



Incyte Reports 2021 Fourth Quarter and Year-End Financial Results, and Provides 2022 Financial Guidance and Updates on Key Clinical Programs

February 8, 2022

- Total product and royalty revenues of \$813 million (+20%) in Q4'21 and \$2.891 billion (+17%) in FY'21
- Jakafi® (ruxolitinib) net product revenues of \$592 million (+15%) in Q4'21 and \$2.135 billion (+10%) in FY'21; Jakafi guidance range of \$2.3 to \$2.4 billion for 2022
- Successful U.S. launch of Opzelura™ (ruxolitinib) cream in atopic dermatitis with nearly 19,000 patients treated from launch (October 11th) through the end of the year
- Vitiligo is the next substantial growth opportunity for ruxolitinib cream – under Priority Review in the U.S. and under review in Europe

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

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 8, 2022-- Incyte (Nasdaq:INCY) today reports 2021 fourth quarter financial results, provides 2022 financial guidance and a status update on the Company's clinical development portfolio.

"2021 was a year of important accomplishments for Incyte. Growth of product and royalty revenues was strong, led by robust demand for Jakafi® (ruxolitinib), continued uptake of Pemazyre® (pemigatinib) in the U.S., and a rapidly growing royalty revenue stream. Throughout the year, we significantly expanded our commercial portfolio with several new approvals, including Pemazyre® (pemigatinib) in cholangiocarcinoma (CCA) in Europe and Japan; Minjuvi® (tafasitamab) in relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in Europe; and, in the U.S., both Jakafi in steroid-refractory chronic graft-versus-host disease (GVHD) and Opzelura™ (ruxolitinib) cream in atopic dermatitis," said Hervé Hoppenot, Chief Executive Officer, Incyte. "Our launch of Opzelura has been very successful thus far. Nearly 19,000 patients were treated in the fourth quarter and feedback from both dermatologists and patients has been very positive. Importantly, we have also made significant progress towards ensuring optimal patient access to Opzelura."

Portfolio Updates

MPNs and GVHD – key highlights

Axatilimab (anti-CSF-1R monoclonal antibody) in chronic GVHD: In December, updated positive data from the Phase 1/2 trial evaluating axatilimab as a monotherapy in patients with recurrent or refractory chronic GVHD despite two or more prior lines of therapy were presented at ASH. A 68% overall response rate and broad clinical benefit across multiple organs were observed at doses being assessed in the pivotal AGAVE-201 trial. Additional trials of axatilimab are planned in patients with steroid-refractory chronic GVHD, including a Phase 2 trial in combination with a JAK inhibitor.

LIMBER (Leadership In MPNs BEyond Ruxolitinib) program: The new drug application (NDA) for once-daily ruxolitinib (QD) is on track for submission in the first half of this year. Two Phase 3 trials of ruxolitinib in combination with piasclisib as a first-line therapy for patients with MF and as a therapy for MF patients with a suboptimal response to ruxolitinib monotherapy are both underway. Combination trials of ruxolitinib with INCB57643 (BET) and INCB00928 (ALK2) are in preparation with initial data expected later this year.

	<u>Indication and status</u>
QD ruxolitinib (JAK1/JAK2)	Myelofibrosis, polycythemia vera and GVHD: clinical pharmacology studies
ruxolitinib + piasclisib (JAK1/JAK2 + PI3Kδ)	Myelofibrosis: Phase 3 (first-line therapy) (LIMBER-313)
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 3 (suboptimal responders to ruxolitinib) (LIMBER-304)
ruxolitinib + INCB57643 (JAK1/JAK2 + BET)	Myelofibrosis: Phase 2 in preparation
ruxolitinib + INCB00928 (JAK1/JAK2 + ALK2)	Myelofibrosis: Phase 2 in preparation
ruxolitinib + CK0804¹ (JAK1/JAK2 + CB-Tregs)	Myelofibrosis: PoC in preparation
itacitinib (JAK1)	Treatment-naïve chronic GVHD: Phase 2/3 (GRAVITAS-309)
axatilimab (anti-CSF-1R)²	Chronic GVHD (third-line plus therapy): Pivotal Phase 2 (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

Piasclisib in warm autoimmune hemolytic anemia (wAIHA): Following positive Phase 2 results, a Phase 3 randomized trial evaluating the efficacy and safety of piasclisib in adults with wAIHA has been initiated. There are currently no FDA approved treatments for wAIHA in the United States, and there are approximately 1 in 8,000 patients living with wAIHA, of which 30% are treatable.

Parsaclisib in non-Hodgkin lymphomas: In January, Incyte announced the withdrawal of the New Drug Application (NDA) in the United States for parsaclisib for the treatment of patients with relapsed or refractory follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL). The decision to withdraw the NDA followed discussions with U.S. Food and Drug Administration (FDA) regarding confirmatory studies that Incyte determined cannot be completed within a reasonable period to support an accelerated approval. The withdrawal of the NDA is a business decision and is not related to any changes in either the efficacy or safety of parsaclisib. The decision impacts only the FL, MZL and MCL indications in the U.S., and does not affect other ongoing clinical trials in the U.S. or other countries. An MAA submission for parsaclisib in MZL is under review with the EMA.

Indication and status¹

pemigatinib	CCA: Phase 3 (FIGHT-302)
(FGFR1/2/3)	Myeloid/lymphoid neoplasms (MLN): Phase 2 (FIGHT-203) Glioblastoma: Phase 2 in preparation NSCLC: Phase 2 in preparation
tafasitamab	Relapsed or refractory DLBCL: Phase 2 (L-MIND); Phase 3 (B-MIND)
(CD19)²	First-line DLBCL: Phase 3 (<i>frontMIND</i>) Relapsed or refractory FL and Relapsed or refractory MZL: Phase 3 (<i>inMIND</i>) Relapsed or refractory B-cell malignancies: PoC (<i>topMIND</i>) with parsaclisib (PI3K δ) Relapsed or refractory B-cell malignancies: PoC with lenalidomide and plamotamab in preparation ³
parsaclisib	
(PI3Kδ)	Autoimmune hemolytic anemia: Phase 3 (PATHWAY)
retifanlimab	SCAC: Phase 3 (POD1UM-303)
(PD-1)⁴	MSI-high endometrial cancer: Phase 2 (POD1UM-101, POD1UM-204) Merkel cell carcinoma: Phase 2 (POD1UM-201) NSCLC: Phase 3 (POD1UM-304)

¹ CCA = cholangiocarcinoma; DLBCL = diffuse large B-cell lymphoma; SCAC = squamous cell anal carcinoma; FL = follicular lymphoma; MZL = marginal zone lymphoma; MCL = mantle cell lymphoma; CLL = chronic lymphocytic leukemia

² Development of tafasitamab in collaboration with MorphoSys.

³ 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.

⁴ Retifanlimab licensed from MacroGenics.

Inflammation and Autoimmunity (IAI) – key highlights

Dermatology

Opzelura launch in AD in the U.S.: In October, Incyte launched its first dermatology product with the FDA approval of Opzelura, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, in AD. Nearly 19,000 new patients started Opzelura in the fourth quarter and feedback from dermatologists and patients has been very positive with efficacy, and in particular the rapid onset and itch reduction, as a top reason for prescribing.

Ruxolitinib cream in vitiligo in the U.S. and Europe: In December, Incyte announced the FDA accepted for Priority Review the supplemental New Drug Application (sNDA) for ruxolitinib cream 1.5% (Opzelura) as a potential treatment for adolescents and adults (age ≥ 12 years) with vitiligo. The Prescription Drug User Fee Act (PDUFA) target action date is April 18, 2022. The Marketing Authorization Application (MAA) is under review at the European Medicines Agency (EMA). Vitiligo represents the second substantial opportunity for Opzelura, an indication where there are no approved therapies for repigmentation. There are over 1.5 million patients living with vitiligo in the United States and over 2 million in Europe.

Ruxolitinib cream in pediatric AD: A Phase 3 randomized trial (TRuE-AD3) evaluating the efficacy and safety of ruxolitinib cream in children ages two to twelve years old with AD is currently ongoing.

Ruxolitinib cream in chronic hand eczema (CHE): Incyte continues to expand the development of ruxolitinib cream into new indications as part of its life cycle management strategy. A Phase 3 trial evaluating ruxolitinib cream in chronic hand eczema is being initiated.

INCB54707 (JAK1) in multiple dermatology indications: Incyte's growing dermatology portfolio includes INCB54707, a JAK1 specific inhibitor, which is being evaluated across multiple indications. Phase 2 trials are currently ongoing in vitiligo, hidradenitis suppurativa and prurigo nodularis, with data in vitiligo and hidradenitis suppurativa expected later this year.

Indication and status

ruxolitinib cream¹	Atopic dermatitis: Phase 3 pediatric study (TRuE-AD3)
(JAK1/JAK2)	Vitiligo: Phase 3 (TRuE-V1, TRuE-V2, primary endpoint met in both studies); sNDA under Priority Review and MAA under review Chronic hand eczema: Phase 3 (TRuE-CHE1) being initiated
INCB54707 (JAK1)	Hidradenitis suppurativa: Phase 2b 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.

Discovery and early development – key highlights

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

Oral PD-L1 Program: In November, Incyte presented data from a Phase 1 study evaluating INCB86550, the first in a series of oral PD-L1 inhibitors in the clinic. INCB86550 is the first oral PD-L1 inhibitor to demonstrate clinical efficacy. Early data were presented for INCB99280 and INCB99318, two other oral PD-L1 inhibitors which are also in the clinic.

MCLA-145 (CD137/PD-L1 bispecific antibody): In January, Incyte announced the decision to opt-out of the continued development of MCLA-145 as part of its ongoing portfolio prioritization and capital allocation review. Incyte will continue to collaborate with Merus and leverage their platform to develop a pipeline of novel agents, as the Company continues to hold worldwide development and commercialization rights to up to ten additional programs.

Modality	Candidates
Small molecules	INCB81776 (AXL/MER), epacadostat (IDO1), INCB86550 (PD-L1), INCB99280 (PD-L1), INCB99318 (PD-L1), INCB106385 (A2A/A2B)
Monoclonal antibodies ¹	INCAGN1876 (GITR), INCAGN2385 (LAG-3), INCAGN1949 (OX40), INCAGN2390 (TIM-3), INCA00186 (CD73)

¹ Discovery collaboration with Agenus.

Partnered – key highlights

Baricitinib in alopecia areata (AA): Regulatory applications for baricitinib as a treatment for alopecia areata have been submitted in the U.S., Europe and Japan. Submissions were based on results from two pivotal Phase 3 trials (BRAVE-AA1 and BRAVE-AA2), which found once-daily baricitinib 4-mg was superior to placebo in achieving significant scalp hair regrowth as early as 24 weeks in adults with severe AA as defined by ≥50% scalp hair loss at baseline. Baricitinib has the potential to be a first-in-disease treatment for the millions of adults worldwide living with AA.

Baricitinib in AD in the U.S.: In January, Incyte and Lilly provided a regulatory update on the sNDA for baricitinib in AD. Based on ongoing discussions with the FDA, Lilly announced that alignment on the indicated population had not yet been reached and given the FDA's position, there would be the possibility of a Complete Response Letter (CRL).

Baricitinib in systemic lupus erythematosus (SLE): In January, Incyte and Lilly announced the discontinuation of the Phase 3 development program for baricitinib in SLE based on top-line efficacy results from two pivotal Phase 3 trials (SLE-BRAVE-I and –II). The primary endpoint of SRI-4 response was reached in SLE-BRAVE-I but was not reached in SLE-BRAVE-II and key secondary endpoints were not met in either study.

Indication and status

ruxolitinib (JAK1/JAK2) ¹	Acute and chronic GVHD: MAA and J-NDA under review
baricitinib (JAK1/JAK2) ²	Atopic dermatitis: Phase 3 (BREEZE-AD); approved in EU and Japan Severe alopecia areata: Phase 3 (BRAVE-AA1, BRAVE-AA2); Submissions in U.S., EU, and Japan
capmatinib (MET) ³	NSCLC (with MET exon 14 skipping mutations): Approved as Tabrecta in U.S. and Japan; MAA under review

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.

2021 Fourth Quarter and Year-End Financial Results

The financial measures presented in this press release for the quarter and year ended December 31, 2021 and 2020 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.

Financial Highlights

Financial Highlights (unaudited, in thousands, except per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Total GAAP revenue	\$ 862,853	\$ 789,509	\$ 2,986,267	\$ 2,666,702
Total GAAP operating income (loss)	110,734	164,229	585,777	(263,676)
Total Non-GAAP operating income (loss)	166,013	218,469	825,032	(40,878)
GAAP (benefit) provision for income taxes	(443,831)	18,252	(378,137)	63,479

GAAP net income (loss)	563,851	149,850	948,581	(295,697)
Non-GAAP net income (loss)	22,565	204,773	611,978	(90,510)
GAAP basic EPS	\$ 2.55	\$ 0.68	\$ 4.30	\$ (1.36)
Non-GAAP basic EPS	\$ 0.10	\$ 0.93	\$ 2.78	\$ (0.42)
GAAP diluted EPS	\$ 2.54	\$ 0.68	\$ 4.27	\$ (1.36)
Non-GAAP diluted EPS	\$ 0.10	\$ 0.93	\$ 2.76	\$ (0.42)

Revenue Details

Revenue Details (unaudited, in thousands)

	Three Months Ended			Twelve Months Ended		
	December 31,		%	December 31,		%
	2021	2020	Change	2021	2020	Change
Net product revenues:						
Jakafi	\$ 592,370	\$ 516,882	15%	\$2,134,508	\$1,937,850	10%
Iclusig	27,039	28,576	(5)%	109,395	105,002	4%
Pemazyre	19,607	14,009	40%	68,531	25,884	165%
Minjuvi	4,354	—	NM	4,910	—	NM
Opzelura	4,668	—	NM	4,668	—	NM
Royalty revenues:						
Jakafi	95,696	87,046	10%	337,991	277,902	22%
Olumiant	66,000	30,996	113%	220,875	110,920	99%
Tabrecta	3,119	2,000	56%	10,389	4,144	151%
Total product and royalty revenues	<u>812,853</u>	<u>679,509</u>	20%	<u>2,891,267</u>	<u>2,461,702</u>	17%
Milestone and contract revenues	50,000	110,000	NM	95,000	205,000	NM
Total GAAP revenues	<u>\$ 862,853</u>	<u>\$ 789,509</u>	9%	<u>\$2,986,267</u>	<u>\$2,666,702</u>	12%

NM = not meaningful

Product and Royalty Revenues Product and royalty revenues for the quarter and year ended December 31, 2021 increased 20% and 17%, respectively, over the prior year comparative periods primarily as a result of increases in Jakafi and Pemazyre net product revenues, and higher product royalty revenues from Jakafi and Olumiant. Jakafi net product revenues for the quarter and year ended December 31, 2021 increased 15% and 10%, respectively, over the prior year comparative periods, primarily driven by growth in patient demand across all indications. The 113% growth in Olumiant royalty revenues for the quarter ended December 31, 2021 reflects an increase in net product sales as a result of the use of Olumiant for the treatment of COVID-19.

Operating Expenses

Operating Expense Summary (unaudited, in thousands)

	Three Months Ended			Twelve Months Ended		
	December 31,		%	December 31,		%
	2021	2020	Change	2021	2020	Change
GAAP cost of product revenues	\$ 43,874	\$ 36,323	21%	\$ 150,991	\$ 131,328	15%
Non-GAAP cost of product revenues ¹	37,886	30,693	23%	127,749	108,830	17%
GAAP research and development	472,827	405,945	16%	1,458,179	2,215,942	(34)%
Non-GAAP research and development ²	442,693	375,770	18%	1,343,863	2,095,586	(36)%
GAAP selling, general and administrative	226,202	166,988	35%	739,560	516,922	43%
Non-GAAP selling, general and administrative ³	208,718	152,148	37%	652,604	460,363	42%
GAAP change in fair value of acquisition-related contingent consideration	1,673	3,595	(53)%	14,741	23,385	(37)%
Non-GAAP change in fair value of acquisition-related contingent consideration ⁴	—	—		—	—	
GAAP collaboration loss sharing	7,543	12,429	(39)%	37,019	42,801	(14)%

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 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 December 31, 2021

increased 16% and 18%, respectively, compared to the same period in 2020 primarily due to the upfront consideration of \$127 million related to our collaborative agreement with Syndax.

For the year ended December 31, 2021, GAAP and Non-GAAP research and development expense decreased 34% and 36%, respectively, compared to the year ended December 31, 2020 primarily due to lower upfront and milestone payments when compared to the prior year period which included upfront consideration of \$805 million related to our collaborative agreement with MorphoSys and \$120 million of expense related to the purchase of an FDA priority review voucher ("PRV") utilized to accelerate the FDA review of Opzelura.

Selling, general and administrative expenses GAAP and Non-GAAP selling, general and administrative expenses for the quarter ended December 31, 2021 increased 35% and 37% respectively, and for the year ended December 31, 2021 increased 43% and 42%, respectively, compared to the same periods in 2020, primarily due to expenses related to the establishment of our dermatology commercial organization and activities to support the launch of Opzelura for the treatment of atopic dermatitis.

Other Financial Information

Operating income (loss) GAAP and Non-GAAP operating income for the quarter ended December 31, 2021 decreased compared to the same period in 2020, due to expenses related to the establishment of our dermatology commercial organization and the launch of Opzelura and upfront consideration related to our collaborative agreement with Syndax, partially offset by growth in total revenues. For the year ended December 31, 2021, Incyte recorded operating income compared to an operating loss for the same period in 2020, on both a GAAP and Non-GAAP basis, primarily due to growth in total revenues, lower upfront consideration and milestones related to our collaborative agreements, and the 2020 PRV purchase, partially offset by higher selling, general and administrative expenses.

(Benefit) provision for income taxes The company released the valuation allowance on the majority of its U.S. deferred tax assets in the fourth quarter of 2021 based on, among other things, its achievement of cumulative profitability over the last several years and its expectations regarding future profitability. The release of this valuation allowance accounts for a \$569 million GAAP income tax benefit. This was partially offset by higher reported tax expense from 2021 operations.

Cash, cash equivalents and marketable securities position As of December 31, 2021 and 2020, cash, cash equivalents and marketable securities totaled \$2.3 billion and \$1.8 billion, respectively.

2022 Financial Guidance

Guidance does not include revenue from Opzelura or the impact of any potential future strategic transactions.

	Current
Jakafi net product revenues	\$2.3 - \$2.4 billion
Other Hematology/Oncology net product revenues ⁽¹⁾	\$210 - \$240 million
GAAP Cost of product revenues	6 – 7% of net product revenues
Non-GAAP Cost of product revenues ⁽²⁾	5 – 6% of net product revenues
GAAP Research and development expenses	\$1,550 - \$1,590 million
Non-GAAP Research and development expenses ⁽³⁾	\$1,420 - \$1,455 million
GAAP Selling, general and administrative expenses	\$950 - \$1,000 million
Non-GAAP Selling, general and administrative expenses ⁽³⁾	\$880 - \$925 million

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, 13726298.

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, 13726298.

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](https://twitter.com/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 (ruxolitinib) cream is 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 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. Additionally, in December 2021, Incyte announced the acceptance and priority review of the supplemental New Drug Application (sNDA) for ruxolitinib cream as a potential treatment for adolescents and adults (age ≥12 years) with vitiligo.

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 monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb[®] engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP).

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 the EU.

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).

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. Incyte has granted Innovent Biologics, Inc. rights to develop and commercialize pemigatinib in hematology and oncology in Mainland China, Hong Kong, Macau and Taiwan. Incyte has retained all other rights to develop and commercialize pemigatinib outside of the United States.

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 financial guidance for 2022, including its expectations regarding sales of Jakafi; Incyte's expectations with regard to the regulatory submissions seeking approval of ruxolitinib cream in vitiligo; Incyte's expectations with regard to filing an NDA for once-daily ruxolitinib; Incyte's expectations with respect to Opzelura, including the Company's ongoing discussions with payers; Incyte's expectations regarding ongoing clinical trials and clinical trials to be initiated, including trials of axatilimab in chronic GVHD, the LIMBER program, a phase 3 clinical trials of pascalisib in warm autoimmune hemolytic anemia, Phase 2 trials of pemigatinib in glioblastoma and non-small cell lung cancer, a proof of concept trial of tafasitamab in combination with lenalidomide and plamotamab in relapsed/refractory B-cell malignancies, phase 3 trials for ruxolitinib cream in pediatric AD and chronic hand eczema, and a Phase 2 trial of INCB00928 in fibrodysplasia ossificans progressiva; Incyte's life cycle management strategy for ruxolitinib cream; Incyte's expectations with regard to its ongoing partnership with Merus; and Incyte's expectations with regard to regulatory submissions for baricitinib and capmatinib.

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; and other risks detailed in the Company's reports filed with the Securities and Exchange Commission. The Company 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		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
	GAAP		GAAP	
Revenues:				
Product revenues, net	\$ 648,038	\$ 559,467	\$ 2,322,012	\$ 2,068,736
Product royalty revenues	164,815	120,042	569,255	392,966
Milestone and contract revenues	50,000	110,000	95,000	205,000
Total revenues	<u>862,853</u>	<u>789,509</u>	<u>2,986,267</u>	<u>2,666,702</u>
Costs and expenses:				
Cost of product revenues (including definite-lived intangible amortization)	43,874	36,323	150,991	131,328
Research and development	472,827	405,945	1,458,179	2,215,942
Selling, general and administrative	226,202	166,988	739,560	516,922
Change in fair value of acquisition-related contingent consideration	1,673	3,595	14,741	23,385
Collaboration loss sharing	7,543	12,429	37,019	42,801
Total costs and expenses	<u>752,119</u>	<u>625,280</u>	<u>2,400,490</u>	<u>2,930,378</u>
Income (loss) from operations	110,734	164,229	585,777	(263,676)
Other income (expense), net	5,716	4,810	10,647	23,206
Interest expense	(752)	(428)	(1,908)	(2,174)
Unrealized (loss) gain on long term investments	4,322	(509)	(24,072)	10,426
Income (loss) before (benefit) provision for income taxes	<u>120,020</u>	<u>168,102</u>	<u>570,444</u>	<u>(232,218)</u>
(Benefit) provision for income taxes	<u>(443,831)</u>	<u>18,252</u>	<u>(378,137)</u>	<u>63,479</u>
Net income (loss)	<u>\$ 563,851</u>	<u>\$ 149,850</u>	<u>\$ 948,581</u>	<u>\$ (295,697)</u>
Net income (loss) per share:				
Basic	\$ 2.55	\$ 0.68	\$ 4.30	\$ (1.36)
Diluted	\$ 2.54	\$ 0.68	\$ 4.27	\$ (1.36)

Shares used in computing net income (loss) per share:

Basic	220,984	219,239	220,428	218,073
Diluted	221,989	221,228	222,074	218,073

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

	December 31, December 31,	
	2021	2020
ASSETS		
Cash, cash equivalents and marketable securities	\$ 2,348,192	\$ 1,801,377
Accounts receivable	616,300	481,994
Property and equipment, net	723,920	559,625
Finance lease right-of-use assets, net	27,548	28,451
Inventory	56,938	35,973
Prepaid expenses and other assets	165,302	101,259
Long term investments	221,266	222,301
Other intangible assets, net	150,755	172,291
Goodwill	155,593	155,593
Deferred income tax asset	467,538	2,054
Total assets	\$ 4,933,352	\$ 3,560,918

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable, accrued expenses and other liabilities	\$ 885,081	\$ 648,793
Finance lease liabilities	34,267	34,857
Acquisition-related contingent consideration	244,000	266,000
Stockholders' equity	3,770,004	2,611,268
Total liabilities and stockholders' equity	\$ 4,933,352	\$ 3,560,918

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
GAAP Net Income (Loss)	\$ 563,851	\$ 149,850	\$ 948,581	\$ (295,697)
<i>Adjustments¹:</i>				
Non-cash stock compensation from equity awards (R&D) ²	30,134	30,175	114,316	120,356
Non-cash stock compensation from equity awards (SG&A) ²	17,484	14,840	66,984	56,559
Non-cash stock compensation from equity awards (COGS) ²	604	246	1,706	962
Non-cash interest ³	109	66	181	683
Changes in fair value of equity investments ⁴	(4,322)	509	24,072	(10,426)
Amortization of acquired product rights ⁵	5,384	5,384	21,536	21,536
Change in fair value of contingent consideration ⁶	1,673	3,595	14,741	23,385
Legal settlements ⁷	—	—	19,972	—
Non-operating tax adjustments ⁸	(568,988)	—	(568,988)	—
Tax effect of Non-GAAP pre-tax adjustments ⁹	(23,364)	108	(31,123)	(7,868)
Non-GAAP Net Income (Loss)	\$ 22,565	\$ 204,773	\$ 611,978	\$ (90,510)

Non-GAAP net income (loss) per share:

Basic	\$ 0.10	\$ 0.93	\$ 2.78	\$ (0.42)
Diluted	\$ 0.10	\$ 0.93	\$ 2.76	\$ (0.42)

Shares used in computing Non-GAAP net income (loss) per share:

Basic	220,984	219,239	220,428	218,073
Diluted	221,989	221,228	222,074	218,073

¹ Included within the Milestone and contract revenues line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2021 are milestones of \$50,000 and \$95,000, respectively, earned from our collaborative partners as

compared to \$110,000 and \$205,000, respectively, for the same periods in 2020. Included within the Research and development expenses line item in the Condensed Consolidated Statements of Operations (in thousands) for the three and twelve months ended December 31, 2021 are upfront consideration and milestones of \$128,152 and \$148,985, respectively, related to our collaborative partners as compared to upfront consideration and milestones of \$25,600 and \$976,082, respectively, related to our collaborative partners and FDA priority review voucher for the same periods in 2020.

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 gain (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 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 Included within the (Benefit) provision for income taxes line item in the Condensed Consolidated Statements of Operations is portions of the provision for income taxes that are not associated with normal, recurring operations. For the three and twelve months ended December 31, 2021 (in thousands), the company recorded a one-time non-cash benefit from income taxes of \$568,988 related to the release of its valuation allowance on the majority of its U.S. deferred tax assets.

⁹ 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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