Incyte Reports 2023 Fourth Quarter and Year-End Financial Results, Provides 2024 Financial Guidance and Highlights R&D Priorities

February 13, 2024

- *Total FY'23 net product and royalty revenues of $3.7 billion (+14% Y/Y); total FY'23 net product revenues of $3.2 billion (+15% Y/Y)*
- *Jakafi® (ruxolitinib) net revenues of $2.6 billion (+8%) for FY'23; Jakafi net revenues guidance range of $2,690 - $2,750 million for FY 2024*
- *Opzelura® (ruxolitinib) cream net revenues of $109 million in Q4'23 and $338 million for FY'23, driven by strong demand in atopic dermatitis and the successful launch in vitiligo*
- *Advancing high potential pipeline provides opportunity for over 10 new launches by 2030*
- *Incyte to host an in-person and webcast investor event on Monday, March 11, 2024 from 9:00-10:30 a.m. PT to discuss key data presentations across its dermatology pipeline at the 2024 AAD Annual Meeting in San Diego, CA*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 13, 2024-- Incyte (Nasdaq:INCY) today reports 2023 fourth quarter financial results, provides 2024 financial guidance and provides a status update on the Company's research and development portfolio.

"We delivered a strong 2023 with total net product and royalty revenues of $3.7 billion, increasing 14% versus 2022. In the fourth quarter, we achieved for the first time, a new milestone of $1 billion in total quarterly revenues, driven by the continued growth of Jakafi® (ruxolitinib) and the successful launch of Opzelura® (ruxolitinib) cream," said Hervé Hoppenot, Chief Executive Officer, Incyte. "Throughout 2023, we focused our R&D efforts on high potential programs and believe we are positioned to deliver more than ten high impact launches by 2030."

Key Product Sales Performance

Jakafi:

Net product revenues for the fourth quarter of 2023 of $695 million; 2023 full year net product revenues of $2.59 billion

- Fourth quarter 2023 net product revenues grew 7% compared with the fourth quarter of 2022 and grew 8% for the full year 2023 when compared to 2022.
- Fourth quarter revenues were negatively impacted by an increase in the number of Medicare Part D patients receiving free product and were positively impacted by an increase in channel inventory.

Opzelura:

Net product revenues for the fourth quarter of 2023 of $109 million; 2023 full year net product revenues of $338 million:

- Net product revenues of $109 million grew 78% compared with the fourth quarter of 2022, driven by growth in patient demand, refills and expansion in payer coverage as the launch in atopic dermatitis (AD) and vitiligo continues. For the full-year, 2023 net product revenues grew 162% over the prior year to $338 million.
- On January 31, 2024, Incyte received approval in France to promote and distribute Opzelura for vitiligo under a process called "Accès Direct." This process is intended to allow for early access to a therapy while a final price is negotiated, which is expected to take up to twelve months. Once price reimbursement is determined, Incyte will begin recognizing revenue in France.

Key Recent Updates

- In February 2024, Incyte entered into an asset purchase agreement with MorphoSys AG which gave Incyte exclusive global rights for tafasitamab, a humanized Fc-modified CD19-targeting immunotherapy marketed in the U.S. as Monjuvi® (tafasitamab-cxix) and outside of the U.S. as Minjuvi® (tafasitamab). Under the terms of the agreement, MorphoSys received a payment of $25 million from Incyte, and Incyte gained global development and commercialization rights for tafasitamab. Incyte will recognize revenue and cost for all U.S. commercialization and clinical development and MorphoSys will no longer be eligible to receive future milestone, profit split and royalty payments.

- In January 2024, Incyte announced the primary endpoint was met in its randomized, placebo-controlled, Phase 2 study evaluating the safety and efficacy of ruxolitinib cream (Opzelura®) in adults with mild/moderate hidradenitis suppurativa (HS). At Week 16, patients receiving ruxolitinib cream 1.5% twice daily (BID) had significantly greater decreases from baseline versus placebo in total abscess and inflammatory nodule (AN) count, the primary endpoint of the study. The overall safety profile of ruxolitinib cream was consistent with previous data, and no new safety signals were observed. The Phase 2 data is anticipated to be presented at an upcoming scientific meeting in 2024. A Phase 3 study is currently being evaluated.
- In January 2024, Incyte highlighted promising early clinical efficacy data for its selective inhibitor of CDK2 (INCB123667), which demonstrated its potential use as monotherapy or combination therapy for late-stage cancers. In a Phase 1 study of INCB123667, early clinical activity was observed with several partial responses (PR) achieved in patients with amplification/over expression of CCNE1, a cell cycle regulator and potential predictive biomarker. Tumor shrinkage was observed across multiple tumor types, including CCNE1 patients with ovarian cancer. The safety profile of for INCB123667 aligns with the mechanism of action. Additional data is expected to be presented in 2024.
- In December 2023, in collaboration with Syndax Pharmaceuticals, the Biologics License Application (BLA) was submitted for axatilimab in chronic graft-versus-host disease (cGVHD) with approval anticipated in the second half of 2024. Plans are underway to initiate two combination trials with axatilimab in cGVHD in mid-2024, including a Phase 2 combination trial with ruxolitinib and a Phase 3 combination trial with steroids.
- JAK2V617Fi (INCB160058), a potent and selective JAK2 pseudokinase domain binder, cleared the Investigational New Drug (IND) process with the FDA and a Phase 1 study is anticipated to initiate in the first half of 2024. INCB160058 has the potential to be a disease modifying therapy and to address a significant patient population. The JAK2 mutation is found in 55% of primary myelofibrosis, 95% of polycythemia vera and 60% of essential thrombocythemia patients.
- A Phase 1 study of KRASG12D (INCB161734) in patients with advanced metastatic solid tumors with a KRAS G12D mutation was recently initiated and the first patient was dosed. KRAS mutations are one of the most common genetic abnormalities in cancer, especially pancreatic and colorectal cancers.
- In December 2023, Incyte received FDA feedback and agreed to the path forward for once daily (QD) ruxolitinib (XR). The potential approval of QD ruxolitinib (XR) is anticipated in approximately two years.

Additional Pipeline Updates

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

- In December 2023, Incyte presented more than 40 hematology and oncology abstracts including a Plenary Scientific Session at the 2023 ASH Annual Meeting. The plenary presentation featured the full data from AGAVE-201 evaluating axatilimab, an anti-CSFR-1R monoclonal antibody, in patients with cGVHD. Other key highlights included additional data from the Phase 1/2 Study of zilurgisertib (INCB000928), Phase 1 data of BETi (INCB057643) and preclinical data of JAK2V617Fi (INCB160058).

- Combination trials of ruxolitinib twice daily (BID) with zilurgisertib (INCB000928) and BETi (INCB057643) are ongoing and continue to enroll. Incyte anticipates initiating a Phase 3 study for BETi in the second half of 2024 and achieving clinical proof-of-concept for zilurgisertib by mid-2024.

- The Phase 1 study evaluating the mCALR monoclonal antibody (INCA033989) is ongoing and enrolling patients.

MPN and GVHD Programs	Indication and Phase
Ruxolitinib XR (QD) (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD
Ruxolitinib + zilurgisertib JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2
Ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2
Ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: Phase 1 (LIMBER-TREG108)
Axatilimab (anti-CSF-1R)[2]	Chronic GVHD: Pivotal Phase 2 (third-line plus therapy) (AGAVE-201); BLA under review in the U.S.
Ruxolitinib + axatilimab[2] (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD: Phase 1/2 in preparation
INCA033989 (mCALR)	Myelofibrosis, essential thrombocythemia: Phase 1
INCB160058 (JAK2V617Fi)	Phase 1

[1] Development collaboration with Cellenkos, Inc.

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

Other Hematology/Oncology – key highlights

CDK2i (INCB123667)

- In January 2024, Incyte highlighted promising early clinical efficacy data for its selective small molecule inhibitor of CDK2 (INCB123667), which demonstrated its potential use as monotherapy or combination therapy for late-stage cancers. In a Phase 1 study of INCB123667, early clinical activity was observed with several partial responses (PR) achieved in patients with amplification/over expression of CCNE1, a cell cycle regulator and potential predictive biomarker. Tumor shrinkage was observed across multiple tumor types, including CCNE1+ patients with ovarian cancer. The safety profile of for INCB123667 aligns with the mechanism of action. Additional data is expected to be presented in 2024.

Oncology Programs	Indication and Phase
Pemigatinib (Pemazyre®) (FGFR1/2/3)	Myeloid/lymphoid neoplasms (MLN): approved in the U.S. and Japan Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302) Glioblastoma: Phase 2 (FIGHT-209)
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) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (*in*MIND)
Retifanlimab (Zynyz®)[1] (PD-1)	Merkel cell carcinoma (MCC): approved in the U.S. 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)
INCB99280 (Oral PD-L1)	Solid tumors (combination): Phase 1 Solid tumors (monotherapy): Phase 2 Cutaneous squamous cell carcinoma (cSCC): Phase 2
INCB99318 (Oral PD-L1)	Solid tumors: Phase 1
INCB123667 (CDK2i)	Solid tumors with Amplification/ Overexpression of CCNE1: Phase 1
INCB161734 (KRASG12D)	Advanced metastatic solid tumors with a KRAS G12D mutation: Phase 1

[1] Retifanlimab licensed from MacroGenics.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Ruxolitinib Cream

- Incyte announced the primary endpoint was met in its randomized, placebo-controlled, Phase 2 study evaluating the safety and efficacy of ruxolitinib cream (Opzelura®) in adults with mild/moderate HS. At Week 16, patients receiving ruxolitinib cream 1.5% twice daily (BID) had significantly greater decreases from baseline versus placebo in total abscess and inflammatory nodule (AN) count, the primary endpoint of the study. The overall safety profile of ruxolitinib cream is consistent with previous data, and no new safety signals were observed. The Phase 2 data is anticipated to be presented at an upcoming scientific meeting in 2024. A Phase 3 study is currently being evaluated.
- Two Phase 2 studies in lichen planus and lichen sclerosus have completed enrollment. Two Phase 3 trials evaluating ruxolitinib cream in prurigo nodularis (PN) are ongoing.

Povorcitinib (INCB54707)

- The Phase 2, randomized, double-blind, placebo-controlled, dose ranging study evaluating the efficacy and safety of povorcitinib in participants with PN met its primary endpoint. A Phase 3 study in PN is being planned.
- **Asthma and chronic spontaneous urticaria:** Two Phase 2 trials in asthma and chronic spontaneous urticaria are enrolling.

IAI and Dermatology Programs	Indication and Phase
Ruxolitinib cream (Opzelura®)[1] (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Approved in the U.S. and Europe Lichen planus: Phase 2 Lichen sclerosus: Phase 2 Hidradenitis suppurativa: Phase 2; Phase 3 being evaluated Prurigo nodularis: Phase 3 (TRuE-PN1, TRuE-PN2)
Ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2

Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 3 (STOP-V1, STOP-V2) Prurigo nodularis: Phase 2; Phase 3 in planning Asthma: Phase 2 Chronic spontaneous urticaria: Phase 2
INCA034460 (anti-IL-15Rβ)	Vitiligo: Phase 1 initiated

[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

Discovery and other early development

Modality	Candidates
Monoclonal antibodies	INCAGN2385 (LAG-3)[1], INCAGN2390 (TIM-3)[1]
Bi-specific antibodies	INCA32459 (LAG-3xPD-1)[2], INCA33890 (TGFβR2xPD-1)[2]

[1] Discovery collaboration with Agenus.

[2] Development in collaboration with Merus.

Partnered

Partnered Programs	Indication and Phase
Ruxolitinib (Jakavi®)[1] (JAK1/JAK2)	Acute and chronic GVHD: Approved in Europe and Japan
Baricitinib (Olumiant®)[2] (JAK1/JAK2)	AD: Approved in Europe and Japan Severe alopecia areata (AA): Approved in the U.S., Europe and Japan
Capmatinib (Tabrecta®)[3] (MET)	NSCLC (with MET exon 14 skipping mutations): Approved in the U.S., Europe and Japan

[1] Ruxolitinib (Jakavi®) licensed to Novartis ex-U.S. for use in hematology and oncology excluding topical administration.

[2] Baricitinib (Olumiant®) licensed to Lilly: approved as Olumiant in multiple territories globally for certain patients with moderate-to-severe rheumatoid arthritis; approved as Olumiant in EU and Japan for certain patients with atopic dermatitis.

[3] Capmatinib (Tabrecta®) licensed to Novartis.

2023 Fourth Quarter and Year-end Financial Results

The financial measures presented in this press release for the quarter and year ended December 31, 2023 and 2022 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,

	2023	2022	2023	2022
Total GAAP revenues	$ 1,013,341	$ 926,700	$ 3,695,649	$ 3,394,635
Total GAAP operating income	187,270	70,093	620,525	579,440
Total Non-GAAP operating income	267,702	152,503	892,783	801,545
GAAP provision for income taxes	69,877	52,154	236,616	188,456
GAAP net income	201,079	28,461	597,599	340,660
Non-GAAP net income	239,124	139,661	795,449	622,676
GAAP basic EPS	$ 0.90	$ 0.13	$ 2.67	$ 1.53
Non-GAAP basic EPS	$ 1.07	$ 0.63	$ 3.56	$ 2.80
GAAP diluted EPS	$ 0.89	$ 0.13	$ 2.65	$ 1.52
Non-GAAP diluted EPS	$ 1.06	$ 0.62	$ 3.52	$ 2.78

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]
	2023	2022			2023	2022		
Net product revenues:								
Jakafi	$ 695,127	$ 647,493	7%	7%	$ 2,593,732	$ 2,409,225	8%	8%
Opzelura	109,243	61,281	78%	78%	337,864	128,735	162%	162%
Iclusig	27,130	27,616	(2%)	(6%)	111,623	105,838	5%	3%
Pemazyre	20,653	23,016	(10%)	(11%)	83,642	83,445	—%	1%
Minjuvi	8,994	4,809	87%	79%	37,057	19,654	89%	87%
Zynyz	582	—	NM	NM	1,250	—	NM	NM
Total net product revenues	861,729	764,215	13%	13%	3,165,168	2,746,897	15%	15%
Royalty revenues:								
Jakavi	103,892	91,189	14%	14%	367,583	331,575	11%	12%
Olumiant	40,359	35,858	13%	12%	136,138	134,547	1%	4%
Tabrecta	4,678	4,233	11%	NA	17,793	15,411	15%	NA
Pemazyre	683	1,205	NM	NM	1,967	1,205	NM	NM
Total royalty revenues	149,612	132,485	13%		523,481	482,738	8%	
Total net product and royalty revenues	1,011,341	896,700	13%		3,688,649	3,229,635	14%	
Milestone and contract revenues	2,000	30,000	(93%)	(93%)	7,000	165,000	(96%)	(96%)
Total GAAP revenues	$ 1,013,341	$ 926,700	9%		$ 3,695,649	$ 3,394,635	9%	

NM = not meaningful

NA = not available

[1] Percentage change in constant currency is calculated using 2022 foreign exchange rates to recalculate 2023 results.

Product and Royalty Revenues Product revenues and product and royalty revenues for the quarter ended December 31, 2023 both increased 13%, and product revenues and product and royalty revenues for the year ended December 31, 2023 increased 15% and 14%, respectively, over the prior year comparative periods, primarily driven by increases in Jakafi and Opzelura net product revenues. Jakafi fourth quarter revenues were negatively impacted by an increase in the number of Medicare Part D patients receiving free product and were positively impacted by an increase in channel inventory. Opzelura net product revenues for the quarter were $109 million, representing a 78% increase year-over-year driven by growth in new patient starts and refills. Olumiant royalties for the quarter were impacted by favorable changes in foreign currency exchange rates.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended December 31,		% Change	Twelve Months Ended December 31,		% Change
	2023	2022		2023	2022	
GAAP cost of product revenues	$ 69,751	$ 59,163	18%	$ 254,990	$ 206,997	23%
Non-GAAP cost of product revenues[1]	63,575	53,022	20%	230,308	182,737	26%

GAAP research and development	444,494	501,360	(11%)	1,627,594	1,585,936	3%
Non-GAAP research and development[2]	408,488	469,048	(13%)	1,500,897	1,473,420	2%
GAAP selling, general and administrative	293,865	272,819	8%	1,161,293	1,002,140	16%
Non-GAAP selling, general and administrative[3]	270,673	253,209	7%	1,069,616	928,960	15%
GAAP loss on change in fair value of acquisition-related contingent consideration	15,058	24,347	(38%)	29,202	12,149	140%
Non-GAAP loss on change in fair value of acquisition-related contingent consideration[4]	—	—	—%	—	—	—%
GAAP (profit) and loss sharing under collaboration agreements	2,903	(1,082)	(368%)	2,045	7,973	(74%)

[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.

[3] Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation and asset impairments.

[4] Non-GAAP loss on change in fair value of acquisition-related contingent consideration is null.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter ended December 31, 2023 increased 18% and 20%, respectively, and for the year ended December 31, 2023 increased 23% and 26% compared to the same periods in 2022 due to growth in net product revenues and inventory reserves for obsolescence.

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended December 31, 2023 decreased 11% and 13%, respectively, and for the year ended December 31, 2023 increased 3% and 2%, respectively, compared to the same periods in 2022. The decrease for the quarter was primarily due to the $70 million upfront payment made as part of the Villaris asset acquisition during the fourth quarter of 2022, offset in part by the $20 million development milestone payment to former Villaris stockholders in the fourth quarter of 2023. The increase for the full year was primarily due to continued investment in our late stage development assets.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended December 31, 2023 increased 8% and 7%, respectively, and for the year ended December 31, 2023 increased 16% and 15%, respectively, compared to the same periods in 2022, primarily due to expenses related to promotional activities to support the launch of Opzelura for the treatment of vitiligo.

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, 2023, compared to the same periods in 2022, was due primarily to fluctuations in foreign currency exchange rates impacting future revenue projections of Iclusig.

Operating income GAAP and Non-GAAP operating income for the year ended December 31, 2023 increased 7% and 11%, respectively, compared to the same period in 2022, primarily driven by growth in product revenues.

Cash, cash equivalents and marketable securities position As of December 31, 2023 and 2022, cash, cash equivalents and marketable securities totaled $3.7 billion and $3.2 billion, respectively.

2024 Financial Guidance

Incyte's guidance includes revenues and expenses related to the recently announced acquisition of exclusive global rights to tafasitamab and excludes any potential impact related to the accounting treatment of the $25 million purchase price paid. Guidance does not include revenue from any potential new product launches or the impact of any potential future strategic transactions. Incyte's guidance is summarized below.

	Current
Jakafi net product revenues	$2,690 - $2,750 million
Other Hematology/Oncology net product revenues[(1)]	$325 - $360 million
GAAP Cost of product revenues	7 – 8% of net product revenues
Non-GAAP Cost of product revenues[(2)]	6 – 7% of net product revenues
GAAP Research and development expenses	$1,720 - $1,760 million
Non-GAAP Research and development expenses[(3)]	$1,580 - $1,615 million
GAAP Selling, general and administrative expenses	$1,210 - $1,240 million
Non-GAAP Selling, general and administrative expenses[(3)]	$1,115 - $1,140 million

[1] Pemazyre in the U.S., EU and Japan; 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, 13744020.

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, 13744020.

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 1.5%

Opzelura, 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®/Minjuvi® (tafasitamab)

Tafasitamab is a humanized Fc-modified CD19 targeting immunotherapy. 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).

In the United States, Monjuvi® (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Please see the U.S. full Prescribing Information for Monjuvi for important safety information.

In Europe, Minjuvi® (tafasitamab) received conditional marketing authorization in combination with lenalidomide, followed by Minjuvi® monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials. Its safety and efficacy for these investigational uses have not been established in pivotal trials.

Minjuvi® and Monjuvi® are registered trademarks of Incyte. Tafasitamab is marketed by under the brand name Monjuvi® in the U.S., and under the brand name Minjuvi® in Europe and Canada.

Xencor is eligible to receive tiered royalties on global net sales of tafasitamab in the single-digit to sub-teen double-digit percentage range. XmAb® is a registered trademark of Xencor, Inc.

About Pemazyre® (pemigatinib)

Pemazyre 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

Ponatinib (Iclusig®) 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-dlwr), 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 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 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, 2023. 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,	
	2023	2022	2023	2022
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 861,729	$ 764,215	$ 3,165,168	$ 2,746,897
Product royalty revenues	149,612	132,485	523,481	482,738
Milestone and contract revenues	2,000	30,000	7,000	165,000
Total revenues	1,013,341	926,700	3,695,649	3,394,635
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	69,751	59,163	254,990	206,997
Research and development	444,494	501,360	1,627,594	1,585,936
Selling, general and administrative	293,865	272,819	1,161,293	1,002,140
Loss on change in fair value of acquisition-related contingent consideration	15,058	24,347	29,202	12,149
(Profit) and loss sharing under collaboration agreements	2,903	(1,082)	2,045	7,973
Total costs and expenses	826,071	856,607	3,075,124	2,815,195
Income from operations	187,270	70,093	620,525	579,440
Interest income and other, net	50,436	26,637	172,348	39,932
Interest expense	(804)	(667)	(2,551)	(2,666)
Unrealized gain (loss) on long term investments	34,054	(15,448)	43,893	(87,590)
Income before provision for income taxes	270,956	80,615	834,215	529,116
Provision for income taxes	69,877	52,154	236,616	188,456
Net income	$ 201,079	$ 28,461	$ 597,599	$ 340,660
Net income per share:				
Basic	$ 0.90	$ 0.13	$ 2.67	$ 1.53
Diluted	$ 0.89	$ 0.13	$ 2.65	$ 1.52
Shares used in computing net income per share:				
Basic	224,226	222,615	223,628	222,004
Diluted	226,125	224,840	225,928	223,958

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

	December 31, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and marketable securities	$ 3,656,043	$ 3,238,965
Accounts receivable	743,557	644,879
Property and equipment, net	751,513	739,310
Finance lease right-of-use assets, net	25,535	26,298
Inventory	269,937	120,959
Prepaid expenses and other assets	236,782	194,144
Long term investments	187,716	133,676
Other intangible assets, net	123,545	129,219
Goodwill	155,593	155,593
Deferred income tax asset	631,886	457,941
Total assets	$ 6,782,107	$ 5,840,984
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,347,669	$ 1,216,603

Finance lease liabilities	32,601	33,262
Acquisition-related contingent consideration	212,000	221,000
Stockholders' equity	5,189,837	4,370,119
Total liabilities and stockholders' equity	$ 6,782,107	$ 5,840,984

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,	
	2023	**2022**	**2023**	**2022**
GAAP Net Income	$ 201,079	$ 28,461	$ 597,599	$ 340,660
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	36,006	32,312	126,697	112,516
Non-cash stock compensation from equity awards (SG&A)[2]	23,192	19,610	86,046	73,180
Non-cash stock compensation from equity awards (COGS)[2]	792	757	3,146	2,724
Non-cash interest[3]	108	143	463	431
Changes in fair value of equity investments[4]	(34,054)	15,448	(43,893)	87,590
Amortization of acquired product rights[5]	5,384	5,384	21,536	21,536
Loss on change in fair value of contingent consideration[6]	15,058	24,347	29,202	12,149
Asset impairment[7]	—	—	5,631	—
Tax effect of Non-GAAP pre-tax adjustments[8]	(8,441)	13,199	(30,978)	(28,110)
Non-GAAP Net Income	$ 239,124	$ 139,661	$ 795,449	$ 622,676
Non-GAAP net income per share:				
Basic	$ 1.07	$ 0.63	$ 3.56	$ 2.80
Diluted	$ 1.06	$ 0.62	$ 3.52	$ 2.78
Shares used in computing Non-GAAP net income per share:				
Basic	224,226	222,615	223,628	222,004
Diluted	226,125	224,840	225,928	223,958

[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, 2023 are milestones of $2,000 and $7,000, respectively, earned from our collaborative partners, as compared to milestones of $30,000 and $165,000, respectively, for the three and twelve months ended December 31, 2022. 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, 2023 are upfront consideration and milestones of $24,000 and $36,650, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $70,000 and $125,950, respectively, for the three and twelve months ended December 31, 2022.

[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 Unrealized gain (loss) on long term 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] 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. The tax benefit for the three months ended December 31, 2022 includes a true up from the interim quarters related to valuation allowances against deferred tax assets associated with the loss on equity investments.

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