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

April 29, 2025

– Total revenues of $1,053 million in the first quarter (Q1'25) (+20% Y/Y); total product revenues of $922 million in Q1'25 (+26%Y/Y)

– Jakafi® (ruxolitinib) net product revenues of $709 million in Q1'25 (+24% Y/Y); increasing full year 2025 Jakafi guidance to a new range of $2,950 - $3,000 million from $2,925 - $2,975 million

– Opzelura® (ruxolitinib) cream net product revenues of $119 million in Q1'25 (+38% Y/Y)

– Niktimvo ™ (axatilimab-csfr) net product revenues of $14 million in the first two months of U.S. launch demonstrating strong commercial execution and high patient need

– New, 18-week data from ongoing Phase 3 study of povorcitinib in hidradenitis suppurativa (HS) demonstrates continued improvement in HiSCR from Week 12 in addition to high response rates in placebo-crossover patients

– Positive Phase 2 topline results for povorcitinib in chronic spontaneous urticaria (CSU) demonstrates proof-of-concept in new indication

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

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

"The double-digit revenue growth in the first quarter driven by the continued growth of Jakafi and Opzelura and the recent launch of Niktimvo, puts us on track to achieve our full year objectives," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We also continued to advance our innovative pipeline, which will be critical for driving long-term growth. The positive Phase 3 results for povorcitinib in hidradenitis suppurativa in addition to the proof-of-concept in chronic spontaneous urticaria, strengthens the potential of povorcitinib as a multibillion-dollar product addressing patient needs across the five indications currently in development."

Key Commercial Highlights

Jakafi® (ruxolitinib):

Net product revenues for the first quarter 2025 of $709 million (+24% Y/Y):

- Net product revenue growth in the first quarter of 2025 versus the same quarter in the prior year, was driven by an increase in paid demand, the positive impact of the Part D redesign under the Inflation Reduction Act, partially offset by growth in 340B, and less de-stocking compared to the first quarter of 2024. Jakafi inventory levels were within normal range at the end of the first quarter of 2025.

Opzelura® (ruxolitinib) cream:

Net product revenues for the first quarter 2025 of $119 million (+38% Y/Y):

- U.S. net product revenue of $95 million in the first quarter of 2025 increased 20% compared to the first quarter of 2024 driven by patient demand and refills in both atopic dermatitis (AD) and vitiligo, partially offset by a reduction in channel inventory. Opzelura inventory levels were within normal range at the end of the first quarter of 2025.
- Ex-U.S. net product revenues of $23 million in the first quarter of 2025 were primarily driven by continued growth in sales in Germany and France, as well as the recent launches in Italy and Spain.

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 enrolling patients. Initial proof of concept data for both studies are anticipated in 2025.
- A Phase 2 trial evaluating axatilimab (Niktimvo ™) in combination with ruxolitinib (Jakafi) in patients with newly diagnosed chronic GVHD is ongoing and enrolling patients.
- A Phase 3 trial evaluating axatilimab in combination with corticosteroids in patients with newly diagnosed chronic GVHD is ongoing and enrolling patients.

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
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 as first-line treatment for 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 and enrolling patients. 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) 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

- In March 2025, results from two Phase 3 studies (TRuE-PN1 and TRuE-PN2) evaluating ruxolitinib cream in patients with prurigo nodularis (PN) were presented in a late-breaking oral session at the American Academy of Dermatology annual meeting. The TRuE-PN1 study met the primary endpoint of a $\geq$ 4-point improvement from baseline in Worst-Itch Numeric Rating Scale (WI-NRS4) at Week 12 and all key secondary endpoints. The TRuE-PN2 study did not reach statistical significance for the primary endpoint, resulting in the key secondary endpoints with nominal p-values. These key secondary endpoints still demonstrate positive trends for ruxolitinib cream 1.5% versus vehicle. These data will inform planned discussions with regulatory authorities on submission.
- A 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.

Povorcitinib (INCB54707)

- In April 2025, Incyte announced positive topline results from the Phase 2 study evaluating povorcitinib in patients with chronic spontaneous urticaria (CSU). The study met the primary endpoint at Week 12 of change from baseline in the Urticaria Activity Score summed over 7 days (UAS7). Povorcitinib was well tolerated with no new safety signals observed. These data will support planned discussions with regulatory agencies and will be presented at an upcoming medical conference.
- In March 2025, positive results from the Phase 3 studies (STOP-HS1 and STOP-HS2) of povorcitinib in patients with HS were presented and demonstrated that both studies met their primary endpoint of Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 12 and at both tested doses (45mg and 75mg). In addition, at Week 12, patients treated with povorcitinib achieved deep levels of clinical response with a greater proportion achieving HiSCR75, reduction in flares,

>3-point decrease in the Skin Pain Numeric Rating Scale (NRS) score and Skin Pain NRS30. Furthermore, povorcitinib demonstrated rapid onset of response, including rapid skin pain reduction. Additional longer-term data demonstrate that at Week 18, HiSCR rates continue to improve over Week 12 in patients treated with povorcitinib including high levels of response in those patients previously treated on placebo and crossed over to active povorcitinib treatment. These data support the planned regulatory submission of povorcitinib for the treatment of HS worldwide.

- Two Phase 3 studies (STOP-PN1 and STOP-PN2) evaluating povorcitinib in patients with PN versus placebo are ongoing and enrolling patients.
- A Phase 2 trial evaluating povorcitinib in asthma is ongoing and enrolling. 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) 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 - key highlights

- In February 2025, Incyte and Genesis Therapeutics, Inc. (Genesis) entered into a strategic collaboration focused on the research, discovery and development of novel small molecule medicines, with an initial focus on collaboration targets selected by Incyte. Incyte receives exclusive rights to develop and commercialize collaboration products leveraged through Genesis' GEMS artificial intelligence (AI) platform.

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

2025 First Quarter Financial Results

The financial measures presented in this press release for the three months ended March 31, 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 March 31,	
	2025	**2024**
Total GAAP revenues	$ 1,052,898	$ 880,889
Total GAAP operating income	205,168	91,898

Total Non-GAAP operating income	283,641	161,183
GAAP net income	158,203	169,548
Non-GAAP net income	229,459	132,719
GAAP basic EPS	$ 0.82	$ 0.76
Non-GAAP basic EPS	$ 1.18	$ 0.59
GAAP diluted EPS	$ 0.80	$ 0.75
Non-GAAP diluted EPS	$ 1.16	$ 0.58

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended March 31,		% Change (as reported)	% Change (constant currency)[1]
	2025	2024		
Net product revenues:				
Jakafi	$ 709,412	$ 571,839	24%	NA
Opzelura	118,705	85,724	38%	39%
Iclusig	29,544	30,343	(3%)	—%
Pemazyre	18,440	17,676	4%	6%
Minjuvi/ Monjuvi	29,551	23,874	24%	25%
Niktimvo	13,613	—	NM	NA
Zynyz	3,009	467	544%	NA
Total net product revenues	922,274	729,923	26%	27%
Royalty revenues:				
Jakavi	92,145	89,595	3%	6%
Olumiant	30,800	30,589	1%	6%
Tabrecta	6,413	5,234	23%	NA
Other	1,266	548	131%	NM
Total royalty revenues	130,624	125,966	4%	
Total net product and royalty revenues	1,052,898	855,889	23%	
Milestone and contract revenues	—	25,000	—%	—%
Total GAAP revenues	$ 1,052,898	$ 880,889	20%	

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 and royalty revenues for the quarter ended March 31, 2025 increased 23% over the prior year comparative period. Total net product revenues for the quarter ended March 31, 2025 increased 26% over the prior year comparative period primarily driven by the following:

- Jakafi net product revenue increased 24% versus the prior year comparable period, driven by an increase in paid demand of 10% reflecting continued demand growth in all indications, the positive impact of the Part D redesign under the Inflation Reduction Act, partially offset by growth in 340B, and 7% favorable impact from less de-stocking compared to the first quarter of 2024. Jakafi inventory levels were within normal range at the end of the first quarter of 2025.
- Opzelura net product revenue increased 38% due to continued growth in new patient starts and refills in the U.S. with U.S. paid demand up 24% versus the first quarter of 2024, partially offset by a reduction in channel inventory, and increased contribution from ex-U.S. driven by continued uptake in Germany and France, as well as growth from the recent launches in Italy and Spain. Opzelura inventory levels were within normal range at the end of the first quarter of 2025.
- Minjuvi/Monjuvi net product revenue increased 24% as a result of the first quarter of 2025 reflecting three months of net product revenues in the U.S., compared to two months of net product revenue in the first quarter of 2024 due to the acquisition of U.S. rights to Monjuvi, which closed in February 2024.
- Niktimvo net product revenue driven by the commercial launch of the product during the first quarter of 2025.

Operating Expenses

Operating Expense Summary

(unaudited, in thousands)

	Three Months Ended March 31,		% Change
	2025	2024	
GAAP cost of product revenues	$ 73,188	$ 60,956	20%
Non-GAAP cost of product revenues[1]	66,945	54,959	22%
GAAP research and development	437,279	429,260	2%
Non-GAAP research and development[2]	400,020	388,437	3%
GAAP selling, general and administrative	325,691	300,256	8%
Non-GAAP selling, general and administrative[3]	302,292	277,335	9%
GAAP loss (gain) on change in fair value of acquisition-related contingent consideration	11,572	(456)	NM
Non-GAAP loss (gain) on change in fair value of acquisition-related contingent consideration	—	—	—%
GAAP (profit) and loss sharing under collaboration agreements	—	(1,025)	—%

[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 severance payments.

[3] Non-GAAP selling, general and administrative expenses exclude the cost of stock-based compensation, MorphoSys transition costs, and Escient severance payments.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter ended March 31, 2025 increased 20% and 22% respectively, compared to the same period in 2024 primarily due to increased royalty expense.

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended March 31, 2025 increased 2% and 3%, respectively, compared to the same period in 2024, reflecting 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 March 31, 2025 increased 8% and 9%, respectively, compared to the same period in 2024 primarily due to timing of consumer marketing activities and of certain other expenses.

Other Financial Information

Change in fair value of acquisition-related contingent consideration The change in fair value of contingent consideration during the quarter ended March 31, 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 March 31, 2025 increased 123% and 76%, respectively, compared to the same period in 2024, driven primarily by growth in net product revenue.

Cash, cash equivalents and marketable securities position As of March 31, 2025 and December 31, 2024, cash, cash equivalents and marketable securities totaled $2.4 billion and $2.2 billion, respectively.

2025 Financial Guidance

Incyte's guidance for the fiscal year 2025 is summarized below. Incyte is raising its full year 2025 Jakafi revenue guidance. 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. Guidance for research and development excludes the $15 million of expense for the full year 2025 related to our recently announced collaboration with Genesis.

	Current	Previous
Jakafi net product revenues	$2,950 - $3,000 million	$2,925 - $2,975 million
Opzelura net product revenues	Unchanged	$630 - $670 million
Other oncology net product revenues[(1)]	Unchanged	$415 - $455 million
GAAP Cost of product revenues	Unchanged	8.5% - 9.0% of net product revenues
Non-GAAP Cost of product revenues[(2)]	Unchanged	7.5% - 8.0% of net product revenues
GAAP Research and development expenses	Unchanged	$1,930 - $1,960 million
Non-GAAP Research and development expenses[(3)]	Unchanged	$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, 13753168.

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, 13753168.

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.

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.

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.

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 additional near-term launches; the potential of povorcitinib to be a multibillion-dollar product; the possibility for 2025 to be a transformational year for Incyte in terms of 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; ongoing clinical trials and clinical trials that may be initiated; expectations regarding discussions with regulators, regulatory submissions and regulatory approvals; plans to present data at upcoming medical conferences; Incyte's exposure to potential tariffs; 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 March 31,	
	2025	**2024**
	GAAP	
Revenues:		
Product revenues, net	$ 922,274	$ 729,923
Product royalty revenues	130,624	125,966
Milestone and contract revenues	—	25,000
Total revenues	1,052,898	880,889
Costs, expenses and other:		
Cost of product revenues (including definite-lived intangible amortization)	73,188	60,956
Research and development	437,279	429,260
Selling, general and administrative	325,691	300,256
Loss (gain) on change in fair value of acquisition-related contingent consideration	11,572	(456)
(Profit) and loss sharing under collaboration agreements	—	(1,025)
Total costs, expenses and other	847,730	788,991
Income from operations	205,168	91,898
Interest income	22,929	46,770
Interest expense	(660)	(430)
(Loss) gain on equity investments	(1,343)	99,947
Other, net	8,096	(2,026)
Income before provision for income taxes	234,190	236,159
Provision for income taxes	75,987	66,611
Net income	$ 158,203	$ 169,548
Net income per share:		
Basic	$ 0.82	$ 0.76
Diluted	$ 0.80	$ 0.75
Shares used in computing net income per share:		
Basic	193,712	224,484
Diluted	198,197	227,219

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

	March 31, 2025	**December 31, 2024**
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,408,658	$ 2,158,092
Accounts receivable	823,134	853,154
Property and equipment, net	765,359	763,411
Finance lease right-of-use assets, net	29,892	30,803
Inventory	429,286	407,199
Prepaid expenses and other assets	243,470	181,382
Equity investments	17,463	18,814

Other intangible assets, net	107,611	113,803
Goodwill	155,593	155,593
Deferred income tax asset	768,899	762,071
Total assets	$ 5,749,365	$ 5,444,322
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,849,681	$ 1,765,733
Finance lease liabilities	37,121	37,961
Acquisition-related contingent consideration	195,000	193,000
Stockholders' equity	3,667,563	3,447,628
Total liabilities and stockholders' equity	$ 5,749,365	$ 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 March 31,	
	2025	**2024**
GAAP Net Income	$ 158,203	$ 169,548
Adjustments[1]:		
Non-cash stock compensation from equity awards (R&D)[2]	36,724	36,792
Non-cash stock compensation from equity awards (SG&A)[2]	23,399	22,373
Non-cash stock compensation from equity awards (COGS)[2]	859	613
Non-cash interest[3]	82	108
Loss (gain) on equity investments[4]	1,343	(99,947)
Amortization of acquired product rights[5]	5,384	5,384
Loss (gain) on change in fair value of contingent consideration[6]	11,572	(456)
MorphoSys transition costs[7]	—	4,579
Escient acquisition related compensation expense[8]	535	—
Tax effect of Non-GAAP pre-tax adjustments[9]	(8,642)	(6,275)
Non-GAAP Net Income	$ 229,459	$ 132,719
Non-GAAP net income per share:		
Basic	$ 1.18	$ 0.59
Diluted	$ 1.16	$ 0.58
Shares used in computing Non-GAAP net income per share:		
Basic	193,712	224,484
Diluted	198,197	227,219

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2025 are milestones of $0 earned from our collaborative partners, as compared to $25,000 of milestones earned for the three months ended March 31, 2024. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 2025 and 2024 are upfront consideration and milestones of $15,500 and $1,000, respectively, related to our collaborative partners.

[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 (gain) on change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

[7] Included within the Research and development line item in the Condensed Consolidated Statements of Operations (in thousands) is $4,031 for the three months ended March 31, 2024, and $548 is included within the Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three months ended March 31, 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.

[8] Included within the Research and development line item in the Condensed Consolidated Statements of Operations (in thousands) is $535 for the three months ended March 31, 2025. Escient acquisition related compensation expense represents non-recurring charges associated with severance payments to former Escient employees.

[9] 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. The Non-GAAP net income for the three months ended March 31, 2024 should have been $132,719 compared to the $145,269 previously disclosed to correct a transposition error in the tax effect of Non-GAAP pre-tax adjustments. For the three months ended March 31, 2024, the tax effect of Non-GAAP pre-tax adjustments should have been ($6,275) instead of $6,275. This correction is reflected in the table above.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250429096014/en/

Media
media@incyte.com

Investors
ir@incyte.com

Source: Incyte