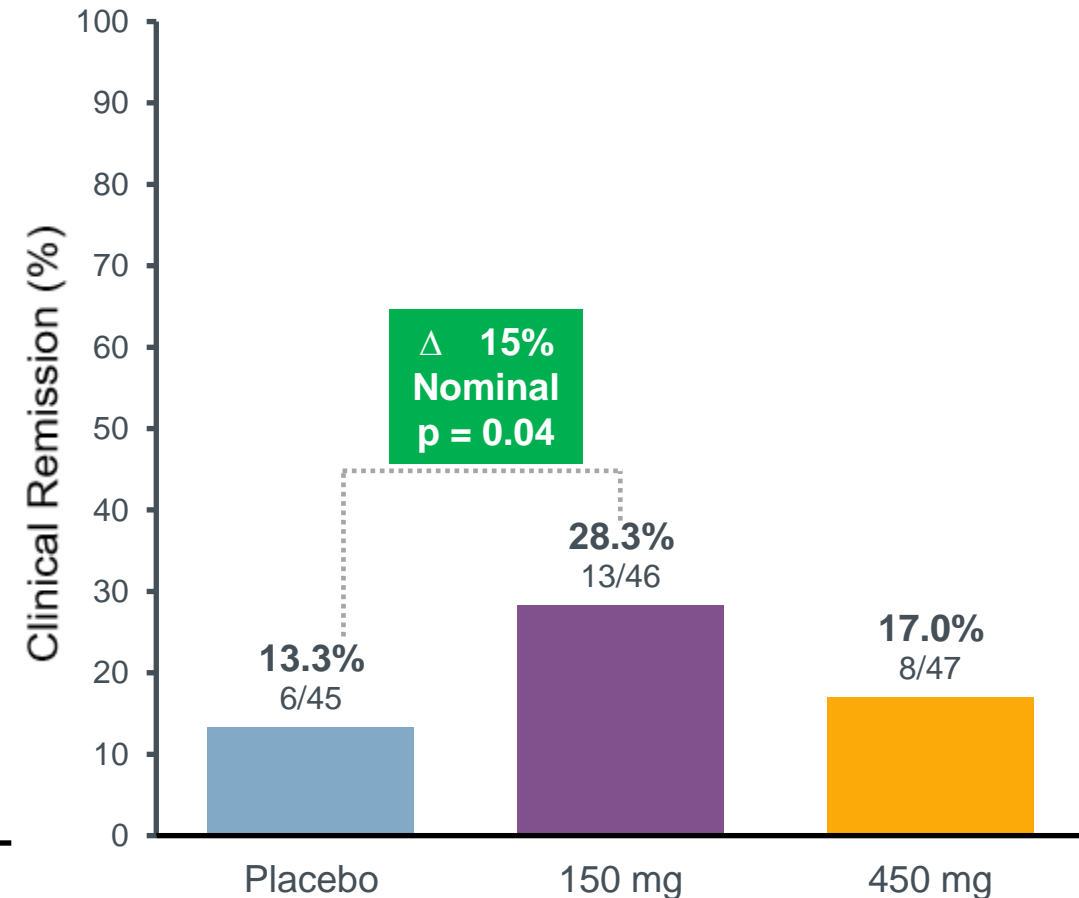
# Clinical Remission at Week 12 - mITT



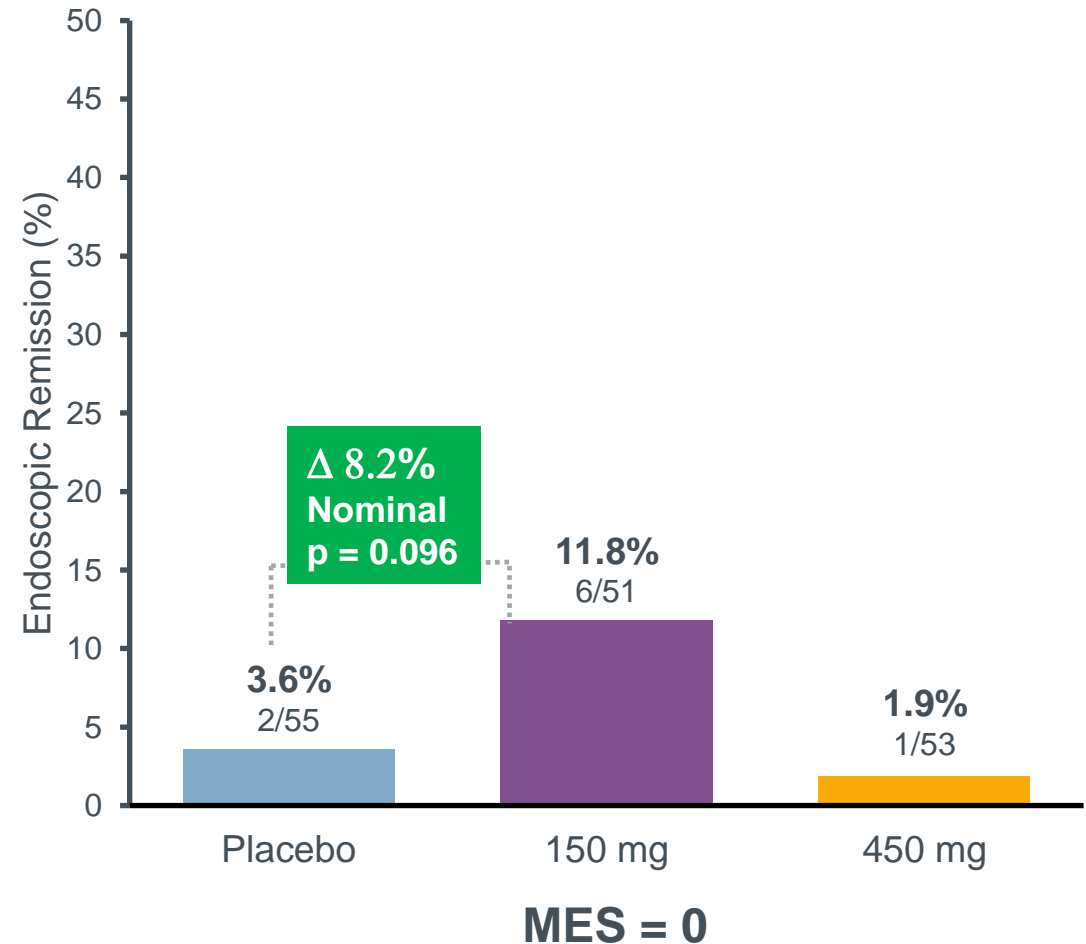
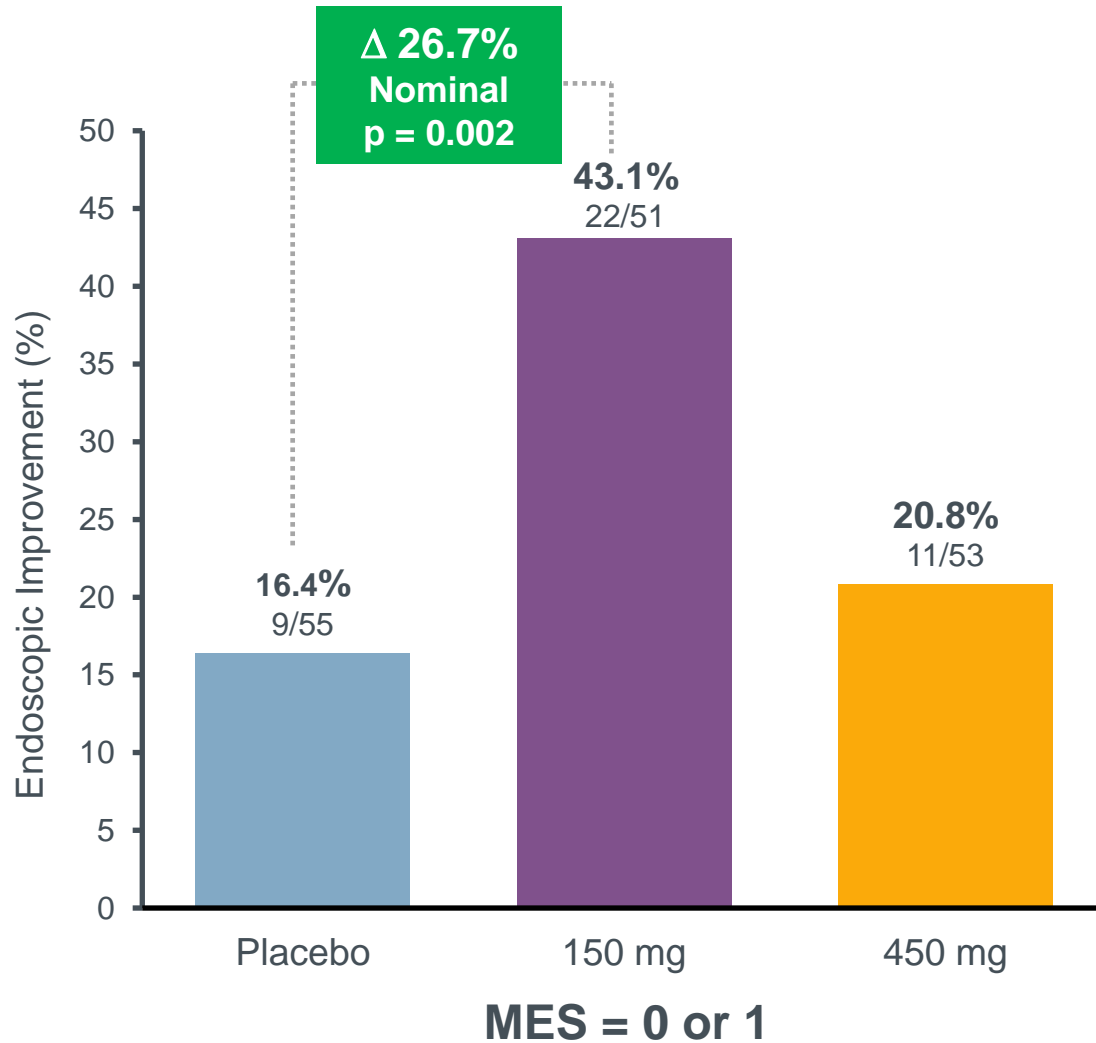
### Modified ITT Population



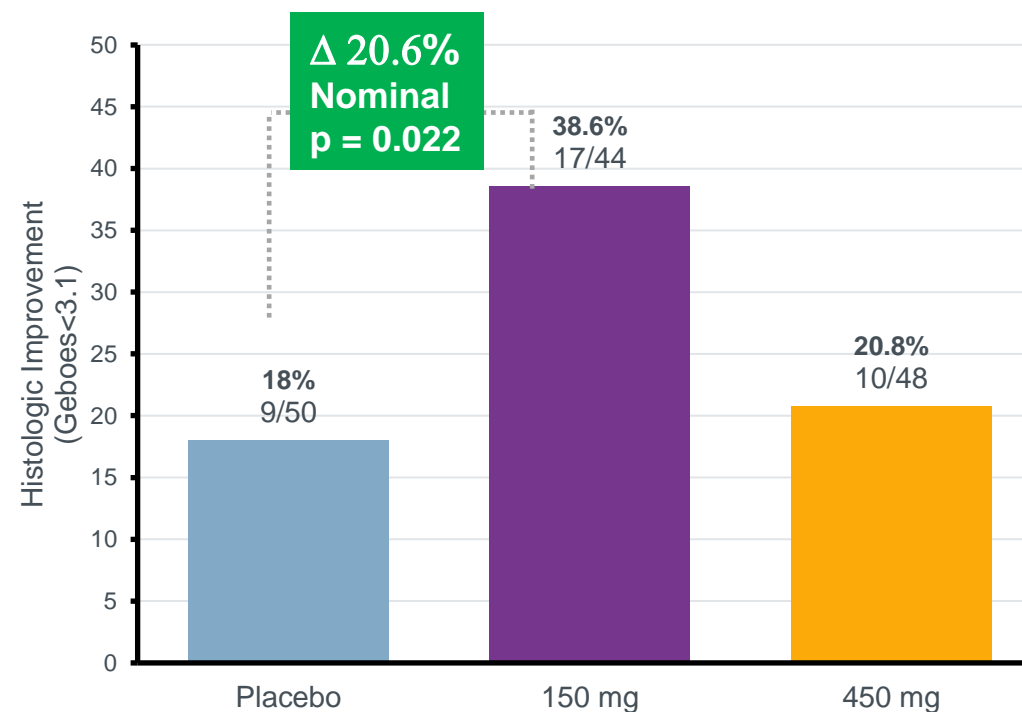
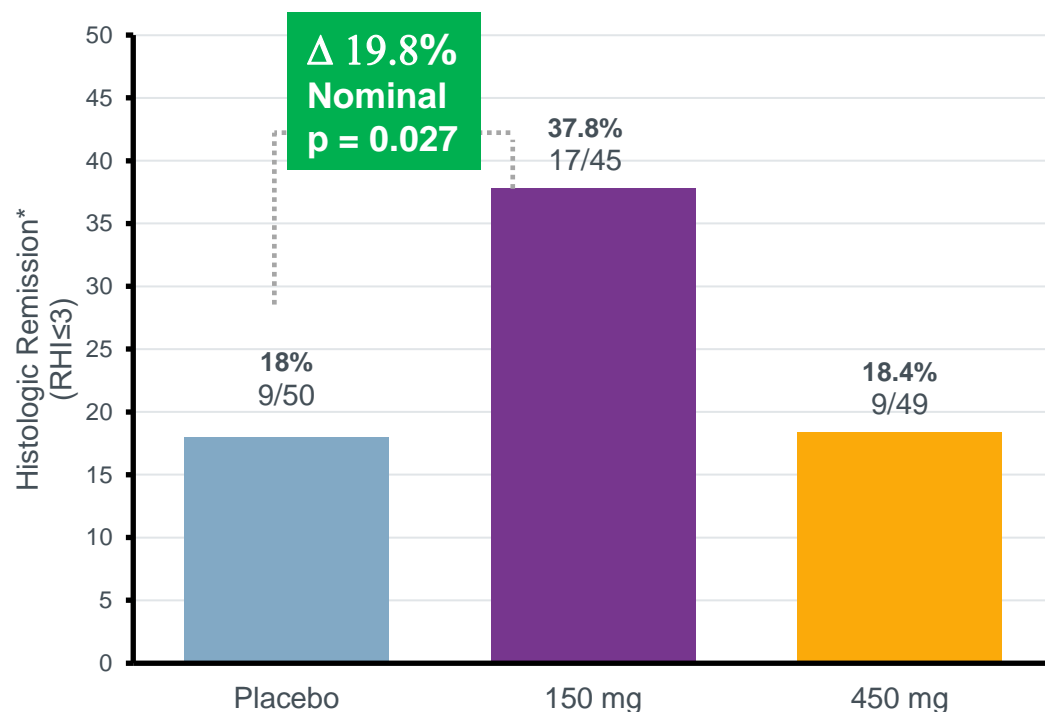
### Biologic Naïve and Biologic-Exposed-Non-Failure Patients



# Endoscopic Improvement and Remission at Week 12 - mITT



# Histologic Remission and Improvement<sup>1</sup> at Week 12 - mITT



\*post hoc analysis

<sup>1</sup>patients who are below the baseline improvement/remission criteria are excluded

# Conclusions and Next Steps

## IDEAL Study

### Summary of Results

- No treatment effect for primary endpoint (clinical remission at week 12, PN-943 450 mg BID vs placebo)
- Clinical remission in 27.5% of PN-943 150 mg BID group vs 14.5% in placebo ( $\Delta$  13%, nominal  $p = 0.08$ ) for mITT analysis
  - $\Delta$  in Biologic-Non-Failure population 15% (nominal  $p = 0.04$ )
- Very good concordance with efficacy across multiple key secondary endpoints including histologic and endoscopic remission/improvement at the 150 mg BID dose
- No significant safety signals detected
- 40-week maintenance extension study (Part 2) ongoing; data expected in 2023

### Next Steps

- Ph3 registrational study design
- Identifying a potential partner

**The IDEAL study supports further development of PN-943 in UC registrational trials**

# Oral, IL-23 Receptor Specific Peptide Antagonist: PN-235

## Janssen Partnership

### Objective

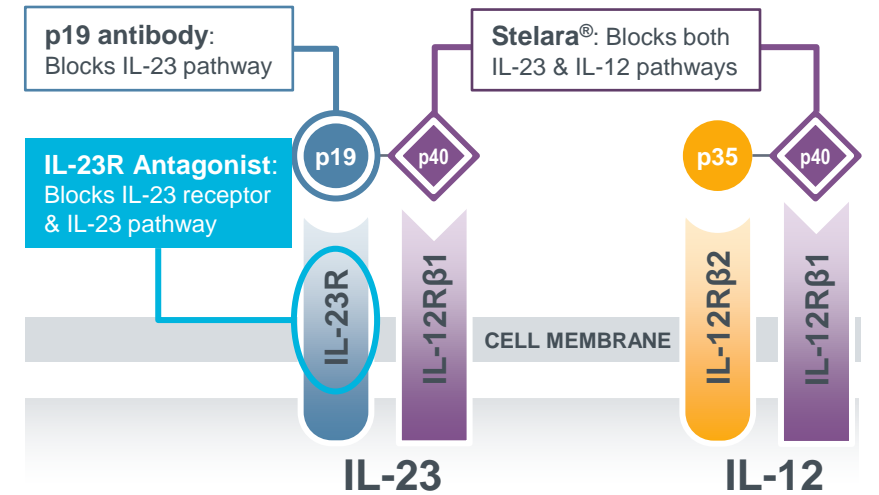
- Extend the Stelara® franchise and transition from injectable to oral targeted therapy
  - Stelara approved for psoriasis, psoriatic arthritis, Crohn's, UC
  - ~\$7.7B total global sales in 2020

### Terms

- May 2017: Partnership initiated
- \$112.5M in upfront and development milestones received to date
- Eligible for about additional \$875M in milestones, up to double digit royalties, US co-detailing rights
  - Study initiation milestones: \$25M (psoriasis, received April 2022)

### Status

- Focus on the PN-235 candidate, with its superior potency and PK/PD profile, for IBD and non-IBD indications
  - **PN-235 (JNJ-77242113)**: Ph1 completed in 2021
  - **Advancing in psoriasis indication in 240 patient Ph2b FRONTIER 1 study, 80 patient Ph2 SUMMIT study, 27 patient Ph1 study in Japanese/Chinese NHVs**
  - **Ph2 study initiations in IBD indications expected in 2023**



### Stelara® is a key Janssen franchise

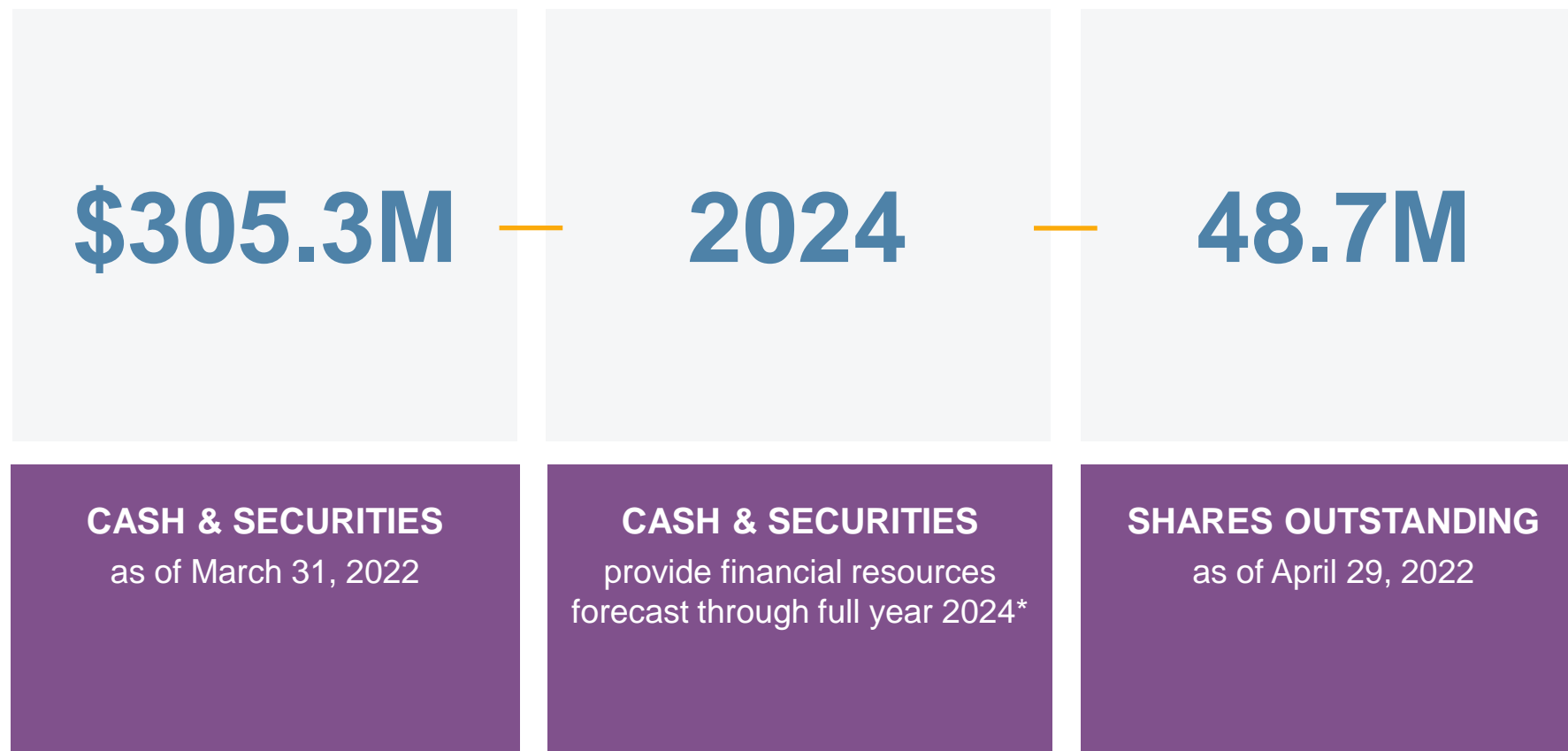
- ~\$7.7B total global sales in 2020





# Financial Highlights

## Financial Resources Forecast Extends Through Full Year 2024\*



*\*Based on our current operating plan and expenditures. These estimates may change as new events occur and additional information is obtained.*

# Upcoming Catalysts in 2022 and Beyond

## Significant Opportunities to Unlock and Capture Value in the 12-24 Months Ahead

Products	Anticipated Events in 2022				2023	
	Q1	Q2	Q3	Q4		
Rusfertide	1	<ul style="list-style-type: none"> <li><b>VERIFY:</b> Ph3 250 patient PV study initiation</li> </ul>				<ul style="list-style-type: none"> <li>Ph3 enrollment completion (1H)</li> <li>Ph2 randomization results (Q1)</li> </ul>
	2	<ul style="list-style-type: none"> <li><b>REVIVE:</b> Ph2 PV study</li> <li><b>PACIFIC:</b> Ph2 PV study</li> </ul>				
	3	<ul style="list-style-type: none"> <li><b>HH</b> clinical PoC achieved; opportunity in phlebotomy resistant HH arthropathy sub-population</li> </ul>				
PN-943	4	<ul style="list-style-type: none"> <li><b>IDEAL:</b> Topline results reported</li> </ul>				
		<ul style="list-style-type: none"> <li><b>Partnering efforts</b></li> </ul>				
PN-235	5	<ul style="list-style-type: none"> <li>Ph2 initiation –\$25M milestone</li> <li><b>Plaque psoriasis: Ph2b FRONTIER 1 (240 patients); Ph2 SUMMIT (80 patients)</b></li> </ul>				<ul style="list-style-type: none"> <li>Ph2 study results</li> <li>IBD study initiation (\$10M milestone)</li> </ul>
Discovery and Pre-Clinical	6	<ul style="list-style-type: none"> <li>Nomination of <b>new development candidate</b> – new target for new indication(s)</li> </ul>				<ul style="list-style-type: none"> <li><b>Oral hepcidin</b> mimetic candidate</li> </ul>



Thank you