Incyte Reports 2022 Third Quarter Financial Results and Provides Updates on Key Clinical Programs

November 1, 2022

– Total net product revenues grew to $713 million (+20% Y/Y) as a result of strong Jakafi® (ruxolitinib) and Opzelura ™ (ruxolitinib) cream net product revenues

– Jakafi net product revenues of $620 million in Q3'22 (+13% Y/Y); raising the bottom end of full year guidance to a new range of $2.38 to $2.40 billion

– Opzelura net product revenues of $38 million in Q3'22 driven by robust demand and broadening payer access; launch in vitiligo underway

– Pipeline progresses with positive povorcitinib data in hidradenitis suppurativa at EADV, oral PD-L1 update at SITC and the pending acquisition of Villaris Therapeutics and auremolimab, a novel anti-IL-15Rβ mAb

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

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 1, 2022-- Incyte (Nasdaq:INCY) today reports 2022 third quarter financial results, and provides a status update on the Company's clinical development portfolio.

"Our total net product revenues grew 20% year over year led by strong Jakafi ® (ruxolitinib) performance and an increasing contribution from Opzelura ™ (ruxolitinib) cream. Over 62,000 units of Opzelura were shipped in the quarter with growth fueled by both atopic dermatitis and vitiligo. This strong demand, coupled with an expansion of reimbursement coverage, positions Opzelura to become a meaningful long-term growth driver for Incyte," said Hervé Hoppenot, Chief Executive Officer, Incyte. "Additionally, our pipeline is progressing across Oncology and Dermatology, and we continue to execute on our strategy for growth and diversification with multiple updates on key programs expected over the next several months."

Portfolio Updates

MPNs and GVHD – key highlights

LIMBER (Leadership In MPNs and GVHD BEyond Ruxolitinib) program: Key LIMBER development programs, including combination trials of ruxolitinib with parsaclisib, INCB57643 (BET) and INCB00928 (ALK2), are ongoing. Additionally, the Prescription Drug User Fee Act (PDUFA) target action date for once-daily (QD) ruxolitinib extended release (XR) formulation is March 23, 2023.

Axatilimab in chronic graft-versus-host disease (cGVHD): AGAVE-201, a global pivotal Phase 2 trial of axatilimab in patients with cGVHD is ongoing with results expected mid-2023. A Phase 1/2 combination trial of axatilimab with ruxolitinib in patients with newly-diagnosed cGVHD is in preparation and is expected to initiate in the first quarter of 2023.

	Indication and status
QD ruxolitinib (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD: NDA under review
ruxolitinib + parsaclisib (JAK1/JAK2 + PI3Kδ)	Myelofibrosis: Phase 3 (first-line therapy) (LIMBER-313) Myelofibrosis: Phase 3 (suboptimal responders to ruxolitinib) (LIMBER-304)
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2
ruxolitinib + CK0804[1] (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: PoC (LIMBER-TREG108)
axatilimab (anti-CSF-1R)[2]	Chronic GVHD: Pivotal Phase 2 (third-line plus therapy) (AGAVE-201)

[1] Development collaboration with Cellenkos, Inc.

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

Other Hematology/Oncology – key highlights

Pemigatinib (Pemazyre®): In August, Pemazyre was approved by the U.S. Food and Drug Administration (FDA) as the first and only targeted treatment for myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement. MLNs with FGFR1 rearrangement are extremely rare and aggressive blood cancers and this approval demonstrates Incyte's commitment to improving and expanding treatments for patients living with rare blood cancers. Phase 2 open-label studies evaluating pemigatinib in glioblastoma and relapsed or refractory advanced non-small cell lung cancer are ongoing.

	Indication and status
pemigatinib (FGFR1/2/3)	Myeloid/lymphoid neoplasms (MLN): approved by FDA Cholangiocarcinoma (CCA): Phase 3 (FIGHT-302) Glioblastoma: Phase 2 (FIGHT-209) Non-small cell lung cancer (NSCLC): Phase 2 (FIGHT-210)

tafasitamab (CD19)[1]	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL): Phase 2 (L-MIND); 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*) Relapsed or refractory B-cell malignancies: PoC with lenalidomide and plamotamab[2]
parsaclisib (PI3Kδ)	Warm autoimmune hemolytic anemia: Phase 3 (PATHWAY)
retifanlimab (PD-1)[3]	Squamous cell anal cancer (SCAC): Phase 3 (POD1UM-303) MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase 2 (POD1UM-201) NSCLC: Phase 3 (POD1UM-304)

[1] Development of tafasitamab in collaboration with MorphoSys.

[2] Clinical collaboration with MorphoSys and Xencor, Inc. to investigate the combination of tafasitamab plus lenalidomide in combination with Xencor's CD20xCD3 XmAb bispecific antibody, plamotamab.

[3] Retifanlimab licensed from MacroGenics.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Opzelura growth coming from both atopic dermatitis (AD) and vitiligo in the U.S.: Over 62,000 units of Opzelura were shipped in the third quarter with positive physician and patient experiences continuing to fuel uptake in AD. The launch in vitiligo is progressing well, contributing to the growth in overall demand. An increasing number of plans are adding Opzelura to formularies, helping to drive net product revenues to $38 million, a growth of 130% versus prior quarter.

Ruxolitinib cream in other indications: Incyte continues to expand the development of ruxolitinib cream into new indications as we seek to maximize the opportunity with Opzelura. Two Phase 2 trials evaluating ruxolitinib cream in lichen planus and lichen sclerosus are in preparation. Lichen planus is a recurrent inflammatory condition affecting the skin and mucosal surfaces and can result in itchy, purple bumps on the skin. Lichen sclerosus is a chronic inflammatory skin disease most commonly affecting women and can result in painful ulcers and intense itching.

Povorcitinib (INCB54707): In August, results from the randomized Phase 2 trial evaluating povorcitinib in patients with hidradenitis suppurativa (HS) were presented at the European Academy of Dermatology and Venereology (EADV) 31st Congress. Based on the positive Phase 2 results, Incyte plans to initiate a Phase 3 study in HS by end of this year.

	Indication and status
ruxolitinib cream[1] (JAK1/JAK2)	AD: Phase 3 pediatric study (TRuE-AD3) Vitiligo: Phase 3 (TRuE-V1, TRuE-V2); approved by FDA; MAA under review Lichen planus: Phase 2 in preparation Lichen sclerosus: Phase 2 in preparation
ruxolitinib cream + UVB (JAK1/JAK2 + phototherapy)	Vitiligo: Phase 2
povorcitinib (JAK1)	Hidradenitis suppurativa: Phase 2b; Phase 3 in preparation Vitiligo: Phase 2 Prurigo nodularis: Phase 2

[1] Novartis' rights for ruxolitinib outside of the United States under our Collaboration and License Agreement with Novartis do not include topical administration.

Acquisition of Villaris Therapeutics further complements dermatology portfolio: In October, Incyte announced an agreement to acquire Villaris Therapeutics, an asset-centric biopharmaceutical company focused on the development of novel antibody therapeutics for vitiligo. Its lead asset, auremolimab (VM6) is a novel, ultra-humanized anti-IL-15Rβ monoclonal antibody designed to target and deplete autoreactive resident memory T cells (T_{RM}) that has demonstrated efficacy as a treatment for vitiligo in preclinical models. Incyte will receive exclusive global rights to develop and commercialize auremolimab for all uses, including in vitiligo and other autoimmune and inflammatory diseases. IND-enabling studies are currently underway, and clinical development for auremolimab is expected to begin in 2023. The agreement is subject to clearance by the U.S. antitrust authorities under the Hart-Scott-Rodino Act and will become effective as soon as this condition has been met.

Discovery and early development – key highlights

Incyte's portfolio of other earlier-stage clinical candidates is included below.

Modality	**Candidates**
Small molecules	INCB81776 (AXL/MER), INCB99280 (PD-L1), INCB99318 (PD-L1), INCB106385 (A2A/A2B), INCB123667 (CDK2)
Monoclonal antibodies[1]	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN2390 (TIM-3), INCA00186 (CD73)
Bi-specific antibodies	INCA32459 (LAG-3xPD-1)[2]

[1] Discovery collaboration with Agenus.

[2] Development in collaboration with Merus

Partnered – key highlights

	Indication and status
ruxolitinib (JAK1/JAK2)[1]	Acute and chronic GVHD: approved in Europe; J-NDA under review
baricitinib (JAK1/JAK2)[2]	AD: Phase 3 (BREEZE-AD); approved in Europe and Japan Severe AA: Phase 3 (BRAVE-AA1, BRAVE-AA2); approved in the U.S., Europe and Japan
capmatinib (MET)[3]	NSCLC (with MET exon 14 skipping mutations): approved in the U.S., Europe and Japan

[1] Jakavi (ruxolitinib) licensed to Novartis ex-US.

[2] Worldwide rights to baricitinib 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] Worldwide rights to capmatinib licensed to Novartis.

2022 Third Quarter Financial Results

The financial measures presented in this press release for the three and nine months ended September 30, 2022 and 2021 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,	
	2022	2021	2022	2021
Total GAAP revenues	$ 823,303	$ 812,987	$ 2,467,935	$ 2,123,414
Total GAAP operating income	138,376	235,410	509,347	475,043
Total Non-GAAP operating income	167,271	293,148	649,042	659,019
GAAP net income	112,775	181,739	312,199	384,730
Non-GAAP net income	133,795	261,824	483,015	589,413
GAAP basic EPS	$ 0.51	$ 0.82	$ 1.41	$ 1.75
Non-GAAP basic EPS	$ 0.60	$ 1.19	$ 2.18	$ 2.68
GAAP diluted EPS	$ 0.50	$ 0.82	$ 1.40	$ 1.73
Non-GAAP diluted EPS	$ 0.60	$ 1.18	$ 2.16	$ 2.65

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]
	2022	2021			2022	2021		
Net product revenues:								
Jakafi	$619,595	$547,373	13%	13%	$ 1,761,732	$ 1,542,138	14%	14%
Iclusig	25,929	28,522	(9%)	6%	78,222	82,356	(5%)	6%
Pemazyre	23,414	17,562	33%	41%	60,429	48,924	24%	38%
Minjuvi	5,932	556	967%	1,143%	14,845	556	2,570%	2,916%
Opzelura	38,140	—	NM	NM	67,454	—	NM	NM
Total net product revenues	713,010	594,013	20%	21%	1,982,682	1,673,974	18%	20%
Royalty revenues:								
Jakavi	85,808	94,655	(9%)	6%	240,386	242,295	(1%)	11%
Olumiant	20,371	86,572	(76%)	(71%)	98,689	154,875	(36%)	(33%)
Tabrecta	4,114	2,747	50%	NM	11,178	7,270	54%	NM
Total royalty revenues	110,293	183,974	(40%)		350,253	404,440	(13%)	
Total net product and royalty revenues	823,303	777,987	6%		2,332,935	2,078,414	12%	
Milestone and contract revenues	—	35,000	(100%)	(100%)	135,000	45,000	200%	200%
Total GAAP revenues	$823,303	$812,987	1%		$ 2,467,935	$ 2,123,414	16%	

NM = not meaningful

[1] Percentage change in constant currency is calculated using 2021 foreign exchange rates to recalculate 2022 results.

Product and Royalty Revenues Product and royalty revenues for the quarter ended September 30, 2022 increased over the prior year comparative period as a result of net product revenues increasing 20% year-over-year, primarily driven by increases in Jakafi and Opzelura net product revenues. Jakafi net product revenues for the quarter ended September 30, 2022 increased 13% over the prior year comparative period, primarily driven by growth in patient demand across all indications. Jakavi and Olumiant royalties for the quarter were impacted by unfavorable changes in foreign currency exchange rates, while Olumiant royalties were also impacted by a decrease in net product sales of Olumiant for use as a treatment for COVID-19 and 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,		%
	2022	2021	Change	2022	2021	Change
GAAP cost of product revenues	$ 54,584	$ 39,869	37%	$ 147,834	$107,117	38%
Non-GAAP cost of product revenues[1]	48,521	33,965	43%	129,715	89,863	44%
GAAP research and development	384,007	334,945	15%	1,084,576	985,352	10%
Non-GAAP research and development[2]	358,268	308,675	16%	1,004,372	901,170	11%
GAAP selling, general and administrative	266,460	190,704	40%	729,321	513,358	42%
Non-GAAP selling, general and administrative[3]	247,474	168,050	47%	675,751	443,886	52%
GAAP (gain) loss on change in fair value of acquisition-related contingent consideration	(21,893)	2,910	(852%)	(12,198)	13,068	(193%)
Non-GAAP (gain) loss on change in fair value of acquisition-related contingent consideration[4]	—	—	—%	—	—	—%
GAAP collaboration loss sharing	1,769	9,149	(81%)	9,055	29,476	(69%)

[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 legal settlements.

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

Research and development expenses GAAP and Non-GAAP research and development expense for the quarter ended September 30, 2022 increased 15% and 16%, respectively, compared to the same period in 2021 primarily due to continued investment in our late stage development assets and certain upfront and milestone payments. Excluding the $33.5 million of upfront and milestone payments for the quarter ended September 30, 2022, GAAP and Non-GAAP research and development expense increased approximately 6% and 7%, respectively, compared to the same period in 2021.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended September 30, 2022 increased 40% and 47%, respectively, compared to the same period in 2021, primarily due to expenses related to our dermatology commercial organization and activities to support the launch of Opzelura for the treatments of atopic dermatitis and vitiligo.

Other Financial Information

Operating income GAAP operating income for the quarter ended September 30, 2022 decreased compared to the same period in 2021, primarily due to an increase in operating expenses partially offset by growth in net product revenues.

Cash, cash equivalents and marketable securities position As of September 30, 2022 and December 31, 2021, cash, cash equivalents and marketable securities totaled $3.0 billion and $2.3 billion, respectively.

2022 Financial Guidance

Incyte is tightening its full year 2022 guidance for Jakafi net product revenues to reflect strong performance of Jakafi and is revising the guidance range for other Hematology/Oncology net product revenues to reflect unfavorable changes in foreign currency exchange rates. In addition, the Company is reaffirming its research and development guidance, which now also includes the upfront payment to Villaris, anticipated in the fourth quarter, and its selling, general and administrative expense guidance. Guidance does not include revenue from any potential new product launches or the impact of any potential future strategic transactions. Incyte's updated guidance is summarized below.

	Current	Previous
Jakafi net product revenues	$2.38 - $2.40 billion	$2.36 - $2.40 billion
Other Hematology/Oncology net product revenues[1]	$200 - $210 million	$210 - $240 million
GAAP Cost of product revenues	6 – 7% of net product revenues	Unchanged
Non-GAAP Cost of product revenues[2]	5 – 6% of net product revenues	Unchanged
GAAP Research and development expenses	$1,550 - $1,590 million	Unchanged
Non-GAAP Research and development expenses[3]	$1,420 - $1,455 million	Unchanged
GAAP Selling, general and administrative expenses	$950 - $1,000 million	Unchanged
Non-GAAP Selling, general and administrative expenses[3]	$880 - $925 million	Unchanged

[1]Pemazyre in the U.S., EU and Japan 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, 13733379.

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, 13733379.

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 is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Jakafi is also indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea, in adults with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF and for treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the United States.

About Opzelura™ (ruxolitinib) Cream

Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States, indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older and 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 October 2021, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura is a trademark of Incyte.

About Monjuvi®/Minjuvi® (tafasitamab)

Tafasitamab is a humanized Fc-modified cytolytic 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 approval, 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 Corporation.

* 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.

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 long-term growth and diversification; Incyte's financial guidance for 2022, including its expectations regarding sales of Jakafi; expectations with respect to demand for and uptake of Opzelura, including the Company's ongoing discussions with payers; expectations with regard to the NDA submission for once-daily ruxolitinib; 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 clinical trials and clinical trials to be initiated, including the LIMBER program, trials of axatilimab in cGVHD, a phase 3 trial of povorcitinib in hidradenitis suppurativa and phase 2 trials of ruxolitinib cream in lichen planus and lichen sclerosus; expectations regarding our pending acquisition of Villaris Therapeutics and auremolimab; and our expectations regarding 2022 newsflow items.

These forward-looking statements are based on the Company'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; the effects of the COVID 19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, sales and marketing efforts and business, development and discovery operations; determinations made by the FDA, EMA, and other regulatory agencies; the Company's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; unexpected variations in the demand for the Company's products and the products of the Company's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for the Company's products and the products of the Company's collaboration partners; sales, marketing, manufacturing and distribution requirements, including the Company'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 the Company's reports filed with the Securities and Exchange Commission, including its annual report and the quarterly report on Form 10-Q for the quarter ended September 30, 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,	
	2022	2021	2022	2021
	GAAP		GAAP	
Revenues:				
Product revenues, net	$ 713,010	$ 594,013	$ 1,982,682	$ 1,673,974
Product royalty revenues	110,293	183,974	350,253	404,440
Milestone and contract revenues	—	35,000	135,000	45,000
Total revenues	823,303	812,987	2,467,935	2,123,414
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	54,584	39,869	147,834	107,117
Research and development	384,007	334,945	1,084,576	985,352
Selling, general and administrative	266,460	190,704	729,321	513,358
(Gain) loss on change in fair value of acquisition-related contingent consideration	(21,893)	2,910	(12,198)	13,068
Collaboration loss sharing	1,769	9,149	9,055	29,476
Total costs and expenses	684,927	577,577	1,958,588	1,648,371
Income from operations	138,376	235,410	509,347	475,043
Other income (expense), net	11,513	1,948	13,295	4,931
Interest expense	(641)	(439)	(1,999)	(1,156)
Unrealized loss on long term investments	(660)	(27,450)	(72,142)	(28,394)
Income before provision for income taxes	148,588	209,469	448,501	450,424
Provision for income taxes	35,813	27,730	136,302	65,694
Net income	$ 112,775	$ 181,739	$ 312,199	$ 384,730
Net income per share:				
Basic	$ 0.51	$ 0.82	$ 1.41	$ 1.75
Diluted	$ 0.50	$ 0.82	$ 1.40	$ 1.73

Shares used in computing net income per share:				
Basic	222,415	220,845	221,801	220,243
Diluted	224,175	222,248	223,626	222,113

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

	September 30, 2022	December 31, 2021
ASSETS		
Cash, cash equivalents and marketable securities	$ 2,977,122	$ 2,348,192
Accounts receivable	618,188	616,300
Property and equipment, net	715,733	723,920
Finance lease right-of-use assets, net	26,679	27,548
Inventory	101,133	56,938
Prepaid expenses and other assets	205,199	165,302
Long term investments	149,124	221,266
Other intangible assets, net	134,603	150,755
Goodwill	155,593	155,593
Deferred income tax asset	426,840	467,538
Total assets	$ 5,510,214	$ 4,933,352
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 1,043,975	$ 885,081
Finance lease liabilities	33,588	34,267
Acquisition-related contingent consideration	206,000	244,000
Stockholders' equity	4,226,651	3,770,004
Total liabilities and stockholders' equity	$ 5,510,214	$ 4,933,352

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP Net Income	$ 112,775	$ 181,739	$ 312,199	$ 384,730
Adjustments[1]*:*				
Non-cash stock compensation from equity awards (R&D)[2]	25,739	26,270	80,204	84,182
Non-cash stock compensation from equity awards (SG&A)[2]	18,986	15,904	53,570	49,500
Non-cash stock compensation from equity awards (COGS)[2]	679	520	1,967	1,102
Non-cash interest[3]	72	72	288	72
Changes in fair value of equity investments[4]	660	27,450	72,142	28,394
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]	(21,893)	2,910	(12,198)	13,068
Legal settlements[7]	—	6,750	—	19,972
Tax effect of Non-GAAP pre-tax adjustments[8]	(8,607)	(5,175)	(41,309)	(7,759)
Non-GAAP Net Income	$ 133,795	$ 261,824	$ 483,015	$ 589,413
Non-GAAP net income per share:				
Basic	$ 0.60	$ 1.19	$ 2.18	$ 2.68
Diluted	$ 0.60	$ 1.18	$ 2.16	$ 2.65
Shares used in computing Non-GAAP net income per share:				
Basic	222,415	220,845	221,801	220,243
Diluted	224,175	222,248	223,626	222,113

[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, 2022 are milestones of $0 and $135,000, respectively, earned from our collaborative partners, as compared to milestones of $35,000 and $45,000, respectively, for the three and nine months ended September 30, 2021. 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, 2022 are upfront consideration and milestones of $33,450 and $55,950, respectively, related to our collaborative partners, as compared to upfront consideration and milestones of $4,333 and $20,833, respectively, for the three and nine months ended September 30, 2021.

[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 Selling, general and administrative expenses line item in the Condensed Consolidated Statements of Operations.

[8] Income tax effects of Non-GAAP pre-tax adjustments are calculated using the applicable statutory tax rate for the jurisdictions in which the charges are incurred, while taking into consideration any valuation allowances against related deferred tax assets.

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Media
Catalina Loveman
+1 302 498 6171
cloveman@incyte.com

Investors
Christine Chiou
+1 302 274 4773
cchiou@incyte.com

Source: Incyte