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# LETTER TO STOCKHOLDERS



Hervé Hoppenot Chairman and CEO



## DEAR FELLOW STOCKHOLDERS,

At Incyte, our belief is that science drives success, and specifically that our efforts to discover and develop novel medicines will create value for patients, society and stockholders. 2018 was another year of significant progress as we seek to build Incyte into a diversified, fast-growing and global biopharmaceutical company. It was also a year where we were reminded of the importance of having a diversified portfolio of products with the potential to improve the lives of patients with cancer and other diseases.

Before highlighting our achievements, an important—although disappointing—event in 2018 was the result of ECHO-301, our Phase 3 trial together with Merck evaluating epacadostat in combination with pembrolizumab, Merck's PD-1 antagonist, for the first-line treatment of patients with advanced or metastatic melanoma. Expectations internally and within the medical community were high, and we were disappointed that the combination did not show a benefit in progression-free survival (PFS) over pembrolizumab monotherapy. We continue to learn as much as we can from the results, but this event reinforced our belief in the importance of having a robust portfolio of development projects. I'd like to now move on to our 2018 achievements.

#### **CONTINUING TO DRIVE MOMENTUM**

2018 was a year of financial strength and continued revenue growth, with total revenues reaching \$1.9B, an increase of over 20 percent versus 2017. GAAP Net Income grew to a profit of \$110M for 2018 as compared to a GAAP Net Loss of \$313M in 2017.

Sales of Jakafi® (ruxolitinib) were strong in 2018, driven by demand in both myelofibrosis (MF) and polycythemia vera (PV).¹ Iclusig® (ponatinib)² continues to grow, and the royalties we receive from Jakavi® (ruxolitinib, from Novartis)³ and Olumiant® (baricitinib, from Lilly)⁴ are contributing more to our top-line growth each year.

The stories of the patients we treat inspire us to do better, and we are committed to maintaining our leadership position in the treatment of patients with myeloproliferative neoplasms (MPNs). We are pursuing three key strategies that aim to improve the outcomes of MPN patients: improved formulations of ruxolitinib, developing ruxolitinib-based combination therapies and pursuing new targets beyond JAK inhibition. I look forward to reporting on these initiatives next year.

Overall, we are very pleased with our progress in 2018 and are increasingly confident in our potential to drive additional top-line growth in the near- and medium-term.

We have a broad and diversified selection of clinical candidates in our growing portfolio of medicines in both oncology and within inflammation and autoimmunity.

#### OPPORTUNITIES FOR NEAR-TERM GROWTH

We are proud to have a growing portfolio in both oncology and within inflammation and autoimmunity. This includes multiple late-stage projects that we believe have significant potential on a standalone basis and, collectively, have the potential to transform Incyte into a company with multiple approved products in the U.S., Europe and Japan, driving significant revenue growth over the next several years.

#### GRAFT-VERSUS-HOST DISEASE (GVHD)

**Ruxolitinib** (JAK1/JAK2) is currently being reviewed by the U.S. Food and Drug Administration (FDA) for use in steroid-refractory acute GVHD and, in collaboration with Novartis, is currently being evaluated in two global Phase 3 trials in steroid-refractory acute and chronic GVHD.

**Itacitinib** (JAK1) is in Phase 3 trials in patients with treatment-naïve acute and treatment-naïve chronic GVHD. Itacitinib represents a significant opportunity for Incyte, as it is being studied in the first-line setting where approximately 15,000 new patients are diagnosed each year in the U.S., Europe and Japan.

#### TARGETED THERAPIES

**Pemigatinib** (FGFR1/2/3) has shown promise in certain cancers with activating FGF/FGFR alterations. Registration-directed trials in patients with cholangiocarcinoma, bladder cancer and 8p11 MPN are all ongoing. We expect to file a New Drug Application (NDA) with the FDA in cholangiocarcinoma this year.

Phase 2 trials of **parsaclisib** (PI3Kδ) for the treatment of patients with follicular lymphoma, marginal zone lymphoma and mantle cell lymphoma are all ongoing. Data are expected to be available in 2020.

#### **IMMUNO-ONCOLOGY**

**INCMGA0012** (PD-1) is being developed in collaboration with MacroGenics and is currently in registration-directed trials in patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer. Initial data are expected in 2020.

#### INFLAMMATION AND AUTOIMMUNITY (IAI)

We see multiple opportunities in inflammation and autoimmunity (IAI) and are advancing a number of clinical programs. Our most advanced IAI program is for **ruxolitinib cream**, which is being evaluated in a Phase 3 trial in patients with mild-to-moderate atopic dermatitis (AD) as well as a Phase 2 trial in patients with vitiligo.

#### PARTNERED PROJECTS

We have two partnered product candidates, **baricitinib** (JAK1/JAK2, Lilly) and **capmatinib** (MET, Novartis)<sup>5</sup>. In June, we, along with Eli Lilly, announced that the FDA approved Olumiant (baricitinib) for the treatment of rheumatoid arthritis (RA). Baricitinib is also being developed in several other indications. Earlier in 2019, the readouts of the first two Phase 3 trials of baricitinib in patients with AD were announced and showed that the trials achieved their primary endpoints. Additionally, data from capmatinib in patients with nonsmall cell lung cancer (NSCLC) with MET exon 14 skipping mutations were presented at the European Society for Medical Oncology (ESMO) 2018 Congress, and Novartis has stated that it plans to submit an NDA in this indication this year.

#### **ANTICIPATED REGULATORY ACTIONS**

We are anticipating the decision from the FDA for potential approval of Jakafi in steroid-refractory acute GVHD in the coming months, which, if approved, would make it the first and only approved treatment for patients with acute GVHD that have had an inadequate response to steroids. In the next 6-18 months, we are also expecting to submit NDAs to the FDA for pemigatinib and itacitinib, and we are expecting Novartis to submit the NDA for capmatinib. Should these drug candidates achieve FDA approval, a total of five molecules discovered by Incyte scientists will have been approved and available to patients, which would be a fitting testament to the expertise of our world-class biologists and chemists.

## INVESTING IN OUR PEOPLE AND MAINTAINING OUR CULTURE

In 2018, Incyte grew to a company of over 1,300 employees, including more than 600 world-class medicinal scientists. We also had the opportunity to strengthen our executive management team with three new members. First, we welcomed Maria Pasquale, J.D., as our General Counsel in April. Ms. Pasquale has nearly 20 years of legal and compliance experience in the biopharmaceutical industry and most recently held the position of Global Chief Compliance Officer at Celgene Corporation. We were excited to also welcome Dashyant Dhanak, M.D., to the team as our Chief Scientific Officer in December, Dr. Dhanak joined us from Janssen Research & Development, where he most recently served as Global Head, Discovery Sciences. In February 2019, we welcomed Christiana Stamoulis as our new Chief Financial Officer. Ms. Stamoulis has over 20 years of experience in the biopharmaceutical industry, 15 in investment banking and management consulting and thereafter in executive positions at Vertex Pharmaceuticals and most recently serving as the President and CFO of Unum Therapeutics. We believe their diverse backgrounds and proven leadership will be great assets for Incyte as we embark on our next stage of growth.

We are committed to maintaining a culture that is driven by a passion for innovative science and where patients are at the forefront of everything we do.

The collective experience and passion of our talented colleagues is foundational to our success, and as our organization continues to grow, we are committed to maintaining a culture that is driven by a passion for innovative science and where patients are at the forefront of everything we do. As such, we were proud to be recognized in October as the number two employer in the biopharma industry by *Science* magazine.

In closing, 2018 represented another year of marked financial, research and organizational progress. Together, we will continue to strive to make a meaningful difference for those living with cancer and other diseases, and in doing so, we aim to create long-term and sustainable value for you, our stockholders.

I thank you for your continued support and look forward to keeping you updated on our progress and achievements.



Forward-looking statements: Safe Harbor rules govern any forward-looking statements made in this Annual Report; for more information, please visit page 41.



# CAM & JANE ON LIFE WITH POLYCYTHEMIA VERA (PV)

For Cam and Jane, navigating life together is an important concept. Married for more than 43 years, they've raised four children and watched nine grandchildren enter the world. Together, they are dedicated to carrying on the legacy of Cam's fifth-generation family farm and recycling business. Mornings start early, with Jane feeding animals and Cam operating machinery or working in the fields to prepare the season's harvest. Each day requires a high level of activity and brings a new challenge, but despite the long and hard days, they always make time for family. And, whenever they have the chance, they pursue passions such as riding Cam's motorcycle or taking a weekend trip in their RV.

Unfortunately, Cam and Jane have navigated a few complicated health journeys, including Cam's diagnosis of a rare blood cancer called polycythemia vera (PV) — a disease that is part of a group of blood cancers known as myeloproliferative neoplasms (MPNs) — which causes blood to thicken, resulting in a variety of impacts on the body.

"I was diagnosed with PV because I noticed impacts on my hearing, extreme itchiness after getting out of the shower and also had intense night sweats," said Cam.

Over the next eight years, with the guidance of his doctor, Cam's PV was treated with phlebotomies – a procedure to draw blood from the body – and then hydroxyurea, a chemotherapy agent and common treatment option for PV. Unfortunately, these treatments weren't working.

"It was hard to see Cam lacking energy – it really had an impact on his daily life. He didn't have any interest in doing the things around the farm and with family that have always made him happy," said Jane.

With Jane at his side and the continued support of his MPN specialist, Cam was ultimately prescribed Jakafi to treat his PV.

Over time, Cam got back to doing the things that he loves.

"Though he never stopped working, he really was a different person. I'm thankful that today he is feeling better," said Jane.

Cam's tenacity and Jane's unwavering support of him throughout this journey are an inspiration for all of us at Incyte. They are also a reminder of why every day we remain committed to following the science to discover and deliver novel medicines that may improve the lives of patients.

## **OBJECTIVES BEFORE END OF 2019**

2019 newsflow for key development projects

## PLANNED REGULATORY UPDATES



Achieve FDA approval for steroid-refractory acute GVHD (REACH1)<sup>6</sup>



Submit NDA for cholangiocarcinoma (FIGHT-202)<sup>7</sup>



NDA for NSCLC to be submitted by Novartis

# PLANNED PIVOTAL CLINICAL UPDATES

baricitinib (JAK1/JAK2) Phase 3 atopic dermatitis results to be reported by Lilly



Phase 3 treatment-naïve acute GVHD results (GRAVITAS-301)



Phase 3 steroid-refractory acute GVHD results (REACH2)



Phase 3 steroid-refractory chronic GVHD results (REACH3)



Phase 2 cholangiocarcinoma data (FIGHT-202)



Phase 2 bladder cancer to complete recruitment (continuous dosing cohort, FIGHT-201)

# PLANNED PIVOTAL TRIAL INITIATIONS

ruxolitinib cream (JAK1/JAK2)

Atopic dermatitis (TRuE-AD1, TRuE-AD2)



Treatment-naïve chronic GVHD (GRAVITAS-309)

pemigatinib (FGFR1/2/3) 1L cholangiocarcinoma (FIGHT-302)

## ruxolitinib cream (JAK1/JAK2)

Vitiligo, if Phase 2 is positive

pemigatinib (FGFR1/2/3)

1L bladder cancer

pemigatinib (FGFR1/2/3)

Solid tumors with driver activations of FGF/FGFR



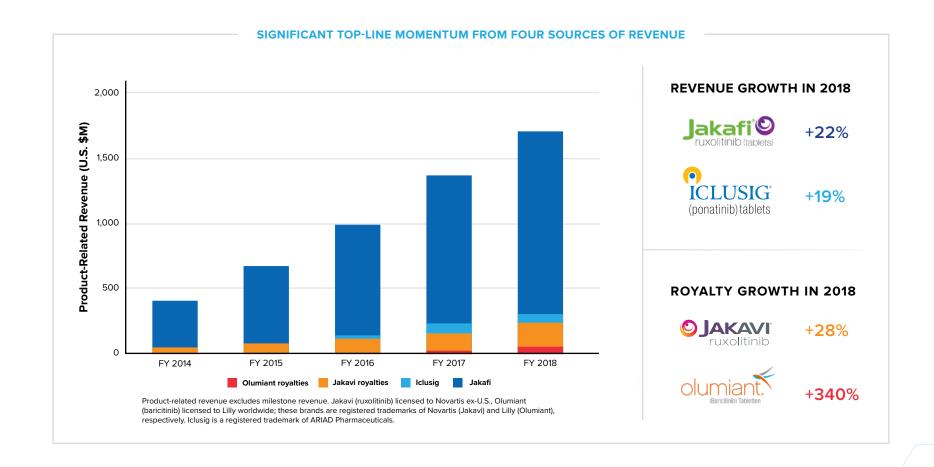
Milestones that have been achieved as of March 25, 2019.

# FINANCIAL STRENGTH



## **INCYTE AT A GLANCE**





## **JAKAFI (RUXOLITINIB)**

Patient demand for Jakafi (JAK1/JAK2 inhibitor) for the treatment of MF and PV remains strong as it enters its seventh full year on the market, with net product revenues totaling \$1.39B in 2018. The total number of patients on therapy grew to over 13,000 patients at the end of 2018—an increase of nearly 2,000 patients from the end of 2017.



#### FINANCIAL STRENGTH

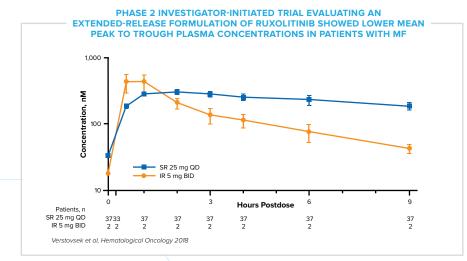
# MAINTAINING OUR LEADERSHIP IN MPNs

We are committed to the treatment of patients with MPNs. As such, we are continuing our work toward discovering and developing therapeutic options with a goal to improve the outcomes for this group of patients in three ways:

# 1

#### IMPROVED FORMULATIONS

Ruxolitinib is the first JAK inhibitor approved for the treatment of MF, but its efficacy can often be associated with cytopenia. It is possible that the severity of cytopenia is in part driven by the peak concentration of ruxolitinib immediately following a dose. Some evidence<sup>8</sup> suggests that an extended-release formulation of ruxolitinib may decrease cytopenia and therefore improve the side-effect profile for some patients. To that end, we are currently working to develop an extended-release formulation of ruxolitinib.



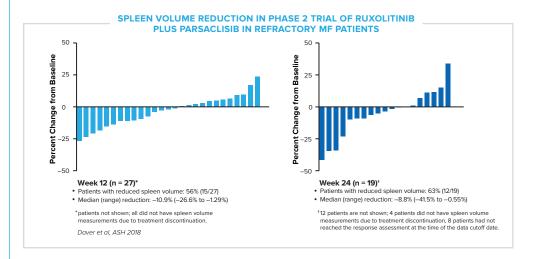
# 2

#### **RUXOLITINIB-BASED COMBINATION THERAPY**

Ruxolitinib + PI3Kδ-1

In pivotal trials, ruxolitinib has been shown to reduce spleen size and improve symptoms in intermediate- or high-risk MF patients.

However, there are some patients who have only suboptimal responses or declining activity over time. We have three ongoing clinical initiatives evaluating ruxolitinib-based combinations to improve responses or to drive patients back into response once they've begun to fail. Activation of the PI3K pathway has been reported in patients with MF.<sup>9,10</sup> Preliminary data of ruxolitinib in combination with parsaclisib (PI3Kδ) were presented at the 60th American Society of Hematology (ASH) Annual Meeting in 2018. These data suggested that the addition of PI3Kδ inhibition to ruxolitinib has the potential to improve outcomes in heavily pre-treated and refractory MF. The preliminary data showed reductions in spleen volume at weeks 12 and 24 in these patients, and additional dosing work is underway. We expect data from additional cohorts of patients later this year. Initial data from ruxolitinib in combination with our PIM inhibitor (INCB53914) and with our JAK1 selective inhibitor (itacitinib) are also expected to be available in 2019 or early 2020.





#### **NEW TARGETS**

Early target discovery work is underway internally as well as through collaborative initiatives with academia and industry, including Syros Pharmaceuticals, Vanderbilt University and The Moffitt Cancer Center, that may uncover new targets to better help patients with MPNs over the longer term.







## **ICLUSIG (PONATINIB)**

Sales of Iclusig, a potent BCR-ABL inhibitor designed to address mutation-driven resistance in patients with treatment-resistant chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), have grown nicely and increased 19 percent in 2018 versus 2017. Over 20 percent of patients with BCR-ABL-mutated CML have the T315I mutation, which has been associated with resistance to treatment and poor outcomes. Iclusig is the only drug currently approved in Europe with activity against T315I.

# ROYALTIES FROM JAKAVI (RUXOLITINIB) AND OLUMIANT (BARICITINIB)

Jakavi royalties have grown strongly, and royalties from Olumiant (JAK1/JAK2), which is now approved in multiple territories globally for the treatment of certain patients with moderate to severe RA, are growing each quarter. Olumiant was launched in the U.S. during 2018.

## **STRONG BALANCE SHEET**

Financially, we are in a strong position, reporting a total of \$1.4B in cash, cash equivalents and marketable securities at the end of 2018.



# KEY PROGRAMS IN ONCOLOGY



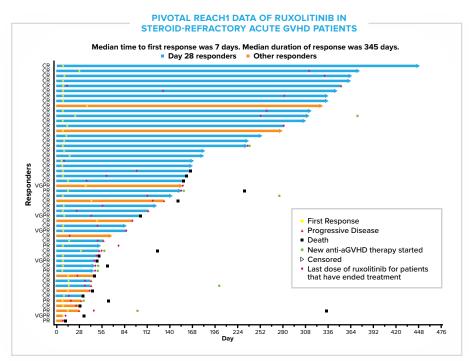
## **GRAFT-VERSUS-HOST DISEASE (GVHD)**

We believe that JAK inhibition has significant potential as a treatment for GVHD, and we have two pivotal programs that span several aspects of this devastating and often fatal disease.



In February 2019, the FDA extended the review period by three months for the sNDA of ruxolitinib for use in patients with acute GVHD who have had an inadequate response to corticosteroids. REACH1 data provided the basis for this application, and these data were highlighted in an oral presentation at the 60th Annual ASH Meeting in December.

Results from two global Phase 3 trials in collaboration with Novartis – REACH2 and REACH3, evaluating ruxolitinib in steroid-refractory acute GVHD and steroid-refractory chronic GVHD, respectively – are expected to be available this year.



## PHASE 1 PROOF-OF-CONCEPT TRIAL OF ITACITINIB IN PATIENTS WITH GVHD

ITACITINIB (200mg and 300mg dose groups, combined)					
RESPONSE N (%)*	FIRST-LINE (N = 12)	STEROID-REFRACTORY (N = 17)			
Complete response (CR)	8 (66.7)	3 (17.6)			
Very Good Partial Response (VGPR)	0	1 (5.9)			
Partial Response (PR)	2 (16.7)	7 (41.2)			
OVERALL RESPONSE**	10 (83.3)	11 (64.7)			

<sup>\*</sup>Last response data available on or before Day 28.

We believe itacitinib has significant potential as a first-line treatment for GVHD, as approximately 15,000 new GVHD patients are diagnosed each year in the U.S., Europe and Japan. In the initial proof-of-concept trial, itacitinib showed an overall response rate of over 80 percent in patients with acute GVHD who had not yet been treated with steroids. We look forward to sharing the results of GRAVITAS-301, a Phase 3 trial evaluating itacitinib in steroid-naïve acute GVHD, later this year. The GRAVITAS-309 trial was initiated in January 2019 and will evaluate itacitinib as a first-line treatment in patients with chronic GVHD.

We are hopeful that the Phase 3 trials of itacitinib and ruxolitinib will support our hypothesis that these compounds may provide significant therapeutic benefit for patients suffering from GVHD.



<sup>\*\*</sup> Patients with complete response, very good partial response, or partial response.

Responses were graded according to CIBMTR (Center for International Blood and Marrow Transplant Research) response criteria. The treatment population was limited to patients who received study treatment. Schroeder et al. ASH 2016



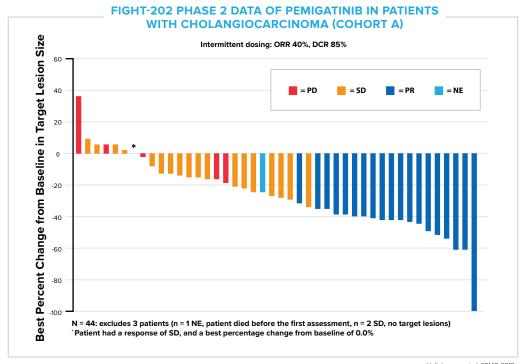
## **PEMIGATINIB**

Pemigatinib is a potent and selective FGFR1/2/3 inhibitor, which is currently in development for patients with cholangiocarcinoma, bladder cancer and 8p11 MPN. At ESMO 2018 in October, preliminary data were presented from FIGHT-201 (bladder cancer) and FIGHT-202 (cholangiocarcinoma). Data from FIGHT-203 (8p11 MPN) were presented at ASH 2018. Safety data from all three trials suggest that pemigatinib has a manageable safety profile. Pending additional data that would support an NDA filing, we are hopeful that second-line cholangiocarcinoma may be the first FDA-approved indication for pemigatinib, potentially followed by bladder cancer and 8p11 MPN. We are also preparing a development program focusing on a tumoragnostic, FGFR-altered, disease indication in the future, and we expect that program to be initiated this year.

#### CHOLANGIOCARCINOMA

We are studying pemigatinib as a first- and second-line therapy for patients with FGFR2 translocated cholangiocarcinoma through the FIGHT-302 and FIGHT-202 studies, respectively.

Recruitment into the FIGHT-202 trial in patients with cholangio-carcinoma is complete, and we are now waiting for the data from the trial to mature. Data presented from the Phase 2 FIGHT-202 trial at ESMO 2018 showed an overall response rate of 40 percent and a median PFS of greater than nine months. Importantly, all tumor response data were assessed by independent review per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.



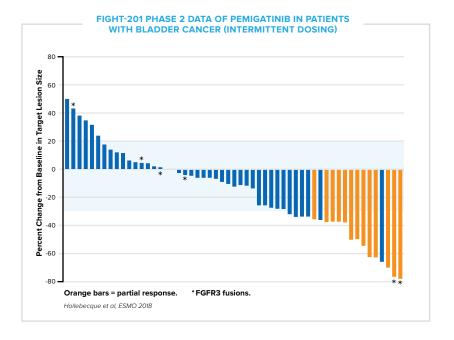
Hollebecque et al, ESMO 2018

#### CHOLANGIOCARCINOMA CONTINUED

If the data continue to evolve as we expect, we intend to submit an NDA seeking approval of pemigatinib in second-line FGFR2 translocated cholangiocarcinoma this year. We were happy to announce in February 2019 that the FDA granted pemigatinib Breakthrough Therapy designation for the treatment of previously treated, advanced/metastatic or unresectable FGFR2 translocated cholangiocarcinoma. Breakthrough Therapy designation is utilized to expedite the development and review of drugs for serious conditions that have shown encouraging early clinical results and may demonstrate substantial improvements over available medicines. We plan to expand this program with FIGHT-302, a Phase 3 trial in first-line cholangiocarcinoma.

#### **BLADDER CANCER**

Encouraging data from the ongoing trial in bladder cancer, FIGHT-201, were also presented at ESMO 2018. It is important to note that the data were from the cohort receiving intermittent dosing. The FIGHT-201 protocol has since been amended to allow continuous pemigatinib dosing, which we anticipate may further improve response rates. This cohort is expected to complete recruitment later this year. If these data are positive, they could form the basis for a regulatory submission seeking approval of this second indication in the U.S. We are also planning to initiate a pivotal program in first-line bladder cancer later this year.



#### **8P11 MPN**

At ASH 2018, data were presented from the FIGHT-203 study of pemigatinib in patients with 8p11 MPN, an ultra-orphan cancer. Of the 13 evaluable patients in the trial, 11 (85 percent) achieved clinical response, including clinical and cytogenetic responses.

FIGHT-203 PHASE 2 DATA OF PEMIGATINIB
IN PATIENTS WITH 8P11 MPN

BEST RESPONSES	ORR	CR (N)	PR (N)
CLINICAL RESPONSES <sup>a</sup>	85%	7	4
CYTOGENETIC RESPONSES <sup>b</sup>	<b>77</b> %	6	4

<sup>&</sup>lt;sup>a</sup> CR, bone marrow with <5% blasts and normal cellularity, normal CBC, complete resolution of EMD; PR, same as CR except 50% reduction of bone marrow blasts (and blast equivalents), but with <5% remaining fibrosis and dysplasia.</p>

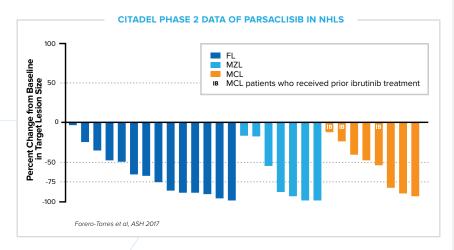
<sup>&</sup>lt;sup>b</sup> CCyR, 0% abnormal metaphases; PCyR, decrease of ≥50% of abnormal metaphases. Verstovsek et al, ASH 2018

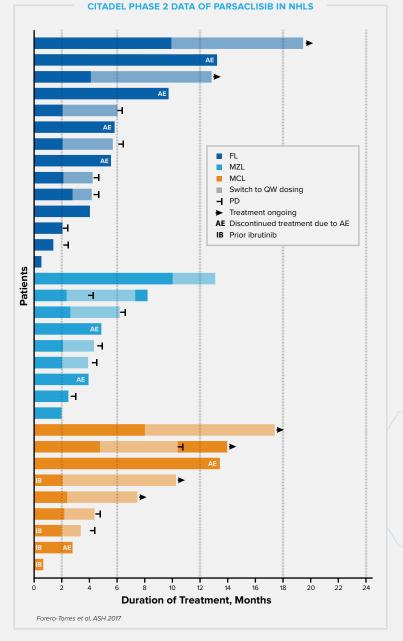


## **PARSACLISIB**

PI3K& inhibition is a potent therapeutic mechanism with the potential for broad application across multiple diseases. At our 2018 Investor & Analyst Event in June, we touched on multiple areas where our investigational novel oral inhibitor of PI3K& inhibitor, parsaclisib, could provide benefit to patients both as monotherapy and in combination with other agents.

The CITADEL program for oncology indications is currently evaluating parsaclisib in several ongoing Phase 2 trials as a monotherapy for non-Hodgkin lymphomas: follicular (FL), marginal zone (MZL) and mantle cell lymphomas (MCL). In Phase 1, we were encouraged to see responses in these three diseases, but we also saw some immune-related and likely on-target toxicities after several months on therapy. The dosing regimen has since been adjusted, and data presented at ASH 2017 suggested this adjustment may enable patients to remain on therapy and hence potentially continue to benefit from the potent activity of the molecule. We look forward to sharing these evolving data as they become available, and we expect that we will start to see additional data in 2020. Each of these trials is designed to support a registration in the U.S. if they are successful.





## **KEY PROGRAMS IN ONCOLOGY**

## INCMGA0012

INCMGA0012 is a PD-1 antagonist that we are developing in collaboration with MacroGenics.

Last year, we declared our intent to run three registration-directed development efforts for INCMGA0012 monotherapy. These initial studies are being conducted in patients with microsatellite instability-high (MSI-high) endometrial cancer, Merkel cell carcinoma and anal cancer. We expect to report initial data in 2020.

Harnessing our own portfolio, we are also planning studies using INCMGA0012 in combination with both small molecules and monoclonal antibodies. We expect that having an in-house PD-1 antagonist will speed our decision making and could obviate the need to either buy supply from a third party and/or to unnecessarily share any plans or data with third parties.





"It's all about the patients. For people that are in my position and not directly working on drug development, it could be easy to lose sight of why you're there. I love our Town Hall meetings as there are often presentations given by patients, and I'm reminded why I do what I do. It's inspiring to think that my colleagues could invent the next life-saving drug."





## INFLAMMATION AND AUTOIMMUNITY (IAI)

Capitalizing on our drug discovery and immunology expertise, we have established a specialty-focused effort in inflammation and autoimmunity.

## **RUXOLITINIB CREAM**

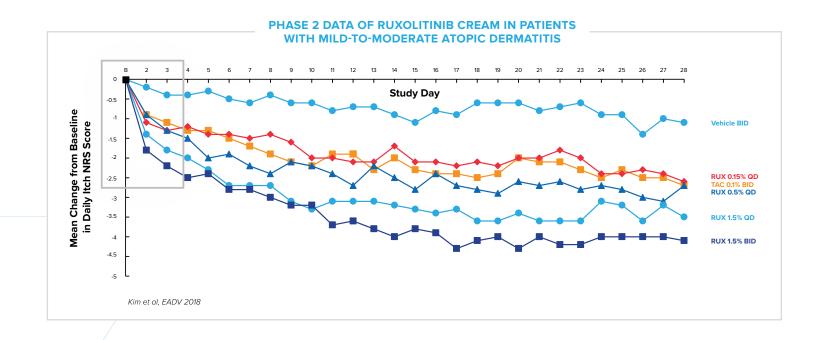
The most advanced IAI project is with our cream formulation of ruxolitinib, which has shown promise in AD and vitiligo.

Phase 2 data of ruxolitinib cream in patients with mild-to-moderate AD were presented in September at the European Academy of Dermatology and Venerology Annual Meeting (EADV) in Paris. The data showed rapid improvements in itch for patients on ruxolitinib cream versus both placebo and steroid cream, which were seen as early as two days after the first usage, as seen in the chart below. These responses, as well as the main efficacy

endpoints based on Eczema Area and Severity Index (EASI) and Investigator's Global Assessment (IGA), were statistically and clinically meaningfully superior to vehicle cream, and the treatment was not associated with any notable safety or tolerability findings.

As a result of these promising data, we have already initiated a Phase 3 program in patients with mild-to-moderate AD. We expect the results of this program to be available in 2020.





## **RUXOLITINIB CREAM** CONTINUED

Ruxolitinib cream also has potential as a treatment for patients with vitiligo, which is a skin disorder characterized by patchy depigmentation of skin, in particular the face, neck and scalp. It is estimated to affect 2-3 million patients in the U.S., but only about 150,000 patients are currently seeking treatment, which is likely due to the fact that there are no approved therapies.

A small, investigator-initiated proof-of-concept trial of ruxolitinib cream showed promising results, with a 23 percent improvement in the mean vitiligo area scoring index (VASI) score across the 11 patients participating. Importantly, four of these patients had a 76 percent improvement in the facial area severity score. As this disease can be cosmetically disfiguring with associated quality-of-life changes, including depression and anxiety, these results encouraged us to launch a randomized, double-blind, vehicle-controlled Phase 2 study of ruxolitinib cream in patients with vitiligo. The trial is ongoing, and we expect to announce initial data this year. If the study results are positive, we expect to move ahead into a Phase 3 program in this condition.



## **INCB54707**

INCB54707 is a differentiated JAK1 inhibitor due to its selectivity as well as its longer half-life compared to ruxolitinib or itacitinib. We have initially chosen to study INCB54707 in hidradenitis suppurativa, which is an inflammatory skin disease characterized by lesions in the axilla, in the groin and under the breast area as a result of inflammation and infection of the sweat glands. A Phase 2 trial is now underway.

## **PARSACLISIB**

We are beginning to study PI3K $\delta$  inhibition across a variety of B-cell mediated and antibody-driven diseases beyond oncology. We believe that there's potential to differentiate from anti-CD20 antibodies based upon the mechanisms of action and the ability for reversible suppression versus long-lasting depletion.

The first indication is autoimmune hemolytic anemia, which occurs when the immune system makes antibodies that attack red blood cells. Symptoms include weakness and fatigue with tachycardia and breathing difficulties, jaundice, dark urine and/or splenomegaly. We will also be studying PI3K $\delta$  inhibition in Sjögren's syndrome, a disease characterized by extreme dryness as a result of destruction of the lacrimal and salivary glands, which can result in debilitating symptoms such as difficulty swallowing.

PARTNERED PRODUCTS



## **OLUMIANT (BARICITINIB)**

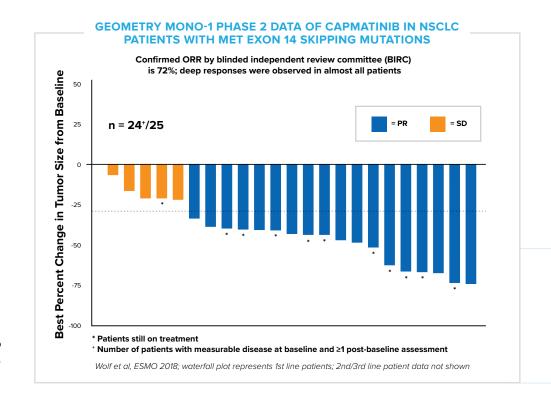
Baricitinib (JAK1/JAK2) was licensed to Eli Lilly in 2009 and is now approved in multiple territories globally as Olumiant for certain patients with moderate to severe RA. Lilly is actively developing baricitinib in other autoimmune diseases and is currently running late-stage trials in moderate-to-severe AD, systemic lupus erythematosus (SLE) and severe alopecia areata. Lilly announced that the first two Phase 3 trials of baricitinib in patients with AD achieved their primary endpoints. The additional three trials in the pivotal program are expected to read out later in 2019. Data from the trials in lupus and alopecia are expected in 2020 and 2021, respectively.

## **CAPMATINIB**

Capmatinib is an oral, reversible inhibitor of the MET receptor tyrosine kinase, and it has shown both high selectivity for MET and is extremely potent against MET exon 14 skipping mutations compared to all other MET inhibitors in development. Capmatinib was licensed globally to Novartis under our 2009 license agreement and has the potential to be the first MET-selective inhibitor to be approved, given the promising data presented at ESMO 2018.

These data were from the GEOMETRY mono-1 study, being run by Novartis, in patients with NSCLC with MET exon 14 skipping mutations, which occur in up to four percent of patients with NSCLC. The response rates seen in this 94-patient trial were clinically meaningful, with an overall response rate in second- and third-line patients of 39 percent and in first-line the response rate was 72 percent. All data were centrally reviewed, and capmatinib showed a manageable safety profile in this challenging patient population.

Novartis is expected to submit an NDA to the FDA for capmatinib in 2019, and we are proud that another Incyte-invented molecule appears to be on a path to potential registration.



2018 Annual Report

# **OPTIONALITY** IN DISCOVERY



## **OPTIONALITY IN DISCOVERY**

Incyte was founded on its expertise in biology and small molecule drug discovery, and this continues to be the heartbeat of the company. Indeed, the majority of the clinical candidates in our portfolio are the product of Incyte's internal discovery unit. Capitalizing on this success, we have continued to increase capacity and add new capabilities to sustain a robust and diverse early clinical portfolio.

## **EARLY STAGE PORTFOLIO**

Beyond our six key late-stage projects, we have multiple candidates under evaluation in human proof-of-concept studies. Additionally, earlier in 2019, we were excited to announce two new clinical candidates, one of which is already being tested in cancer patients.

INCB86550 is a first-in-class oral, small molecule PD-L1 inhibitor. Its preclinical efficacy profile appears comparable to anti-PD-L1 antagonist antibodies but it also has a novel mechanism of action that leads to internalization of cell surface PD-L1 on cancer and immune cells. This may support inhibition of PD-1 and PD-L1 axis signaling. We believe this is an important molecule as its profile may allow for rapid dose titration in patients and offers the potential to develop all-oral combinations with other targeted agents. We initiated clinical testing in December of 2018.

In January 2019, Merus announced the clearance of an IND application for MCLA-145, a first-in-class PD-L1 x CD137 bispecific antibody, which is being co-developed by Merus and Incyte. The new agent is expected to enter the clinic in the second quarter of this year. Incyte holds ex-U.S. commercialization rights to MCLA-145.

## **MULTIPLE DISCOVERY PLATFORMS**

We have now established three core drug discovery platforms: small molecules, monoclonal antibodies and bispecific antibodies. We believe this multi-faceted approach in discovery allows us to pursue a diverse spectrum of the most promising therapeutic targets.

To supplement our small molecule discovery capabilities, we initiated monoclonal antibody discovery efforts in 2015 through a discovery

alliance with Agenus. This partnership was productive and has since yielded four clinical candidates. Incyte's discovery team has also progressed its monoclonal antibodies platform internally to develop molecules independent of any collaborations.

We strongly believe bispecific antibodies have the potential to play an important role in the future of biotherapeutics and were excited to enter into a long-term research collaboration with Merus to discover and develop novel bispecific antibodies, including and beyond the collaboration mentioned in the section above. This further expands our monoclonal antibody discovery capabilities, which we believe will create additional opportunities for drug discovery over the coming years.



## **INCYTE RESEARCH INSTITUTE**

A core belief of Incyte is that close integration of both our research and development organizations at a single campus helps to fuel success. To underscore this philosophy, on January 1, 2018, we launched the Incyte Research Institute (IRI) located at the Wilmington, Delaware campus. The IRI encompasses our biology and chemistry discovery organizations, research laboratories and intellectual property teams.

Creation of the IRI recognizes the critical role of collaborative scientific research in the discovery of innovative medicines at Incyte. We are confident the IRI will continue to be internally and externally recognized as an exceptionally productive discovery organization.

2018 Annual Report

CORPORATE **RESPONSIBILITY** 



## **CORPORATE RESPONSIBILITY**

At Incyte, in addition to our commitment to innovation and the pursuit of research and development excellence, we are also committed to enhancing the communities in which we operate, improving the treatment and experience of patients, supporting our colleagues and operating our business in a way that protects the environment. To learn more about Our Commitment, <u>click here</u>.

## **PATIENTS**

At Incyte, we believe in the power of research to advance scientific innovation and improve patient health and outcomes. Every day we are driven to discover and deliver medicines that will positively impact the lives of people with cancer and other serious diseases. We support our patients through commitments in four key areas: Safety, Scientific Excellence, Access to Medicine and Education and Awareness.

#### **SAFETY**

Patient safety is at the forefront of all our activities. We are committed to adhering to the applicable laws and regulations in all territories in which we operate clinical trials, and to conducting those clinical trials in an ethical manner. We are also committed to the supervision of all ongoing trials through an institutional review board, an ethics committee and/or a research ethics board in an effort to protect the safety of trial participants before, during and after patients are treated.

#### SCIENTIFIC EXCELLENCE

We hold our clinical research to the highest standards of scientific and ethical rigor, and we strive to implement programs and initiatives to allow for broad access to our medicines for appropriate patients. We execute on this commitment through our rigorous discovery process, our adherence to clinical trial standards set by the FDA and other global regulatory bodies and

our focus on data transparency from applicable trials through presentations of both positive and negative data at appropriate medical meetings and in peer-reviewed journals. Publication of these data is scientifically responsible and may serve to benefit both patients as well as the entire scientific community as we collectively seek to improve the treatment of cancer and other diseases.

The effort to bring transformative treatments to patients with cancer is a significant undertaking, and we are committed to partnering with companies, universities and research institutions to share knowledge, resources and ideas that may best benefit patients. We may also provide investigational products and/ or financial support for research by third parties related to our products that address therapeutic areas of interest to us. We are committed to ensuring that these investigator-initiated research trials are submitted, reviewed and, if approved, conducted and funded in a standardized, consistent and transparent manner.

#### **ACCESS TO MEDICINE**

Incyte is committed to ensuring that eligible patients have access to applicable clinical trials by providing them with information and resources to support their treatment journey.

#### CORPORATE RESPONSIBILITY

We may also choose to provide individual patients with access to unapproved or investigational products through Incyte's compassionate use program.

Our IncyteCARES (Connecting to Access,
Reimbursement, Education and Support) program
supports eligible patients in the U.S. before
and during applicable treatment by providing
ongoing education, resources as well as a dedicated
nursing support program. For more information,
please click here.

Since February 2017, Incyte has partnered with The Max Foundation in its drug donation program to assist patients with cancer in Central Asia and Eastern Europe who are unable to access treatment with Iclusig.

IncyteCARES

#### **EDUCATION AND AWARENESS**

Incyte is committed to providing patients with resources to support their treatment journey. Voices of MPN is a website created by Incyte to help connect MPN patients to information, educational programs and community activities as well as to provide a forum where people can share stories and promote disease awareness.

Each year, in partnership with CURE Magazine, Incyte sponsors the MPN Heroes® Recognition Program, which honors and celebrates individuals and organizations for their contributions in caregiving, community leadership or scientific advances in the MPN community. To learn more about our efforts, please click here.

In 2018, Incyte launched CML Life, a patient support program for patients in Europe suffering from chronic myeloid leukemia (CML), regardless of their treatment or their stage of disease. CML Life seeks to help patients, caregivers and heath care professionals better understand and manage CML from diagnosis to treatment, with the goal of facilitating treatment engagement and adherence. This program has been co-created and co-developed with the patients that may eventually be using it, as well as the health care professionals who may also be supporting its use. For more information, please click here.







"I volunteer with Serviam Girls Academy to help them identify opportunities to introduce underserved young girls and teens to STEM (Science Technology Engineering Math) subjects. We identify opportunities for scientists and science-based companies to meet with the girls to learn more about possible careers, and recently, Incyte hosted the group here. Seeing how involved Incyte is in the community here in Delaware has inspired me to become more involved as well."





## **EMPLOYEES**

Incyte is committed to ensuring our colleagues are happy and healthy. We promote an inclusive company culture grounded in scientific excellence and foster a collaborative, innovative and respectful work environment in which everyone can contribute to their fullest potential. We appreciate, celebrate and thrive on one another's differences and strengths and are proud to be an Equal Opportunity Employer.

In 2018, Incyte was proud to be recognized as the number two employer in the biopharma industry by *Science* magazine. The *Science* and *Science Careers*' 2018 annual Top Employers Survey polled employees in biotechnology, pharmaceutical and related industries to determine the 20 best employers in these industries as well as their driving characteristics. Respondents were asked to evaluate companies based on 23 different characteristics, including financial strength, easy adaptation to change and a research-driven environment. Incyte was specifically recognized by its team members for its innovation, work culture and respect for employees.

At Incyte, we support our colleagues in their professional development. Opportunities for growth are offered through challenging job assignments, performance management, training and tuition reimbursement. These opportunities enhance career aspirations, job satisfaction as well as personal enrichment.

Over the years, we have added numerous benefits to support our colleagues in their professional as well as personal endeavors. A competitive benefits package is offered, as well as many complimentary tools for health, such as on-site flu shots and a webinar series on the importance of sleep. A patient support program is another one of many complimentary benefits provided by Incyte, which offers broad assistance with a variety of healthcare and insurance-related issues to help colleagues make more informed healthcare decisions.



Furthermore, our cafeterias provide nutrition-conscious meal options, helping to ensure our colleagues can make more informed dietary choices while at work. The addition of standing-desks has also helped to promote healthy living.

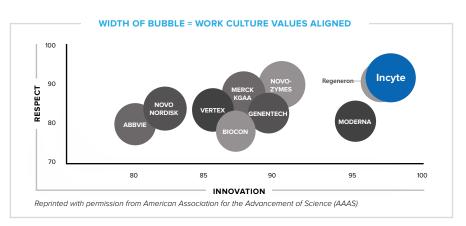


Incyte was specifically recognized by its team members for its innovation, work culture and respect for employees.

Learning seminars are often offered on-site, including nutrition and financial planning seminars. Additionally, Incyte offers office-based group fitness classes at work as well as healthy competitions, such as the 6-week Walking Challenge.

At the heart of Incyte's business is the value we place on improving the world's health, and a high level of environmental, health and safety performance is simply another expression of this value.

A strong safety culture is a fundamental part of how we work, and our philosophy is that everyone at Incyte has a responsibility to create and maintain a safe and healthy workplace with a goal to reduce risk and prevent injuries. Our management team recognizes this responsibility and is committed to providing the resources necessary to achieve this goal.



#### CORPORATE RESPONSIBILITY

## COMMUNITY

Incyte is committed to being an active participant in improving the communities in which we live and work. *Incyte Involved* is a program comprised of three initiatives focused on philanthropy as well as employee and community engagement. These include the Incyte Charitable Giving Foundation, the Community Service Program and the Matching Gifts Program.

In 2018 alone, Incyte donated over \$620,000 to more than 20 organizations through the Incyte Charitable Giving Foundation.

Through the Foundation, we also launched the Incyte Cancer Care Assistance Fund for Delaware, which provides emergency financial assistance for cancer patients, their caregivers and family members living in Delaware. This Fund was launched in collaboration with Cancer Support Community Delaware, which independently processes applications and determines the need. Since its launch in February 2018, 72 individuals have received emergency funding to cover bills such as rent, mortgage, car insurance and the cost of groceries. Most of these people have lost their jobs or are on disability due to their cancer and unfortunately had to face the choice of either paying these bills or treating their cancer. We are proud to be able to help so many patients and their families, not only with providing treatment options but with emotional and financial support.

Our Community Service Program provides our colleagues with paid time off to volunteer in their communities. In 2018, Incyte colleagues donated over 1,200 hours of time working with organizations, including the Food Bank of Delaware, MANNA and Salvation Army. This is a remarkable increase of nearly 60 percent since 2017 and almost triple the number of hours since 2016.



Learn more about *Incyte Involved*.

Beyond these formal programs, we also enjoy being involved in many other charitable events and drives. During the 2018 U.S. Business National Meeting, over 200 Incyte employees from across the country volunteered for either the Houston Food Bank, which provides meals and support for those in need, or B.I.G. Love Cancer Care, which offers support for children with cancer and their families.

## **COMMUNITY** CONTINUED

Other philanthropic events included our ninth year of participating in the Light the Night Walk, which benefits the Leukemia & Lymphoma Society, and our first annual Kind to Kids Back to School Drive in which we collected book bags, boxes of school supplies and cash donations.

We feel it is especially important to support those who are less fortunate during the holiday season. Every year we have an annual food drive to collect food and cash donations for the Food Bank of Delaware and an annual Salvation Army Angel Tree Program, in which Delaware-based employees can buy toys for one or more local children in need. Last year, Incyte collectively donated over 600 pounds of food for the Food Bank of Delaware and donated over 600 gifts to families in Delaware. In Europe, our Christmas Food Donation Program helps provide meals to Swiss families in need.

By participating in charitable activities, we deliver a positive impact on the greater communities in which we live and work.





## ABOUT CANCER SUPPORT COMMUNITY DELAWARE

Cancer Support Community Delaware is a statewide nonprofit organization whose mission is to ensure that all people impacted by cancer are empowered by knowledge, strengthened by action and sustained by community. Support groups and programs are professionally led and are provided at no cost to help participants and caregivers cope with the emotional and life changing aspects of cancer. Learn more at cancersupportdelaware.org.

## MAKING A DIFFERENCE IN DELAWARE

Making a difference in the lives of patients and giving back to our local communities is an integral part of the Incyte culture and who we are as a company.

In 2017, we proudly announced the establishment of the Incyte Cancer Care Assistance Fund for Delaware with our partners, the Cancer Support Community Delaware (CSCDE). The fund provides emergency financial assistance for cancer patients, their caregivers and family members living in Delaware.

Nicole Pickles, Executive Director of CSCDE, reflects on what Incyte and CSCDE have been able to accomplish through the Fund in its first two years of giving, and what it means for Delaware to have this type of support from Incyte.

"The Incyte Cancer Care Assistance Fund for Delaware is a critical resource for our local community.

The people we're helping through the Fund have emergent needs as they navigate their disease and its impact across all aspects of their lives. Many of these individuals have lost their jobs, are on disability or their income has been substantially reduced because of their cancer. In addition to trying to process what is often an overwhelming diagnosis, they are having difficulty coping on a daily basis.

In 2018, we exceeded our expectations for the Fund – we paid bills for 72 people, including rent, mortgage, utilities, medical bills, car insurance and food. The response we've received has been heartwarming, with recipients noting they are 'truly grateful for the help,' and that the support allowed them to have 'one less thing to worry about at this time.'

Through the Fund, we are reaching people living with cancer in Delaware that we would never have been able to reach. Applications for funding have come from all three of our counties, including Kent and Western Sussex County, which are home to medically and socioeconomically underserved communities. The Fund is uniquely positioned to meet the needs of local individuals living with cancer because Incyte partnered closely with CSCDE to learn about Delaware and what our communities truly needed.

We value Incyte's consistent and unwavering dedication to those touched by cancer. Through its support for the Fund and in many other ways, Incyte is an anchor to CSCDE - helping us to provide greater knowledge and understanding of the important resources available to cancer patients from prevention to education, social and emotional support, patient care and advocacy."

## **ENVIRONMENT**

At Incyte, we seek to operate in a way that reduces our environmental impact. This includes programs for data collection and analysis in order to measure and reduce hazardous air emissions, greenhouse gases and water use. In 2019, Incyte launched Greencyte, which is a cross-functional and global team dedicated to seeking ways to minimize our impact on the environment.

#### **UNITED STATES**

Incyte's Environmental Health and Safety (EHS) team works closely with our hazardous waste vendor and researchers to identify waste minimization and pollution prevention. Their initiatives allow the

Hazardous Waste Team to divert materials for recycling, recovery or reuse. We encourage researchers to work with the EHS team to identify additional efforts to reduce our waste and improve our environmental stewardship goals.

We manage all hazardous waste in compliance with EPA regulations, and all hazardous waste is recycled, reused, fuel-blended or disposed of at an EPA approved disposal facility.

As Incyte expands, so must our facilities. As we construct new buildings, our team makes sure to

keep environmental responsibility as a priority. When building the expanded headquarters in Wilmington, for example, the team removed approximately 160 trees and then planted over 400 new trees, more than doubling the original number of trees on-site.

Beyond these broader business initiatives, employees take an active role in our commitment to environmental sustainability. For example, the commercial operations team uses only Forest Stewardship Council® (FSC)-certified printers for Incyte's marketing materials.

In addition, we now only use paper made from recycled material for all printed pieces. Throughout our offices, there are sorting bins to separate waste from recycling both in public areas and at each individual's work station. In the cafeteria at our newly-expanded U.S. headquarters, reusable plates, silverware and trays are used to limit the amount of landfill waste. Incyte has also moved to the use of paper straws and has set up frequent and accessible recycling stations throughout the Wilmington campus. Incyte also incentivizes the purchase of electric cars by employees by providing electric car charging units in our parking lots for complimentary use during the workday.



## **ENVIRONMENT** CONTINUED

### **EUROPE**

In Europe, our first production site is under construction in Yverdon-les-Bains, Switzerland. The building and its construction is following strict Swiss regulations regarding environment protection and energy consumption. At the construction site, waste is carefully managed. Additionally, the concrete is produced on-site, which reduces the number of trucks required from an average of 15 daily down to only four, thus reducing pollution as well as positively impacting our neighbors. Water for concrete production is reused, and nothing is released into nature. Additionally, a study was conducted to optimize the future energy consumption of the building itself. The energy produced from the heating and cooling equipment will be partially recovered using heat exchangers, and solar panels will be used on the roof.

Our new and consolidated European headquarters to be opened in Morges, Switzerland, is currently being constructed through the renovation of an industrial site. The renovation, as at the site in Yverdon-les-Bains, will be completed according to the latest Swiss construction norms, which favor lower energy consumption and minimize environmental impact. Solar panels have already been added to the roof, the thermal insulation will be beyond what is required by Swiss regulation and the roof will retain rain water through "vegetalized" areas which will also reduce the need for cooling. The selection of Morges as the location of our European headquarters was made in part due to its close proximity to the railway station (and connections to Lausanne and Geneva), with the intent of reducing the need for employees to commute by car.



### **CORPORATE RESPONSIBILITY**

## **COMPLIANCE & TRANSPARENCY**

We aim to make a difference – for patients, medical professionals, organizations, the broader healthcare community and all our global stakeholders. To achieve these goals, we are committed to conducting business ethically. We hold ourselves accountable to the highest standards to ensure that all of our interactions are conducted appropriately. We regularly review and amend our practices according to current laws and regulations, as well as both our own standards and the standards required of us by the communities in which we live and work.

All new team members are required to read and acknowledge their commitment to comply with Incyte's Code of Business Conduct and Ethics, which serves as our roadmap for acting ethically whenever and wherever we conduct business. It provides, among other things, that:

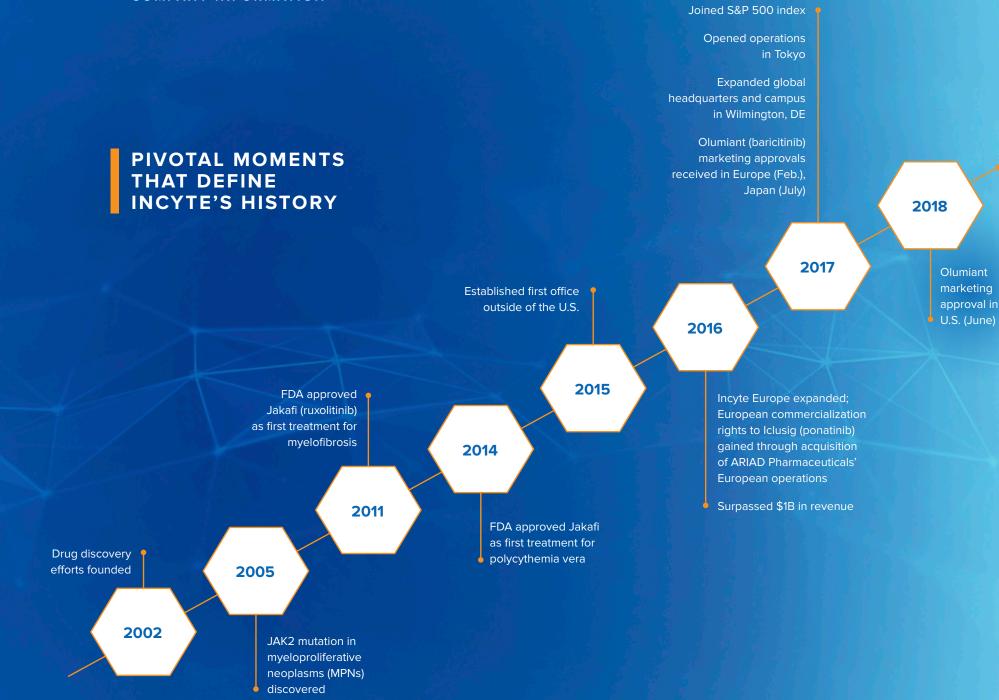
- We foster a respectful and safe workplace
- · We conduct business ethically
- We operate honestly and transparently
- We act as a good corporate citizen

For more details, please visit our Compliance & Transparency page.

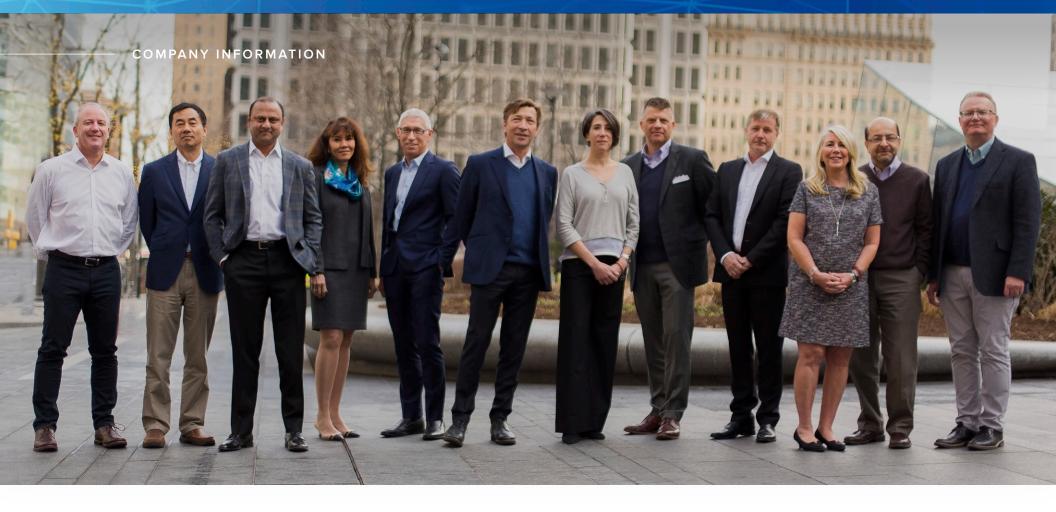


# COMPANY INFORMATION





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## **LEADERSHIP TEAM**

LEFT TO RIGHT

STEVEN H. STEIN, MD

Chief Medical Officer

**WENQING YAO, PHD** 

Head of Discovery Chemistry

VIJAY IYENGAR, MD

Head of Global Strategy & Corporate Development

MARIA E. PASQUALE

General Counsel

JONATHAN E. DICKINSON

General Manager, Europe

HERVÉ HOPPENOT

Chairman, Chief Executive Officer

**CHRISTIANA STAMOULIS** 

Chief Financial Officer

LOTHAR H. FINKE, MD, PHD

General Manager & Head of Development, Japan

MICHAEL MORRISSEY

Head of Global Technical Operations

PAULA J. SWAIN

Head of Human Resources

DASHYANT DHANAK, PHD

Chief Scientific Officer

BARRY P. FLANNELLY, PHARMD, MBA

General Manager, U.S.

## **CORPORATE**

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## **TDD** for Hearing Impaired

800.231.5469

### **Foreign Stockholders**

201.680.6578

### **TDD Foreign Stockholders**

201.680.6610

#### **Outside Counsel**

Pillsbury Winthrop Shaw Pittman LLP

### **Independent Registered Public Accounting Firm**

Ernst & Young LLP

#### **Market Information**

Incyte Common Stock trades on The Nasdaq Global Select Market under the symbol INCY.

#### **Investor Relations**

You can obtain recent press releases and other publicly available information on Incyte by visiting our website at www.incyte.com.

#### Contact

Michael Booth, DPhil Vice President, Investor Relations mbooth@incyte.com

Lauren Kwiecinski, MBA Senior Director, Investor Relations Ikwiecinski@incyte.com

#### **Annual Meeting**

The Annual Meeting of Stockholders will be held April 26, 2019, at 1:00 p.m., Eastern Daylight Time, at Incyte Corporation, 1801 Augustine Cut-Off, Wilmington, DE 19803.

## FORWARD-LOOKING STATEMENTS

Except for the historical information set forth herein, the matters set forth in this annual report contain predictions, estimates and other forwardlooking statements, including without limitation statements regarding: our confidence in our potential to drive additional top-line growth in the near-and medium-term; our belief that our multiple late-stage projects have significant potential on a standalone basis and, collectively, have the potential to drive significant revenue growth over the next several years; our expectations to file an NDA for pemigatinib in cholangiocarcinoma in 2019 and for NDAs for pemigatinib in cholangiocarcinoma, itacitinib in GVHD and capmatinib to be submitted in the next 6 to 18 months; our expectations for the availability of data from the clinical trials of parsaclisib, itacitinib, ruxolitinib in GVHD, pemigatinib, INCMGA0012, ruxolitinib in combination therapies and ruxolitinib cream; our expectations regarding planned pivotal trial initiations for pemigatinib in first line cholangiocarcinoma, first line bladder cancer and solid tumors and for ruxolitinib cream in vitiligo; our expectation to initiate a development program with pemigatinib focusing on a tumor-agnostic, FGFR-altered, disease indication in 2019; our expectation that having an in-house PD-1 antagonist will speed our decision-making and could obviate the need to either buy supply from a third party and/ or to unnecessarily share any plans or data with third parties; plans and expectations regarding development activities of our collaboration partners, including the expectation that an NDA will be submitted for capmatinib in 2019 and expectations for data from clinical trials of baricitinib; and whether our collaboration with Merus will create additional opportunities for drug discovery over the coming years; and the potential therapeutic and commercial value of our drug candidates.

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: delays in obtaining results from clinical trials or in drug development generally; the ability to enroll sufficient numbers of subjects for clinical trials; further research and development and the results of clinical trials; the efficacy or safety of our products and product candidates and the products and product candidates of our collaboration partners; the effects of market competition; clinical trials, including pivotal trials, possibly being unsuccessful or insufficient to meet applicable regulatory standards for clinical advancement or approval or warrant continued development; other market, economic or strategic factors and technological advances; our dependence on our relationships with our collaboration partners; and other risks detailed from time to time in our reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2018. We disclaim any intent or obligation to update these forward-looking statements.

## **ENDNOTES**

- Jakafi (ruxolitinib) is approved in intermediate or high-risk myelofibrosis (MF), including primary myelofibrosis, postpolycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, and in patients with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea.
- 2. Iclusig is marketed by ARIAD Pharmaceuticals, Inc in the U.S. and by Incyte in the European Union and select countries. In the European Union, Iclusig is indicated for adult patients with CP-, AP-, or BP-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, and adult patients with 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.
- Ex-U.S. rights to ruxolitinib license to Novartis; commercialized by Novartis as Jakavi.

- 4. Worldwide rights to baricitinib licensed to Eli Lilly; Olumiant (baricitinib) is approved for the treatment of mild to moderate rheumatoid arthritis in patients with inadequate response to standard-of-care therapies.
- 5. Worldwide rights to capmatinib licensed to Novartis.
- 6. Development of ruxolitinib in GVHD in collaboration with Novartis.
- 7. FIGHT-201 and FIGHT-202 have the potential to enable registration.
- 8. Verstovsek et al (2018) Hematological Oncology 36:701-708.
- 9. Grimwade L, et al. Br J Haematol. 2009;147:495-506.
- 10. Oku S, et al. Br J Haematol. 2010;150:334–44.

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