

## **2023 Fourth Quarter & Full-Year Financial and Corporate Update**

February 13th, 2024



## Fourth Quarter & FY 2023 Earnings Call Agenda





## **Forward Looking Statements**

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including any discussion of the following: Incyte's potential for continued performance and growth; Incyte's financial guidance for 2024, including its expectations regarding sales of Jakafi; expectations regarding demand for and sales of Opzelura, among other products; expectations regarding the potential and progress of programs in our pipeline, including INCB123667, INCB160058 and INCB161734; expectations regarding ongoing clinical trials and clinical trials to be initiated, including combination trials of ruxolitinib twice daily (BID) with zilurgisertib (INCB000928) and BETi (INCB057643), a phase 3 study of BETi and achieving clinical proof-of-concept for zilurgisertib, a phase 1 study evaluating the mCALR monoclonal antibody (INCA033989), a phase 3 trial of povorcitinib in prurigo nodularis, a phase 1/2 trial of ruxolitinib and axatilimab in chronic GVHD, various trials in our oral small molecule PD-L1 program, various phase 2 and 3 trials for ruxolitinib cream, and additional clinical trials across our MPH/GVHD, oncology, IAI and dermatology programs; our expectations regarding regulatory filings; expectations regarding the potential approval of QD Ruxolitinib (XR) in approximately two years; expectations regarding the number of products Incyte may launch by 2030, and our expectations regarding 2024 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: further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; determinations made by the FDA, EMA, and other regulatory agencies; Incyte's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte's collaboration partners; the effects of announced or unexpected variations on limitations on reimbursement or coverage for Incyte's products and the products of Incyte's ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected 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 for the year ended December 31, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.



# Fourth Quarter & FY 2023 Review

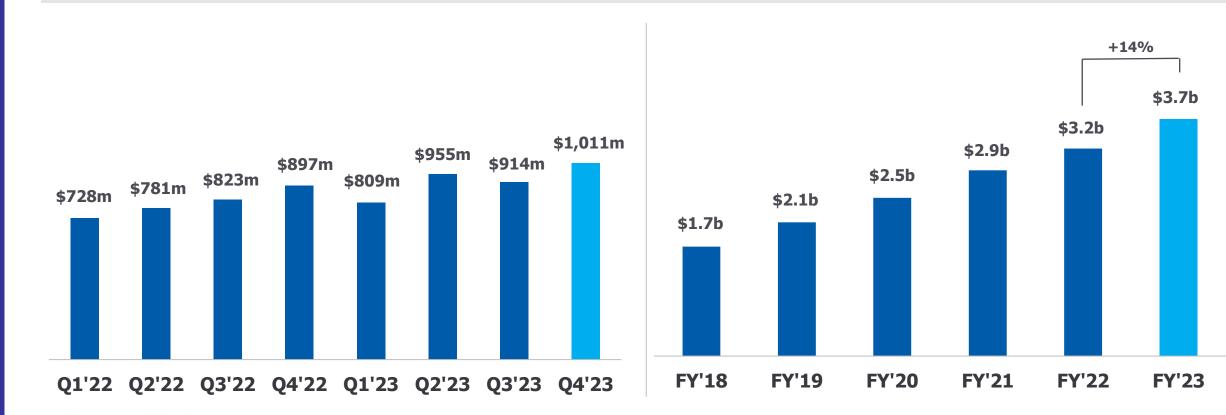
Hervé Hoppenot, Chief Executive Officer





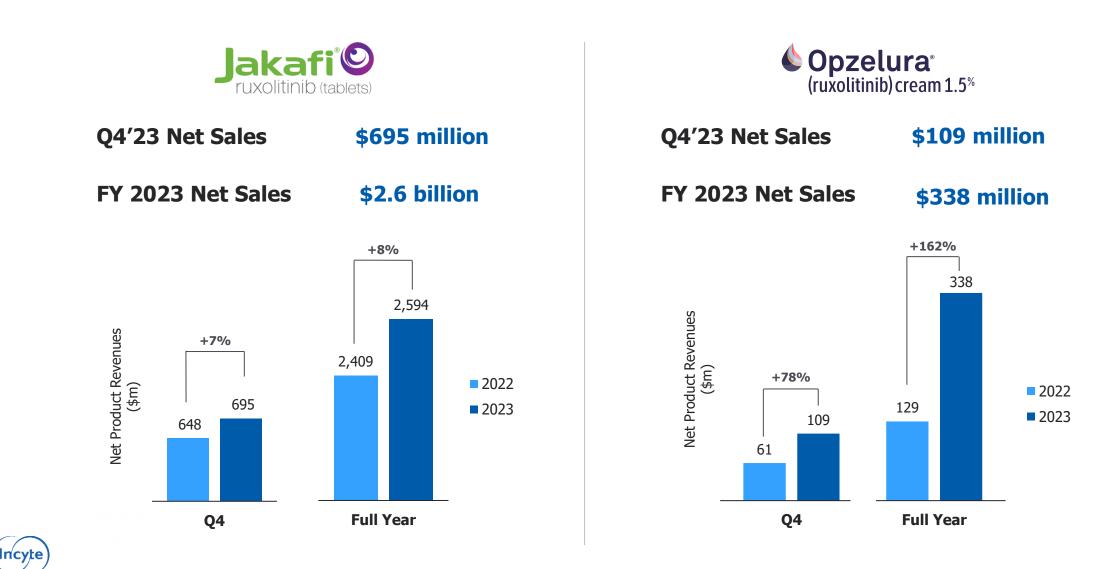
## **Total Quarterly Revenues Reached \$1 Billion For First Time**

## **Total Product & Royalty Revenue**





**Double-Digit Revenue Growth Driven by Opzelura Launch** 



# >10 Potential High Impact Launches by 2030

Product	Indication	Status	2024	2025	2026	2027	2028	2029	2030+
Axatilimab	3L+ cGVHD	BLA submitted							
	1L (+ steroids)	Phase 3							
	1L (+ rux)	Phase 2							
	Pediatric AD	Phase 3							
	Prurigo N	Phase 3							
Ruxolitinib Cream	HS (mild/mod)	Phase 2							
	Lichen P	Phase 2							
	Lichen S	Phase 2							
	HS (mod/sev)	Phase 3							
Povorcitinib	Vitiligo	Phase 3							
	Prurigo N	Phase 3*							
BETi	MF	Phase 1							
Zilurgisertib	MF	Phase 1							
mCALR	MF & ET	Phase 1							
JAK2V617Fi	MF, PV & ET	Phase 1*							
	cSCC (monotherapy)	Phase 2							
Oral PD-L1	Solid Tumors (combination)	Phase 2							
CDK2	Solid Tumors	Phase 1							
10 <u>(0)/(</u> \$)									



# Gained Exclusive Global Rights to Monjuvi<sup>®</sup>/Minjuvi<sup>®</sup>

### **Impact of Asset Purchase Agreement:**

- ✓ Incyte now records revenues for Monjuvi in the U.S.
- ✓ MorphoSys is no longer eligible to receive:
  - Profit share in the U.S.
  - Royalties ex-U.S.
  - Milestones
- ✓ Significant operating efficiencies and cost synergies in commercial and development activities
- $\checkmark\,$  Adds to top line, with limited impact on operating income in 2024
- ✓ Incyte to capture full potential upside from future indications
  - Phase 3 data in 2L FL/MZL expected in 2024
  - Phase 3 data in 1L DLBCL expected in 2025
- ✓ Expected to be value accretive to Incyte

# **U.S.** Commercial Update

Barry Flannelly, General Manager, North America





# Jakafi Growth Driven by Increase in Total Patients Across All Indications



Q4'23 net sales: \$695m (+7% Y/Y) FY'23 net sales: \$2,594m (+8% Y/Y)

# Total patients grew across all indications (+6% versus 2022)

- Growth driven by PV and GVHD
- Maintaining market share in MF

## **Fourth Quarter Dynamics**

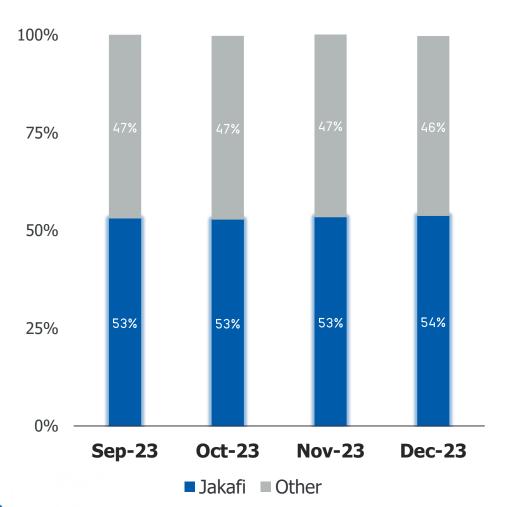
- Transient increase in free drug
- Increase in channel inventory

## FY'24 guidance of \$2.69 to \$2.75 billion

### Indication % by indication 30,000 FY'23 25,000 MF: 42% 20,000 15,000 **PV: 32%** 10,000 5,000 **GVHD: 19%** Other: 7% 0 2020 2021 2022 2023 2019

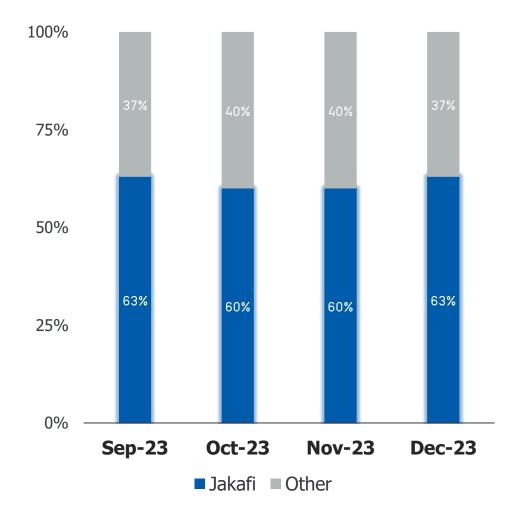
Total Patients on Jakafi by

## Jakafi: Maintaining Market Leadership & Share in Myelofibrosis



MF Total Patient Market Share

**MF New Patients** 



## **Continued Strong Demand Growth of Opzelura**



ncyte

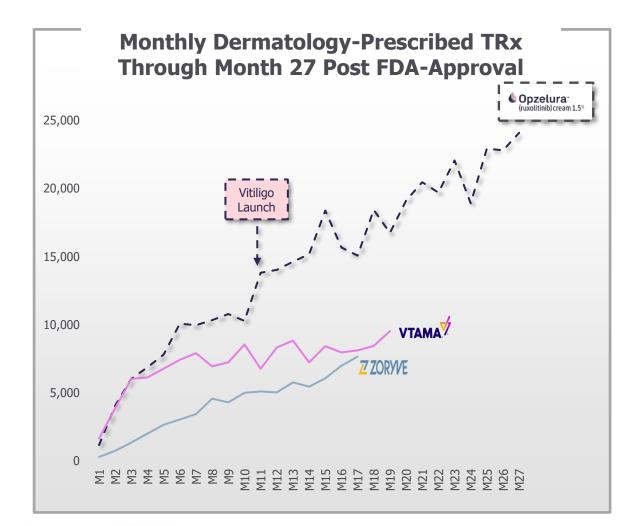
Q4'23 net sales: \$109m (+78% Y/Y)

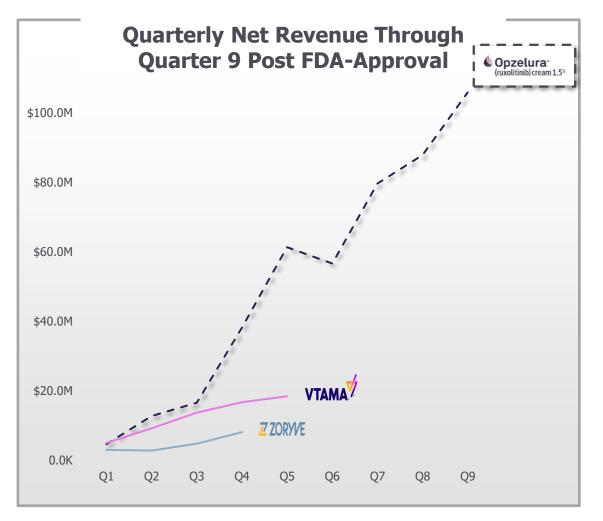
5% FY'23 net sales: \$338m (+162% Y/Y)

#### (Weekly) **US net sales: \$106m** in Q4'23 01'23 02′23 03'23 Q4′23 04'21 01'22 Q2'22 03′22 Q4′22 14,000 • **\$330m** for FY'23 12,000 Ex-US net sales: \$3m in Q4'23 • **\$8m** for FY'23 10,000 **Continued strong growth in U.S. TRx and refills** 8,000 ✓ TRx grew 77% Y/Y ✓ Refills grew 22% Q/Q 6,000 4,000 **Opzelura Refills** (Quarterly) 22% 2,000 Oct-21 Dec-21 Jan-22 Feb-22 Jan-22 Jun-22 Jun-22 Jun-22 Sep-22 Sep-22 Sep-22 Jan-23 Jun-23 Jun-22 Jun-23 Jun-22 Jun-23 Ju 01'23 02'23 03'23 04 '23

**Opzelura TRx** 

## **Opzelura: One of the Most Successful Dermatology Launches**







Source: IQVIA NPA through Dec 2023. Dermatologists include Dermatology and Dermato-Pathology specialties Competitor Net Revenue derived from Q3'23 Earnings reports (Riovant and Arcutis)

# **Key 2024 Initiatives to Drive Demand Growth of Opzelura**

## **Atopic Dermatitis**

- Differentiate on rapid itch control with results within minutes and hours
- ✓ Educate on long term results with as needed use
- Provider education on strong market access position for Opzelura and fulfillment process

## **Non-Segmental Vitiligo**

- ✓ Increased DTC investment
- Launch of Vitiligo Adherence Programs to educate patients and set treatment expectations
- Highlight 2-year data to demonstrate long term efficacy and safety

OR SCAN HERE





# Research & Development

Pablo Cagnoni, President, Head of Research & Development





## 2024 R&D Focus

MPN / GVHD	Oncology	IAI / Dermatology
Lead and Transform	Focus and Accelerate	Grow Opzelura and Expand Portfolio
Axatilimab	Oral PD-L1 advancement	<b>Opzelura</b> new indications
Ruxolitinib combinations + BETi + ALK2i	CDK2i PoC expected in 2024	<b>Povorcitinib</b> pivotal trials
mutCALR MAb	KRASG12Di in the clinic	Novel MoA's: IL-15RB & Others
<b>JAK2 V617Fi</b>	Build <b>next wave</b> beyond immuno- oncology	Novel Indications
QD Ruxolitinib (XR)		



## **R&D Execution in 2023 Supports Future Growth Drivers**

## **2023 R&D Key Achievements**

### **MPN/GVHD** Franchise

- Axatilimab: BLA submitted in 3L+ cGVHD
- BETi/ALK2i: Monotherapy and combination with ruxolitinib data
- mCALR mAb: Phase 1 initiated
- **JAK2V617Fi:** IND filed

### Oncology

- Oral PD-L1: Monotherapy and combination studies initiated
- CDK2i: Early signs of clinical activity
- KRASG12Di: Phase 1 initiated; first patient dosed

### IAI / Dermatology

#### **Opzelura**

- EU approval in vitiligo
- Positive Phase 3 pediatric AD data
- Positive Phase 2 data in mild/moderate HS

### Povorcitinib

- Positive Phase 2 data in PN
- Positive Phase 2 data in vitiligo
- Phase 3 studies in vitiligo initiated
- Phase 2 studies in asthma and CSU initiated

### IL-15Rβ

Phase 1 study initiated



## **Important Updates Expected in 2024**

## **Key Program Milestones in 2024**

### **MPN/GVHD** Franchise

### **Axatilimab:**

- FDA approval in 3L+ cGVHD
- Initiate Phase 3 study in combination with steroids in 1L cGVHD
- Initiate Phase 2 study in combination with ruxolitinib in 1L cGVHD
- BETi + ruxolitinib: Initiate Phase 3 study
- ALK2i + ruxolitinib: Achieve proof-of-concept

### Oncology

**CDK2i:** Phase 1 data presentation; establish proof-of-concept **Tafasitamab:** Phase 3 data in FL/MZL (inMIND)

### IAI / Dermatology

#### **Ruxolitinib Cream**

- Phase 2 data presentation in hidradenitis suppurativa
- sNDA submission in pediatric atopic dermatitis
- Phase 2 data in lichen sclerosus
- Phase 2 data in lichen planus
- Phase 2 data in combination with NB-UVB

#### **Povorcitinib**

- Phase 2 data presentation in prurigo nodularis
- Initiate Phase 3 study in prurigo nodularis

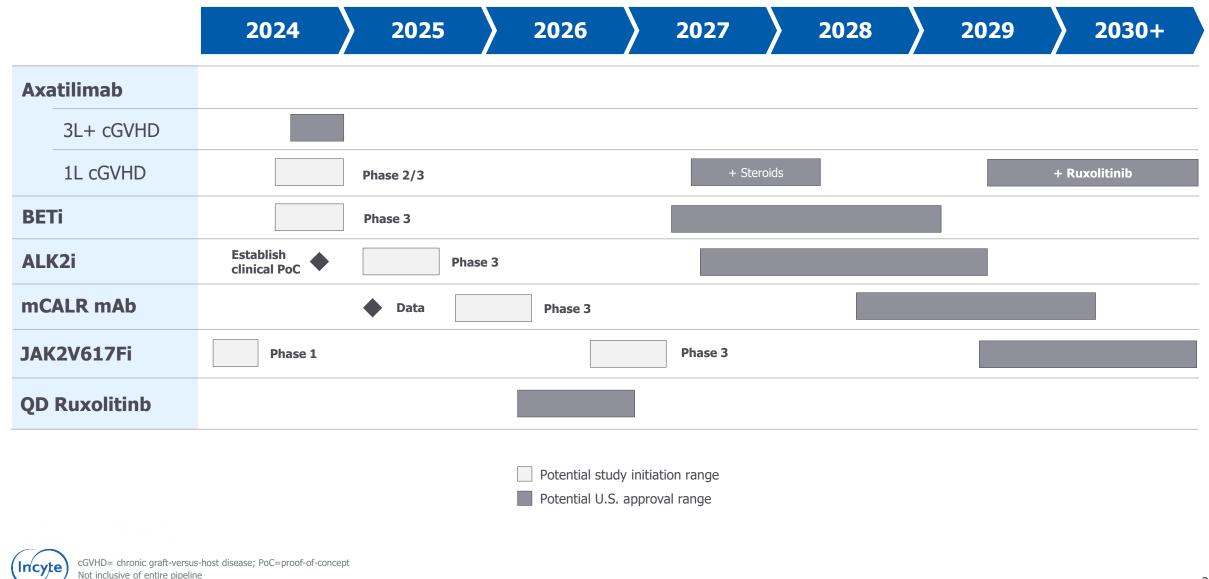
# **Clinical Development**

Steven Stein, Chief Medical Officer





# **Transformative Potential with MPN/GVHD Pipeline**

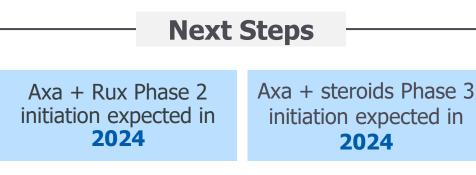


## **BLA submitted for Axatilimab in 3L+ cGVHD**

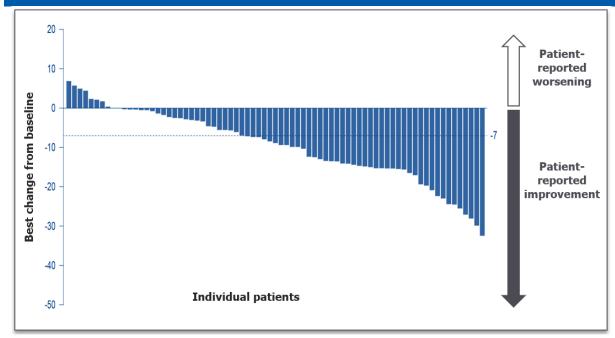
Approval anticipated in second half of 2024

### Primary efficacy endpoint of ORR met

- ✓ 73.8% ORR in the Axatilimab 0.3 mg/kg Q2W cohort
- Responses were durable and included a reduction in symptom burden
- Well tolerated with most common AEs consistent with on target effects of CSF-1R inhibition



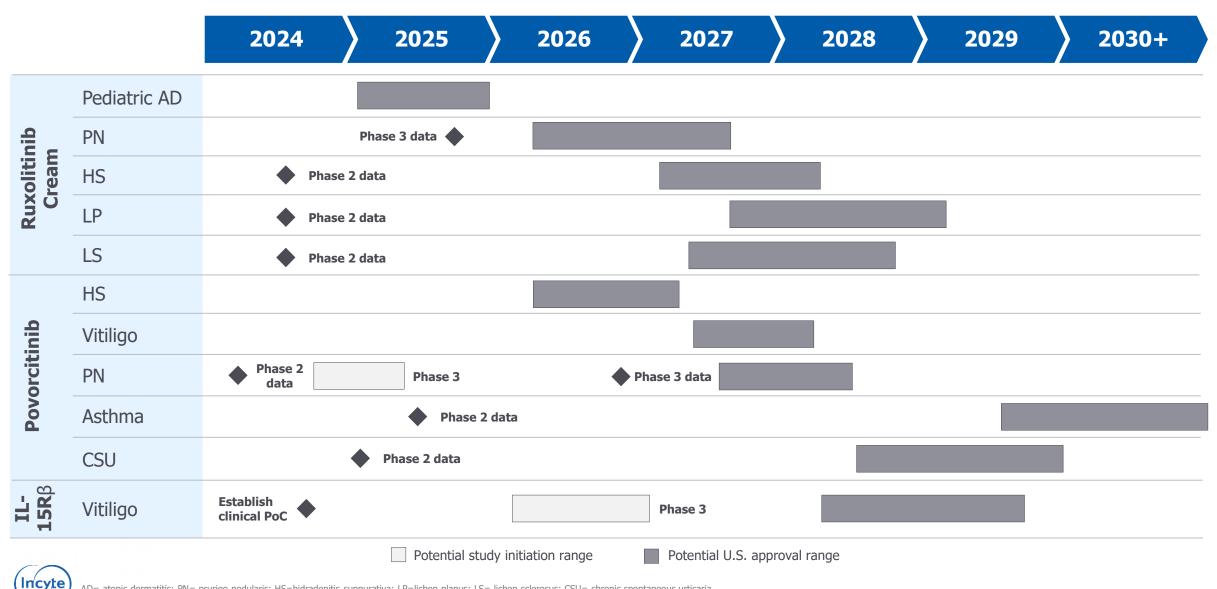
### Symptom Improvement for Axatilimab 0.3 mg/kg Q2W



Adapted from: Wolff Daniel, et al. Safety and Efficacy of Axatilimab at 3 Different Doses in Patients with Chronic Graft-Versus-Host Disease (AGAVE-201). Presented at ASH 2023.



# **Expanding IAI/Dermatology Pipeline**



## **Improvement in Disease Severity From Baseline Through Week 52 with Povorcitinib in HS**

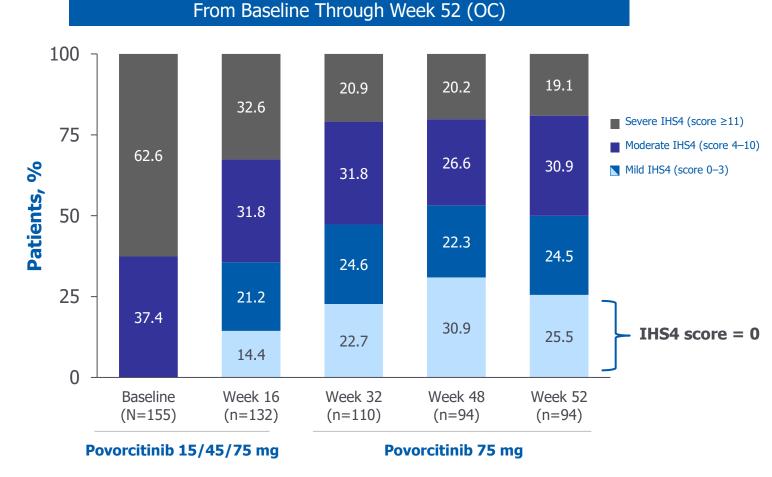
Efficacy During the Open-Label Extension Period of a Phase 2 Study

### Data presented at EHSF 2024

- Improvement in disease severity (IHS4) through Week 52
  - 25.5% of patients achieved an IHS4 score of 0 at Week 52
  - IHS4 score of 0 represents no nodules, abscesses or draining tunnels

Next Steps -

Two Phase 3 studies are enrolling (STOP-HS1 and STOP-HS2)



**Improvement in IHS4 Disease Severity** 

#### 쳤다니?

Incyte

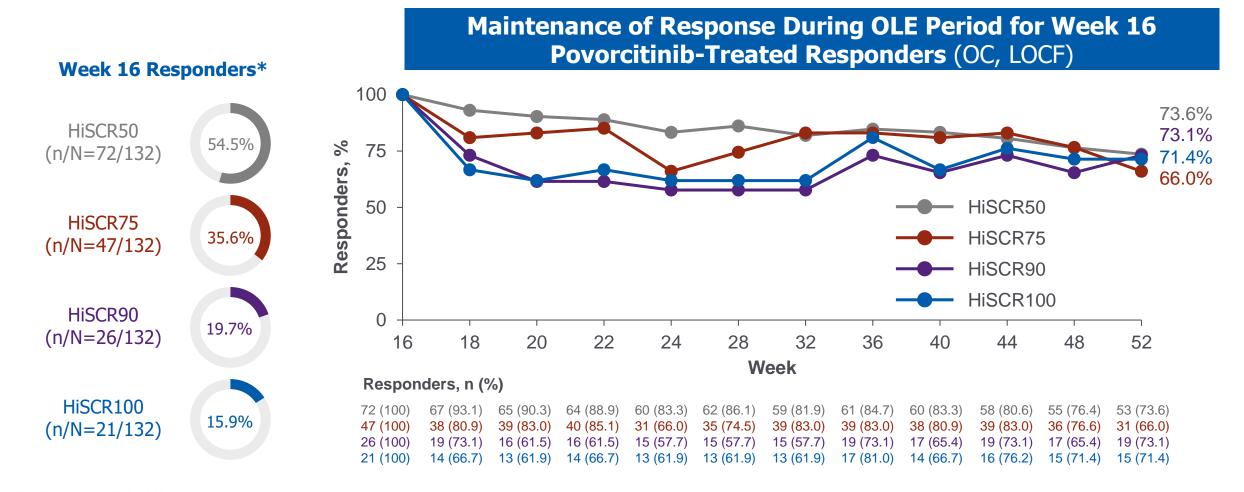
HS=hidradenitis suppurativa; EHSF= European Hidradenitis Suppurativa Foundation; IHS4=International hidradenitis suppurativa severity score system; OC=observed cases.

Per protocol, observed cases included patients randomized to any dose of povorcitinib during the placebo-controlled period.

Adapted from Bechara, F. et al. Maintenance of Response to Povorcitinib in patients With Hidradenitis Suppurativa: Efficacy During the Open-Label Extension Period of a Phase 2 Study. Presented at EHSF 2024.

## **Maintenance of Response with Povorcitinib in HS**

Efficacy During the Open-Label Extension Period of a Phase 2 Study





HiSCR=Hidradenitis Suppurativa Clinical Response; HiSCR50/75/90/100, ≥50%/75%/90%/100% reduction from baseline in AN count with no increase in the number of abscesses or draining tunnels; LOCF=last observation carried forward; OC=observed cases; OLE=open-label extension.

This analysis included 132 patients who received povorcitinib 15/45/75 mg from Day 1.

Adapted from Bechara, F. et al. Maintenance of Response to Povorcitinib in patients With Hidradenitis Suppurativa: Efficacy During the Open-Label Extension Period of a Phase 2 Study. Presented at EHSF 2024.

## **High-Potential Oncology Pipeline**

Advancing Research in Areas Where We Believe Can Have the Greatest Impact

	2024	2025	2026	2027	2028	2029	2030+
Tafasitamab							
FL/MZL	Phase 3 data 🔶						
1L DLBCL		Phase 3 data 🔶					
Oral PD-L1							
Monotherapy		Phase 2 data	•				
Combination(s)	Phase 2 data 🔶			Phase 3			
CDK2i	Establish clinical PoC	Р	hase 3				

Potential study initiation range

Potential U.S. approval range



## **KRASG12D Program**

### INCB161734

- Potent, selective and orally available G12D inhibitor
- KRAS<sup>G12D</sup> mutation found in:
  - 40% of PDAC patients
  - 15% of CRC patients
  - 5% of NSCLC patients
- Currently no approved G12D-targeting agents approved
  - High unmet need

## **Next Steps**

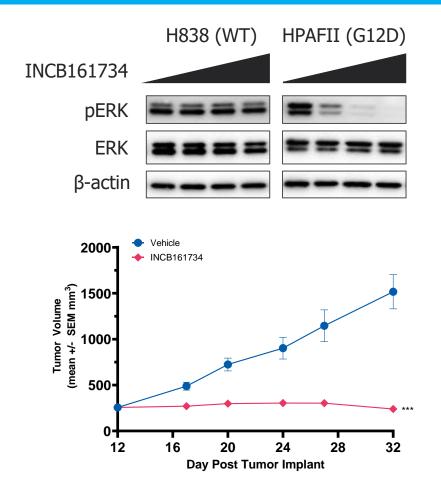
### Phase 1 study initiated

#### CLVE.



PDAC= pancreatic ductal adenocarcinoma; CRC= colorectal cancer; NSCLC= non-small cell lung cancer 1. in preclinical xenograft models \*\*\*  $p \leq 0.0005$ 

### **Robust preclinical anti-tumor activity<sup>1</sup>**



# **Financial Results**

Christiana Stamoulis, Chief Financial Officer





## **Non-GAAP adjustments**

- Management has chosen to present financial highlights for the quarter and year-to-date periods ended December 31, 2023 and 2022 on both a GAAP and Non-GAAP basis in the belief that this Non-GAAP information is useful for investors.
- Management uses such information internally and externally for establishing budgets, operating goals and financial planning purposes. These metrics are also used to manage the Company's business and monitor performance. The Company adjusts, where appropriate, for expenses in order to reflect the Company's core operations.
- The Company believes these adjustments are useful to investors by providing an enhanced understanding of the financial performance of the Company's core operations. The metrics have been adopted to align the Company with disclosures provided by industry peers.
- As changes in exchange rates are an important factor in understanding period-to-period comparisons, Management believes the presentation of certain revenue results on a constant currency basis in addition to reported results helps improve investors' ability to understand its operating results and evaluate its performance in comparison to prior periods. Constant currency information compares results between periods as if exchange rates had remained constant period over period. The Company calculates constant currency by calculating current year results using prior year foreign currency exchange rates and generally refers to such amounts calculated on a constant currency basis as excluding the impact of foreign exchange or being on a constant currency basis. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Results on a constant currency basis, as the Company presents them, may not be comparable to similarly titled measures used by other companies and are not measures of performance presented in accordance with GAAP.



## **Financial Highlights: Revenues**

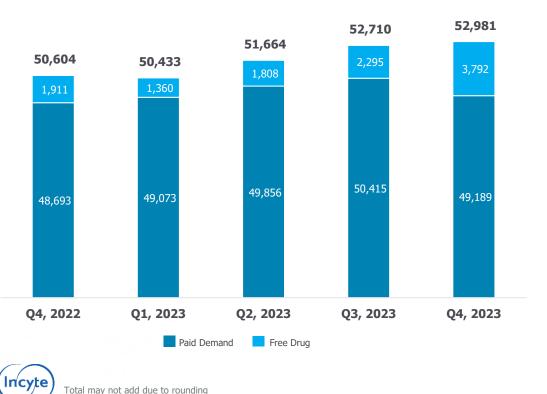
\$ millions	Q4 2023 GAAP	Q4 2022 GAAP		2023 GAAP	2022 GAAP	
Net product revenues	862	764	13%	3,165	2,747	15%
Jakafi	695	647	7%	2,594	2 <i>,</i> 409	8%
Opzelura	109	61	78%	338	129	162%
Other Hematology/Oncology <sup>1</sup>	57	55	3%	234	209	12%
Royalty revenues	150	132	<b>13%</b>	523	483	8%
Jakavi	104	91	14%	368	332	11%
Olumiant	40	36	13%	136	135	1%
Tabrecta	5	4	11%	18	15	15%
Pemazyre	1	1	NM	2	1	NM
Total net product and royalty revenues	1,011	897	<b>13%</b>	3,689	3,230	14%
Milestone and contract revenue	2	30	(93%)	7	165	(96%)
Total revenues	1,013	927	<b>9%</b>	3,696	3,395	<b>9%</b>



## **2023 Jakafi Net Sales Drivers**

Q4 2023 Net Sales: **\$695 million (+7% Y/Y)** FY 2023 Net Sales: **\$2,594 million (+8% Y/Y)** 

### **Total Demand (Paid + Free Bottles)**

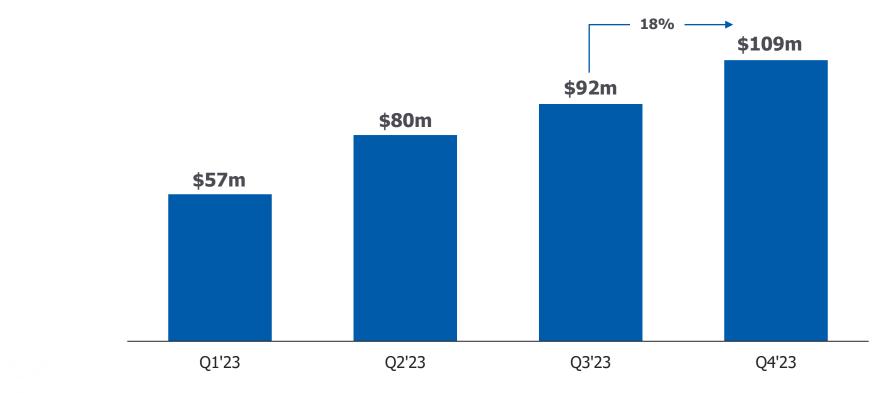


### Quarterly Net Sales & Channel Inventory Impact



## **2023 Opzelura Performance**

Q4 2023 Net Sales: **\$109 million (+78% Y/Y)** FY 2023 Net Sales: **\$338 million (+162% Y/Y)** 





## **Financial Highlights: Operating Expenses**

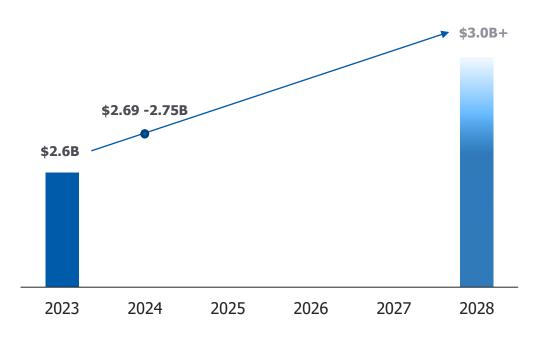
\$ millions	Q4 2023	Q4 2022	YoY Change	2023	2022	YoY Change
	GAAP	GAAP		GAAP	GAAP	
COGS	70	59	18%	255	207	23%
As a percentage of net product revenues	8%	8%		8%	8%	
R&D	444	501	(11%)	1,628	1,586	3%
R&D – ongoing	420	431	(3%)	1,591	1,460	9%
R&D – upfront and milestones	24	70	(66%)	37	126	(71%)
SG&A	294	273	8%	1,161	1,002	16%
(Profit) and loss sharing under collaboration agreements <sup>1</sup>	3	(1)	NM	2	8	NM



## **Financial Guidance: Full Year 2024**

	FY 2024 GAAP <sup>1</sup>	FY 2024 Non-GAAP <sup>1,2</sup>
Net product revenues		
Jakafi	\$2.69 - \$2.75 billion	\$2.69 - \$2.75 billion
Other Hematology/Oncology <sup>3</sup>	\$325 - \$360 million	\$325 - \$360 million
Costs and expenses		
GAAP Cost of product revenues	7 – 8% of net product revenues	6 – 7% of net product revenues
GAAP Research and development expenses	\$1,720 - \$1,760 million	\$1,580 - \$1,615 million
GAAP Selling, general and administrative expenses	\$1,210 - \$1,240 million	\$1,115 - \$1,140 million

#### Jakafi FY 2024 Guidance



#### SOLVE

Incyte

1. Guidance includes revenues and expenses related to the recently announced acquisition of the exclusive global rights to tafasitamab and excludes any potential impact related to the accounting treatment of the \$25 million purchase price paid.

2. A reconciliation from GAAP to Non-GAAP financial measures is provided on slide 38.

Includes Pemazyre in the U.S., EU and Japan; Monjuvi and Zynyz in the US and Minjuvi and Iclusig in EU.







# **Financial Back-Up Slides**



## **Financial Highlights: Fourth Quarter**

\$ millions	Q4 2023	Q4 2022	Q4 2023	Q4 2022	YoY Change
	GAAP	GAAP	Non-GAAP	Non-GAAP	
Net product revenues	862	764	862	764	<b>13</b> %
Jakafi	695	647	695	647	7%
Opzelura	109	61	109	61	78%
Iclusig	27	28	27	28	(2%)
Pemazyre	21	23	21	23	(10%)
Minjuvi	9	5	9	5	87%
Zynyz	1	-	1	-	NM
Royalty revenues	150	132	150	132	<b>13%</b>
Jakavi	104	91	104	91	14%
Olumiant	40	36	40	36	13%
Tabrecta	5	4	5	4	11%
Pemazyre	1	1	1	1	NM
Total net product and royalty revenues	1,011	897	1,011	897	<b>13%</b>
Milestone and contract revenue	2	30	2	30	(93%)
Total revenues	1,013	927	1,013	927	<b>9</b> %
Costs and expenses	826	857	746	774	(4%)
COGS <sup>1</sup>	70	59	64	53	20%
R&D <sup>2</sup>	444	501	408	469	(13%)
$R\&D - ongoing^2$	420	431	384	399	
% total revenues	41%	47%	38%	43%	
R&D – upfront and milestones	24	70	24	70	
SG&A <sup>3</sup>	294	273	271	253	7%
% total revenues	29%	29%	27%	27%	
Loss on contingent consideration <sup>4</sup>	15	24	-	-	
(Profit) and loss sharing under collaborating agreements	3	(1)	3	(1)	NM



Totals may not add due to rounding. NM= not meaningful

<sup>1</sup> Non-GAAP excludes \$5.4 million of amortization of acquired product rights for Q4 2023 and 2022 and \$0.8 million of stock compensation for Q4 2023 and 2022.

<sup>2</sup> Non-GAAP excludes \$36.0 million and \$32.3 million of stock-based compensation for Q4 2023 and 2022, respectively.

<sup>3</sup> Non-GAAP excludes \$23.2 million and \$19.6 million of stock-based compensation for Q4 2023 and 2022, respectively.

<sup>4</sup> Non-GAAP excludes loss of \$15.1 million and \$24.3 million due to the change in fair value of contingent consideration for Q4 2023 and 2022, respectively.

## **Financial Highlights: Full Year**

\$ millions	2023	2022	2023	2022	YoY Change
	GAAP	GAAP	Non-GAAP	Non-GAAP	
Net product revenues	3,165	2,747	3,165	2,747	15%
Jakafi	2,594	2,409	2,594	2,409	8%
Opzelura	338	129	338	129	162%
Iclusig	112	106	112	106	5%
Pemazyre	84	83	84	83	0%
Minjuvi	37	20	37	20	89%
Zynyz	1	-	1	-	NM
Royalty revenues	523	483	523	483	8%
Jakavi	368	332	368	332	11%
Olumiant	136	135	136	135	1%
Tabrecta	18	15	18	15	15%
Pemazyre	2	1	2	1	NM
Total net product and royalty revenues	3,689	3,230	3,689	3,230	14%
Milestone and contract revenue	7	165	7	165	(96%)
Total revenues	3,696	3,395	3,696	3,395	9%
Costs and expenses	3,075	2,815	2,803	2,593	8%
COGS <sup>1</sup>	255	207	230	183	26%
R&D <sup>2</sup>	1,628	1,586	1,501	1,473	2%
$R\&D - ongoing^2$	1,591	1,460	1,464	1,347	
% total revenues	43%	43%	40%	40%	
R&D – upfront and milestones	37	126	37	126	
SG&A <sup>3</sup>	1,161	1,002	1,070	929	15%
% total revenues	31%	30%	29%	27%	
Loss on contingent consideration <sup>4</sup>	29	12	-	-	
(Profit) and loss sharing under collaborating agreements	2	8	2	8	NM

Totals may not add due to rounding. NM= not meaningful

Incyte

<sup>1</sup> Non-GAAP excludes \$21.5 million of amortization of acquired product rights for YTD 2023 and 2022, and \$3.1 million and \$2.7 million of stock compensation for YTD 2023 and 2022, respectively.

<sup>2</sup> Non-GAAP excludes \$126.7 million and \$112.5 million of stock-based compensation for YTD 2023 and 2022, respectively.

<sup>3</sup> Non-GAAP excludes \$86.0 million and \$73.2 million of stock-based compensation for YTD 2023 and 2022, respectively, and asset impairment of \$5.6 million and \$0 for YTD 2023 and 2022, respectively.

<sup>4</sup> Non-GAAP excludes loss of \$29.2 million and of \$12.1 million due to the change in fair value of contingent consideration for YTD 2023 and 2022, respectively.

## **2024 Financial Guidance Non-GAAP Reconciliation**

	GAAP Guidance	Adjustments	Non-GAAP Guidance
Net product revenues			
Jakafi Other Hematology/Oncology <sup>1</sup>	\$2.69 – \$2.75 billion \$325 – \$360 million	-	\$2.69 – \$2.75 billion \$325 – \$360 million
Costs and expenses			
COGS	7 – 8% net product revenues	Amortization of acquired product rights for Iclusig and stock-based compensation	6 – 7% net product revenues
R&D	\$1,720 – \$1,760 million	Stock-based compensation (\$140 - \$145 million)	\$1,580 – \$1,615 million
SG&A	\$1,210 – \$1,240 million	Stock-based compensation (\$95 - \$100 million)	\$1,115 – \$1,140 million







# Solve On