

2020 Second Quarter Financial and Corporate Update AUGUST 4, 2020 -

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# **FORWARD-LOOKING STATEMENTS**

Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the potential impacts of the COVID-19 pandemic and measures taken to address the pandemic on our business, operations and financial results, including expectations regarding effects on commercial operations, supply chain, regulatory timelines and clinical trials, and the timing of return to work; our expectations for recent product approvals to lead to revenue growth; our expectations to maintain the momentum of Jakafi in myeloproliferative neoplasms and to drive additional growth in GVHD; our expectations with respect to the launches of Pemazyre and Monjuvi; our expectations with respect to royalties from Tabrecta; the expected timing for submission of an NDA for ruxolitinib cream for atopic dermatitis and the expected timing of any FDA decision with respect thereto; our expectations with respect to the initiation of the pivotal program of ruxolitinib plus parsaclisib in patients with myelofibrosis; the potential impacts of the COVID-19 pandemic and measures taken to address the pandemic on our business, operations and financial results; the expected timing for results from the clinical trial of ruxolitinib cream for vitiligo and for submission of an NDA for the one-a-day formulation of ruxolitinib; expectations with respect to the launch of Monjuvi; plans and expectations regarding clinical trials for our LIMBER program and tafasitamab; the presentation of clinical trial results and the sNDA submission for ruxolitinib for GVHD; plans and expectations with respect to clinical trials of ruxolitinib and baricitinib for patients with COVID-19; expectations regarding the receipt or presentation of clinical trial results for various of our and our collaborative partners' product candidates; expectations regarding the timing of FDA decisions for our and our collaborative partners' product candidates and related product launches of any approved product candidates; expectations regarding the commencement of clinical trials and completion of clinical trial enrollment for various of our and our collaborative partners' product candidates; expectations regarding our target discovery efforts and discovery of new targets; expectations regarding the market opportunities for our and our collaborative partners' product candidates; our reaffirmed 2020 GAAP and Non-GAAP guidance, and expectations underlying that guidance; and our expectations regarding 2020 newsflow items.

These forward-looking statements are based on our current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; the effects of the COVID-19 pandemic and measures to address the pandemic on our clinical trials, supply chain and other third-party providers, sales and marketing efforts, and business, development and discovery operations; 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 and regulatory agencies outside of the United States; our dependence on relationships with and changes in the plans and expenditures of our collaboration partners; the efficacy or safety of our products and the products of our collaboration partners; the effects of our collaboration partners; sales, marketing, manufacturing and distribution requirements, including our and our collaboration partners' ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional new products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our quarterly report on Form 10-Q for th



# **SECOND QUARTER REVIEW**

HERVÉ HOPPENOT – CEO



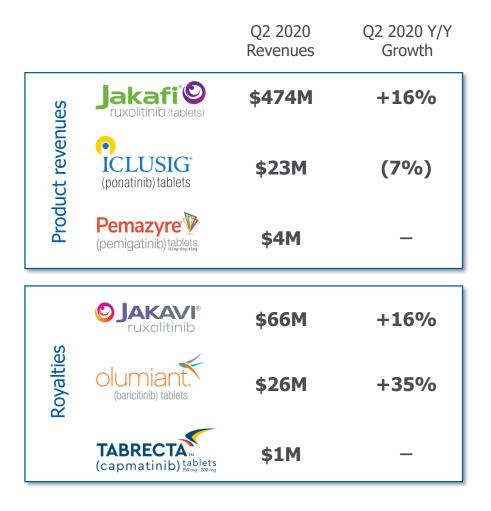
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# **CONTINUED STRONG EXECUTION**



### Multiple successes across key clinical programs

- Two additional FDA approvals:
  - Tabrecta<sup>™</sup> (capmatinib)<sup>1</sup>
  - Monjuvi<sup>®</sup> (tafasitamab-cxix)<sup>2</sup>
- Successful REACH3 trial of ruxolitinib in steroid-refractory chronic GVHD<sup>3</sup>
- EHA updates: POC ruxolitinib + parsaclisib data and updated tafasitamab data

### Strong financial position

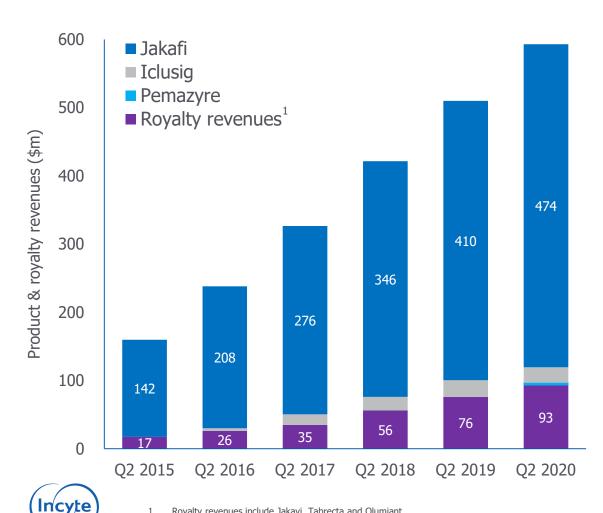
- \$1.6 billion in cash and equivalents at end Q2 2020
- No changes to revenue or expense guidance for FY 2020

Incyte

- Jakavi (ruxolitinib) licensed to Novartis ex-US, Tabrecta (capmatiinib) licensed to Novartis worldwide, Olumiant (baricitinib) licensed to Lilly worldwide; these brands are trademarks of Novartis (Jakavi and Tabrecta) and Lilly (Olumiant). Iclusig (ponatinib) is a registered trademark of ARIAD. Monjuvi (tafasitamab-cxix) is a registered trademark of MorphoSys. GVHD = graft-versus-host disease; MF = myelofibrosis. EHA = European Hematology Association. 1. Worldwide rights to capmatinib licensed to Novartis; Indicated for treatment of adults with metastatic non-small cell lung cancer (NSCLC) with a mutation that leads to MET exon 14 skipping (METex14)
- 2. Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys; approved as Monjuvi for treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT)
- 3. Development of ruxolitinib in GVHD in collaboration with Novartis.

# **NEW APPROVALS ADD TO MOMENTUM**

MULTIPLE REVENUE SOURCES EXPECTED TO DRIVE GROWTH AND DIVERSIFICATION



Opportunities and key objectives for 2020
<ul> <li>Revenue growth:</li> </ul>
<ul> <li>Maintain momentum of Jakafi<sup>®</sup> in MPNs</li> </ul>
<ul> <li>Drive growth of Jakafi in GVHD</li> </ul>
<ul> <li>Execute successful launches:</li> </ul>
<ul> <li>Monjuvi<sup>®</sup> (tafasitamab-cxix)<sup>2</sup></li> </ul>
<ul> <li>Pemazyre<sup>®</sup> (pemigatinib)</li> </ul>
<ul> <li>Tabrecta<sup>™</sup> (capmatinib)<sup>3</sup> royalties on sales in US and Japan</li> </ul>
<ul> <li>Planned regulatory submission:</li> <li>NDA for ruxolitinib cream in atopic dermatitis</li> </ul>
Progress in LIMBER development:

Initiation of ruxolitinib + parsaclisib pivotal program 

Royalty revenues include Jakavi, Tabrecta and Olumiant. 1.

2. Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys.

3. Worldwide rights to capmatinib licensed to Novartis

# **BUSINESS UPDATE IN THE TIME OF COVID-19**

## **Commercial & Supply**

#### Revenues

☑ No material impact to date

### **Product Launches**

- ☑ Launch of Pemazyre<sup>®</sup> (pemigatinib) progressing well
- $\mathbf{M}$  Monjuvi<sup>®</sup> (tafasitamab-cxix)<sup>1</sup> launch activities underway

### Supply

Manufacturing processes proceeding as usual

## Regulatory

### No impact to date on key regulatory timelines

- ☑ Tabrecta<sup>™</sup> (capmatinib)<sup>2</sup> approved in U.S. and Japan
- $\checkmark$  Monjuvi<sup>®</sup> (tafasitamab-cxix)<sup>1</sup> approved in U.S.
- MAA validated for tafasitamab

2.

 $\checkmark$  NDA submission for ruxolitinib cream planned for end 2020

## **Clinical development**

### Continued progress of key pipeline programs

- ☑ Both ruxolitinib cream programs on schedule
- ☑ QD ruxolitinib submission still expected 2021
- BET and ALK2 monotherapy trials now opening
- □ Pemigatinib bladder Phase 2 data delayed to 2021

### Discovery

Returned to full lab operations in May



# **U.S. COMMERCIAL UPDATE**

BARRY FLANNELLY - GENERAL MANAGER, NORTH AMERICA



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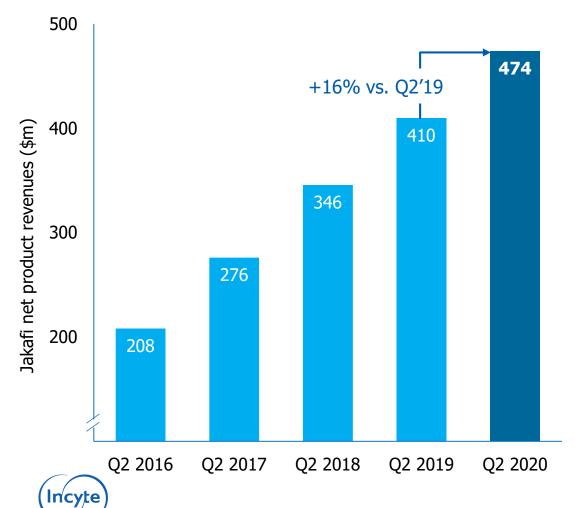
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# JAKAFI®: GROWTH IN ALL THREE INDICATIONS

POTENTIAL FOR FOURTH INDICATION WITH SUCCESS OF REACH3 IN CHRONIC GVHD



Strong growth of Jakafi in Q2

- Robust demand in all three indications
- Growing pool of total patients on therapy
- Regional COVID-19 reductions in new patient starts
- Rebound of new patient starts in June

#### Commercial efforts in virtual environment

- Expansion of multi-channel engagements, including virtual programs and digital content
- Maintaining levels of service and responsiveness

# PEMAZYRE®: SUCCESSFUL CHOLANGIOCARCINOMA LAUNCH



~1,000 HCP targets 2/3 already Jakafi<sup>®</sup> prescribers

Targeting



Co-approval of product and FMI companion diagnostic<sup>1</sup>

Testing





### **Education & Access**

Multi-channel engagement to educate HCPs during COVID-19

Good depth of prescribers; both academic and community settings

Rapid Rx shipping (>80% within 7 days of initial HCP referral)

No unexpected reimbursement issues



1. FMI = Foundation Medicine. FoundationOne CDx is FMI's comprehensive genomic profiling assay and broad companion diagnostic platform; this companion diagnostic helps identify patients with FGFR2 fusions or rearrangements who may be eligible for Pemazyre.

# MONJUVI® (TAFASITAMAB): NOW FDA APPROVED

OPPORTUNITY TO TRANSFORM SECOND-LINE TREATMENT OF DLBCL



- 1. First FDA approved 2L therapy in DLBCL
- 2. New, non-chemotherapeutic option for patients
- 3. Compelling clinical profile in USPI<sup>1</sup>
  - ✓ 55% ORR; 37% CR; mDOR 21.7 months
  - $\checkmark\,$  No unexpected toxicities

### **Commercial & medical teams ready**

- Joint field team c. 150 FTEs
- 11,000 potential prescribers
- ~80% overlap with Jakafi<sup>®</sup>

### $\sim$ 10,000 new eligible patients annually

- Payor interactions already underway
- Expect broad access
- Patient assistance program in place



Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. r/r DLBCL = relapsed or refractory diffuse large B-cell lymphoma; ORR = objective response rate; CR = complete response; mDOR = median duration of response 1. USPI = U.S. Prescribing Information

# **CLINICAL DEVELOPMENT**

STEVEN STEIN – CHIEF MEDICAL OFFICER



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# REACH3: RUXOLITINIB SUCCESS IN cGVHD

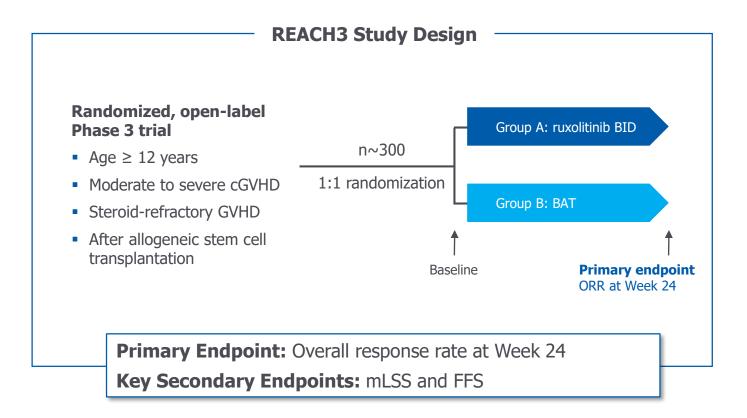
## A PHASE 3, RANDOMIZED, SUPERIORITY STUDY OF RUXOLITINIB VERSUS BAT

#### **Key Results**

- Ruxolitinib met primary endpoint of superior overall response rate (ORR) at Week 24 compared to BAT<sup>1</sup>
  - Statistically significant improvements in both key secondary endpoints mLSS<sup>2</sup> and FFS<sup>3</sup>
- Safety profile of ruxolitinib consistent with previously reported studies of ruxolitinib in GVHD

#### **Next Steps**

- Data from REACH3 expected to be submitted for presentation at upcoming medical congress
- Preparations for sNDA submission





Development of ruxolitinib in GVHD in collaboration with Novartis. REACH3: NCT03112603

1. BAT = best available therapy

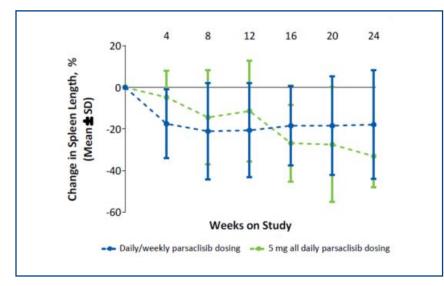
. mLSS = modified Lee chronic GVHD symptom scale

3. FFS = failure-free survival (time to relapse or recurrence of underlying disease or death due to underlying disease, non-relapse mortality, or addition or initiation of another systemic therapy for cGVHD)

# LIMBER: TWO PIVOTAL PHASE 3 TRIALS TO START

### RUXOLITINIB + PARSACLISIB TO ENTER COMPREHENSIVE DEVELOPMENT PROGRAM

#### Spleen Volume Reduction at Weeks 12 and 24<sup>1</sup>



#### Safety

- Addition of parsaclisib to ruxolitinib was well tolerated, with limited grade 3/4 adverse events
- TEAEs common to PI3Kδ inhibitors (eg. hepatic, rash, colitis) were infrequent with the addition of parsaclisib



#### Two pivotal trials planned in myelofibrosis (MF) patients

#### Inadequate responders to ruxolitinib

MF patients with suboptimal response to ruxolitinib monotherapy

- ruxolitinib  $\geq$ 3 months with stable dose for  $\geq$ 8 weeks
- ruxolitinib +/- parsaclisib 5mg daily

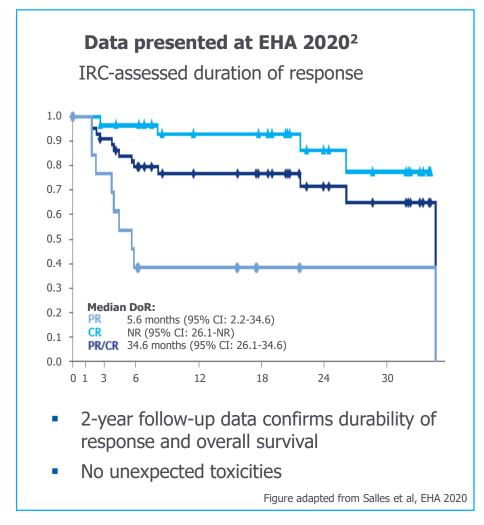
#### **First-line**

MF patients naive to JAK or PI3K $\delta$  inhibitors

ruxolitinib +/- parsaclisib 5mg daily

# TAFASITAMAB: UPDATED L-MIND DATA PRESENTED AT EHA

	Primary analysis presented at ICML'19	Updated 2-yr data presented at EHA'20
	Nov 2018 data-cut <sup>1</sup>	Nov 2019 data-cut <sup>2</sup>
ORR	60% (48/80)	59% (47/80)
CR	43% (34/80)	41% (33/80)
SD	14% (11/80)	15% (12/80)
mPFS	12.1 months	16.2 months
mDoR	21.7 months	34.6 months
mOS	NR (12-months OS: 74%)	31.6 months





Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys. ORR = Objective response rate; CR = complete response 1. Salles et al, ICML 2019

2. Salles et al, EHA 2020

# TAFASITAMAB: CLINICAL DEVELOPMENT OVERVIEW

NEAR-TERM OPPORTUNITIES IN DLBCL AND OTHER NON-HODGKIN LYMPHOMAS

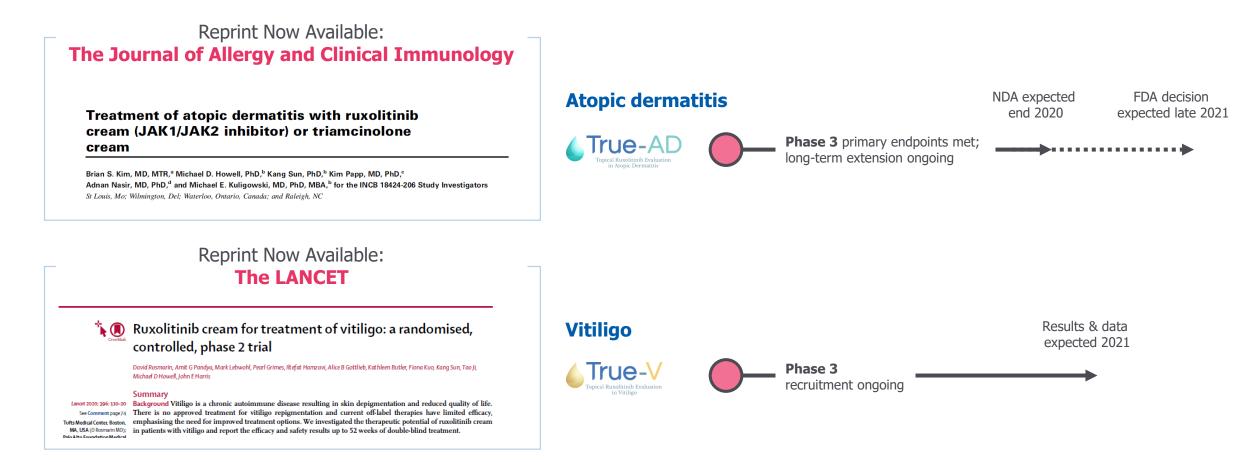
	Study	Arms	Status	Proof-of-Concept	Pivotal	 2.5
r/r BCL	<b>L-MIND</b> (~80 pts)	+ lenalidomide	Approved	Primary Endpoint: ORR (2-year analysis presented at EHA 2020)		
DLI	<b>B-MIND</b> (~450 pts)	+ bendamustine vs bendamustine + rituximab	Ongoing	Primary Endpoint: PFS (IDMC futility passed November 2019)		2.5
SCL	<b>FIRST-MIND</b> (~60 pts)	+ R-CHOP or + lenalidomide + R-CHOP	Primary completion expected 2020	Safety		
1L DLBC	<b>Pivotal trial</b> (TBD pts)	TBD based on FIRST-MIND	Initiation planned in 2021	Pivotal trial planned to start in 2021		
NHL	<b>COSMOS</b> (~24 pts)	+ idelalisib or venetoclax	Completed	Safety (primary analysis presented at ASH 2019)		
r/r CLL/NHI	TBD	+ parsaclisib	Initiation planned by end 2020	Efficacy and safety trial planned		



# TWO KEY RUXOLITINIB CREAM DEVELOPMENT PROGRAMS

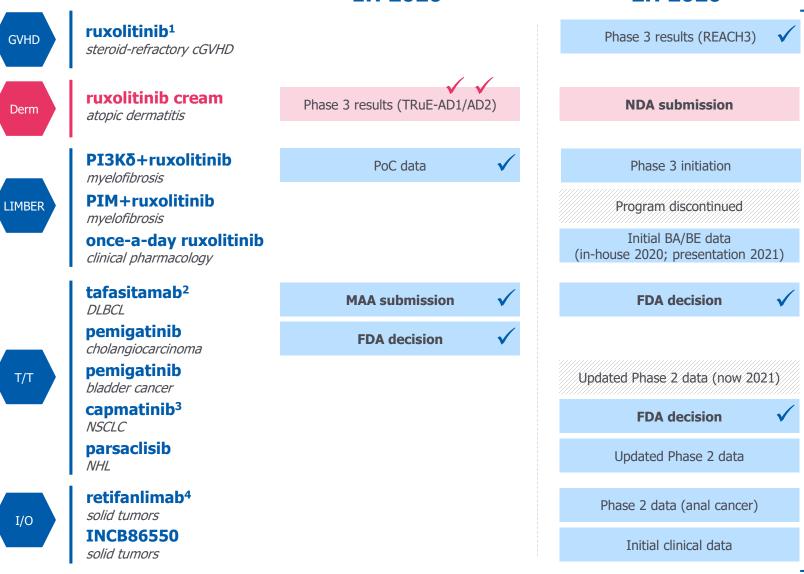
### NDA SUBMISSION IN ATOPIC DERMATITIS ON TRACK FOR END 2020

Incyte



### 1H 2020

### 2H 2020





T/T = targeted therapies; I/O = immunotherapies.

Incyte

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4. retifanlimab previously known as INCMGA0012.

# **COVID-19 CLINICAL DEVELOPMENT**

### RUXOLITINIB AND BARICITINIB TRIALS UNDERWAY

	Size, Age	On ventilation at recruitment	Arms	Status & Primary endpoint
<b>RUXCOVID</b> <sup>1</sup> (ruxolitinib)	n~400 12+ yrs	Not allowed	A: ruxolitinib 5mg BID + SoC B: SoC	<b>Ongoing</b> Proportion of patients who die, develop respiratory failure, or require ICU care by Day 29
<b>RUXCOVID-DEVENT<sup>2</sup></b> (ruxolitinib)	n~500 18+ yrs	Necessary	A: ruxolitinib 5mg BID + SoC B: ruxolitinib 15mg BID + SoC C: SoC	<b>Ongoing</b> Proportion of patients who have died due to any cause through Day 29
<b>ACTT-2</b> (baricitinib)	n~1,000 18+ yrs	Allowed	A: baricitinib 4mg QD + remdesivir B: remdesivir	<b>Ongoing</b> Time to recovery by Day 29 <sup>3</sup>
<b>COV-BARRIER</b> (baricitinib)	n~400 12+ yrs	Not allowed	A: baricitinib 4mg QD + SoC B: SoC	<b>Ongoing</b> Proportion of patients who die or require non- invasive ventilation/high-flow oxygen or invasive mechanical ventilation by Day 28



SOC = standard of care; ACTT = Adaptive COVID-19 Treatment Trial

1. Co-sponsored by Incyte and Novartis (global trial)

2. Sponsored by Incyte (US)

3. Day of recovery is defined as the first day on which the subject satisfies one of the following three categories from the ordinal scale: 1) Not hospitalized, no limitations on activities; 2) Not hospitalized, limitation on activities and/or requiring home oxygen; 3) Hospitalized, not requiring supplemental oxygen and no longer requires ongoing medical care. <a href="https://clinicaltrials.gov/ct2/show/NCT04401579">https://clinicaltrials.gov/ct2/show/NCT04401579</a>

# FINANCIAL RESULTS

CHRISTIANA STAMOULIS – CFO



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## **NON-GAAP ADJUSTMENTS**

- The financial measures other than Non-GAAP operating income / (loss) presented in this
  presentation for the three and six months ended June 30, 2020 and 2019 have been prepared
  by the Company in accordance with U.S. Generally Accepted Accounting Principles ("GAAP").
- Management has chosen to present Non-GAAP operating income / (loss) for the three and six months ended June 30, 2020 and 2019 and to release both GAAP and Non-GAAP financial guidance for the year ending December 31, 2020 in the belief that this Non-GAAP information is useful for investors, when considered in conjunction with Incyte's GAAP financial guidance.
- 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.





<b>Financial Highlights</b> \$ millions	Three Months Ended Jun 30, 2020 GAAP	Three Months Ended Jun 30, 2019 GAAP	Three Months Ended Jun 30, 2020 Non-GAAP <sup>1</sup>	Three Months Ended Jun 30, 2019 Non-GAAP <sup>1</sup>	YoY Change Non-GAAP
Net product revenues	500	434	500	434	15%
Jakafi	474	410	474	410	16%
Iclusig	23	24	23	24	(7%)
Pemazyre	4	-	4	-	
Royalties	93	76	93	76	22%
Jakavi	66	57	66	57	16%
Olumiant	26	19	26	19	35%
Tabrecta	1	-	1	-	
Total product and royalty revenues	593	510	593	510	<b>16%</b>
Milestones and contract revenues	95	20	95	20	
Total revenues	688	530	688	530	30%
Costs and expenses	457	431	400	379	5%
COGS	33	29	28	24	15%
R&D	287	289	254	262	(3%)
R&D – ongoing	283	264	250	237	6%
% total revenues	41%	50%	36%	45%	
R&D – upfront and milestones	4	25	4	25	
SG&A	118	106	104	93	12%
% total revenues	17%	20%	15%	18%	
Contingent consideration	6	7	-	-	
Collaboration loss sharing	13	-	13	-	
Operating income	231	99	289	151	<b>91%</b>
% total revenues	34%	19%	42%	29%	



1. Non-GAAP costs and expenses exclude stock-based compensation and other expenses; a reconciliation from GAAP to Non-GAAP financial measures is provided on slide 25.

# FINANCIAL GUIDANCE: FULL YEAR 2020

\$ millions	FY 2020 GAAP	FY 2020 Non-GAAP <sup>1</sup>
Net product revenues		
Jakafi	1,880 - 1,950	1,880 - 1,950
Iclusig	100 - 105	100 – 105
Costs and expenses		
COGS	130 – 135	107 – 112
R&D <sup>2</sup>	1,210 - 1,280	1,079 – 1,149
SG&A	505 – 535	447 – 477
Change in fair value of contingent consideration	25 – 27	0

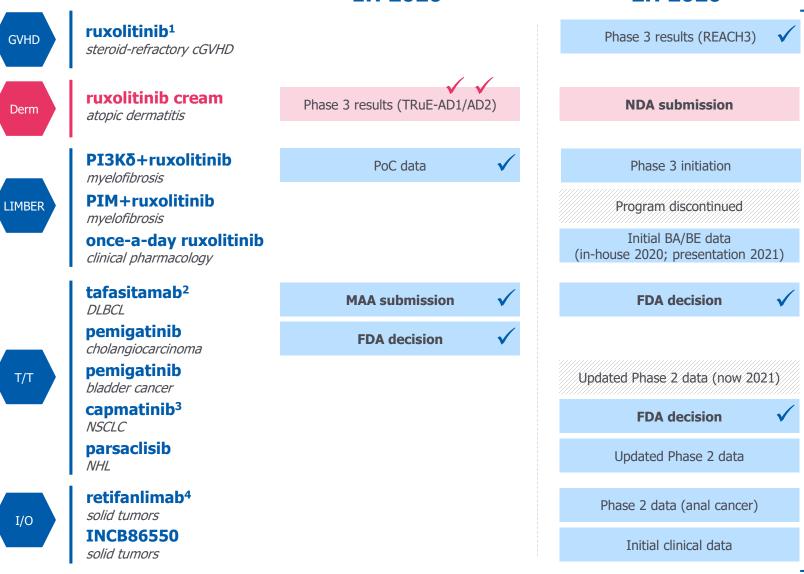


1. Non-GAAP costs and expenses exclude stock-based compensation and other expenses; a reconciliation from GAAP to Non-GAAP financial measures is provided on slide 27.

2. R&D financial guidance excludes \$805 million of upfront consideration related to the MorphoSys collaboration.

### 1H 2020

### 2H 2020





T/T = targeted therapies; I/O = immunotherapies.

Incyte

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2. Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys.

3. Worldwide rights to capmatinib licensed to Novartis.

4. retifanlimab previously known as INCMGA0012.

# FINANCIAL BACK-UP SLIDES



# 2020 AND 2019 NON-GAAP RECONCILIATION

\$ millions	Three Months Ended Jun 30, 2020	Three Months Ended Jun 30, 2019	Six Months Ended Jun 30, 2020	Six Months Ended Jun 30, 2019
GAAP operating income (loss)	231	99	(433)	173
Adjustments				
Non-cash stock compensation from equity awards	46	41	89	81
Amortization of acquired product rights	5	5	11	11
Change in fair value of contingent consideration	6	7	13	13
Non-GAAP operating income (loss)	289	151	(321)	278



Financial Highlights \$ millions	Six Months Ended Jun 30, 2020 GAAP	Six Months Ended Jun 30, 2019 GAAP	Six Months Ended Jun 30, 2020 Non-GAAP <sup>1</sup>	Six Months Ended Jun 30, 2019 Non-GAAP <sup>1</sup>	YoY Change Non-GAAP
Net product revenues	987	830	987	830	19%
Jakafi	933	785	933	785	19%
Iclusig	50	45	50	45	11%
Pemazyre	4	0	4	0	
Royalties	175	138	175	138	27%
Jakavi	123	102	123	102	20%
Olumiant	51	35	51	35	46%
Tabrecta	1	0	1	0	
Total product and royalty revenues	1,162	968	1,162	968	20%
Milestones and contract revenues	95	60	95	60	
Total revenues	1,257	1,028	1,257	1,028	22%
Costs and expenses	1,690	855	1,578	750	110%
COGS	61	52	49	41	20%
R&D	1,372	560	1,311	505	160%
R&D – ongoing	563	535	502	480	5%
% total revenues	45%	52%	40%	47%	
R&D – upfront and milestones	809	25	809	25	
SG&A	229	230	202	204	(1%)
% total revenues	18%	22%	16%	20%	
Contingent consideration	13	13	-	-	
Collaboration loss sharing	15	0	15	-	
Operating income (loss)	(433)	173	(321)	278	-
% total revenues	-	17%	-	27%	



1. Non-GAAP costs and expenses exclude stock-based compensation and other expenses; a reconciliation from GAAP to Non-GAAP financial measures is provided on slide 25.

# **2020 FINANCIAL GUIDANCE NON-GAAP RECONCILIATION**

\$ millions	GAAP Guidance	Adjustments	Non-GAAP Guidance
Net product revenues			
Jakafi	1,880 – 1,950	-	1,880 - 1,950
Iclusig	100 – 105	-	100 – 105
Costs and expenses			
COGS	130 – 135	Amortization of acquired product rights for Iclusig and stock-based compensation (23)	107 – 112
R&D <sup>1</sup>	1,210 – 1,280	Stock-based compensation (131)	1,079 – 1,149
SG&A	505 – 535	Stock-based compensation (58)	447 – 477
Change in fair value of contingent consideration	25 – 27	Change in fair value of estimated future Iclusig royalties (25 – 27)	0





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