Incyte Reports 2023 Third Quarter Financial Results and Provides Updates on Key Clinical Programs

October 31, 2023

– Total revenues of $919 million in the third quarter (Q3'23) (+12% Y/Y)

– Jakafi® (ruxolitinib) net product revenues of $636 million (+3% Y/Y) in Q3'23, $1.9 billion (+8% Y/Y) YTD 2023, driven by growth in total patients across all indications; tightening full year 2023 guidance to a new range of $2.59 - $2.62 billion

– Opzelura® (ruxolitinib) cream net product revenues of $92 million (+141% Y/Y) in Q3'23, $229 million YTD 2023; continued uptake in atopic dermatitis (AD) and vitiligo and enhanced payer coverage

– Phase 2 study evaluating povorcitinib in prurigo nodularis (PN) met its primary endpoint

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

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 31, 2023-- Incyte (Nasdaq:INCY) today reports 2023 third quarter financial results, and provides a status update on the Company's clinical development portfolio.

"Our double-digit revenue growth during the quarter was driven by sustained performance of Jakafi® (ruxolitinib) and an increasing contribution from Opzelura® (ruxolitinib) with continued strong patient demand and enhanced payer coverage," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We made significant progress with our early programs in myeloproliferative neoplasms (MPNs), including mCALR and JAK2V617F, which have the potential to be disease modifying therapies that represent a fundamentally new approach to the way patients with MPNs are treated. Additionally, we recently received positive top line results from the Phase 2 study of povorcitinib in prurigo nodularis (PN) and plans are underway to initiate a Phase 3 study in 2024. With approximately 100,000 treated PN patients in the U.S., povorcitinib has the potential to be an efficacious therapy for those patients who currently have limited treatment options."

Key Company Updates

- In September, Incyte was notified by the Centers for Medicare and Medicaid Services that ruxolitinib phosphate qualified for the Small Biotech Exception.
- Beginning January 1, 2024, Opzelura will be listed as a Preferred Brand on the CVS Caremark and Aetna formularies impacting roughly 30 million commercial lives in the U.S.

Key Product Sales Performance

Jakafi:

Net product revenues for the quarter of $636 million:

- Net product revenues grew 3% compared with the third quarter of 2022.
- Channel inventory at the end of the third quarter of 2023 decreased by approximately $14 million versus the second quarter of 2023. Underlying demand in the third quarter of 2023 continued to grow both year-over-year and quarter-over-quarter.

Opzelura:

Net product revenues for the quarter of $92 million:

- Net product revenues of $92 million grew 141% compared with the third quarter of 2022, driven by growth in patient demand, refills and expansion in payer coverage as the launch in AD and vitiligo continues.

Pipeline Updates

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

- Combination trials of **ruxolitinib twice daily (BID) with zilurgisertib (ALK2)** and **INCB57643 (BET)** are ongoing and continue to enroll. Additional data from these studies are anticipated to be shared in the fourth quarter of 2023.
- The Phase 1 study evaluating **INCA033989 (mCALR)** is ongoing and enrolling patients.
- In October, we announced the development of a new program targeting the JAK2V617F mutation, which is present in 55-60% of myelofibrosis (MF) and essential thrombocythemia (ET) patients, and in 95% of polycythemia vera (PV) patients. **INCB160058** is a small molecule inhibitor, targeting the JAK2V617F mutation and we expected to file the IND by

year-end 2023.

	Indication and status
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)
Ruxolitinib + axatilimab[2] (JAK1/JAK2 + anti-CSF-1R)	Chronic GVHD: Phase 1/2 in preparation
INCA033989 (mCALR)	Myelofibrosis, essential thrombocythemia: 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

Oral small molecule PD-L1 program: Combination studies evaluating INCB99280 in combination with axitinib (VEGF) and in combination with ipilimumab (CTLA-4) are enrolling. Two Phase 2 monotherapy studies evaluating INCB99280 in patients with select solid tumors who are checkpoint inhibitor naive and in metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC, are enrolling.

	Indication and status
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®)[1] (CD19)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 3 (B-MIND) First-line DLBCL: Phase 3 (frontMIND) Relapsed or refractory follicular lymphoma (FL) and relapsed or refractory marginal zone lymphoma (MZL): Phase 3 (inMIND)
Retifanlimab (Zynyz®)[2] (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

[1] Development of tafasitamab in collaboration with MorphoSys.

[2] Retifanlimab licensed from MacroGenics.

[3] Clinical trial collaboration and supply agreement with Mirati Therapeutics.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Opzelura

- New results of a pooled analysis of long-term extension (LTE) data from the pivotal Phase 3 TRuE-V program assessing **Opzelura** cream 1.5% in patients 12 years of age and older with nonsegmental vitiligo who previously experienced limited or no response to treatment at Week 24 were presented at the European Academy of Dermatology and Venereology (EADV) Congress 2023 as a late-breaking oral presentation . These results showed patients who initially experienced limited or no facial or total body repigmentation at six months achieved improved repigmentation after continued treatment with Opzelura for up to two years.
- Expanded results from the pivotal Phase 3 TRuE-AD3 study evaluating the safety and efficacy of **ruxolitinib cream (Opzelura)** in children (age ≥2 to <12 years) with atopic dermatitis (AD), the most common type of eczema, met its primary endpoint and was presented at EADV. Significantly more patients treated with ruxolitinib cream (0.75% and 1.5%) achieved Investigator's Global Assessment Treatment Success than patients treated with vehicle control (non-medicated cream).

- **Ruxolitinib cream** in other indications: three Phase 2 studies in lichen planus, lichen sclerosus and mild to moderate hidradenitis suppurativa (HS) have completed enrollment. Two Phase 3 trials evaluating ruxolitinib cream in prurigo nodularis (PN) are ongoing.

Povorcitinib (INCB54707)

- Positive 52-week data from a Phase 2b clinical trial evaluating the safety and efficacy of **povorcitinib**, an investigational oral JAK1 inhibitor, in adult patients with extensive nonsegmental vitiligo were presented at EADV as a late-breaking oral presentation. Results showed that treatment with oral povorcitinib was associated with substantial total body and facial repigmentation across all treatment groups at Week 52 and further reinforces the efficacy profile and potential of povorcitinib as an oral treatment for patients with extensive nonsegmental vitiligo.
- 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.

	Indication and status
Ruxolitinib cream (Opzelura®)[1] (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2); approved in the U.S. and Europe Lichen planus: Phase 2 Lichen sclerosus: Phase 2 Hidradenitis suppurativa: Phase 2 Prurigo nodularis: Phase 3 (TRuE-PN1, TRuE-PN2)
Ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2
Povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 2b; Phase 3 (STOP-HS1, STOP-HS2) Vitiligo: Phase 2; Phase 3 planned Prurigo nodularis: Phase 2 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.

Discovery and other early development – key highlights

INCA33890 (TGFβR2xPD-1): A Phase 1 study evaluating INCA33890 in patients with select advanced solid tumors has been initiated.

Modality	**Candidates**
Small molecules	INCB123667 (CDK2)
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 – key highlights

Jakavi® (ruxolitinib)- In August, Novartis announced that Jakavi was approved in Japan for the use in GVHD after hematopoietic stem cell transplant.

	Indication and status
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 Third Quarter Financial Results

The financial measures presented in this press release for the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Total GAAP revenues	$ 919,025	$ 823,303	$2,682,308	$2,467,935
Total GAAP operating income	214,705	138,376	433,255	509,347
Total Non-GAAP operating income	273,294	167,271	625,081	649,042
GAAP net income	171,269	112,775	396,520	312,199
Non-GAAP net income	248,719	133,795	556,325	483,015
GAAP basic EPS	$ 0.76	$ 0.51	$ 1.77	$ 1.41
Non-GAAP basic EPS	$ 1.11	$ 0.60	$ 2.49	$ 2.18
GAAP diluted EPS	$ 0.76	$ 0.50	$ 1.76	$ 1.40
Non-GAAP diluted EPS	$ 1.10	$ 0.60	$ 2.46	$ 2.16

Revenue Details

Revenue Details
(unaudited, in thousands)

	Three Months Ended September 30,		% Change (as reported)	% Change (constant currency)[1]	Nine Months Ended September 30,		% Change (as reported)	% Change (constant currency)[1]
	2023	2022			2023	2022		
Net product revenues:								
Jakafi	$ 636,252	$ 619,595	3%	3%	$1,898,605	$1,761,732	8%	8%
Opzelura	91,836	38,140	141%	140%	228,621	67,454	239%	239%
Iclusig	27,721	25,929	7%	(1%)	84,493	78,222	8%	7%
Pemazyre	18,942	23,414	(19%)	(20%)	62,989	60,429	4%	5%
Minjuvi	8,348	5,932	41%	43%	28,063	14,845	89%	90%
Zynyz	98	—	NM	NM	668	—	NM	NM
Total net product revenues	783,197	713,010	10%	10%	2,303,439	1,982,682	16%	16%
Royalty revenues:								
Jakavi	96,551	85,808	13%	11%	263,691	240,386	10%	12%
Olumiant	29,615	20,371	45%	47%	95,779	98,689	(3%)	2%
Tabrecta	4,139	4,114	1%	NA	13,115	11,178	17%	NA

Pemazyre	523	—	NM	NM	1,284	—	NM	NM
Total royalty revenues	130,828	110,293	19%		373,869	350,253	7%	
Total net product and royalty revenues	914,025	823,303	11%		2,677,308	2,332,935	15%	
Milestone and contract revenues	5,000	—	NM	NM	5,000	135,000	(96%)	(96%)
Total GAAP revenues	$ 919,025	$ 823,303	12%		$2,682,308	$2,467,935	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 September 30, 2023 increased 10% and 11%, respectively, over the prior year comparative period, primarily driven by increases in Jakafi and Opzelura net product revenues. The increase in Jakafi net product revenues was primarily driven by growth in patient demand and was partially offset by a decrease in inventory. Total Opzelura net product revenues for the quarter were $92 million, representing a 141% increase year-over-year driven by increased patient demand and expanded coverage. Jakavi royalties for the quarter were impacted by favorable changes in foreign currency exchange rates and Olumiant royalties for the quarter were impacted by unfavorable changes in foreign currency exchange rates. In the third quarter of 2022, Olumiant royalties were impacted by a one-time deduction related to securing intellectual property rights.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2023	2022	Change	2023	2022	Change
GAAP cost of product revenues	$ 60,091	$ 54,584	10%	$ 185,239	$ 147,834	25%
Non-GAAP cost of product revenues[1]	53,914	48,521	11%	166,733	129,715	29%
GAAP research and development	375,709	384,007	(2%)	1,183,100	1,084,576	9%
Non-GAAP research and development[2]	348,868	358,268	(3%)	1,092,409	1,004,372	9%
GAAP selling, general and administrative	267,893	266,460	1%	867,428	729,321	19%
Non-GAAP selling, general and administrative[3]	241,896	247,474	(2%)	798,943	675,751	18%
GAAP (gain) loss on change in fair value of acquisition-related contingent consideration	(426)	(21,893)	(98%)	14,144	(12,198)	(216%)
Non-GAAP (gain) loss on change in fair value of acquisition-related contingent consideration[4]	—	—	— %	—	—	— %
GAAP loss and (profit) sharing under collaboration agreements[5]	1,053	1,769	(40%)	(858)	9,055	(109%)

[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 (gain) loss on change in fair value of acquisition-related contingent consideration is null.

[5] Growth rate in GAAP loss and (profit) sharing under collaboration agreements represents a decrease in loss position for the three and nine months ended September 30, 2023.

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter ended September 30, 2023 increased 10% and 11%, respectively, compared to the same period in 2022 primarily due to growth in net product revenues.

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended September 30, 2023 decreased 2% and 3%, respectively, compared to the same period in 2022 primarily due to a decrease in one-time collaboration related expenses partially offset by 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 September 30, 2023 increased 1% and decreased 2%, respectively, compared to the same period in 2022. The Non-GAAP decrease is driven by the $5.6 million asset impairment charge relating to assets written off under an agreement with Wilmington Friends School Inc. to purchase property.

Other Financial Information

Operating income GAAP and Non-GAAP operating income for the three months ended September 30, 2023 increased 55% and 63%, respectively, compared to the same period in 2022, driven by growth in product revenues.

Cash, cash equivalents and marketable securities position As of September 30, 2023 and December 31, 2022, cash, cash equivalents and marketable securities totaled $3.5 billion and $3.2 billion, respectively.

2023 Financial Guidance

Incyte is tightening its full year 2023 guidance for Jakafi net product revenues. Incyte's guidance is summarized below. Guidance does not include revenue from any potential new product launches or the impact of any potential future strategic transactions.

	Current	Previous
Jakafi net product revenues	$2.59 - $2.62 billion	$2.58 - $2.63 billion
Other Hematology/Oncology net product revenues[(1)]	Unchanged	$215 - $225 million
GAAP Cost of product revenues	Unchanged	7 – 8% of net product revenues
Non-GAAP Cost of product revenues[(2)]	Unchanged	6 – 7% of net product revenues
GAAP Research and development expenses	Unchanged	$1,610 - $1,650 million
Non-GAAP Research and development expenses[(3)]	Unchanged	$1,485 - $1,520 million
GAAP Selling, general and administrative expenses	Unchanged	$1,050 - $1,150 million
Non-GAAP Selling, general and administrative expenses[(3)]	Unchanged	$965 - $1,060 million

[1]Pemazyre in the U.S., EU and Japan; 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, 13741786.

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, 13741786.

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

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

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. 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).

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 MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in Europe and Canada.

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 2023, including its expectations regarding sales of Jakafi; expectations with respect to demand for and payer coverage of Opzelura; expectations regarding the potential and progress of programs in our pipeline, including mCALR and JAK2V617F; expectations regarding ongoing clinical trials and clinical

trials to be initiated, including combination trials of ruxolitinib twice daily (BID) with zilurgisertib (ALK2) and INCB57643 (BET), a phase 3 trial of povorcitinib in prurigo nodularis and phase 2 trials of povorcitinib in asthma and chronic spontaneous urticaria, 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; our expectations regarding regulatory filings, including the planned submission of an IND for INCB100658 by year-end 2023; and our expectations regarding 2023 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 for the year ended December 31, 2022. 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 783,197	$ 713,010	$2,303,439	$1,982,682
Product royalty revenues	130,828	110,293	373,869	350,253
Milestone and contract revenues	5,000	—	5,000	135,000
Total revenues	919,025	823,303	2,682,308	2,467,935
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	60,091	54,584	185,239	147,834
Research and development	375,709	384,007	1,183,100	1,084,576
Selling, general and administrative	267,893	266,460	867,428	729,321
(Gain) loss on change in fair value of acquisition-related contingent consideration	(426)	(21,893)	14,144	(12,198)
Loss and (profit) sharing under collaboration agreements	1,053	1,769	(858)	9,055
Total costs and expenses	704,320	684,927	2,249,053	1,958,588
Income from operations	214,705	138,376	433,255	509,347
Interest income and other, net	46,371	11,513	121,912	13,295
Interest expense	(623)	(641)	(1,747)	(1,999)
Unrealized (loss) gain on long term investments	(26,654)	(660)	9,839	(72,142)
Income before provision for income taxes	233,799	148,588	563,259	448,501
Provision for income taxes	62,530	35,813	166,739	136,302
Net income	$ 171,269	$ 112,775	$ 396,520	$ 312,199
Net income per share:				
Basic	$ 0.76	$ 0.51	$ 1.77	$ 1.41
Diluted	$ 0.76	$ 0.50	$ 1.76	$ 1.40
Shares used in computing net income per share:				
Basic	224,078	222,415	223,428	221,801
Diluted	226,167	224,175	225,756	223,626

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

	September 30, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and marketable securities	$ 3,516,453	$ 3,238,965
Accounts receivable	657,263	644,879
Property and equipment, net	733,046	739,310
Finance lease right-of-use assets, net	24,880	26,298
Inventory	199,286	120,959
Prepaid expenses and other assets	254,421	194,144
Long term investments	153,663	133,676
Other intangible assets, net	129,249	129,219
Goodwill	155,593	155,593
Deferred income tax asset	564,385	457,941
Total assets	$ 6,388,239	$ 5,840,984
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,217,869	$ 1,216,603
Finance lease liabilities	31,923	33,262
Acquisition-related contingent consideration	207,000	221,000
Stockholders' equity	4,931,447	4,370,119
Total liabilities and stockholders' equity	$ 6,388,239	$ 5,840,984

INCYTE CORPORATION

RECONCILIATION OF GAAP NET (LOSS) INCOME TO SELECTED NON-GAAP ADJUSTED INFORMATION

(unaudited, in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP Net Income	$ 171,269	$ 112,775	$ 396,520	$ 312,199
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	26,841	25,739	90,691	80,204
Non-cash stock compensation from equity awards (SG&A)[2]	20,366	18,986	62,854	53,570
Non-cash stock compensation from equity awards (COGS)[2]	793	679	2,354	1,967
Non-cash interest[3]	108	72	355	288
Changes in fair value of equity investments[4]	26,654	660	(9,839)	72,142
Amortization of acquired product rights[5]	5,384	5,384	16,152	16,152
(Gain) loss on change in fair value of contingent consideration[6]	(426)	(21,893)	14,144	(12,198)
Asset impairment[7]	5,631	—	5,631	—
Tax effect of Non-GAAP pre-tax adjustments[8]	(7,901)	(8,607)	(22,537)	(41,309)
Non-GAAP Net Income	$ 248,719	$ 133,795	$ 556,325	$ 483,015
Non-GAAP net income per share:				
Basic	$ 1.11	$ 0.60	$ 2.49	$ 2.18
Diluted	$ 1.10	$ 0.60	$ 2.46	$ 2.16
Shares used in computing Non-GAAP net income per share:				
Basic	224,078	222,415	223,428	221,801
Diluted	226,167	224,175	225,756	223,626

[1] Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and nine months ended September 30, 2023 are milestones of $5,000 for both periods, as compared to milestones of $0 and $135,000, respectively, earned from our collaborative partners for the three and nine months ended September 30, 2022. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and nine months ended September 30, 2023 are upfront consideration and milestones of $2,950 and $12,650, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $33,450 and $55,950, respectively, for the three and nine months ended September 30, 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 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 (Gain) 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 an estimated annual effective tax rate, taking into consideration any permanent items and valuation allowances against related deferred tax assets.

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