Incyte Reports 2024 Fourth Quarter and Year-End Financial Results, Provides 2025 Financial Guidance and Highlights 2025 R&D Milestones

February 10, 2025

– Total revenues of $1.2 billion (+16% Y/Y) in the fourth quarter 2024 and $4.2 billion (+15% Y/Y) for the full year 2024

– Jakafi® (ruxolitinib) net revenues of $773 million (+11% Y/Y) in the fourth quarter 2024 and $2.8 billion (+8% Y/Y) for the full year 2024; Jakafi net revenues guidance range of $2,925 - $2,975 million for the full year 2025

– Opzelura® (ruxolitinib) cream net revenues of $162 million (+48% Y/Y) in the fourth quarter 2024 and $508 million (+50% Y/Y) for the full year 2024; Opzelura net revenues guidance range of $630 - $670 million for the full year 2025

– Ruxolitinib extended-release (XR) has met the bioequivalence criteria set by the FDA; these data are anticipated to be submitted to the FDA by year-end 2025

– 2025 expected to be a year of defining catalysts with four launches, four pivotal study readouts, at least three Phase 3 study initiations and seven proof of concept study readouts

Conference Call and Webcast Scheduled Today at 8:00 a.m. ET

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 10, 2025-- Incyte (Nasdaq:INCY) today announced financial results for the fourth quarter and full year ended December 31, 2024 and provided full year 2025 financial guidance.

"2024 was an important year for Incyte, with a 15% increase in total revenues, driven by strong growth from both Jakafi and Opzelura, as well as significant progress across our R&D pipeline," said Hervé Hoppenot, Chief Executive Officer, Incyte. "Looking ahead to 2025, we anticipate a year of continued strong revenue growth and diversification, as well as several defining milestones that will serve as an inflection point for Incyte. A year ago, we set the goal to achieve more than 10 impactful product launches by 2030. In 2025, a number of key catalysts across the entire portfolio will bring that goal closer to reality."

2025: A Year of Defining Catalysts

Incyte expects to deliver at least 18 key milestones in 2025. These include:

- **Four new product launches:** Niktimvo™ in 3L+ chronic graft-versus-host disease (GVHD), ruxolitinib cream in pediatric atopic dermatitis (AD), tafasitamab in relapsed/refractory follicular lymphoma (FL), and retifanlimab in squamous cell anal carcinoma (SCAC).
- **At least three Phase 3 study initiations:** BET inhibitor in 2L myelofibrosis (MF), ruxolitinib cream in mild to moderate hidradenitis suppurativa (HS) and CDK2 inhibitor in ovarian cancer.
- **Four pivotal readouts:** Povorcitinib in moderate to severe HS, ruxolitinib cream in prurigo nodularis (PN), tafasitamab in 1L diffuse large B-cell lymphoma (DLBCL), and ruxolitinib XR for MF, polycythemia vera (PV), and GVHD.
- **Seven proof of concept readouts:** Povorcitinib in chronic spontaneous urticaria (CSU) and asthma, mutCALR in MF and essential thrombocythemia (ET), JAK2V617F mutant-specific inhibitor in MF, and both KRASG12D and TGFβR2xPD-1 in solid tumors.

Key Recent Company Updates

- A bioequivalence study of ruxolitinib extended-release (XR) has been completed. These data are anticipated to be submitted to the U.S. Food and Drug Administration (FDA) by year-end 2025 once the stability studies are complete.
- In January 2025, Incyte and Syndax Pharmaceuticals announced that the FDA approved Niktimvo™ (axatilimab-csfr) in 9 mg and 22 mg vial sizes. Niktimvo is now commercially available in the U.S. and the commercial launch is underway.
- In December 2024, additional results from the pivotal Phase 3 inMIND trial evaluating treatment with tafasitamab (Monjuvi®), a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody, in combination with lenalidomide and rituximab compared with placebo plus lenalidomide and rituximab in patients with relapsed or refractory follicular lymphoma were featured in the late-breaking session at the 2024 American Society of Hematology (ASH) Annual Meeting. The study met its primary endpoint by demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) by investigator assessment in 548 patients with relapsed or refractory FL. Tafasitamab was generally well-tolerated, and safety was consistent with other CD19 and immunotherapy combination regimens. These data have been submitted to the FDA and approval for this indication is expected in the second half of 2025.
- In December 2024, Incyte shared additional data from its BET inhibitor (INCB057643) in patients with relapsed or refractory myelofibrosis and other advanced myeloid neoplasms at the 2024 ASH Annual Meeting. These results showed treatment with INCB057643 was generally well tolerated and improvements in anemia, spleen size, and symptom burden were observed in patients receiving INCB057643 monotherapy and in combination with ruxolitinib. Incyte plans to initiate a

Phase 3 monotherapy study in the post Jakafi patient population in 2025.

- In December 2024, the supplemental Biologics License Application (sBLA) submission for retifanlimab (Zynyz®) in advanced/metastatic squamous cell anal carcinoma was filed with the FDA with approval anticipated in the second half of 2025.
- In October 2024, the sNDA submission for ruxolitinib cream (Opzelura®) in pediatric atopic dermatitis was filed with the FDA with approval anticipated in the second half of 2025.

Jakafi:

Net product revenues for the fourth quarter of 2024 of $773 million; 2024 full year net product revenues of $2.79 billion

- Fourth quarter 2024 net product revenues increased 11% compared to the fourth quarter of 2023 and 8% for the full year 2024 when compared to 2023.
- Net product revenues were primarily driven by paid demand, which increased 14% in the fourth quarter of 2024 and 9% for the full year 2024 when compared to the same periods in 2023, with growth across all indications.
- Channel inventory at the end of the fourth quarter of 2024 was within the normal range.

Opzelura:

Net product revenues for the fourth quarter of 2024 of $162 million; 2024 full year net product revenues of $508 million:

- Fourth quarter 2024 net product revenues increased 48% compared to the fourth quarter of 2023 and 50% for the full year 2024 when compared to 2023.
- Net product revenues were primarily driven by patient demand and refills for both atopic dermatitis and vitiligo and increased contribution from Europe.

Additional Pipeline Updates

Myeloproliferative Neoplasms (MPNs) and Graft-Versus-Host Disease (GVHD) – key highlights

- The Phase 1 studies evaluating mutCALR in myelofibrosis (MF) and essential thrombocythemia (ET) and JAK2V617Fi in MF are ongoing and enrolling patients. Initial proof of concept data for both studies are anticipated in 2025.
- A Phase 2 trial evaluating the safety and efficacy of axatilimab (Niktimvo ™) in combination with ruxolitinib (Jakafi®) in patients with newly diagnosed chronic GVHD was initiated in the fourth quarter of 2024 and is enrolling patients.
- A Phase 3, randomized, double-blind, placebo-controlled, multi-center trial that will investigate the use of axatilimab in combination with corticosteroids as initial treatment for chronic GVHD has been initiated and is enrolling patients.

MPN and GVHD Programs	Indication and Phase
Ruxolitinib XR (QD) (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD
Ruxolitinib + INCB57643 (JAK1/JAK2 + BETi)	Myelofibrosis: Phase 2
Ruxolitinib + axatilimab[1] (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD: Phase 2
Steroids + axatilimab[1] (Steroids + anti-CSF-1R)	Chronic GVHD: Phase 3
INCA33989 (mutCALR)	Myelofibrosis, essential thrombocythemia: Phase 1
INCB160058 (JAK2V617Fi)	Myelofibrosis: Phase 1

[1] Clinical development of axatilimab in GVHD conducted in collaboration with Syndax Pharmaceuticals.

Other Hematology/Oncology – key highlights

- Incyte plans to initiate Phase 3 studies for its potentially first-in-class CDK2 inhibitor (INCB123667), in ovarian cancer in 2025 and is also evaluating INCB123667 in combination with other treatments.
- The Phase 3 study evaluating tafasitamab in first-line DLBCL is ongoing. The Phase 3 data are anticipated in the first half of 2025.
- The Phase 1 studies evaluating KRASG12D and TGFßR2×PD-1 in solid tumors are ongoing and enrolling patients. Initial proof of concept data for both studies are anticipated in 2025.

Heme/Oncology Programs	Indication and Phase

Tafasitamab (Monjuvi®/Minjuvi®) (CD19)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 3 (B-MIND) First-line DLBCL: Phase 3 (*front*MIND) Relapsed or refractory follicular lymphoma (FL): Phase 3 (*in*MIND)
Retifanlimab (Zynyz®)[1] (PD-1)	Squamous cell anal cancer (SCAC): Phase 3 (POD1UM-303) Non-small cell lung cancer (NSCLC): Phase 3 (POD1UM-304) MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204)
INCB123667 (CDK2i)	Solid tumors with CCNE1 amplification/Cyclin E overexpression: Phase 1
INCB161734 (KRASG12D)	Advanced metastatic solid tumors with a KRASG12D mutation: Phase 1
INCA33890 (TGFßR2×PD-1)[2]	Advanced or metastatic solid tumors: Phase 1

[1] Retifanlimab licensed from MacroGenics.

[2] Development in collaboration with Merus.

Inflammation and Autoimmunity (IAI) – key highlights

Ruxolitinib Cream

- Two Phase 3 trials (TRuE-PN1 and TRuE-PN2) evaluating ruxolitinib cream in prurigo nodularis (PN) are fully enrolled. Data from the Phase 3 studies are anticipated in the first half of 2025.
- The Phase 3 trial for ruxolitinib cream in mild to moderate hidradenitis suppurativa (HS) is on track to initiate in the first half of 2025 following achieving alignment on the study design with FDA.
- In February 2025, Opzelura was granted approval by the Swiss Agency for Therapeutic Products (Swissmedic) for the treatment of non-segmental vitiligo with facial involvement in patients 12 years of age and older.
- In October 2024, Opzelura was granted a Notice of Compliance by Health Canada for the topical treatment of both mild to moderate atopic dermatitis and nonsegmental vitiligo in patients 12 years of age and older.

Povorcitinib (INCB54707)

- In October 2024, two Phase 3 studies (STOP-PN1 and STOP-PN2) evaluating povorcitinib in patients with PN versus placebo were initiated and are enrolling.
- The Phase 3 studies of povorcitinib in patients with HS (STOP-HS1 and STOP-HS2) are fully enrolled. Data from both pivotal studies are anticipated in the first half of 2025.
- Two Phase 2 trials evaluating povorcitinib in asthma and chronic spontaneous urticaria (CSU) are enrolling. Data for CSU are anticipated in the first half of 2025 and data in asthma are anticipated in the second half of 2025.

IAI and Dermatology Programs	**Indication and Phase**
Ruxolitinib cream (Opzelura®)[1] (JAK1/JAK2)	Atopic dermatitis: Phase 3 pediatric study (TRuE-AD3) Hidradenitis suppurativa: Phase 2; Phase 3 expected to initiate in 2025 Prurigo nodularis: Phase 3 (TRuE-PN1, TRuE-PN2)
Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 3 (STOP-V1, STOP-V2) Prurigo nodularis: Phase 3 (STOP-PN1, STOP-PN2) Chronic spontaneous urticaria: Phase 2 Asthma: Phase 2
INCA034460 (anti-CD122)	Vitiligo: Phase 1

[1] Novartis' rights to ruxolitinib outside of the United States under our Collaboration and License Agreement with Novartis do not include topical administration.

Other

Other Program	**Indication and Phase**
Zilurgisertib (ALK2)	Fibrodysplasia ossificans progressiva: Pivotal Phase 2

2024 Fourth Quarter and Year-end Financial Results

The financial measures presented in this press release for the quarter and year ended December 31, 2024 and 2023 have been prepared by the Company in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"), unless otherwise identified as a Non-GAAP financial measure. Management believes that Non-GAAP information is useful for investors, when considered in conjunction with Incyte's GAAP disclosures. 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.

Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used in conjunction with and to supplement Incyte's operating results as reported under GAAP. Non-GAAP measures may be defined and calculated differently by other companies in our industry.

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

Financial Highlights
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Total GAAP revenues	$ 1,178,698	$ 1,013,341	$ 4,241,217	$ 3,695,649
Total GAAP operating income	301,513	187,270	61,366	620,525
Total Non-GAAP operating income	376,265	267,702	413,883	892,783
GAAP net income	201,212	201,079	32,615	597,599
Non-GAAP net income	281,353	239,124	227,591	795,449
GAAP basic EPS	$ 1.04	$ 0.90	$ 0.16	$ 2.67
Non-GAAP basic EPS	$ 1.46	$ 1.07	$ 1.10	$ 3.56
GAAP diluted EPS	$ 1.02	$ 0.89	$ 0.15	$ 2.65
Non-GAAP diluted EPS	$ 1.43	$ 1.06	$ 1.08	$ 3.52

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended December 31,		% Change (as reported)	% Change (constant currency)[1]	Twelve Months Ended December 31,		% Change (as reported)	% Change (constant currency)[1]
	2024	2023			2024	2023		
Net product revenues:								
Jakafi	$ 773,114	$ 695,127	11%	11%	$ 2,792,107	$ 2,593,732	8%	8%
Opzelura	161,602	109,243	48%	48%	508,293	337,864	50%	50%
Iclusig	27,369	27,130	1%	1%	114,319	111,623	2%	2%
Pemazyre	23,142	20,653	12%	12%	81,748	83,642	(2%)	(2%)
Minjuvi/ Monjuvi	32,807	8,994	265%	265%	119,236	37,057	222%	222%
Zynyz	1,373	582	136%	136%	3,185	1,250	155%	155%
Total net product revenues	1,019,407	861,729	18%	18%	3,618,888	3,165,168	14%	14%
Royalty revenues:								
Jakavi	114,187	103,892	10%	13%	418,840	367,583	14%	16%
Olumiant	38,485	40,359	(5%)	(3%)	135,572	136,138	—%	2%
Tabrecta	6,286	4,678	34%	NA	22,746	17,793	28%	NA
Pemazyre	333	683	NM	NM	2,171	1,967	NM	NM
Total royalty revenues	159,291	149,612	6%		579,329	523,481	11%	
Total net product and royalty revenues	1,178,698	1,011,341	17%		4,198,217	3,688,649	14%	
Milestone and contract revenues	—	2,000	—%	—%	43,000	7,000	514%	514%

Total GAAP revenues	$ 1,178,698	$ 1,013,341	16%	$ 4,241,217	$ 3,695,649	15%

NM = not meaningful

NA = not applicable

[1] Percentage change in constant currency is calculated using 2023 foreign exchange rates to recalculate 2024 results.

Product and Royalty Revenues Total net product and royalty revenues for the quarter and year ended December 31, 2024 increased 17% and 14%, respectively, over the prior year comparative periods, primarily driven by the following:

- For the quarter ended December 31, 2024, Jakafi net product revenue increased 11% primarily driven by a 14% increase in paid demand. Channel inventory at the end of the fourth quarter of 2024 was within the normal range. For the year ended December 31, 2024, Jakafi net product revenue increased 8% primarily driven by a 9% increase in paid demand.
- For the quarter and year ended December 31, 2024, Opzelura net product revenue increased 48% and 50%, respectively, driven by continued growth in new patient starts and refills in the U.S. and increased contribution from Europe. Opzelura net product revenues included $24 million and $61 million ex-U.S. revenue for the fourth quarter and full year, respectively.
- For the quarter and year ended December 31, 2024, Minjuvi/Monjuvi net product revenue increased 265% and 222%, respectively, as we recognize all revenue from sales of Monjuvi in the United States following the acquisition of exclusive global rights for tafasitamab in February 2024.
- For the quarter and full year ended December 31, 2024, total royalty revenues increased by 6% and 11%, respectively, primarily driven by growth in Jakavi royalty revenues.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended December 31,		% Change	Twelve Months Ended December 31,		% Change
	2024	2023		2024	2023	
GAAP cost of product revenues	$ 88,485	$ 69,751	27%	$ 312,068	$ 254,990	22%
Non-GAAP cost of product revenues[1]	82,427	63,575	30%	288,266	230,308	25%
GAAP research and development	466,034	444,494	5%	2,606,848	1,627,594	60%
Non-GAAP research and development[2]	420,297	408,488	3%	2,423,167	1,500,897	61%
GAAP selling, general and administrative	326,710	293,865	11%	1,242,157	1,161,293	7%
Non-GAAP selling, general and administrative[3]	299,709	270,673	11%	1,116,926	1,069,616	4%
GAAP (gain) loss on change in fair value of acquisition-related contingent consideration	(4,044)	15,058	(127%)	19,803	29,202	(32%)
Non-GAAP (gain) loss on change in fair value of acquisition-related contingent consideration	—	—	—%	—	—	—%
GAAP (profit) and loss sharing under collaboration agreements	—	2,903	—%	(1,025)	2,045	(150%)

[1] Non-GAAP cost of product revenues excludes the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the cost of stock-based compensation.

[2] Non-GAAP research and development expenses exclude the cost of stock-based compensation, MorphoSys transition costs, and Escient acquisition related compensation expense related to cash settled unvested Escient equity awards and severance payments.

[3] Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation, MorphoSys transition costs, Escient acquisition related compensation expense related to cash settled unvested Escient equity awards and severance payments, and asset impairments.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter and year ended December 31, 2024 increased 27% and 30%, and 22% and 25%, respectively, compared to the same periods in 2023 primarily due to growth in net product revenues, increased royalty expense and increased manufacturing related costs.

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended December 31, 2024 increased 5% and 3%, respectively, compared to the same period in 2023, primarily driven by continued investment in our late-stage development assets and timing of certain expenses. GAAP and Non-GAAP research and development expense for the year ended December 31, 2024 increased

60% and 61%, respectively, compared to the same period in 2023, primarily due to the Escient acquisition upfront consideration and related compensation expense and severance payments, and other milestone payments. For the year ended December 31, 2024, excluding the Escient acquisition upfront payment, related compensation expense and severance payments and other milestone payments, research and development expense increased 14% compared to the same period in 2023 as a result of continued investment in our late-stage development assets and timing of certain expenses.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended December 31, 2024 increased 11% compared to the same period in 2023, primarily due to the timing of consumer marketing activities and of certain other expenses. GAAP and Non-GAAP selling, general and administrative expenses for the year ended December 31, 2024 increased 7% and 4%, respectively, compared to the same period in 2023, primarily due to $22.1 million of Escient acquisition related compensation expense including severance payments, and timing of consumer marketing activities and of certain other expenses. Excluding the Escient acquisition related compensation expense and severance payments, selling, general and administrative expenses for the year ended December 31, 2024 increased 5% compared to the prior year.

Other Financial Information

Change in fair value of acquisition-related contingent consideration The change in fair value of contingent consideration during the quarter and year ended December 31, 2024, compared to the same periods in 2023, was primarily due to fluctuations in foreign currency exchange rates impacting future revenue projections of Iclusig.

Operating income GAAP and Non-GAAP operating income for the quarter ended December 31, 2024 increased 61% and 41%, respectively, compared to the same period in 2023, primarily driven by growth in total revenues and stable operating expenses. GAAP and Non-GAAP operating income for the year ended December 31, 2024 decreased 90% and 54%, respectively, compared to the same period in 2023, primarily driven by the $679.4 million of expense relating to the IPR&D assets acquired in the Escient acquisition, $38.0 million of Escient acquisition related compensation expense and severance payments, and the $100.0 million milestone payment made to MacroGenics. Excluding upfront and milestone payments and the Escient acquisition related compensation expense and severance payments, operating income for the year ended December 31, 2024 increased 34% compared to the prior year primarily driven by growth in net product revenue.

Cash, cash equivalents and marketable securities position As of December 31, 2024 and 2023, cash, cash equivalents and marketable securities totaled $2.2 billion and $3.7 billion, respectively. The decrease in cash, cash equivalents and marketable securities during 2024 was driven primarily by the $2.0 billion share repurchase completed in June 2024, and the total cash consideration paid to Escient shareholders of $783 million, partially offset by proceeds of sales of equity investments and operating cash flows during the year ended December 31, 2024.

2025 Financial Guidance

Incyte's guidance for the fiscal year 2025 is summarized below. Guidance for Opzelura includes net product revenue for pediatric atopic dermatitis which has an anticipated approval in the second half of 2025. Guidance for other oncology net product revenues include net product revenue for Monjuvi in follicular lymphoma and Zynyz in squamous cell anal carcinoma. Approvals for these indications are anticipated in the second half of 2025.

	Current
Jakafi net product revenues	$2,925 - $2,975 million
Opzelura net product revenues	$630 - $670 million
Other oncology net product revenues[1]	$415 - $455 million
GAAP Cost of product revenues	8.5% - 9.0% of net product revenues
Non-GAAP Cost of product revenues[2]	7.5% - 8.0% of net product revenues
GAAP Research and development expenses	$1,930 - $1,960 million
Non-GAAP Research and development expenses[3]	$1,780 - $1,805 million
GAAP Selling, general and administrative expenses	$1,280 - $1,310 million
Non-GAAP Selling, general and administrative expenses[3]	$1,160 - $1,185 million

[1]Pemazyre in the U.S., EU and Japan; Niktimvo, Monjuvi and Zynyz in the U.S.; and Iclusig and Minjuvi in the EU.

[2]Adjusted to exclude the amortization of licensed intellectual property for Iclusig relating to the acquisition of the European business of ARIAD Pharmaceuticals, Inc. and the estimated cost of stock-based compensation.

[3] Adjusted to exclude the estimated cost of stock-based compensation.

Conference Call and Webcast Information

Incyte will hold a conference call and webcast this morning at 8:00 a.m. ET. To access the conference call, please dial 877-407-3042 for domestic callers or 201-389-0864 for international callers. When prompted, provide the conference identification number, 13751174.

If you are unable to participate, a replay of the conference call will be available for 90 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference identification number, 13751174.

The conference call will also be webcast live and can be accessed at investor.incyte.com.

About Incyte

A global biopharmaceutical company on a mission to *Solve On*., Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has

operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

About Jakafi® (ruxolitinib)

Jakafi® (ruxolitinib) is a JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea; intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults; steroid-refractory acute GVHD in adult and pediatric patients 12 years and older; and chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Jakafi is a registered trademark of Incyte.

About Opzelura® (ruxolitinib) Cream

Opzelura® (ruxolitinib) cream, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, approved by the U.S. Food & Drug Administration for the topical treatment of nonsegmental vitiligo in patients 12 years of age and older, is the first and only treatment for repigmentation approved for use in the United States. Opzelura is also approved in the U.S. for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

In Europe, Opzelura (ruxolitinib) cream 15mg/g is approved for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura and the Opzelura logo are registered trademarks of Incyte.

About Monjuvi® (tafasitamab-cxix)

Monjuvi® (tafasitamab-cxix) is a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP). MorphoSys and Incyte entered into: (a) in January 2020, a collaboration and licensing agreement to develop and commercialize tafasitamab globally; and (b) in February 2024, an agreement whereby Incyte obtained exclusive rights to develop and commercialize tafasitamab globally.

Following accelerated approval by the U.S. Food and Drug Administration in July 2020, Monjuvi® (tafasitamab-cxix) is being commercialized in the United States by Incyte. In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency in August 2021.

XmAb® is a registered trademark of Xencor, Inc.

Monjuvi, Minjuvi, the Minjuvi and Monjuvi logos and the "triangle" design are (registered) trademarks of Incyte.

About Pemazyre® (pemigatinib)

Pemazyre® (pemigatinib) is a kinase inhibitor indicated in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test*. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Pemazyre is also the first targeted treatment approved for use in the United States for treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

In Japan, Pemazyre is approved for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy.

In Europe, Pemazyre is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Pemazyre is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations.

Pemazyre is marketed by Incyte in the United States, Europe and Japan.

Pemazyre is a trademark of Incyte.

* Pemazyre® (pemigatinib) [Package Insert]. Wilmington, DE: Incyte; 2020.

About Iclusig® (ponatinib) tablets

Iclusig® (ponatinib) targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

In the EU, Iclusig is approved for the treatment of adult patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, or the treatment of adult patients with Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

Click here to view the Iclusig EU Summary of Medicinal Product Characteristics.

Incyte has an exclusive license from Takeda Pharmaceuticals International AG to commercialize ponatinib in the European Union and 29 other countries, including Switzerland, UK, Norway, Turkey, Israel and Russia. Iclusig is marketed in the U.S. by Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

About Zynyz® (retifanlimab-dlwr)

Zynyz® (retifanlimab) is an intravenous PD-1 inhibitor indicated in the U.S. for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Zynyz is marketed by Incyte in the U.S. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a trademark of Incyte.

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 2025, including its expectations regarding sales of and demand for Jakafi and Opzelura; the launch of Niktimvo and the expected revenue contribution from near-term launches; additional label expansion opportunities; the possibility for 2025 to be a transformational year for Incyte in terms of potential launches, phase 3 study initiations, pivotal readouts and proof of concept readouts; Incyte's potential to have more than 10 high impact launches by 2030; the potential and progress of programs in our pipeline, including povorcitinib and mutCALR; ongoing clinical trials and clinical trials that may be initiated, including a BETi phase 3 study, pivotal studies in three indications for povorcitinib and phase 3 studies for Incyte's CDK2 inhibitor; and expectations regarding regulatory filings, regulatory approvals and 2025 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 in the marketplace; market competition; unexpected variations in the demand for Incyte's products and the products of Incyte's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for Incyte's products and the products of Incyte's collaboration partners; sales, marketing, manufacturing and distribution requirements, including Incyte's and its collaboration partners' 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, 2024. Incyte disclaims any intent or obligation to update these forward-looking statements.

INCYTE CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 1,019,407	$ 861,729	$ 3,618,888	$ 3,165,168
Product royalty revenues	159,291	149,612	579,329	523,481
Milestone and contract revenues	—	2,000	43,000	7,000
Total revenues	1,178,698	1,013,341	4,241,217	3,695,649
Costs, expenses and other:				
Cost of product revenues (including definite-lived intangible amortization)	88,485	69,751	312,068	254,990
Research and development	466,034	444,494	2,606,848	1,627,594
Selling, general and administrative	326,710	293,865	1,242,157	1,161,293

(Gain) loss on change in fair value of acquisition-related contingent consideration	(4,044)	15,058	19,803	29,202
(Profit) and loss sharing under collaboration agreements	—	2,903	(1,025)	2,045
Total costs, expenses and other	877,185	826,071	4,179,851	3,075,124
Income from operations	301,513	187,270	61,366	620,525
Interest income	21,198	46,482	128,710	158,414
Interest expense	(419)	(804)	(2,280)	(2,551)
Realized and unrealized (loss) gain on equity investments	(10,181)	34,054	116,025	43,893
Other, net	1,613	3,954	12,809	13,934
Income before provision for income taxes	313,724	270,956	316,630	834,215
Provision for income taxes	112,512	69,877	284,015	236,616
Net income	$ 201,212	$ 201,079	$ 32,615	$ 597,599
Net income per share:				
Basic	$ 1.04	$ 0.90	$ 0.16	$ 2.67
Diluted	$ 1.02	$ 0.89	$ 0.15	$ 2.65
Shares used in computing net income per share:				
Basic	193,152	224,226	207,110	223,628
Diluted	197,423	226,125	210,530	225,928

INCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	December 31, 2024	December 31, 2023
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,158,092	$ 3,656,043
Accounts receivable	853,154	743,557
Property and equipment, net	763,411	751,513
Finance lease right-of-use assets, net	30,803	25,535
Inventory	407,199	269,937
Prepaid expenses and other assets	181,382	236,782
Equity investments	18,814	187,716
Other intangible assets, net	113,803	123,545
Goodwill	155,593	155,593
Deferred income tax asset	762,071	631,886
Total assets	$ 5,444,322	$ 6,782,107
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,765,733	$ 1,347,669
Finance lease liabilities	37,961	32,601
Acquisition-related contingent consideration	193,000	212,000
Stockholders' equity	3,447,628	5,189,837
Total liabilities and stockholders' equity	$ 5,444,322	$ 6,782,107

INCYTE CORPORATION
RECONCILIATION OF GAAP NET INCOME TO SELECTED NON-GAAP ADJUSTED INFORMATION
(unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
GAAP Net Income	$ 201,212	$ 201,079	$ 32,615	$ 597,599
Adjustments[1]:				
Non-cash stock compensation from equity awards (R&D)[2]	44,110	36,006	161,251	126,697

Non-cash stock compensation from equity awards (SG&A)[2]	26,935	23,192	102,542	86,046
Non-cash stock compensation from equity awards (COGS)[2]	674	792	2,266	3,146
Non-cash interest[3]	82	108	415	463
Realized and unrealized loss (gain) on equity investments[4]	10,181	(34,054)	(116,025)	(43,893)
Amortization of acquired product rights[5]	5,384	5,384	21,536	21,536
Loss on change in fair value of contingent consideration[6]	(4,044)	15,058	19,803	29,202
Asset impairment[7]	—	—	—	5,631
MorphoSys transition costs[8]	—	—	7,084	—
Escient acquisition related compensation expense[9]	1,693	—	38,035	—
Tax effect of Non-GAAP pre-tax adjustments[10]	(4,874)	(8,441)	(41,931)	(30,978)
Non-GAAP Net Income	$ 281,353	$ 239,124	$ 227,591	$ 795,449
Non-GAAP net income per share:				
Basic	$ 1.46	$ 1.07	$ 1.10	$ 3.56
Diluted	$ 1.43	$ 1.06	$ 1.08	$ 3.52
Shares used in computing Non-GAAP net income per share:				
Basic	193,152	224,226	207,110	223,628
Diluted	197,423	226,125	210,530	225,928

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2024 are milestones of $0 and $43,000, respectively, earned from our collaborative partners, as compared to milestones of $2,000 and $7,000, respectively, for the three and twelve months ended December 31, 2023. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2024 are upfront consideration and milestones of $3,000 and $104,414, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $24,000 and $36,650, respectively, for the three and twelve months ended December 31, 2023.

[2] As included within the Cost of product revenues (including definite-lived intangible amortization) line item; the Research and development expenses line item; and the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.

[3] As included within the Interest expense line item in the Condensed Consolidated Statements of Operations.

[4] As included within the Realized and unrealized gain (loss) on equity investments line item in the Condensed Consolidated Statements of Operations.

[5] As included within the Cost of product revenues (including definite-lived intangible amortization) line item in the Condensed Consolidated Statements of Operations. Acquired product rights of licensed intellectual property for Iclusig is amortized utilizing a straight-line method over the estimated useful life of 12.5 years.

[6] As included within the Loss on change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

[7] As included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.

[8] Included within the Research and development line item in the Condensed Consolidated Statements of Operations (in thousands) is $0 and $6,489 for the three months and year ended December 31, 2024, respectively, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations (in thousands) is $0 and $595 for the three months and year ended December 31, 2024, respectively. MorphoSys transition costs primarily represent employee related costs to transition research and development and selling, general and administrative activities to us under the former collaboration agreement with MorphoSys.

[9] Included within the Research and development line item in the Condensed Consolidated Statements of Operations (in thousands) is $1,627 and $15,941, respectively, for the three months and year ended December 31, 2024, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations (in thousands) is $66 and $22,094, respectively, for the three months and year ended December 31, 2024. Escient acquisition related compensation expense represents non-recurring charges associated with (i) cash settled unvested Escient equity awards in connection with the acquisition, and (ii) severance payments to former Escient employees.

[10] Income tax effects of Non-GAAP pre-tax adjustments are calculated using the applicable statutory tax rate for the jurisdictions in which the charges are incurred, while taking into consideration any valuation allowances against related deferred tax assets.

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