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

August 1, 2023

- *Total net product revenues of $827 million in the second quarter (Q2'23) (+25% Y/Y)*
- *Jakafi® (ruxolitinib) net product revenues of $682 million (+14% Y/Y) in Q2'23; raising the bottom end of full year guidance to a new range of $2.58 - $2.63 billion for FY 2023*
- *Opzelura® (ruxolitinib) cream net product revenues of $80 million (+384% Y/Y) in Q2'23; continued uptake in atopic dermatitis (AD) and vitiligo*
- *Two pivotal studies in high potential programs met their primary endpoint: ruxolitinib cream in pediatric atopic dermatitis (TRuE-AD3) and axatilimab in chronic GVHD (AGAVE-201)*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 1, 2023-- Incyte (Nasdaq:INCY) today reports 2023 second quarter financial results, and provides a status update on the Company's clinical development portfolio.

"We delivered a strong quarter with total net product revenues growing 25% year over year led by double-digit Jakafi® (ruxolitinib) growth and continued momentum from Opzelura® (ruxolitinib) cream in atopic dermatitis and vitiligo in the United States," said Hervé Hoppenot, Chief Executive Officer, Incyte. "We continue to advance multiple programs in our pipeline, and recently announced positive topline results for two high potential programs, ruxolitinib cream in pediatric atopic dermatitis and axatilimab in chronic graft-versus-host disease."

Key Product Sales Performance

Jakafi:

Net product revenues for the quarter of $682 million:

- Net product revenues grew 14% compared with the second quarter of 2022, driven by strong underlying patient demand growth across all indications.
- Channel inventory at the end of the second quarter of 2023 returned to normal levels.

Opzelura:

Net product revenues for the quarter of $80 million:

- Net product revenues of $80 million grew 384% compared with the second quarter of 2022, driven by growth in patient demand and expansion in payer coverage as the launch in AD and vitiligo continues.
- Opzelura was approved in Europe for the treatment of nonsegmental vitiligo with facial involvement and is now available in Germany and Austria.

Pipeline Updates

MPNs and GVHD – key highlights

LIMBER (Leadership In MPNs and GVHD BEyond Ruxolitinib):

- AGAVE-201, a global pivotal Phase 2 trial of **axatilimab** in patients with chronic GVHD met its primary endpoint across all cohorts with an overall response rate (ORR) of 74% at the dose of 0.3 mg/kg administered every two weeks. We plan to share the full dataset at a future medical meeting. A Phase 1/2 combination trial of axatilimab in combination with ruxolitinib is planned to initiate by year-end 2023.
- Combination trials of **ruxolitinib twice daily (BID) with zilurgisertib (ALK2)** and **INCB57643 (BET)** are ongoing and progressing well. At this year's American Society of Clinical Oncology (ASCO) annual meeting, updated data for zilurgisertib in both monotherapy and in combination with ruxolitinib BID demonstrated early signals of clinical activity with hepcidin reduction and anemia improvement observed. Also at ASCO, data for INCB57643 (BET) demonstrated improvements in spleen size and symptom burden at ≥ 8mg monotherapy and 4mg in combination with ruxolitinib.
- A Phase 1 study evaluating **INCA033989 (mCALR)** has been initiated. Additionally, a Phase 1 study evaluating ruxolitinib BID in combination with Cellenkos' **CK0804** in MF is continuing to recruit patients.

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 initiated

[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: Two studies evaluating INCB99280 in combination with axitinib (VEGF) and in combination with ipilimumab (CTLA-4) have been initiated. A Phase 2 study evaluating INCB99280 in patients with select solid tumors who are checkpoint inhibitor naive was also initiated. Additionally, a Phase 2 study evaluating INCB99280 in metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC was initiated.

Collaboration with Replimune Group, Inc. In July, Incyte and Replimune Group, Inc. announced a clinical trial collaboration and supply agreement to investigate the combination of INCB99280 and RP1 in patients with cutaneous squamous cell carcinoma. RP1 is Replimune's lead oncolytic immunotherapy product candidate and is based on a proprietary new strain of herpes simplex virus engineered for robust tumor selective replication and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF, intended to maximize tumor killing potency, the immunogenicity of tumor cell death, and the activation of a systemic anti-tumor immune response.

	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: 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 initiated
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

- **Ruxolitinib cream in pediatric AD:** The Phase 3 trial of ruxolitinib cream in pediatric AD (TRuE-AD3) met its primary endpoint. The study demonstrated that significantly more patients treated with ruxolitinib cream 0.75% and 1.5% achieved Investigator's Global Assessment Treatment Success (IGA-TS) than patients treated with vehicle control. There are an estimated 2-3 million pediatric AD patients (ages 2-11) in the United States.
- **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

- **Asthma and chronic spontaneous urticaria:** Two Phase 2 trials in asthma and chronic spontaneous urticaria have been initiated.

Auremolimab

- **IND cleared:** Auremolimab, an anti-IL-15Rβ monoclonal antibody, received IND clearance and is expected to enter the clinic later this year.

	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 initiated (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 initiated Chronic spontaneous urticaria: Phase 2 initiated
Auremolimab (anti-IL-15Rβ)	Vitiligo: Phase 1 in preparation

[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

	Indication and status
Ruxolitinib[1] (JAK1/JAK2)	Acute and chronic GVHD: approved in Europe; J-NDA under review
Baricitinib[2] (JAK1/JAK2)	AD: approved in Europe and Japan Severe AA: approved in the U.S., Europe and Japan
Capmatinib[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.

Organizational Update

Dr. Dashyant Dhanak, who has served as Incyte's Chief Scientific Officer since 2018, will be leaving the Organization effective August 2, 2023, in order to pursue other interests. Under his leadership, Incyte has filed more than fifteen Investigational New Drug (IND) applications, and has made great advancements in the biotherapeutics and small molecule pipeline.

2023 Second Quarter Financial Results

The financial measures presented in this press release for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Total GAAP revenues	$ 954,610	$ 911,397	$1,763,283	$1,644,632
Total GAAP operating income	193,780	254,431	218,550	370,971
Total Non-GAAP operating income	262,058	309,624	351,787	481,771
GAAP net income	203,548	161,432	225,251	199,424
Non-GAAP net income	223,029	226,353	307,606	349,220
GAAP basic EPS	$ 0.91	$ 0.73	$ 1.01	$ 0.90
Non-GAAP basic EPS	$ 1.00	$ 1.02	$ 1.38	$ 1.58
GAAP diluted EPS	$ 0.90	$ 0.72	$ 1.00	$ 0.89
Non-GAAP diluted EPS	$ 0.99	$ 1.01	$ 1.36	$ 1.56

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]
	2023	2022			2023	2022		
Net product revenues:								
Jakafi	$ 682,384	$ 597,673	14%	14%	$1,262,353	$1,142,137	11%	11%
Opzelura	80,233	16,560	384%	384%	136,785	29,314	367%	367%
Iclusig	29,087	26,224	11%	9%	56,772	52,293	9%	11%
Pemazyre	21,572	18,983	14%	14%	44,047	37,015	19%	21%
Minjuvi	13,159	4,411	198%	191%	19,715	8,913	121%	122%
Zynyz	570	—	NM	NM	570	—	NM	NM
Total net product revenues	827,005	663,851	25%	24%	1,520,242	1,269,672	20%	20%
Royalty revenues:								
Jakavi	90,448	83,711	8%	10%	167,140	154,578	8%	12%
Olumiant	32,009	30,254	6%	10%	66,164	78,318	(16%)	(10%)
Tabrecta	4,799	3,581	34%	NA	8,976	7,064	27%	NA
Pemazyre	349	—	NM	NM	761	—	NM	NM
Total royalty revenues	127,605	117,546	9%		243,041	239,960	1%	
Total net product and royalty revenues	954,610	781,397	22%		1,763,283	1,509,632	17%	
Milestone and contract revenues	—	130,000	(100%)	(100%)	—	135,000	(100%)	(100%)
Total GAAP revenues	$ 954,610	$ 911,397	5%		$1,763,283	$1,644,632	7%	

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 June 30, 2023 increased 25% and 22%, 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 across all indications and inventory level normalizing at the end of the second quarter of 2023. Total Opzelura net product revenues for the quarter were $80 million, representing a 384% increase year-over-year driven by increased patient demand and expanded coverage. Among other Hematology and Oncology, Minjuvi net product revenues grew 198% driven in part by the recognition of $6 million of previously deferred revenue related to the Early Access Program in France, which ended in June 2023. Jakavi and Olumiant royalties for the quarter were impacted by unfavorable changes in foreign currency exchange rates.

Operating Expenses

Operating Expense Summary
(unaudited, in thousands)

	Three Months Ended June 30,		%	Six Months Ended June 30,		%
	2023	2022	Change	2023	2022	Change
GAAP cost of product revenues	$ 68,326	$ 50,636	35%	$125,148	$ 93,250	34%
Non-GAAP cost of product revenues[1]	62,150	44,575	39%	112,819	81,194	39%
GAAP research and development	400,750	347,196	15%	807,391	700,569	15%
Non-GAAP research and development[2]	367,921	319,059	15%	743,541	646,104	15%
GAAP selling, general and administrative	283,929	253,277	12%	599,535	462,861	30%
Non-GAAP selling, general and administrative[3]	263,030	235,595	12%	557,047	428,277	30%
GAAP loss on change in fair value of acquisition-related contingent consideration	8,374	3,313	153%	14,570	9,695	50%
Non-GAAP loss on change in fair value of acquisition-related contingent consideration[4]	—	—	—%	—	—	—%
GAAP (profit) and loss sharing under collaboration agreements[5]	(549)	2,544	(122%)	(1,911)	7,286	(126%)

[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.

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

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

Cost of product revenues GAAP and Non-GAAP cost of product revenues for the quarter ended June 30, 2023 increased 35% and 39%, 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 June 30, 2023 increased 15%, compared to the same period in 2022 primarily due to continued investment in our late stage development assets.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended June 30, 2023 increased 12% compared to the same period in 2022, primarily due to expenses related to promotional activities to support the launch of Opzelura for the treatment of vitiligo.

Other Financial Information

Operating income GAAP and Non-GAAP operating income for the three months ended June 30, 2023 decreased 24% and 15%, respectively, compared to the same period in 2022, primarily due to lower milestone and contract revenue for the quarter ended June 30, 2023 compared to the same period in 2022, and increased investment in our late stage development assets and in supporting the launch of Opzelura for the treatment of vitiligo.

Cash, cash equivalents and marketable securities position As of June 30, 2023 and December 31, 2022, cash, cash equivalents and marketable securities totaled $3.4 billion and $3.2 billion, respectively.

2023 Financial Guidance

Incyte is tightening its full year 2023 guidance for Jakafi net product revenues as a result of its strong second quarter performance. 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	$2.58 - $2.63 billion	$2.55 - $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, 13739925.

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, 13739925.

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).

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.

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 uptake of Opzelura; the potential for ruxolitinib cream to expand into other indications; expectations regarding the potential and progress of programs in our pipeline, including axatilimab in chronic graft-versus-host disease and ruxolitinib cream in pediatric atopic dermatitis; expectations regarding ongoing clinical trials and clinical trials to be initiated, including the LIMBER program, Incyte's oral PD-L1 program, various phase 2 and phase 3 trials for ruxolitinib cream, phase 2 and 3 trials of povorcitinib in multiple indications, and a phase 1 trial of auremolimab in vitiligo; our and our collaborators' potential for receiving additional regulatory approvals within the next 1-2 years and the corresponding potential for launches of new products and/or indications; expectations regarding ongoing launches by us and our collaborators; 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 827,005	$ 663,851	$1,520,242	$1,269,672
Product royalty revenues	127,605	117,546	243,041	239,960
Milestone and contract revenues	—	130,000	—	135,000
Total revenues	954,610	911,397	1,763,283	1,644,632
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	68,326	50,636	125,148	93,250
Research and development	400,750	347,196	807,391	700,569
Selling, general and administrative	283,929	253,277	599,535	462,861
Loss on change in fair value of acquisition-related contingent consideration	8,374	3,313	14,570	9,695
(Profit) and loss sharing under collaboration agreements	(549)	2,544	(1,911)	7,286
Total costs and expenses	760,830	656,966	1,544,733	1,273,661
Income from operations	193,780	254,431	218,550	370,971
Interest income and other, net	42,668	522	75,541	1,782
Interest expense	(655)	(678)	(1,124)	(1,358)
Unrealized gain (loss) on long term investments	41,811	(24,897)	36,493	(71,482)
Income before provision for income taxes	277,604	229,378	329,460	299,913
Provision for income taxes	74,056	67,946	104,209	100,489
Net income	$ 203,548	$ 161,432	$ 225,251	$ 199,424
Net income per share:				
Basic	$ 0.91	$ 0.73	$ 1.01	$ 0.90
Diluted	$ 0.90	$ 0.72	$ 1.00	$ 0.89
Shares used in computing net income per share:				
Basic	223,248	221,660	223,104	221,493
Diluted	225,649	223,661	225,541	223,277

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

	June 30, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and marketable securities	$3,423,366	$ 3,238,965
Accounts receivable	637,994	644,879
Property and equipment, net	749,352	739,310
Finance lease right-of-use assets, net	25,631	26,298
Inventory	177,985	120,959
Prepaid expenses and other assets	200,561	194,144
Long term investments	170,316	133,676
Other intangible assets, net	134,954	129,219
Goodwill	155,593	155,593
Deferred income tax asset	532,507	457,941
Total assets	$6,208,259	$ 5,840,984
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$1,217,910	$ 1,216,603
Finance lease liabilities	32,657	33,262

Acquisition-related contingent consideration	217,000	221,000
Stockholders' equity	4,740,692	4,370,119
Total liabilities and stockholders' equity	$6,208,259	$ 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
GAAP Net Income	$ 203,548	$ 161,432	$225,251	$199,424
Adjustments[1]:				
Non-cash stock compensation from equity awards (R&D)[2]	32,829	28,137	63,850	54,465
Non-cash stock compensation from equity awards (SG&A)[2]	20,899	17,682	42,488	34,584
Non-cash stock compensation from equity awards (COGS)[2]	792	677	1,561	1,288
Non-cash interest[3]	139	108	247	216
Changes in fair value of equity investments[4]	(41,811)	24,897	(36,493)	71,482
Amortization of acquired product rights[5]	5,384	5,384	10,768	10,768
Loss on change in fair value of contingent consideration[6]	8,374	3,313	14,570	9,695
Tax effect of Non-GAAP pre-tax adjustments[7]	(7,125)	(15,277)	(14,636)	(32,702)
Non-GAAP Net Income	$ 223,029	$ 226,353	$307,606	$349,220
Non-GAAP net income per share:				
Basic	$ 1.00	$ 1.02	$ 1.38	$ 1.58
Diluted	$ 0.99	$ 1.01	$ 1.36	$ 1.56
Shares used in computing Non-GAAP net income per share:				
Basic	223,248	221,660	223,104	221,493
Diluted	225,649	223,661	225,541	223,277

[1] There were no milestones 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, 2023, as compared to milestones of $130,000 and $135,000, respectively, earned from our collaborative partners for the three and six months ended June 30, 2022. 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, 2023 are upfront consideration and milestones of $7,000 and $9,700, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $2,500 and $22,500, respectively, for the three and six months ended June 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 Loss on change in fair value of acquisition-related contingent consideration line item in the Condensed Consolidated Statements of Operations.

[7] 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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