Incyte Reports 2025 Second Quarter Financial Results and Provides Updates on Key Clinical Programs

July 29, 2025

– Total revenues of $1,216 million in the second quarter (Q2'25) (+16% Y/Y); total product revenues of $1,059 million in Q2'25 (+17%Y/Y)

– Jakafi® (ruxolitinib) net product revenues of $764 million in Q2'25 (+8% Y/Y); raising full year 2025 guidance to a new range of $3,000 - $3,050 million [previously $2,950 - $3,000 million]

– Opzelura® (ruxolitinib) cream net product revenues of $164 million in Q2'25 (+35% Y/Y)

– Niktimvo ™ (axatilimab-csfr) net product revenues of $36 million in the second quarter, demonstrating strong commercial execution; raising full year 2025 Other Oncology guidance to a new range of $500 - $520 million [previously $415 - $455 million]

– Zynyz® (retifanlimab-dlwr) and Monjuvi® (tafasitamab-cxix) approved by the U.S. FDA for the first line treatment of adult patients with advanced squamous cell carcinoma of the anal canal (SCAC) and for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) in combination with rituximab and lenalidomide, respectively

– Bill Meury appointed as President and Chief Executive Officer effective June 26, 2025, upon the retirement of Hervé Hoppenot

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

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 29, 2025-- Incyte (Nasdaq:INCY) today reports 2025 second quarter financial results, and provides a status update on the Company's clinical development portfolio.

"As I begin my tenure as CEO, I look forward to leading Incyte through its next phase of growth and value creation for patients, partners and shareholders. Our second quarter results reflect strong growth for Jakafi® (ruxolitinib), Opzelura® (ruxolitinib) cream and Niktimvo ™ (axatilimab), positioning us well to deliver on our 2025 objectives," said Bill Meury, Chief Executive Officer, Incyte. "During the quarter, we achieved two regulatory milestones with the approvals of Zynyz® (retifanlimab-dlwr) for squamous cell anal carcinoma and Monjuvi® (tafasitamab-cxix) for follicular lymphoma, further expanding our ability to address patients' needs. Continued progress and diversification of our portfolio, including advancements with povorcitinib and mutCALR, are strengthening the foundation for sustainable, long-term growth."

Key Commercial Highlights

Jakafi:

Net product revenues for the second quarter 2025 of $764 million (+8% Y/Y):

- Net product revenue growth in the second quarter of 2025 versus the same quarter in the prior year, was driven by an increase in paid demand of 8% reflecting continued demand growth in all indications. Jakafi inventory levels were within normal range at the end of the second quarter of 2025.

Opzelura:

Net product revenues for the second quarter 2025 of $164 million (+35% Y/Y):

- U.S. net product revenue of $132 million in the second quarter of 2025 increased 19% compared to the second quarter of 2024 driven by increased patient demand and refills in both atopic dermatitis (AD) and vitiligo. Opzelura inventory levels were within normal range at the end of the second quarter of 2025.
- Ex-U.S. net product revenues of $32 million in the second quarter of 2025 were primarily driven by continued growth in sales in France, and the recent launches in Italy and Spain.

Pipeline Updates

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

- In June 2025, data from the Phase 1 study evaluating INCA033989 in mutCALR positive patients with essential thrombocythemia (ET) were presented during a late-breaking session at the 2025 European Hematology Association (EHA) Congress in Milan, Italy. The data showed rapid and durable normalization of platelet counts across all dose levels and importantly, a reduction in peripheral blood mutCALR variant allele frequency (VAF) correlating with hematologic response. INCA033989 was well tolerated with a favorable safety profile with no dose limiting toxicities reported. Together, the data demonstrates the potential of INCA033989 for disease modification by directly inhibiting and eliminating oncogenic mutCALR cells, while sparing healthy cells and restoring normal blood cell production. The Phase 1 data in patients with myelofibrosis (MF) as monotherapy and in combination with ruxolitinib are anticipated in the second half of 2025.

- A Phase 1 study evaluating JAK2V617Fi in MPNs is ongoing. Initial proof of concept data are anticipated in the first half of 2026.
- A Phase 2 trial evaluating axatilimab (Niktimvo) in combination with ruxolitinib (Jakafi) in patients with newly diagnosed chronic GVHD is ongoing.
- A Phase 3 trial evaluating axatilimab in combination with corticosteroids in patients with newly diagnosed chronic GVHD is ongoing.

MPN and GVHD Programs	Indication and status
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
INCA033989 (mutCALR)	Myelofibrosis, essential thrombocythemia: Phase 1
INCB160058 (JAK2V617Fi)	Myeloproliferative Neoplasms (MPNs): Phase 1

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

Other Hematology/Oncology – key highlights

- In May 2025, Zynyz was approved by the U.S. Food and Drug Administration (FDA) in combination with chemotherapy and as a single agent for the treatment of adult patients with advanced squamous cell carcinoma of the anal canal (SCAC). The Priority Review and FDA approval were based on data from two trials: the Phase 3 POD1UM-303/InterAACT2 and the Phase 2 POD1UM-202 trial. Incyte has also submitted a Type II variation Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and a Japanese New Drug Application (J-NDA) for retifanlimab in advanced SCAC.
- In June 2025, Monjuvi was approved by the FDA for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) in combination with rituximab and lenalidomide. The Priority Review and FDA approval were based on data from the pivotal Phase 3 inMIND trial.
- 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 as first-line treatment for diffuse large B-cell lymphoma (DLBCL) is ongoing. The Phase 3 data are anticipated in the second half of 2025.
- The Phase 1 studies evaluating KRASG12D and TGFßR2×PD-1 in solid tumors are ongoing. Initial proof of concept data for both studies are anticipated in the second half of 2025.

Heme/Oncology Programs	Indication and status
Tafasitamab (Monjuvi®/Minjuvi®) (CD19)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 3 (B-MIND) First-line DLBCL: Phase 3 (*front*MIND)
Retifanlimab (Zynyz®)[1] (PD-1)	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

- In April 2025, Incyte announced positive topline results from the Phase 3 (TRuE-AD4) study evaluating ruxolitinib cream in adult patients with moderate atopic dermatitis. The study met the co-primary endpoints at Week 8, with a statistically significant proportion of patients achieving both Investigator's Global Assessment Treatment Success (IGA-TS) and EASI75, which is defined as a 75% or greater improvement in the Eczema Area Severity Index score from baseline. In addition, the study met all key secondary endpoints. Ruxolitinib cream was well tolerated with no new safety signals. The full dataset will be presented at an upcoming medical conference.

- In June 2025, two Phase 3 studies (TRuE-HS2 and TRuE-HS2) evaluating ruxolitinib cream in mild to moderate hidradenitis suppurativa (HS) were initiated and are ongoing.

- In June 2025, the FDA extended the review period for the supplemental New Drug Application (sNDA) for ruxolitinib cream (Opzelura) for the treatment of children 2-11 years old with mild to moderate atopic dermatitis (AD). The Prescription Drug User Fee Act (PDUFA) action date was extended by three months to September 19, 2025.

Povorcitinib (INCB54707)

- Two Phase 3 studies (STOP-V1 and STOP-V2) evaluating povorcitinib versus placebo in patients with vitiligo are ongoing. The Phase 3 data are anticipated in 2026.

- Two Phase 3 studies (STOP-PN1 and STOP-PN2) evaluating povorcitinib versus placebo in patients with PN are ongoing. The Phase 3 data are anticipated in 2026.

- A Phase 2 trial evaluating povorcitinib in asthma is ongoing. Data are anticipated in the second half of 2025.

IAI and Dermatology Programs	Indication and status
Ruxolitinib cream (Opzelura)[1] (JAK1/JAK2)	Atopic dermatitis: Phase 3 pediatric study (TRuE-AD3); sNDA under review in the U.S. Hidradenitis suppurativa: Phase 3 (TRuE-HS1, TRuE-HS2) 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

2025 Second Quarter Financial Results

The financial measures presented in this press release for the three and six months ended June 30, 2025 and 2024 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Total GAAP revenues	$ 1,215,529	$ 1,043,759	$ 2,268,427	$ 1,924,648
Total GAAP operating income (loss)	530,314	(478,130)	735,482	(386,232)
Total Non-GAAP operating income (loss)	382,579	(378,801)	666,220	(217,618)
GAAP net income (loss)	404,999	(444,601)	563,202	(275,053)
Non-GAAP net income (loss)	311,927	(396,132)	541,386	(263,413)
GAAP basic EPS	$ 2.09	$ (2.04)	$ 2.91	$ (1.24)
Non-GAAP basic EPS	$ 1.61	$ (1.82)	$ 2.79	$ (1.19)
GAAP diluted EPS[1]	$ 2.04	$ (2.04)	$ 2.84	$ (1.24)
Non-GAAP diluted EPS[1]	$ 1.57	$ (1.82)	$ 2.73	$ (1.19)

[1] All stock options and stock awards were excluded from the diluted share calculation for the three and six months ended June 30, 2024 because their effect would have been anti-dilutive, as we were in a net loss position.

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended June 30,		% Change (as reported)	% Change (constant currency)[1]	Six Months Ended June 30,		% Change (as reported)	% Change (constant currency)[1]
	2025	2024			2025	2024		
Net product revenues:								
Jakafi	$ 763,788	$ 705,973	8%	NA	$ 1,473,200	$ 1,277,812	15%	NA
Opzelura	164,499	121,695	35%	34%	283,204	207,419	37%	36%
Iclusig	32,729	26,862	22%	16%	62,273	57,205	9%	8%
Pemazyre	22,192	20,269	9%	8%	40,632	37,945	7%	7%
Minjuvi/ Monjuvi	31,131	31,116	0%	(1%)	60,682	54,990	10%	10%
Niktimvo	36,154	—	NM	NA	49,767	—	NM	NA
Zynyz	8,921	651	1,270%	NA	11,930	1,118	967%	NA
Total net product revenues	1,059,414	906,566	17%	16%	1,981,688	1,636,489	21%	21%
Royalty revenues:								
Jakavi	109,714	99,317	10%	7%	201,859	188,912	7%	8%
Olumiant	33,482	31,702	6%	4%	64,282	62,291	3%	5%
Tabrecta	6,632	5,298	25%	NA	13,045	10,532	24%	NA
Other	1,287	876	47%	NM	2,553	1,424	79%	NM
Total royalty revenues	151,115	137,193	10%		281,739	263,159	7%	
Total net product and royalty revenues	1,210,529	1,043,759	16%		2,263,427	1,899,648	19%	
Milestone and contract revenues	5,000	—	NM	NM	5,000	25,000	(80%)	(80%)
Total GAAP revenues	$ 1,215,529	$ 1,043,759	16%		$ 2,268,427	$ 1,924,648	18%	

NM = not meaningful

NA = not applicable

[1] Percentage change in constant currency is calculated using 2024 foreign exchange rates to recalculate 2025 results.

Product and Royalty Revenues Total net product revenues for the quarter ended June 30, 2025 increased 17% over the prior year comparative period. Total net product and royalty revenues for the quarter ended June 30, 2025 increased 16% over the prior year comparative period, primarily driven by the following:

- Jakafi net product revenue increased 8% versus the prior year comparable period, driven by an increase in paid demand of 8% reflecting continued demand growth in all indications. Jakafi inventory levels were within normal range at the end of

the second quarter of 2025.

- Opzelura net product revenue increased 35% due to increased patient demand and refills in the U.S. in both AD and vitiligo, and increased contribution from ex-U.S. driven by continued uptake in France, and growth from the recent launches in Italy and Spain. Opzelura inventory levels were within normal range at the end of the second quarter of 2025.
- Niktimvo net product revenue reflects continued strong uptake of the product following its commercial launch during the first quarter of 2025.
- Zynyz net product revenue increase driven by the approval of the product in squamous cell anal carcinoma in the second quarter of 2025.
- Total royalty revenues for the quarter increased 10% versus the prior year comparable period, primarily driven by growth in Jakavi royalty revenue.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended June 30,		% Change	Six Months Ended June 30,		% Change
	2025	2024		2025	2024	
GAAP cost of product revenues	$ 78,766	$ 76,634	3%	$ 151,954	$ 137,590	10%
Non-GAAP cost of product revenues[1]	72,544	70,899	2%	139,489	125,858	11%
Contract dispute settlement	(242,251)	—	NM	(242,251)	—	NM
Non-GAAP contract dispute settlement[2]	—	—	NM	—	—	NM
GAAP research and development	494,917	1,138,380	(57%)	932,196	1,567,640	(41%)
Non-GAAP research and development[3]	455,635	1,089,089	(58%)	855,655	1,477,526	(42%)
GAAP selling, general and administrative	331,022	305,982	8%	656,713	606,238	8%
Non-GAAP selling, general and administrative[4]	304,771	262,572	16%	607,063	539,907	12%
GAAP loss (gain) on change in fair value of acquisition-related contingent consideration	22,761	893	NM	34,333	437	NM
Non-GAAP loss (gain) on change in fair value of acquisition-related contingent consideration	—	—	NM	—	—	NM
GAAP (profit) and loss sharing under collaboration agreements	—	—	NM	—	(1,025)	NM

[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 contract dispute settlement excludes the contract dispute settlement reached with Novartis.

[3] 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.

[4] Non-GAAP selling, general and administrative 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.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter ended June 30, 2025 increased 3% and 2% respectively, compared to the same period in 2024, primarily driven by growth in net product revenues, the Niktimvo profit share and increased manufacturing related costs, partially offset by the impact of the contract dispute settlement with Novartis.

Contract dispute settlement In May 2025, Incyte and Novartis entered into a settlement agreement with respect to litigation relating to the duration of royalty payments owed under the Collaboration and License Agreement between Incyte and Novartis. Under the settlement agreement, the royalty rate payable by Incyte on future net sales of Jakafi in the United Stated is reduced by 50% beginning January 1, 2025 and Incyte paid Novartis $280.0 million as the settlement of disputed royalties on net sales of Jakafi in the United States through December 31, 2024. The reduced royalty paid for the quarter ending March 31, 2025, was approximately $14.9 million. The difference of $242.2 million between the accrued royalties and the total amount paid by us to Novartis as disclosed above was recorded in contract dispute settlement on the condensed consolidated statement of operations for the three and six months ended June 30, 2025.

Research and development expenses GAAP and Non-GAAP research and development expenses for the quarter ended June 30, 2025 decreased 57% and 58%, respectively, compared to the same period in 2024, primarily due to $691.9 million of expense relating to the Escient acquisition that occurred during the quarter ended June 30, 2024. Excluding the upfront consideration paid related to the Escient transaction and other upfront and

milestone payments, research and development expenses for the quarter ended June 30, 2025 increased 8% compared to the same period in 2024 primarily driven by 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 June 30, 2025 increased 8% and 16%, respectively, compared to the same period in 2024, primarily due to increased legal costs relating to the Novartis contract dispute settlement and other matters and timing of consumer marketing activities. The 2024 Non-GAAP selling, general and administrative expenses exclude $21.5 million of expense relating to the Escient acquisition that occurred during the second quarter of 2024.

Other Financial Information

Change in fair value of acquisition-related contingent consideration The change in fair value of contingent consideration during the quarter ended June 30, 2025, compared to the same period in 2024, 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 three months ended June 30, 2025 increased 211% and 201%, respectively, compared to the same period in 2024, driven primarily by the aforementioned costs relating to the Escient acquisition in 2024, the Novartis contract dispute settlement in 2025 and growth in net product revenues.

Cash, cash equivalents and marketable securities position As of June 30, 2025 and December 31, 2024, cash, cash equivalents and marketable securities totaled $2.4 billion and $2.2 billion, respectively. The balance reflects the Novartis contract dispute settlement payment made during the second quarter of 2025, which offsets cash flows from operating activities.

2025 Financial Guidance

Incyte's guidance for the fiscal year 2025 is summarized below. Incyte is raising its revenue guidance for Jakafi to account for higher demand in the first half of 2025. Incyte is also raising its revenue guidance for other oncology products, to reflect the strength of the Niktimvo launch, higher demand for Zynyz in the first half of the year and the positive impact of foreign currency exchange rates. Incyte is updating its cost of product revenues guidance to reflect the reduction in the Jakafi royalty rate payable to Novartis, as a result of the contract dispute settlement. Furthermore, Incyte is updating its expense guidance for research and development to reflect the increase due to upfront and ongoing expenses related to new collaborations with Genesis and Biotheryx.

	Current	Previous
Jakafi net product revenues	$3,000 - $3,050 million	$2,950 - $3,000 million
Opzelura net product revenues	Unchanged	$630 - $670 million
Other oncology net product revenues[(1)]	$500 - $520 million	$415 - $455 million
GAAP Cost of product revenues	8.0% - 9.0% of net product revenues	8.5% - 9.0% of net product revenues
Non-GAAP Cost of product revenues[(2)]	7.0% - 8.0% of net product revenues	7.5% - 8.0% of net product revenues
GAAP Research and development expenses	$1,965 - $1,995 million	$1,930 - $1,960 million
Non-GAAP Research and development expenses[(3)]	$1,815 - $1,840 million	$1,780 - $1,805 million
GAAP Selling, general and administrative expenses	Unchanged	$1,280 - $1,310 million
Non-GAAP Selling, general and administrative expenses[(3)]	Unchanged	$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, 13754581.

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, 13754581.

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. 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). Incyte licenses exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc.

In the U.S., Monjuvi is approved by the U.S. Food and Drug Administration in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

Additionally, Monjuvi received accelerated approval in the United States in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). In Europe, Minjuvi® (tafasitamab) received conditional Marketing Authorization from the European Medicines Agency in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory DLBCL who are not eligible for ASCT.

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.

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-dlwr) is a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), indicated in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) and as a single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression or intolerance to platinum-based chemotherapy in the U.S.

Zynyz is also indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in the U.S. 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 United States. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a registered trademark of Incyte.

About Niktimvo™ (axatilimab-csfr)

Niktimvo™ (axatilimab-csfr) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the U.S. for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialize axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab in chronic GVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD – a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids (NCT06585774) are underway. Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

Niktimvo is a trademark of Incyte.

All other trademarks are the property of their respective owners.

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 ability to achieve both its full-year and long-term objectives; Incyte's financial guidance for 2025, including its expectations regarding sales of and demand for Jakafi and Opzelura; expected revenue contribution from Niktimvo and other hematology and oncology products; Incyte's potential to have more than 10 high impact launches by 2030; the disease modifying/curative potential of INCA033989 and plans to develop same; the potential blockbuster opportunity presented by povorcitinib and plans to develop same, including the submission of an NDA in early 2026; the possibility for H2 of 2025 to be transformational for Incyte in terms of regulatory approvals, data readouts and initiation of pivotal studies; the potential and progress of programs in our pipeline; ongoing clinical trials and clinical trials to be initiated; expectations regarding discussions with regulators, regulatory submissions and 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	GAAP		GAAP	

Revenues:				
Product revenues, net	$ 1,059,414	$ 906,566	$ 1,981,688	$ 1,636,489
Product royalty revenues	151,115	137,193	281,739	263,159
Milestone and contract revenues	5,000	—	5,000	25,000
Total revenues	1,215,529	1,043,759	2,268,427	1,924,648
Costs, expenses and other:				
Cost of product revenues (including definite-lived intangible amortization)	78,766	76,634	151,954	137,590
Contract dispute settlement	(242,251)	—	(242,251)	—
Research and development	494,917	1,138,380	932,196	1,567,640
Selling, general and administrative	331,022	305,982	656,713	606,238
Loss on change in fair value of acquisition-related contingent consideration	22,761	893	34,333	437
(Profit) and loss sharing under collaboration agreements	—	—	—	(1,025)
Total costs, expenses and other	685,215	1,521,889	1,532,945	2,310,880
Income (loss) from operations	530,314	(478,130)	735,482	(386,232)
Interest income	25,136	41,476	48,065	88,246
Interest expense	(594)	(657)	(1,254)	(1,087)
(Loss) gain on equity investments	(4,151)	39,241	(5,494)	139,188
Other, net	7,307	8,293	15,403	6,267
Income (loss) before provision for income taxes	558,012	(389,777)	792,202	(153,618)
Provision for income taxes	153,013	54,824	229,000	121,435
Net income (loss)	$ 404,999	$ (444,601)	$ 563,202	$ (275,053)
Net income (loss) per share:				
Basic	$ 2.09	$ (2.04)	$ 2.91	$ (1.24)
Diluted	$ 2.04	$ (2.04)	$ 2.84	$ (1.24)
Shares used in computing net income (loss) per share:				
Basic	193,995	218,175	193,853	221,329
Diluted	198,744	218,175	198,526	221,329

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

	June 30, 2025	December 31, 2024
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,421,738	$ 2,158,092
Accounts receivable	842,892	853,154
Property and equipment, net	798,543	763,411
Finance lease right-of-use assets, net	29,001	30,803
Inventory	451,531	407,199
Prepaid expenses and other assets	330,044	181,382
Equity investments	13,313	18,814
Other intangible assets, net	126,419	113,803
Goodwill	155,593	155,593
Deferred income tax asset	652,280	762,071
Total assets	$ 5,821,354	$ 5,444,322
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,407,216	$ 1,765,733
Finance lease liabilities	36,235	37,961
Acquisition-related contingent consideration	207,000	193,000
Stockholders' equity	4,170,903	3,447,628
Total liabilities and stockholders' equity	$ 5,821,354	$ 5,444,322

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
GAAP Net Income (Loss)	$ 404,999	$ (444,601)	$ 563,202	$ (275,053)
Adjustments[1]:				
Non-cash stock compensation from equity awards (R&D)[2]	37,700	34,541	74,424	71,333
Non-cash stock compensation from equity awards (SG&A)[2]	26,071	21,748	49,470	44,121
Non-cash stock compensation from equity awards (COGS)[2]	838	351	1,697	964
Non-cash interest[3]	81	144	163	252
Loss (gain) on equity investments[4]	4,151	(39,241)	5,494	(139,188)
Amortization of acquired product rights[5]	5,384	5,384	10,768	10,768
Loss on change in fair value of contingent consideration[6]	22,761	893	34,333	437
Contract dispute settlement[7]	(242,251)	—	(242,251)	—
MorphoSys transition costs[8]	—	2,373	—	6,952
Escient acquisition related compensation expense[9]	1,762	34,039	2,297	34,039
Tax effect of Non-GAAP pre-tax adjustments[10]	50,431	(11,763)	41,789	(18,038)
Non-GAAP Net Income (Loss)	$ 311,927	$ (396,132)	$ 541,386	$ (263,413)
Non-GAAP net income (loss) per share:				
Basic	$ 1.61	$ (1.82)	$ 2.79	$ (1.19)
Diluted[11]	$ 1.57	$ (1.82)	$ 2.73	$ (1.19)
Shares used in computing Non-GAAP net income (loss) per share:				
Basic	193,995	218,175	193,853	221,329
Diluted[11]	198,744	218,175	198,526	221,329

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and six months ended June 30, 2025 are milestones of $5,000 and $5,000 earned from our collaborative partners, as compared to $0 and $25,000 of milestones earned for the three and six months ended June 30, 2024. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and six months ended June 30, 2025 are upfront consideration and milestones of $12,550 and $28,050, respectively, related to our collaborative partners as compared to upfront consideration and milestones of $414 and $1,414, respectively, for the three and six months ended June 30, 2024.

[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 (Loss) gain 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 Contract dispute settlement 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 $2,232 and $6,263 for the three and six months ended June 30, 2024, and $141 and $689 is included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and six months ended June 30, 2024. 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 $1,582 and $2,117 for the three and six months ended June 30, 2025, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations is $180 for the three and six months ended June 30, 2025. Included within the Research and development line item in the Condensed Consolidated Statements of Operations is $12,518 for the three and six months ended June 30, 2024, and included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations is $21,521 for the three and six months ended June 30, 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 an estimated annual effective tax rate, taking into consideration any permanent items and valuation allowances against related deferred tax assets.

[11] All stock options and stock awards were excluded from the diluted share calculation for the three and six months ended June 30, 2024 because their effect would have been anti-dilutive, as we were in a net loss position.

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