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# 2025: A Year of Defining Catalysts

J.P. Morgan Healthcare Conference

Hervé Hoppenot | January 13th, 2025



# Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the opportunities for growth presented by Incyte's pipeline and products; expectations regarding Incyte's R&D and commercial execution; expected revenue contribution from near-term launches; additional label expansion opportunities; projected launches, pivotal readouts, phase 3 study initiations and proof of concept readouts; the timing of clinical trials and regulatory submissions; potential high impact launches and high impact pipeline programs; Incyte's positioning for 2026 and beyond; and expectations regarding 2025 catalysts and newsflow items.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: future research and development, including the possibility that clinical trials will be unsuccessful or otherwise fail to meet applicable regulatory standards and/or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials, including the ability to enroll subjects in accordance with planned schedules; determinations made by FDA and other regulatory agencies; Incyte's relationships with its collaboration partners; the efficacy or safety of Incyte's products; the acceptance of Incyte's products in the marketplace; market competition; variations in demand for Incyte's products; price regulation or limitations on reimbursement/coverage for Incyte's products; sales, marketing, manufacturing and distribution requirements, including Incyte's ability to successfully commercialize and build commercial infrastructure for newly approved products; unplanned expenses, including expenses relating to litigation or strategic activities; variations in foreign currency exchange rates; and other risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its annual report on form 10-K and the 10-Q filed for the quarter ending on September 30, 2024. Incyte disclaims any intent or obligation to update these forward-looking statements.

# 2024: Strong Revenue Growth and Significant R&D Progress

## Key Commercial Highlights

First 9 months 2024  
Total Revenue:

**\$3.1 billion**      **+14%** Y/Y

**Jakafi**<sup>®</sup>  
ruxolitinib (tablets)

**+6%**<sup>1</sup> Y/Y

**Opzelura**<sup>™</sup>  
(ruxolitinib) cream 1.5%

**+52%**<sup>1</sup> Y/Y

## R&D and Regulatory Achievements

- ✓ **Niktimvo** approved by FDA for 3L+ cGVHD
- ✓ Submitted sNDA for **Ruxolitinib Cream** in pediatric AD
- ✓ Submitted sBLA for **Retifanlimab** in SCAC
- ✓ Submitted sBLA for **Tafasitamab** in r/r FL
- ✓ Disclosed **CDK2i** PoC data and pivotal study plans
- ✓ Disclosed **BETi** data and pivotal study plans
- ✓ Refocused pipeline with emphasis on novel biology and highest patient impact

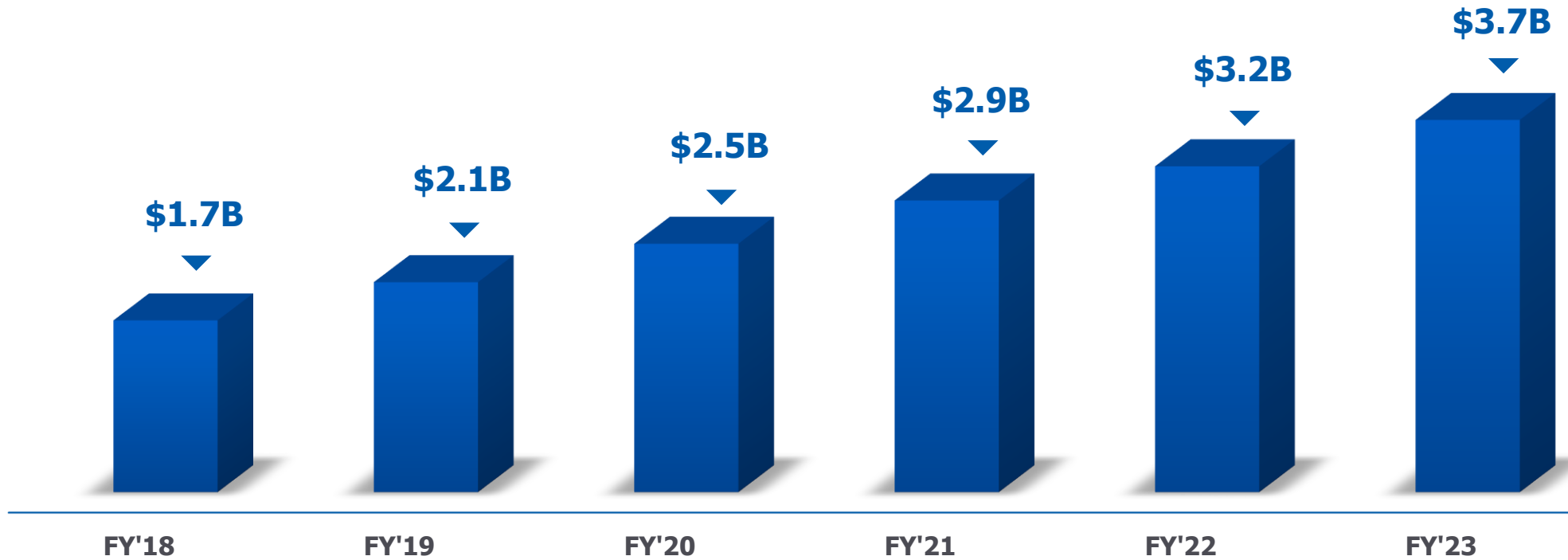
**Strong Cash Flow; Expanding Operating Margins**  
**Completed \$2B Share Repurchase**  
**Strong Balance Sheet with ~\$2B Cash and No Debt**<sup>1</sup>



cGVHD= chronic graft-versus-host disease; AD= atopic dermatitis; SCAC= squamous cell anal carcinoma; r/r= relapsed/refractory; FL= follicular lymphoma; PoC= proof-of-concept  
1. As of 9/30/2024

# ~17% Total Revenue CAGR Over Past 5 Years

## Total Revenue\*



\* Revenue excludes one-time items. CAGR= compound annual growth rate (2018-2023)

# 2025: Transformational Year for Incyte

4

Potential Launches

**Niktimvo™**

3L+ GVHD

**Retifanlimab**

SCAC

**Tafasitamab**

r/r FL

**Ruxolitinib Cream**

Pediatric AD

3+

Phase 3 Study Initiations

**BETi**

2L MF

**Ruxolitinib Cream**

Mild to Moderate HS

**CDK2i**

Ovarian Cancer

4

Pivotal Readouts

**Povorcitinib**

Moderate to Severe HS

**Ruxolitinib Cream**

Prurigo Nodularis

**Tafasitamab**

1L DLBCL

**Ruxolitinib XR**

MF, PV, GVHD

7

Proof of Concept Readouts

**Povorcitinib**

CSU

**Povorcitinib**

Asthma

**mCALR**

MF

**mCALR**

ET

**JAK2V617Fi**

MF

**KRASG12D**

Solid Tumors

**TGFBR2xPD-1**

Solid Tumors

# Expected Revenue Contribution from Near-term Launches

Four new launches in 2025 represent potential for ~\$1 billion incremental revenues by 2029

Niktimvo™	Ruxolitinib Cream	Tafasitamab	Retifanlimab
<p><b>Approved</b> in 3L+ chronic Graft-Versus-Host Disease (GVHD)</p> <ul style="list-style-type: none"> <li>US launch expected in <b>Q1'25</b></li> </ul> <p>Added to <b>NCCN Clinical Practice Guidelines in Oncology</b></p>	<p>sNDA submitted for pediatric Atopic Dermatitis (AD)</p> <ul style="list-style-type: none"> <li>Approval anticipated in <b>H2'25</b></li> </ul> <p>Potential to be <b>first topical JAK inhibitor approved</b> for pediatric patients in the United States</p>	<p>sBLA submitted for Follicular Lymphoma (FL)</p> <ul style="list-style-type: none"> <li>Approval anticipated in <b>H2'25</b></li> </ul> <p>First study to validate <b>combination approach of an anti-CD19 with anti-CD20</b> in FL</p>	<p>sBLA submitted for Squamous Cell Anal Carcinoma (SCAC)</p> <ul style="list-style-type: none"> <li>Approval anticipated in <b>H2'25</b></li> </ul> <p>Potential to become the <b>new standard of care (SoC) treatment</b> for advanced SCAC</p>
<p><b>~6,000</b> (Currently treated 3L+ patients in US)</p>	<p><b>~2-3 million</b> (pediatric AD patients in US)</p>	<p><b>~23,000</b> (r/r FL patients in US/EU)</p>	<p><b>~8,000</b> (a/m SCAC patients in US/EU)</p>

## Additional Label Expansion Opportunities:

**Niktimvo in 1L cGVHD**  
(~4,000 newly diagnosed pts/year in US)

**Ruxolitinib Cream in PN**  
(>200k PN pts in US)

**Ruxolitinib Cream in HS**  
(~150k mild/mod HS pts in US)

**Tafasitamab in 1L DLBCL**  
(~32,000 treated 1L DLBCL pts (IPI 3-5) in US/EU)



# >10 Potential High Impact Launches by 2030

Product	Indication	Status	2025	2026	2027	2028	2029	2030+
Derm/IAI <sup>†</sup>	Ruxolitinib Cream	Pediatric AD	sNDA	█				
		Prurigo Nodularis	Phase 3		█			
		HS (mild/mod)	Phase 3			█		
	Povorcitinib	HS (mod/sev)	Phase 3		█			
		Vitiligo	Phase 3			█		
		Prurigo Nodularis	Phase 3				█	
MPN/GVHD	Axatilimab	3L cGVHD	Approved	█				
		1L cGVHD	Phase 2					█ + ruxolitinib
		1L cGVHD	Phase 3				█ + steroids	
	BETi	MF	Phase 3*				█	
	mCALR	MF & ET	Phase 1				█	
	JAK2V617Fi	MF, PV & ET	Phase 1					█
Ruxolitinib XR	MF, PV, GVHD	BE		█				
Oncology	KRASG12D	Solid Tumors	Phase 1					█
	TGFβR2×PD-1	Solid Tumors	Phase 1					█
	CDK2i	Solid Tumors	Phase 3*			█		
	Retifanlimab	SCAC	Phase 3	█				
	Tafasitamab	FL	Phase 3	█				
1L DLBCL		Phase 3		█				

\* In planning

Potential U.S. approval/launch range and U.S. addressable market size █ < \$1B █ \$1-3B █ > \$3B



† MRGPRX2 removed due to paused enrollment

# Overview of Three High Impact Pipeline Programs

**IAI/  
Dermatology**

## **Povorcitinib**

Potential for:

- Near-term revenue contribution
- Best-in-class therapy
- Address multi billion-dollar markets

**MPN**

## **mCALR**

- Transformative potential
- Multi-billion market opportunity

**Oncology**

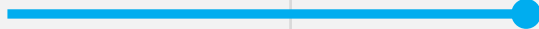

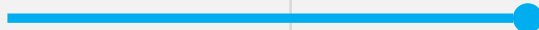
## **CDK2 Inhibitor**

- Opportunity to be first-in-class
- Address significant patient need



# Povorcitinib: Pivotal Studies in Three Indications

Potential for best-in-class efficacy across indications with high unmet need

Indication	Development Stage		U.S. Positioning	U.S. Prevalence
	POC	Pivotal		
<b>Hidradenitis Suppurativa (moderate/severe)</b>			<b>First Oral</b>	>300K <sup>1</sup>
<b>Vitiligo (BSA ≥ 5%)</b>			<b>First Oral</b>	>1.5M
<b>Prurigo Nodularis</b>			<b>First Oral</b>	>200K <sup>2</sup>



BSA= body surface area

1. Garg A, Kirby JS, Lavian J, Lin G, Strunk A. Sex- and Age-Adjusted Population Analysis of Prevalence Estimates for Hidradenitis Suppurativa in the United States. JAMA Dermatol. 2017a Aug 1;153(8):760-764
2. Ständer S, Augustin M, Berger T, Elmariah S, Korman NJ, Weisshaar E, Yosipovitch G. Prevalence of prurigo nodularis in the United States of America: A retrospective database analysis. JAAD Int. 2020 Dec 1;2:28-30

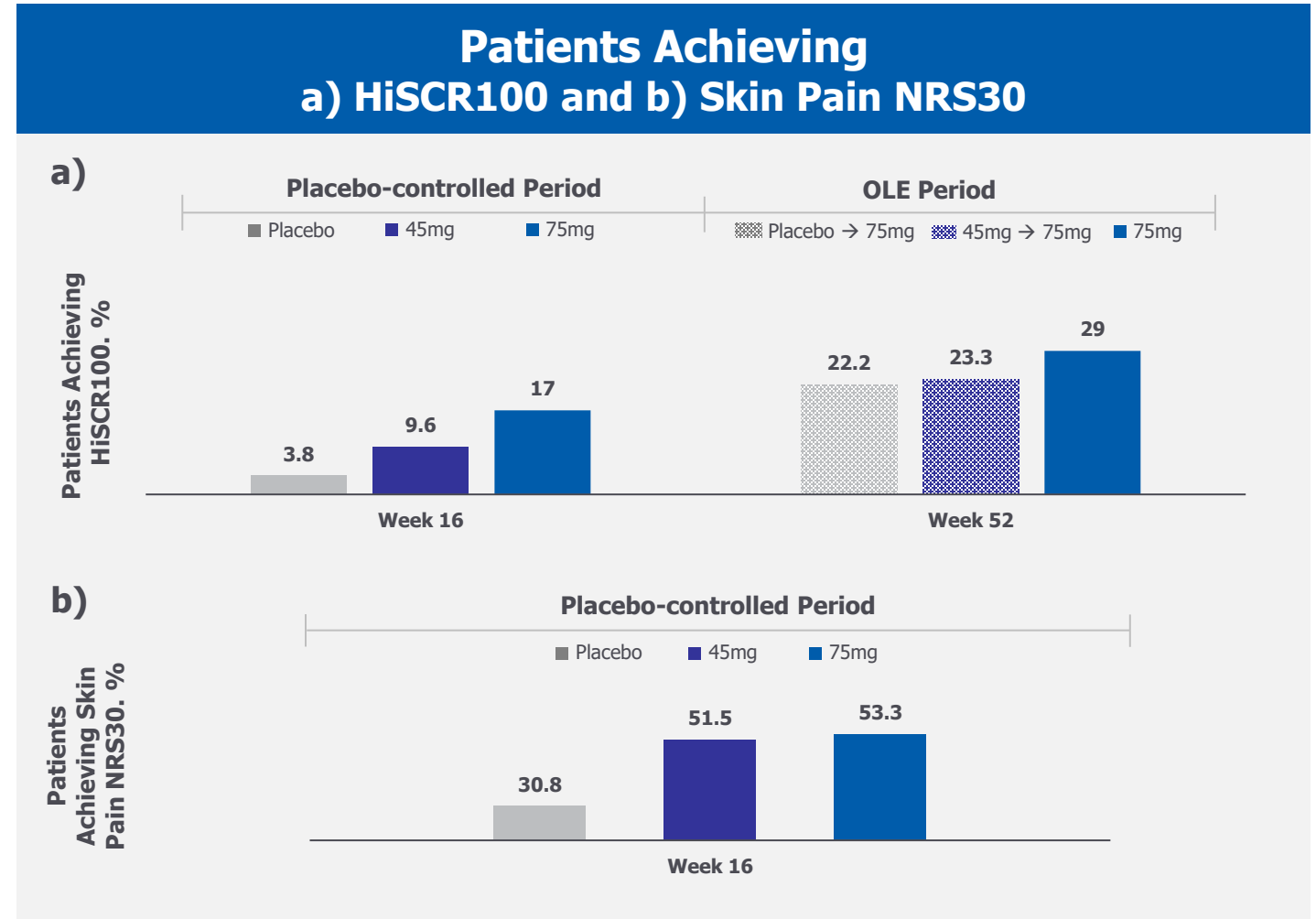
# Povorcitinib in Moderate/Severe Hidradenitis Suppurativa

Potential to change the current standard of care

- ✓ Phase 3 studies **fully enrolled**
- ✓ Limited efficacious treatment options with **no oral therapy approved**
  - **Biologic-like efficacy**
  - Significant and fast **impact on pain**
- ✓ >300K moderate-severe patients in the U.S.<sup>1</sup> with **greater than \$3 billion total market opportunity**

## Next Steps

Phase 3 data expected in **H1 2025**



OLE= open label extension

1. Calao M, Wilson JL, Spelman L, Billot L, Rubel D, Watts AD, Jemec GBE. Hidradenitis Suppurativa (HS) prevalence, demographics and management pathways in Australia: A population-based cross-sectional study. PLoS One. 2018 Jul 24;13(7) Adapted from Kirby S, et al. JAAD. 2023; DOI:10.17632 and Kirby S, EHSF 2023. S-0906

# Povorcitinib in Extensive Nonsegmental Vitiligo

- ✓ Phase 3 studies **enrolling**

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- ✓ Limited treatment options with **no oral therapy approved**

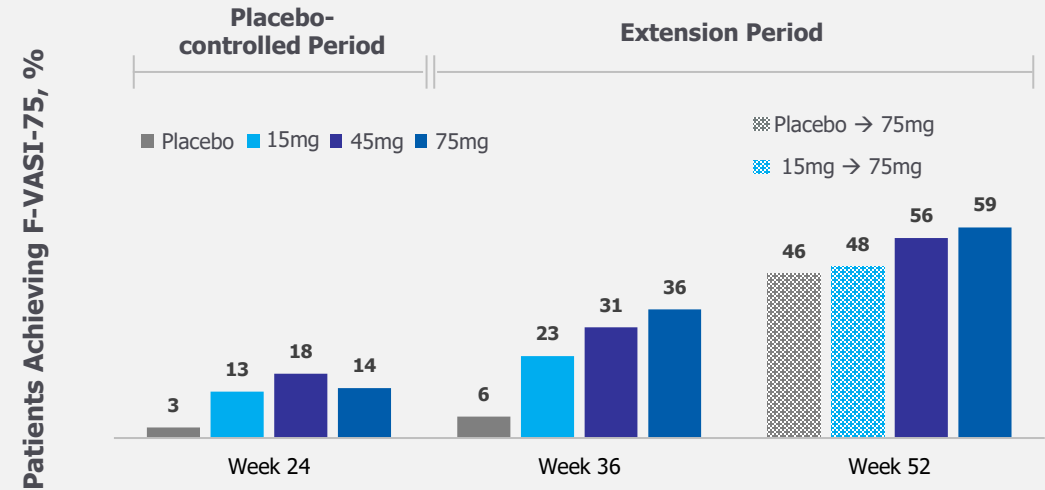
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- ✓ >1.5M diagnosed (BSA  $\geq$  5%) **vitiligo** patients in the U.S. with **greater than \$3 billion total market opportunity**

## Next Steps

Phase 3 data expected in **2026**

## Phase 2 Results in Extensive Nonsegmental Vitiligo



F-VASI percent improvement from baseline<sup>1</sup>:

44.4%

85.2%

99%



F-VASI75 = The proportion of participants achieving at least a 75% improvement in the facial vitiligo area scoring index; F-VASI = facial vitiligo area scoring index

1. Patient received povorcitinib 15mg qd through Week 24 then switched to povorcitinib 75mg qd through Week 52

Pandya A., et al. Efficacy and Safety of Povorcitinib for Extensive Vitiligo: 52-Week Results From a Double-Blinded, Placebo-Controlled, Dose-Ranging Phase 2b Study

# Povorcitinib in Prurigo Nodularis

✓ Phase 3 studies **enrolling**

✓ Limited treatment options with **no oral therapy approved**

✓ >200K patients with prurigo nodularis in the U.S. **with ~ \$1 billion total market opportunity**

## Next Steps

Phase 3 data expected in **2026**

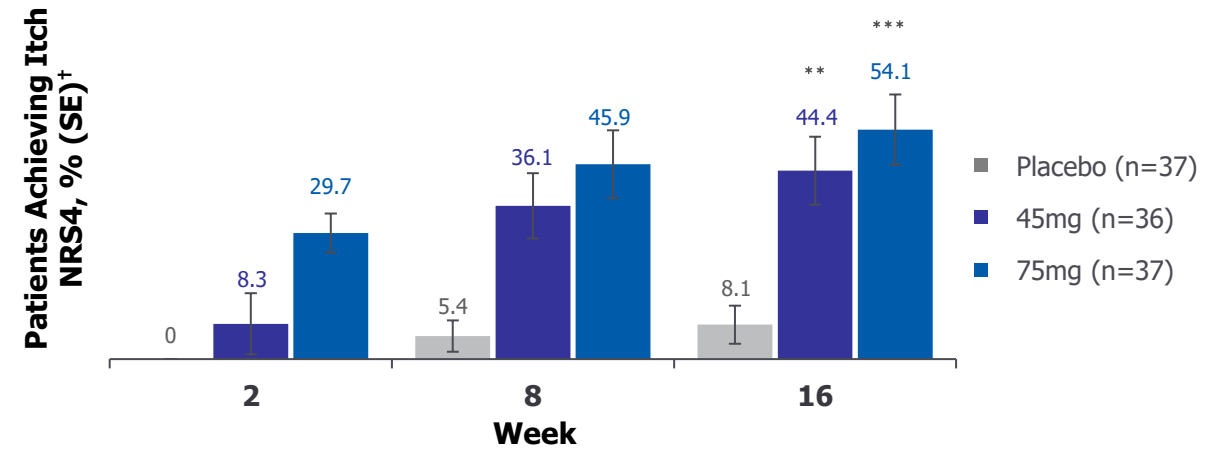


\*\*  $P < 0.001$  vs placebo; \*\*\*  $P < 0.0001$  vs placebo.

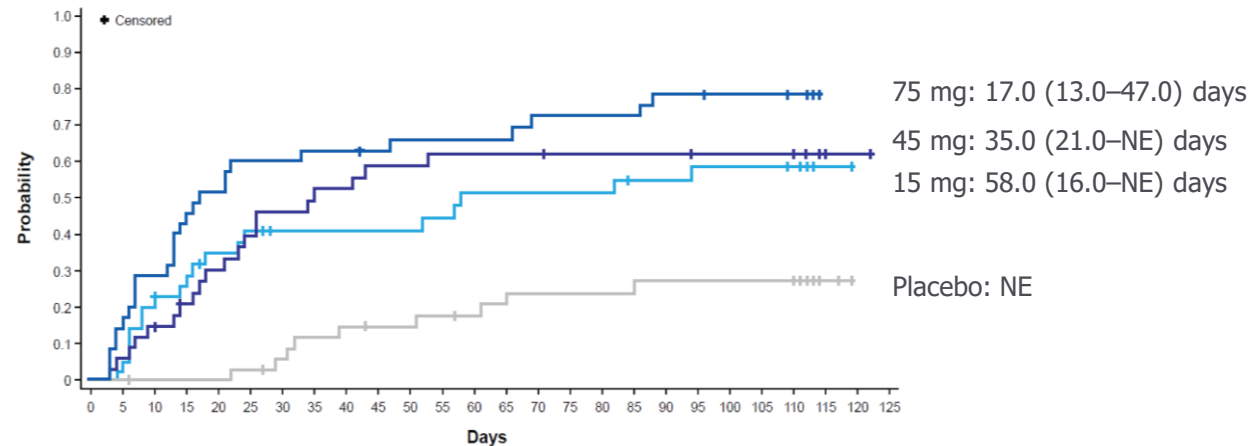
† Patients with missing postbaseline data or use of rescue therapy were imputed as nonresponders.  $P$  value calculated for odds ratio of active treatment vs placebo in the intent-to-treat population.

## a) Patients Achieving Itch NRS4 b) Median (95% CI) Time to Itch NRS4

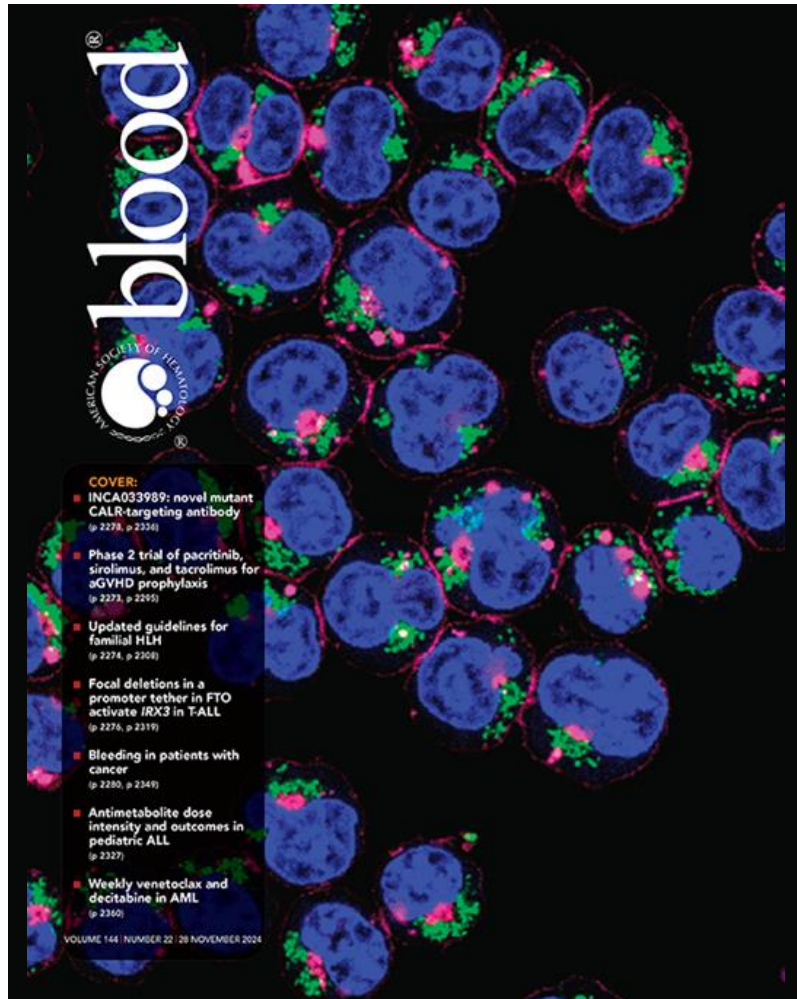
a)



b)



# mCALR: Featured in *Blood*, November 2024



## Selective targeting of mutated calreticulin by the monoclonal antibody INCA033989 inhibits oncogenic function of MPN

28 NOVEMBER 2024 | VOLUME 144, ISSUE 22

“ This study opens the door to a potentially transformative therapy, combining potent JAK-STAT inhibition with the ability to spare nonmutant hematopoiesis, potentially reversing the competitive advantage of the malignant clone and enabling healthy, wild-type hematopoiesis to regenerate.”

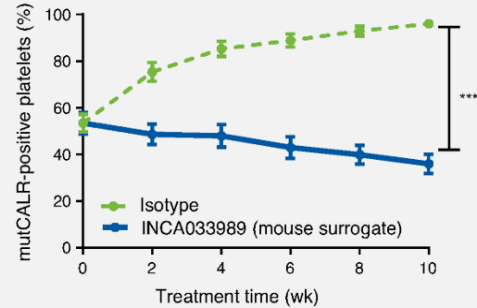
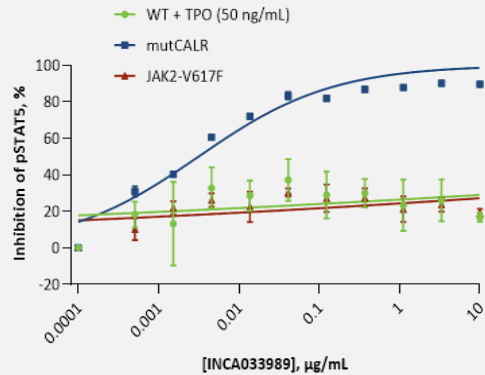
– Camelia Benlabiod and Bethan Psaila, University of Oxford



# mCALR: Potential to Eradicate the Malignant Clone

Disease-modifying potential with first-in-class targeted therapy for mCALR positive MF and ET patients

## mCALR Selective Inhibition<sup>1,2</sup>

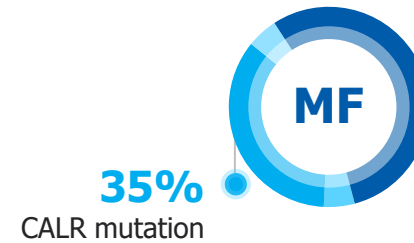


\*\*\* p < .001

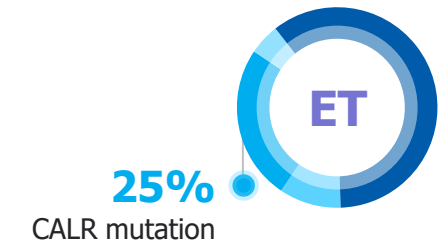
## Mutation Prevalence<sup>3</sup> & US/EU Opportunity

~65,000 total MF patients<sup>4</sup>

~250,000 total ET patients<sup>4</sup>



~23,000 mCALR+ MF patients



~63,000 mCALR+ ET patients

## Next Steps

Proof-of-concept data expected in 2025

MF= myelofibrosis; ET= essential thrombocythemia; WT= wild type; TPO= thrombopoietin

1. Reis ES, et al. ASH 2022. Oral presentation.
2. Reis ES, et al. Selective targeting of mutated calreticulin by the monoclonal antibody INCA033989 inhibits oncogenic function of MPN. Blood. 2024 Nov 28;144(22):2336-2348. doi: 10.1182/blood.2024024373. PMID: 39255409.
3. Adapted from Klampfl T, et al. N Engl J Med. 2013;369:2379-2390
4. Includes US and Europe

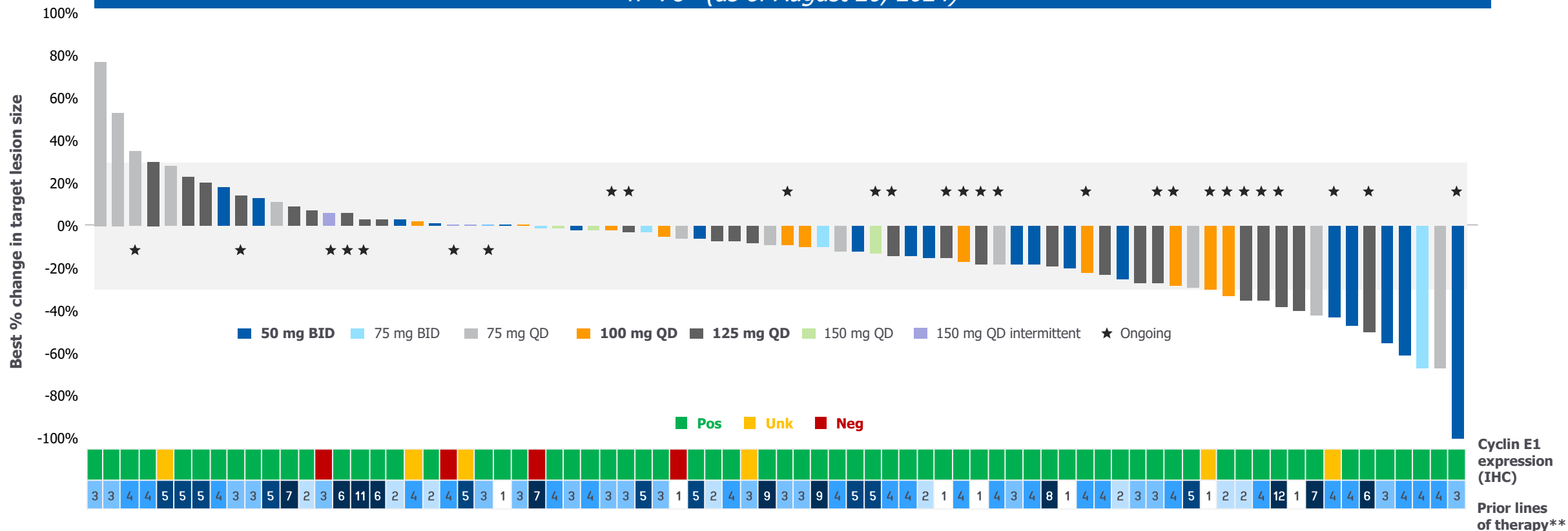


# CDK2 Inhibitor in Ovarian Cancer

Multiple complete and partial responses with a favorable adverse event profile

## Dose Escalation and Dose Expansion, Ovarian Cancer Patients

n=78\* (as of August 26, 2024)



## Next Steps

Pivotal trial in ovarian cancer to **initiate in 2025**



\* Total 89 ovarian cancer patients with 78 patients shown here having at least 1 postbaseline scan; 8 additional patients ongoing but before 1st postbaseline scan; 3 additional patients discontinued treatment prior to 1st postbaseline scan  
 \*\* As of 26 August 2024, number of prior lines currently under data cleaning  
 BID= twice daily; CDK= cyclin-dependent kinase; IHC= immunohistochemistry; intermittent= (5 days on, 2 days off); QD= once daily; UNK= unknown  
 Data on file. Incyte Corporation (as of 26 August 2024)

# CDK2i Development Path

Potential registration scenarios for ovarian cancer – study designs\*

#	Study Design	Phase	Clinical Setting (Cyclin E1+ by IHC)	Line of Therapy	Treatment Arms	Primary Endpoint	Data	Market Opportunity
1	Expand current study or single arm monotherapy (Accelerated approval)	2	Platinum resistant ovarian cancer; endometrial cancer	2-4L	INCB123667	ORR	H2'26	~25,000 PROC treatment eligible patients in US/EU
2	Randomized controlled trial (incl. IA for ORR)	3	Platinum resistant ovarian cancer	2-4L	INCB123667 vs. Chemotherapy	PFS (IA: ORR)	H2'27	
3	Randomized controlled trial	3	Maintenance after 1L chemotherapy	1L	INCB123667+ Bevacizumab vs. Bevacizumab	PFS	2029	~25,000 HRD- 1L maintenance eligible patients in US/EU

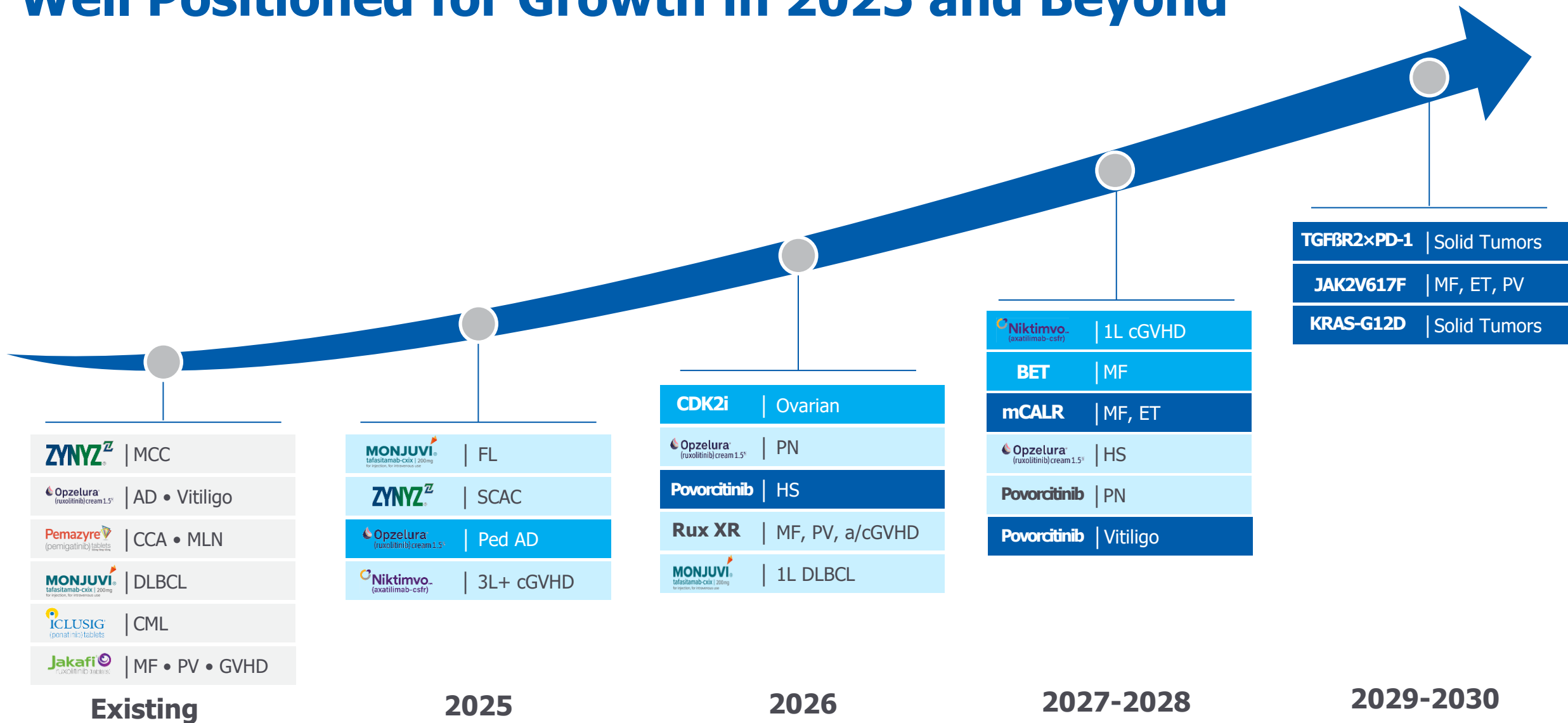
**For patient selection/stratification, an IHC-based co-diagnostic is currently being developed and will be included into the pivotal studies of the clinical development program**



1L/2L/4L= first/second/forth line of treatment; IA= interim analysis; IHC= immunohistochemistry; ORR= overall response rate; PFS= progression-free survival; PROC= platinum-resistant ovarian cancer; HRD= homologous recombination deficiency  
 \* Regulatory Feedback Pending



# Well Positioned for Growth in 2025 and Beyond



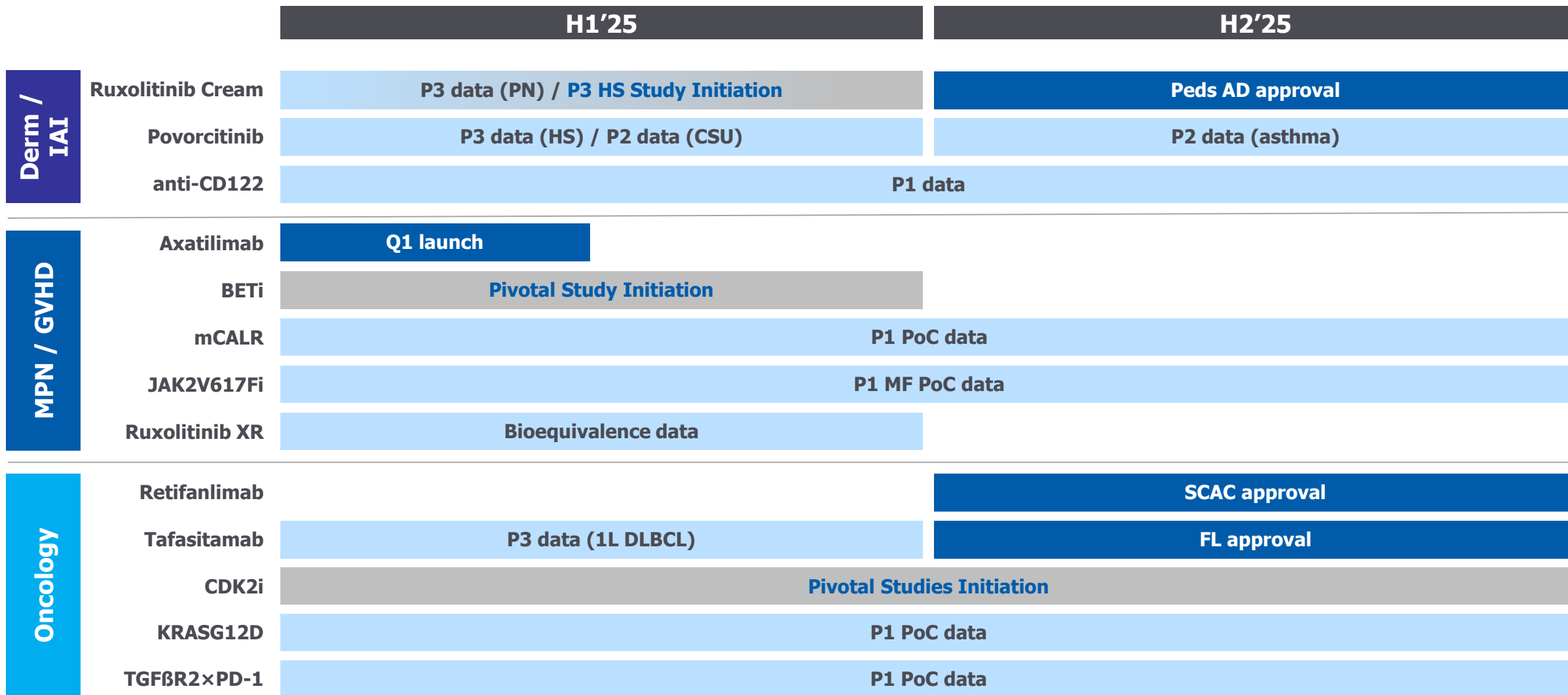
Potential U.S. approval range and U.S **addressable market size**

■ < \$1 billion   
 ■ \$1-3 billion   
 ■ > \$3 billion



Anticipated earliest approval

# 2025: A Year of Defining Catalysts



MPN= myeloproliferative neoplasms; GVHD= graft-versus-host disease; IAI= inflammation and autoimmunity; SCAC= squamous cell anal carcinoma; FL= follicular lymphoma; PoC= proof-of-concept; MF= myelofibrosis; DLBCL= diffuse large B-cell lymphoma; AD= atopic dermatitis; PN= prurigo nodularis; HS= hidradenitis suppurativa; CSU= chronic spontaneous urticaria



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