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PRESENTATION

Operator

Greetings, and welcome to the Incyte 2020 First Quarter Financial Results Conference call. (Operator Instructions) Please note this conference is being recorded.

I will now turn the conference over to your host, Mike Booth, Head of Investor Relations. You may begin.

Michael Booth *- Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

Thank you, Kevin. Good morning, and welcome to Incyte's First Quarter 2020 Earnings Conference Call and Webcast. The slides used today are available for download on the Investors section of incyte.com.

I'm joined on the call today by Hervé, Barry, Steven and Christiana, who will deliver our prepared remarks, and by Dash, who will join us for the Q&A session. (Operator Instructions)

Before we begin, I'd like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for 2020 guidance, the commercialization of our products and our development plans and expectations for the compounds in our pipeline as well as the development plans of our collaboration partners. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-K for the year ended December 31, 2019, and from time to time in our other SEC documents.

In addition, I would like to caution everyone that the COVID-19 pandemic is an evolving situation, and as it's still relatively early to be able to assess the full impacts of governmental, business and social actions and policies and overall economic conditions on our business.

Accordingly, it is important to keep in mind that our statements on this webcast speak as of today. We'll now begin the call with Hervé.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Thank you, Mike, and good morning, everyone. I hope that all of you and your families are safe and healthy. During this unprecedented and uncertain time, it's evident that the COVID-19 pandemic has had a profound impact on almost every aspect of people's lives and has affected businesses all around the world.

Before we begin, I want to take a moment to thank the millions of people who are at the front line, from doctors, nurses, to all other essential workers who are continuing to provide their much needed services. With this pandemic at the forefront of everyone's mind, I want to start our earnings call by providing an update as it relates to the COVID-19 impact on four areas of our business.

Namely our -- on commercial, supply, regulatory and clinical operations. When we enacted our global business continuity plans over 2 months ago, our key priorities were to ensure that patients continue to receive their life-saving medicine, that we continue to provide our customers with the support they need—and importantly, to do this in a manner that minimizes the health risks to our employees and our customers. I'm proud of the team here at Incyte for continuing to deliver throughout this period, and I'm extremely grateful to those working on-site to maintain our critical operations.

Today, there has been no impact on our commercial business, and we saw continued strong performance in the first quarter. We have ample drug supply and our manufacturing processes are proceeding without interruption.

On the regulatory front, there has been no impact to date on key timelines. We recently announced one of our three anticipated approvals in 2020, and we continue to expect FDA decisions on both capmatinib and tafasitamab in the coming months. We do not expect disruption to other key regulatory timelines, including the NDA submission of ruxolitinib cream for atopic dermatitis at the end of the year.

With regards to clinical development, as of today, while our late-stage programs remain broadly on track, we anticipate that short-term effects may continue to emerge across different aspects of our global clinical trial programs, including new patient recruitment. The degree of impact may vary by disease state and by severity of disease as well as by geography, as some regions are more adversely impacted.

In terms of our effort to help address this pandemic, we recently initiated the global Phase III RUXCOVID trial in partnership with Novartis to assess ruxolitinib in patients with COVID-19 associated cytokine storm.

In the U.S., we are also starting another trial, evaluating ruxolitinib as a potential treatment for COVID-19 patients who are on mechanical ventilation. We have also opened an emergency expanded access program, which will allow eligible patients with severe COVID-19 to receive ruxolitinib.

Studies are also ongoing with baricitinib, where Lilly has recently entered into an agreement with the National Institute of Allergy and Infectious Diseases, which is part of the NIH, to study baricitinib as an arm in its COVID-19 clinical trial. Multiple investigator-initiated trials for both ruxolitinib and baricitinib are ongoing and planned as part of the global evaluation of whether JAK-inhibition plays a role in improving outcomes in COVID-19.

Turning to our first quarter performance. The results reflect the benefit of our long-term strategy and our execution on the plans we have previously laid out. In the first quarter of the year, we continued our strong commercial execution with Jakafi achieving 22% growth over the first quarter of last year to reach $459 million, and total product and royalty revenues growing by 24% year-over-year to $569 million for the quarter.

Our financial position is also strong with $1.3 billion in cash at the end of Q1 2020. In the recent months, we also made significant progress on the regulatory and clinical development fronts.

We recently received the FDA approval of Pemazyre, which brings another Incyte discovered molecule to market and provides further testament to the strong R&D capabilities we have here at Incyte. By the end of 2020, with our respective collaboration partners, Novartis and MorphoSys, we could see two additional new product approvals with capmatinib as a treatment for certain patients with metastatic non-small- cell lung cancer and tafasitamab for relapsed,refractory DLBCL, both of which are under Priority Review with the FDA.

In addition, we presented positive data from our TRuE-AD Phase III program at the Revolutionizing Atopic Dermatitis conference, and we remain on track to submit an NDA for ruxolitinib cream at the end of the year. Despite the uncertainties brought down by COVID-19, I remain confident about our future prospects as we continue to execute on our goals.

Slide 6 shows our ongoing revenue momentum over the last several years with four sources of revenue driving top line growth. We will be adding a fifth revenue stream following the recent approval of Pemazyre.

Looking to the remainder of 2020, our key priorities are to maintain our revenue momentum and to drive continued growth of Jakafi in the U.S. We are also focused on executing a successful launch of Pemazyre, which Barry will cover shortly and preparing for the potential FDA approval of tafasitamab. Our LIMBER development program remains a key priority, and we are working towards the planned initiation of our BET and ALK2 programs and the expected opening of the pivotal rux plus parsaclisib trial. 2020 is shaping to be a transformational year for Incyte, and I look forward to updating you throughout the year.

I'll now pass the call over to Barry, who will provide more detail on both first quarter Jakafi performance as well as our commercial activities for Pemazyre.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Thank you, Hervé, and good morning, everyone. Slide 8 shows strong growth of Jakafi quarter-over-quarter, mostly driven by increases in patient volume.

As expected, gross to net was much higher in Q1 due to our portion of the donut hole we are responsible for under Medicare Part D and the increase in true out-of-pocket cost or TrOOP that began in 2020. The chart on the right shows the total number of patients on therapy across all three indications.

The total number of patients and new patients treated with Jakafi for MF, PV and GVHD continues to grow. In GVHD, Jakafi is rapidly becoming the standard of care in the steroid-refractory acute setting. We are very pleased to have REACH2 published in the New England Journal of Medicine, underscoring the importance of Jakafi as a treatment option for patients with steroid-refractory acute GVHD.

In the 300-patient randomized REACH2 trial, ruxolitinib demonstrated a 62% overall response rate versus 39% seen with Best Available Therapy. REACH2 was the first randomized trial to show a benefit in this hard-to-treat patient population and showed convincingly that ruxolitinib was more effective than investigators' choice of therapy from a list of 9 commonly used options in patients in whom steroid therapy had failed.

We also applaud the FDA for granting full approval to ruxolitinib last year based on the single-arm REACH1 trial. Results from REACH3, our study evaluating ruxolitinib in the steroid-refractory chronic GVHD, are expected in the second half of this year. Our long-term outlook for Jakafi remains positive. Patient demand remains strong, and as a result, we are reiterating our guidance for the full year.

It is during this time, however, that we must stay focused and work even harder to engage our customers to provide them with continued support and to drive disease awareness. We have much success in implementing our digital and virtual strategies, and our top priority is to ensure that patients are able to receive their medicine. Our commercial focus in the U.S. remains on the success of Jakafi, and we take these learnings and apply similar methods to our launch of Pemazyre. Pemazyre is the first treatment innovation for patients with cholangiocarcinoma in 25 years, and represents an important addition to our portfolio of oral cancer medicines. We have launched Pemazyre and are focusing on a targeted group of approximately 1,000 physicians, two-thirds of which are already prescribing Jakafi.

This allows our commercial team to leverage existing relationships, helping to facilitate part of the promotional effort behind Pemazyre. We will also drive Health Care Professional interaction through our virtual programs and digital promotional assets building on some of the existing strategies we are already successfully utilizing with Jakafi. Our sales, market access and medical affairs teams are actively scheduling virtual appointments with our customers and are using the technology in place to share resources and materials in virtual meetings.

All of these efforts complement our ongoing unbranded, educational campaign focused on cholangiocarcinoma. And of course, as more patients are treated with targeted therapies like Pemazyre, it is increasingly important to continue to educate and promote appropriate FGFR testing in order to enable the proper identifications of those patients who stand to benefit most from Pemazyre. While we appreciate that the commercial potential for cholangiocarcinoma may be relatively modest, every patient we can help matters. So we are also developing pemigatinib in other tumor types that are driven by FGFR alterations.

With that, I'll turn the call over to Steven.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Thanks, Barry, and good morning, everyone. Starting with ruxolitinib cream, we were very pleased to share with you the positive results from our Phase III TRuE-AD program at the Revolutionizing Atopic Dermatitis conference a few weeks ago.

As you can see on the graphs on the left, ruxolitinib cream achieved clinical and statistical significance in the primary endpoint of Investigator Global Assessment Treatment Success, or IGA-TS at week 8.

Similarly, clinical and statistical significance was demonstrated in a 75% reduction in the Eczema Area and Severity Index score or EASI-75, and in the analysis of the 4-point reduction in the Itch Numerical Rating Scale, or NRS4, which is what the FDA has defined to be a meaningful endpoint in terms of itch reduction. With the highest concentration of 1.5%, we see substantial and more importantly, a very rapid reduction of itch with rux cream within 12 hours of initiation of therapy. The strength of these data show that ruxolitinib cream has been able to demonstrate a dual mode of action -- anti-inflammatory and anti-pruritic activities, which together, could make for a very effective therapy. As it relates to safety, there were no notable safety findings, either locally or systemically that were associated with treatment. We are on track with the development timelines for ruxolitinib cream. The long-term safety data are being collected and we continue to expect to submit the NDA for ruxolitinib cream at the end of this calendar year. The vitiligo trials remain ongoing, and we continue to expect data in 2021.

Turning now to Pemazyre.

Pemazyre was approved based on data from the FIGHT-202 study, where treatment with pemigatinib resulted in an objective response rate of 36%, and a median duration of response of over 9 months in patients with FGFR2 fusions or rearrangements. The most common adverse event was hyperphosphatemia, most of which was low-grade and manageable. The full data set from FIGHT-202 was recently published in the Lancet. We are very proud to offer a therapy for patients living with cholangiocarcinoma, where prognosis is poor and where there's been limited treatment options to date. We continue to study pemigatinib in clinical trials for bladder cancer, in 8p11 myeloproliferative neoplasm as well as the tumor-agnostic indications.

Now turning to efforts in COVID-19. Cytokine is a severe immune overreaction that can be triggered by a viral infection and leads to serious complications, including acute respiratory distress syndrome, which is a form of respiratory failure that is one of the leading causes of mortality in COVID-19 patients.

Patients with severe COVID-19 experience massive immune cell infiltration with associated pro-inflammatory cytokines, ultimately leading to alveolar damage. Many of the elevated cytokines that perpetuate the cytokine storm, exemplified by interferon gamma, IL-6, GM-CSF and G-CSF signal either through JAK1 or JAK2. We believe that treating cytokine storm with ruxolitinib as an inhibitor of both JAK1 and JAK2, may mitigate COVID-19 associated cytokine storm and thus reduce the overall disease burden.

We recently initiated our RUXCOVID program to evaluate ruxolitinib as a potential therapy for patients with COVID-19 associated cytokine storm. Our team in collaboration with our partners at Novartis initiated a global Phase III program. We anticipate recruiting approximately 400 patients with COVID-19 associated cytokine storm in RUXCOVID. And we'll be evaluating ruxolitinib, 5 milligrams BID plus standard of care versus standard of care alone. The composite primary endpoint is the proportion of patients who die, develop respiratory failure, require mechanical ventilation or require ICU care by day 29.

We are also opening a second Phase III trial in the United States, the 369 trial, that will evaluate ruxolitinib in patients with acute respiratory distressed syndrome secondary to COVID-19. ARDS is a type of respiratory failure, characterized by rapid onset of widespread inflammation in the lungs. And this trial will evaluate 2 doses of ruxolitinib, 5 milligrams BID and 15 milligrams BID and is expected to recruit around 500 patients. The key difference between RUXCOVID and the 369 trial is that patients in the former are not on ventilation, whereas those in the 369 trial are on mechanical ventilation.

My last slide is our news flow summary. As you can see, we have begun the year well and have already announced several important milestones, including positive Phase III data from ruxolitinib cream and the recent FDA approval of Pemazyre.

With that, I would like to turn the call over to Christiana for the financial update.

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

Thanks, Steven, and good morning, everyone. The financial update this morning will include GAAP and non-GAAP numbers. For a full reconciliation of GAAP to non GAAP, please refer to Slide 25 and 26 in the backup section of the deck and to the press release we issued this morning.

Before turning to our results for the quarter, I'd like to review the accounting treatment for our collaboration with MorphoSys. As a reminder, our collaboration with MorphoSys has 2 components: The co-development and co-commercialization of tafasitamab by Incyte and MorphoSys in the U.S. and the exclusive development and commercialization of tafasitamab by Incyte outside the U.S

In terms of how we'll be accounting for the collaboration, if tafasitamab is approved, MorphoSys will record all sales in the U.S. and Incyte will record all sales outside the U.S. Our COGS will include only COGS outside of the U.S. as well as royalties payable to MorphoSys on net sales outside the U.S.

Our R&D expense will include a 55% share of global and U.S.-specific development costs as well as 100% of any development costs, specific to territories outside the U.S. In addition, it will include any upfront and milestones that are payable prior to approval.

Our SG&A expense will include only our commercialization cost for tafasitamab outside the U.S. Finally, we will record our 50% of the U.S. net commercialization profit or loss as a single line item in our financial results, as a revenue item when it constitutes a net profit or as an operating expense item when it constitutes a net loss. COGS and all costs associated with the commercialization efforts related to tafasitamab in the U.S. will be included in this profit or loss sharing line, not in the COGS and SG&A expense line.

Now moving to our results for the first quarter. Revenue growth continued to be strong across all products, with total product and royalty revenues of $569 million, representing an increase of 24% over the first quarter of 2019. This is comprised of $459 million in Jakafi and $27 million in Iclusig net product revenues, $56 million in Jakavi royalties from Novartis and $25 million in Olumiant royalties from Lilly.

Our total cost and expenses for the quarter on a non-GAAP basis of $1.2 billion include the $805 million related to the upfront consideration to MorphoSys, which consisted of a $750 million upfront payment and a $55 million premium on our purchase of MorphoSys stock.

Excluding R&D upfront and milestone expenses, total COGS, ongoing R&D and SG&A expenses for the quarter were $371 million on a non-GAAP basis. Ongoing R&D expense for the quarter was $251 million on a non-GAAP basis, representing a 3% increase from the prior year quarter. SG&A expense for the quarter was $98 million on a non-GAAP basis, representing a 12% decrease over the prior year quarter. This was primarily due to the timing of certain expenses.

Collaboration loss for the quarter was $2.1 million, which represents a 50% share of the U.S. net commercialization loss for tafasitamab. Our financial position continues to be strong as we ended the quarter with $1.3 billion in cash and marketable securities.

The decrease from $2.1 billion at 2019 year-end reflects the upfront payment and stock purchase related to the MorphoSys collaboration, partially offset by the cash flow generated during the quarter.

Moving on to our guidance for 2020, we are reiterating our revenue, COGS, R&D and SG&A expense guidance for the year. While Jakafi and Iclusig performance in the first quarter was strong, the COVID-19 situation presents uncertainty. Therefore, we believe it is prudent to retain the full range of the previously communicated revenue guidance of $1.88 to $1.95 billion for Jakafi and $100 million to $105 million for Iclusig. For R&D, we are reiterating our previous guidance of $1.21 to $1.28 billion.

As a result of reallocation of funds between programs in our portfolio, we now expect this to cover also our 55% share of tafasitamab co-development costs. For clarity, this guidance range excludes the $805 million upfront consideration recorded in Q1 related to our collaboration with MorphoSys. Finally, at this early stage, we will not be providing guidance of Pemazyre sales or on our collaboration, net profit or loss resulting from the commercialization activities for tafasitamab in the U.S.

Operator, that concludes our prepared remarks. Please give your instructions and open the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is coming from Marc Frahm from Cowen & Company.

Marc Alan Frahm - *Cowen and Company, LLC, Research Division - Director*

Maybe a question for Steven. It seems like we're going to be getting a decent amount of data out of the LIMBER program over the next 6, 9 months maybe if you can set the stage there? When we see PI3-kinase data in the first half, should we think of that as setting kind of the bar for all other combos to warrant advancements? Or do you think that combinations are likely to be effective in kind of different patient populations, and therefore, yes, they kind of need to be evaluated all on their own?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Marc, it's Steven. Thanks for the question. So obviously, as Hervé alluded upfront, I mean, this remains of critical importance to us and of major focus to us and thankfully, despite the pandemic, remains on track as well. In terms of this year's execution, there are three aspects beyond everything else going on in LIMBER. One is to get the monotherapy safety components of ALK2 and the BET program done and moved to the combinations of RUX plus ALK2 and RUX plus BET. And then as you alluded to, is start the pivotal Phase III of RUX plus PI3-kinase delta. They're all slightly different. We don't have a biomarker selection per se, but they're different intents behind the program. So if you look at ALK2, the combination there, it's important to both focus on enhancing efficacy, which we expect, but also also safety in terms of anemia there and hopefully ameliorate the anemia through the hepcidin inhibition, which then would translate to being able to maintain ruxolitinib dosing and hopefully also enhance efficacy.

So it's a dual play in that aspect. In terms of BET/BRD inhibition, obviously, we've watched the consolidation data evolve, both in the first-line and later settings. And if some maturity of that data needed, and we have to make sure there are apple-apple comparisons as much as possible in terms of patients treated. But the idea is to do the same thing there in terms of enhance the efficacy of ruxolitinib in those settings, particularly in second-line and potentially in first-line as well. And obviously, we'll just see where the data leads us in terms of getting that combination done as efficiently as possible.

For delta, we very carefully built that data set. We've done different experiments with scheduling and dosing. We've now come down to the constant dosing being the way to go in terms of delta. In terms of the magnitude of the dose, we think we've weaved the therapeutic ratio correctly in terms of getting the efficacy we need from delta inhibition, but not the enhanced toxicity from it, and that's why we're initiating the Phase III studies. The bars may well end up being somewhat different in first-line versus later lines. I think as we speak today, the first-line bar in terms of spleen volume response, which we set with ruxolitinib years ago remains a 35% measured reduction plus associated symptom reduction.

In later line settings, we'll see as we work with regulators, whether a lower bar may be acceptable, for example, something like a 20% spleen volume reduction with associated clinical benefit in other endpoints like symptoms, and that remains to be worked out with regulators.

So the programs are full steam ahead as much as possible given COVID-19, and we're confident that they are in a good place and then have slightly different intents to all three programs.

Marc Alan Frahm - *Cowen and Company, LLC, Research Division - Director*

Okay. And if I can do a follow-up based on that. You mentioned one of the big things is the BET inhibitor getting it in eventually into a combination. In the press release, it says, you're preparing a Phase II, does that mean you started combination dosing already? Or is that Phase II, the beginning of combination dosing?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So Marc, just to remind you, we had numerous BET inhibitors in the clinic over the last few years. We put ourselves on a hold from on-target thrombocytopenia a little over a year ago and then sort of resurrected that second BET inhibitor to go into the clinic now. So what I'm saying is we know that compound pretty well. Obviously, now we're dosing at a much smaller absolute dose in terms of about a 20% to 30% dose range versus what we were in the clinic before and expected on-target toxicity should obviously be much less. We just need to prove that to ourselves hopefully relatively efficiently with monotherapy and then start the combination as soon as possible. So that will be the Phase II component, if you will, or be when we move into the combination part. But I think the semantics aren't that important, what you call it here because it's about just getting sufficient safety and then go into combination as efficiently as possible.

Operator

Our next question is coming from Cory Kasimov from JPMorgan.

Cory William Kasimov - *JP Morgan Chase & Co, Research Division - Senior Biotechnology Analyst*

I wanted to ask you about your work that you're doing in COVID-19. And I guess, first, do you have much insight into the timelines for rux in the COVID-19 studies, especially CRS? And when you're thinking about standard of care, do you think you're going to have to build remdesivir into your protocols? And then secondly, I recognize this isn't the primary purpose of this work, but can you discuss any general thoughts you have about the potential of market opportunity, if rux were to ultimately be approved here?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So, Cory, it's Steven. I'll start off and then hand it over to Hervé for your second question. So again, there are two studies. There's RUXCOVID, the global study with Novartis in patients who are sick in hospital with evidence of elevated cytokines, but not ventilated yet, and then hopefully not. And then the second protocol, the 369 protocol is in ventilated patients, and we're testing two dose levels there. We knew that the standard of care would likely evolve and would evolve relatively rapidly. So we wrote in allowing standard of care in combination with the treatment arm, in this case, ruxolitinib as well as the standard of care arm to be as dictated on the day. So it's open to whatever would have evolved and very much had prepared for remdesivir being the potential standard of care, which it looks like it is now. So there's no issue related to that. What we will have to watch from a statistical point of view, obviously, is that the arms' full with appropriate numbers of both patients. But given where we're conducting the studies in Europe with Novartis and here in the United States with us, and the sites that are involved, we expect that to be the case, and remdesivir would be rapidly adopted as a standard of care and wouldn't be a problem. There's no interaction to worry about in terms of drug-drug interaction with that particular antiviral and ruxolitinib. So we're ready to do that.

And then for the market opportunity part, I'll hand it over to Hervé.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes. Thank you. So first, I mean, we -- obviously, we hope that it would be a relatively short-lived phenomenon. So frankly, we don't see COVID-19 as a commercial opportunity of any magnitude for ruxolitinib. We moved very fast. I mean, it was -- there is a very strong preclinical rationale. There is a lot of work that was done already with JAK inhibition in CRS from CAR-T treatment. So there was -- there is a very good science. We had the scientists, both at Novartis and Incyte, work together to put the program in place. And frankly, it was very interesting to see the speed at which we were able to work on this with Novartis, where we made the decision to go into the protocol on the phone with Vas in a few minutes. We had the team's work over the weekend to get the protocol be prepared so that it could be submitted. And the speed at which everything moved was really driven by the emergency of trying to find a solution for this pandemic with -- on the COVID-19 situation around the world. We think over time -- and then we put in place an early access program in the U.S. that will be -- is open already and will be providing the opportunity for all patients to receive ruxolitinib as part of this protocol free of charge. So that's where we are. The Phase III studies are starting. We will have the results, I assume, in Q3. And then we will work with the FDA to see what we do from there. But from our side, we don't see it as a meaningful market opportunity. Over time, I think it's really trying to deal with the situation that we are all facing.

Operator

Next question is coming from Salveen Richter from Goldman Sachs.

Salveen Jaswal Richter - *Goldman Sachs Group Inc., Research Division - VP*

The first one maybe for Hervé. How are you thinking about capital allocation and BD strategy in the context of your launch outlook? You've got three this year and potentially three to four next year. And then given the pipeline outlook as well? And then a second question here with Pemazyre. Can you discuss how the groundwork around the launch in cholangiocarcinoma sets you up for bladder cancer?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes. So I'll let Barry speak about Pemazyre. On the capital allocation and the BD strategy, I think we are very much in a mode that has been demonstrated by what we have done over the past few months. I mean, we are trying to continue to build a portfolio that will grow our revenue line, continue to grow the revenue line at a fast pace over the next 5, 6 years, so that we have the diversified portfolio in 2025 to -- in that window, 2025 to 2030. I think the agreement with MorphoSys is a good example of that. It's synergistic from the commercial standpoint. It's dealing with the customer base that we know very well in hematology. It's adding a new product to our hematology portfolio, and it has a large potential to contribute to our revenue growth. So we will continue to look for that type of opportunity. There is a dermatology field that is also now the second division that we have -- that we are building. So it could be another place where, if there are good opportunities in that field where we could also

invest. We have a strong cash position now. We also have a very strong cash flow. So that's really the drive for our capital allocation and busy strategy to continue to grow the revenue and diversify the portfolio with a target in the years '25 to '30 as a sort of where we want to see the impact of these new products and these investments.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

So the second part of your question, Salveen. So Pemazyre launch is going very well. We are very proud of the company that we got approved on a Friday night by the FDA, and we had drug in our distribution center by Sunday, and we shipped out drug on Monday. So prescriptions are coming in for Pemazyre. And to date, we have no indication that there's been any problem with market access or payers not paying for it. So in our sense, it's actually going very well, despite the fact that we're doing a virtual launch, and we've learned lots of things. We've been doing virtual activities, digital activities, for Jakafi for a while now, and we're getting even better on it for Pemazyre. So that's going very well. For bladder cancer, the most important thing for cholangiocarcinoma and then for bladder cancer is that physicians are, in fact, testing for FGFR alterations. And we think that as we continue to work to educate health care professionals, on making sure they're testing in cholangiocarcinoma situation for FGFR2 fusions or rearrangements, that that will then have us set up very well from moving to bladder cancer because, again, the most important thing is to identify the most appropriate patients that could benefit from Pemazyre in bladder cancer, when we have the data available.

Operator

Our next question is coming from Brian Abrahams from RBC.

Brian Corey Abrahams - *RBC Capital Markets, Research Division - Senior Biotechnology Analyst*

I guess a question on the commercial side for Barry. Just wondering if you're seeing any changes in prescription patterns for Jakafi exiting first quarter and maybe early in second quarter as a result of COVID-19, things like accelerations of refills or fills, longer duration scripts, any impact on compliance in either direction? And I'm wondering also if you're starting to see any impact to GVHD as transplant practices evolve?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure, Brian. So for the first part of your question is to have we seen any changes in the amount of drug that patients are getting? And the answer is no. Generally speaking, all of our patients on Jakafi get a 30 day supply, particularly for MF and PV. And that there was only about 3% of patients that actually might receive a prescription for more than a 30 day supply, and that hasn't changed. At least in the first quarter, and now moving into second quarter, we haven't seen any changes for that.

As opposed to new patient starts, again, in the first quarter, we had a very good first quarter. New patient starts were very good. And in fact, that should be able to carry us through for the next couple of quarters until we get back to a more normal state. So, we're very confident in that sense. There might be some indications those high-impact areas, whether it's for GVHD, MF or PV. So places like New York City, for example, you might see a slowdown in new patient starts, but in fact, because we are an oral therapy that's well-known, has been on the market for GVHD and of course, for MF and PV for a long period of time, those refills and those patients are coming back, and that's why we're still confident in our guidance that we provided today.

Operator

Next question is coming from Tyler Van Buren from Piper Jaffray.

Tyler Martin Van Buren - *Piper Sandler & Co., Research Division - Principal & Senior Biotech Analyst*

I had another question on rux for COVID-19. So I guess recently, I had a call with a pulmonologist, who is the Head of an ICU COVID-19 Task Force. And she was discussing the history of immunomodulators and respiratory distress syndrome. And clearly, CRS here manifesting in respiratory distress is a little different than CRS that you see with cell therapy. And she mentioned that immunomodulators historically have every single therapy or every single trial has failed in respiratory distress syndrome. So I guess I wanted to ask you guys why maybe that history is not relevant here? And why COVID-19 is different?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes, Tyler, it's Steven. Thanks for your question. And it's always good to have these learnings from prior studies invoked. I think the central difference here, I have to be careful of just attaching semantic labels to things that then apply to other things. If you look biologically and pathophysiologically at what's going on, on the information we have out of China and now other places. In these patients, there is elevation, moderate elevations of cytokines that have been documented like IL-6. There's evidence of acute phase reactants coming up like D-dimer, C reactive protein and ferritin as well. And then we have evidence that with drugs like ruxolitinib, you can use appropriately suppress those. And then the question is, will they translate to a clinical improvement in that setting. So just to be clear, it's not across the board for every single patient with this entity. These RUXCOVID is for sick patients in hospital, who are pre-ventilation, but have biochemical evidence of cytokine storm or cytokine elevation and acute phase reactants being positive and then are randomized to ask the question very clearly. And in this setting, induced by COVID-19, does ameliorating those cytokines result in clinical improvement? And it's different from ARDS due to other entities that in the past may have caused it. And that's why I think it's a key question to ask. And then you've seen the IL-6 data evolve. I mean, now the question is beyond direct IL-6 inhibition, does a more broad inhibitor like a JAK inhibitor like ruxolitinib or baricitinib, able to modulate this -- these cytokine elevations and then have a clinical benefit beyond that will be answered in these randomized studies.

So I think your word of caution is good, but this is a different entity, and we have to be careful of some of the semantics.

Tyler Martin Van Buren - *Piper Sandler & Co., Research Division - Principal & Senior Biotech Analyst*

That's helpful. And maybe just a brief follow-up. As we think about JAK inhibition in comparison to IL-6, is there any reason to believe that JAK inhibition will be better?

Dashyant Dhanak - *Incyte Corporation - Executive VP & Chief Scientific Officer*

Yes, this is Dash. I'll take that question. So yes, in principle, as Steven mentioned, it's something like an IL-6 antibody, you're only really blocking the one cytokine that's believed to be involved in the disease process. With something like JAK inhibition -- excuse me, you're now targeting multiple cytokines, which we know all signal downstream through the JAK-STAT pathway. So in principle, we would argue, and I think there's data out there to support this that by going further downstream of targeting multiple cytokines, you should have a big event -- effect than targeting a single protein that we know is involved in the process.

Operator

Our next question is coming from Vikram Purohit from Morgan Stanley.

Vikram Purohit - *Morgan Stanley, Research Division - Equity Analyst*

So I had a couple on tafasitamab. So first, I wanted to see if the MAA submission is still on track for mid-2020 in the EU? And secondly, I wanted to see if COVID-19-related disruption is having any impact to your build-out of the team and infrastructure? You'll eventually need to be able to

commercialize tafasitamab in Europe. And lastly, for the initial Phase I data, I believe we're expecting in first-line DLBCL by the end of the year. What can we expect to see there? And how should we frame our expectations for what the benchmark should be there?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So Vikram, it's Steven. I'll do your first and third question and then the commercial question, someone else will take. So just to cut to the chase. In terms of the MAA filing, yes, it's completely on track, and we have had no problems getting that together and getting ready to submit it appropriately. In terms of first-line diffuse large B-cell lymphoma, the Phase I looks at the regimen of tafa len plus the care standard, R-CHOP, and its safety profile there versus tafa plus R-CHOP alone without the len addition. That is ongoing and that we should have data by the end of the year to then enable a decision on which of those two regimens should potentially be used against R-CHOP in a larger randomized Phase III first-line study. So that remains on track to be done, the safety component.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Maybe I can speak about Europe and maybe Barry can speak about the U.S., which is coming sooner. So in Europe, we are at the stage of the submission. So we are sort of targeting next year. And as you know, we have in place a team in hematology today already. We will be expanding that team, and we hope, we expect that the expansion will take place after the confinement has been lifted in that case. If it's not the case, obviously, it will lead us to a different direction. Regarding the U.S. and the prep for the U.S., maybe Barry can say a word more.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure. So obviously, we're co-promoting with MorphoSys. So MorphoSys has their team fully in place already, sales, medical, market access and so forth. We actually have our medical affairs and market access team in place. And in fact, they're actively bringing on our salespeople. As far as COVID-19 goes, in our current situation, it's a very good time actually for them to train and become experts in diffuse large B-cell lymphoma. And tafasitamab, if they're not already there. So training continues to go on, interaction with health care professionals goes on as we continue to prepare for this launch. But -- and we don't think it will interfere with it. And even if we have to do a lot of our launch of tafasitamab virtually, we're fully prepared to do that as well.

Operator

Our next question is coming from Matt Phipps from William Blair.

Matthew Christopher Phipps - *William Blair & Company L.L.C., Research Division - Senior Research Analyst*

Two quick ones on the I/O programs. Just the decision to not start a stage 3 nonsmallcell lung cancer trial, I think that's probably prudent. But how do you think you get a return on investment with your PD-1 antibody? And then as a follow-up for the oral compound, when you see data late this year, is there a potential to kind of quickly advance this to later stage trials, if you hit kind of a pharmacodynamic and safety profile? or are we going to just move to a kind of mid-stage expansion indications to see more efficacy data.?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes. Maybe I can take the first question on the antibody on the PD-1 antibody O12, and Steven can speak about the perspective on the project for '550 and the rest of the portfolio of oral products. I think if you remember, I mean, the rationale at the beginning, that is still totally true is -- it is very useful in the portfolio to have a PD-1 antibody that you can combine with other products that would be potentially used in the same patient population. The typical example would be FGFR in bladder cancer, but there are many other combinations that are being done. And I think that rationale is absolutely true. On top of it, we have the so-called niche indication program that where we could have in the relatively short-term

potential for an approval of the product. So this is ongoing and doing well. And then we had this program in lung cancer and where we have one of the two Phase III studies in lung cancer in first line non-small cell lung cancer is ongoing. And we decided not to do the other one, mainly because the design of the study was such that it would be problematic to gain FDA approval without doing a study that was extraordinarily large or very risky. So, we are in a situation where we believe there is a clear rationale of having an antibody, anti-PD-1 in our portfolio, where we have a short-term opportunity with some of the niche indication. And we have to take a little bit more time, the potential to have that product approved in the first-line treatment of non-small cell lung cancer, and that would give us overall an ROI that would be very satisfying on top of a strategic opportunity also to have a springboard for our oral PD-1 program. So I will let Steven speak about the oral program.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Thanks, Hervé. In terms of the oral PD-L1 inhibitor or the number we call '550 been in the clinic for a little over a year now Obviously, started off with a first-in-human dose escalation to get to a recommended Phase II dose that we know is in the pharmacologically active range in terms of PD-L1 inhibition and all we want to see in the tumor microenvironment as well. And then move on to treating tumors, which, broadly speaking, we call benchmarking. But looking at areas that are potentially I/O naive settings like lung, melanoma, where we can treat those patients in that part of the world, and that's going on now to get their data to see the efficacy bars that -- the efficacy signals that we get from the drug in those various entities. Once we're able to look at that this year, internally, we would then decide, do we have proof-of-concept, where it exists and where to go.

And the way we then approach it, which is the meat of your question, is what are the rapid registration approaches then once we have internal proof-of-concept and where we want to go and chase those various entities. And then looking more broadly, given that it's an oral therapy, given that it lends itself to maintenance and adjuvant settings, again, if we've achieved proof of concept, have the efficacy we've seen, look at those bigger Phase IIIs in those sort of settings and then include potentially large tumor types as well. But the program continues to progress well. And we're enrolling patients as we speak in the benchmarking setting to work as quickly as we can to proof-of-concept. And I think we've demonstrated once we hit that and once we're comfortable internally, we could move to later trials very quickly.

Operator

The next question is coming from Tazeen Ahmad from Bank of America.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

A couple of questions. Going back to Jakafi estimates for the year. On reiterating your guidance, I just wanted to get a little bit of color on your thoughts maybe about mix. Can you give us an idea of what percent of sales right now are coming from Medicaid? And what part of maintaining guidance assumes that, that proportion stays the same? And I'm asking this question because the unemployment rate at least temporarily has ticked up higher. How does that come into your calculations about revenue streams from Jakafi for the rest of the year? And then a pipeline question, if I might also ask, what have you been able to learn from the launch of Balversa? And the reason for this question is more to get a sense of how you're thinking about pemi's second indication in urothelial? And if there's any learnings you've gotten from that?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure, Tazeen. So as far as our mix of patients, so I guess, in this situation, we're fortunate that most of our patients are, in fact, covered by other government programs, Medicare Part D, VA, DoD, TriCare and so forth. Our commercial patient population is about 30%, 35% that it makes up. And yes, Medicaid is really only about 4% of our payer mix right now. Could it go up? Sure. But again, if it's like 30% or is it going to go up 10%? We really don't think it's a big factor at all, and as we go forward with our forecasting for the rest of the year and the guidance that we provided today. We'll have to see. Obviously, there's uncertainty there, but nevertheless, we think we're okay with reinforcing our current guidance.

As far as what we learned from Balversa, I don't know what we've learned. We haven't heard a lot from Janssen or at least I haven't heard a lot from Janssen. They don't seem to be releasing their sales on Balversa themselves and the most important thing perhaps is that they're continuing to educate on testing for FGFR alterations that could help us in the future.

Operator

The Next question is coming from Jay Olson from Oppenheimer.

Jay Olson - *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst*

Curious about your work in dermatology. What are the gating factors to filing your topical rux NDA for atopic dermatitis? And then what are your plans to build your dermatology commercial infrastructure? And for vitiligo, how is that study enrolling? And how has it been impacted by COVID-19?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Jay, it's Steven. Again, I'll do your first and third question and someone will take your middle one. So in terms -- remember, the atopic dermatitis studies have completed enrollment. Obviously, we've presented the data now, and we alluded to it in the prepared remarks. And we're moving full steam ahead to get that file in place. We were slightly worried about the impact of COVID-19 on the ability to go to sites, monitor and gather data, but we haven't had any problems to date and that's why we said on the prepared remarks, we remain on track to do that submission by the end of this year. That remains the plan, and it's full steam ahead on that. Why the end of the year? It's to wait for the safety follow-ups. So we need that adequate range of safety follow-up from the last patient as to make the complete submission and get it in by the end of the year. In terms of the vitiligo studies, they were enrolling really well. There's a minor impact from COVID-19. But as Hervé said on his remarks, which I think are really important to remind you, different parts of the world are impacted at different times. And again, our studies remain on track there, and we remain on track to deliver those studies in 2021 as planned.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

On the commercial plan, so what we have said, and it's still very true today is, in the U.S., we are in the process of building a team. So we have already an excellent clinical development team that is in place. We are looking at all the other components of what will be a commercial group that is of high-quality with a lot of experience in the field, with market access, with medical affairs and with the commercial group. So all of that is ongoing. You have the timeline. The submission is planned for the end of this year. So you can expect the end of next year as being the potential launch date and we -- so we are on track to doing that. Outside of the U.S., frankly, we are looking at many different optionalities, which could be going alone in Europe or having a partner and both options are still open and we have discussions ongoing to identify what would be the best way to do it. I can tell you following the excellent data we had in atopic dermatitis, it's certainly stimulated a lot of interest. And I would say for the rest of the world, we are more certain that we will need a partnership instead of building, and we are also looking at the right timing for putting these partnerships in place for Asia and some other regions of the year. So the plan is really being executed now, and it's in good shape. And for the U.S., as we said, I mean, the buildup of the commercial team is already starting with the first component with market access and some marketing people.

Operator

Next question is coming from Michael Schmidt from Guggenheim.

Michael Werner Schmidt - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

Maybe just going back to bladder cancer. Could you just remind us of Pemazyre's profile there? And how you think it might compare not only to Balversa, but also to other recently launched drugs such as Seattle Genetics Padcev? And then the second question was going back to tafasitamab and the U.S. launch. We've obviously seen some early FDA action recently. And I was just wondering, more curious about potential overlap here in terms of marketing with your current Jakafi target market and the utilization of that sales force for launching tafasitamab in the U.S.?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So Michael, it's Steven. I'll take your first question, and thank you for it. So again, in terms of bladder cancer and FGFR3 being the driver there, obviously, we have the monotherapy data, both with intermittent dosing and continuous dosing coming in and looking at it. We already spoke on a call a couple of weeks ago that there has been some COVID-19 impact in our ability to gather that data in-house and present it. So it's more likely in early 2021, that we'll have that monotherapy data for you. We have an ongoing first-line study in combination with a PD-1 inhibitor with pembro. And obviously, you alluded to how does it fit in, in terms of the Seattle drug. And we'll have to see. Again, this is a targeted agent for FGFR3, and there may be evolving care standard, and we'll have to watch carefully, and we may have to change the first-line study as that market evolves and that profile of treating patients evolve. But we're on track in terms of getting that bladder data early next year.

What's very important to us, though, is the tumor-agnostic program, given the potential ability to impact multiple different cancers with multiple different histologies is enrolling incredibly well and there, we've seen a little to no COVID-19 impact there. We're able to find those patients and get them onto that study, and that's going to be important to our overall life cycle management of the drug.

And then for your next question, I'll hand it over to Barry.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Yes, Michael. So your comment about the FDA and approvals, we're prepared anytime between now and the PDUFA date to launch tafasitamab. And yes, actually, the nice thing about tafasitamab and diffuse large B-cell lymphoma it overlaps completely with our current target population for myelofibrosis, polycythemia vera and GVHD.

Operator

Our next question is coming from Mara Goldstein from Mizuho.

Mara Goldstein - *Mizuho Securities USA LLC, Research Division - MD of Equity Research Department*

Great. I appreciate it. Just on GVHD and Jakafi, do you have a sense of how the duration of treatment has evolved at this point? And then I just had a question on the LIMBER program. And when you look at the totality of that program, do you see it enhancing the overall number of patients that can be brought into the MF population?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

So I will take the first part and hand it over to Steven for the second part. So duration of therapy. All we really have to go by, it's a little bit harder to get to the duration of therapy for GVHD than it is for MF and PV, for example -- but so we just go by the clinical trials and approximately 6 months is what we believe for the duration of therapy for acute steroid-refractory GVHD.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. And for your second question in terms of the LIMBER program and the potential ability to reach more patients with MF, I think the clean answer is yes. So let me give you an example. So, if you look at ALK2, one of the main reasons patients -- the small number of patients that discontinue therapy is due to the development of anemia that becomes unmanageable. If the ALK2 effect on hepcidin inhibition works and manages that, then patients won't experience that, they'll be able to stay on drug and get extra benefit from it. In addition, it would open up potentially patients who can't go on drug being able to be treated then with the combination. So that's one good example. If you look at our formulation work, the XR formulation, the once-daily formulation, I mean there's potentially convenience there in terms of once-daily being better for patients, although that hasn't been an issue to date, but that's a potential upside. In addition, if ultimately that drug has a -- because of its PK effect and having a less Cmax as it ends up having a flatter profile in terms of the induction of anemia, that's another issue where in MF patients, there may be increased use there.

And then lastly, I'll just add, beyond everything, whether it's with BET or with delta, if you have the desired enhanced efficacy, then treating physicians will overall be more likely to use your product in that setting. So the clean answer -- yes, if we get everywhere we want to get, I think, is pretty clear.

Operator

Our next question is coming from George Farmer from BMO Capital Markets.

George Farmer - *BMO Capital Markets*

Wondering, Hervé, if you can comment a bit more on the PD-1 strategy. What are your commercial expectations in front-line lung cancer? And can you elaborate at all on any more -- on any of the niche indications that you had mentioned?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

So yes, as we said, the niche indications are relatively small in terms of the number of patients for each of them. They are potential way to have the product approved, which could be very important for many other aspects of the program and the combination with some of our pipeline products, et cetera. In the first line, non-small cell lung cancer, as you know, the approach we have is a me-too approach in the first-line treatment of patients receiving chemotherapy in non-small cell lung cancer. So it will be a chemo plus '012 versus chemo, and if this is successful and allows us to get FDA approval in that indication, it will give us a position where it will become an alternative to existing treatment in that setting. And frankly, it's such a large number of patients that we believe it can be productive from the revenue standpoint. It is also an opportunity to develop our oral PD-1 in the right setting. Because as you can imagine, if you give chemotherapy to a patient, it's not the right place to use an oral PD-1 versus an IV PD-1. While after the chemotherapy is over, they are 18 months of treatment with single-agent injectable antibody that could be obviously better managed with an oral product. So there is a scenario where it will help us organize the treatment of patients with non-small cell lung cancer, where you receive chemo plus an injectable PD-1, and then you can have the consolidation of the next months of treatment being done with an oral product. So there is a number of ways where this can fit very well with our portfolio. And where by itself, it is not a small number of patients in first-line lung cancer, there are a number of ways where we could gain market share just by having the approval in that indication.

Operator

Your next question is coming from Ren Benjamin from JMP Securities.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Senior Research Analyst*

Maybe for Steven, can you talk a little bit more about the data collection and validation disruptions on FIGHT-201. Is that something that's particular to that study and shouldn't impact other studies? Or if it could impact other studies like a TRuE-V -- what kind of measures you have in place to

prevent that from happening? And then as a follow-up, maybe for Barry, I keep getting amazed by the growth in MF. Every time I think we're hitting a plateau, you continue to find more patients. I see that -- it looks like about 8,000 patients for MF, 4,500 for PV and 1,500 for GVHD, roughly. Can you just talk a little bit more about how much growth you might potentially see in MF? And where these patients are coming from?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So Ren, it's Steven. I'll start. So across the board, there has obviously been a COVID impact on the program. And particularly, obviously, in places like New York City in terms of the ability to get studies done there and access sites to get data. And I think for FIGHT-201, the particular issue was to try to get it ready to present it in a meeting in the second half of this year in time just to meet those medium time lines, and we realized from a site access point of view in terms of getting it in, we're just not going to be able to do that in a timely manner. So that's the issue peculiar to that related to the particular meeting. And nothing more than that.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

So, Ren, yes, MF continues to be the backbone, even though PV continues to grow faster quarter-over-quarter in terms of new patients or total patients. But MF certainly hangs in there just -- 8,000 patients might be right. We think the prevalent population is still 15,000. Obviously, we have about 3,500 to 4,500 new MF patients a year. But I think mostly it's because we're starting new patients earlier, physicians recognizing that when they start earlier, that's when their survival benefit really comes through. And obviously, the duration of therapy, we have many patients that have been on therapy for 8 years or more, in fact, so it's really starting patients earlier, getting all the new patients that are newly diagnosed and the duration of therapy.

Operator

Our next question today is coming from Christopher Marai from Nomura.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Just a follow-up on some of your GVHD comments for Jakafi. I was wondering if you could elaborate on the number of patients treated, whether that's for just the acute setting or the acute and the chronic setting? And then and how do you look at growth going forward, given the emerging competitive landscape there for Jakafi in GVHD?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

So the number of patients in GVHD, so if it is approximately 1,000 patients, maybe so far that are on it. Obviously, there is spontaneous use of Jakafi in chronic GVHD. So it's some of those patients included there. We think the chronic indication that's coming if we get data at the end of this year, towards the end of this year for REACH3,it's very important for the continued growth in that patient population. But Jakafi, as we said at the beginning in the prepared statements that it's fast becoming the standard of care in acute steroid-refractory GVHD. Some of the other studies, some of the other drugs that are being developed in acute GVHD or chronic GVHD so far, there hasn't been necessarily pivotal data, compelling data that would -- we would think would interfere with the current use of Jakafi in steroid-refractory or than chronic GVHD.

Christopher N. Marai - *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*

Okay. And then just thinking about your PD-1 antibody and some of those combinations that you alluded to, when might we start to see some of the first combination data? And perhaps, what combination data would you be looking at as potentially most exciting relative to, I guess, combinations with your current internal pipeline?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes, Christopher, it's Steven. So as Hervé said, the three niche tumors are on track - squamous cell anal carcinoma, MSI-high endometrial and the Merkle. And then the lung program, the --what we call the sort of clone study is on track as well. But in addition, and thanks for bringing it up, there are multiple studies ongoing, looking at combinations preparing for the future here, if you will, on how do you use the PD-1. So both with external compounds like VEGF inhibitors, but internally as well, one that would be of particular importance to us, is the FGFR combination. Those are enrolling now, and I expect we'll present data in the next year. So more likely in '21, you'll be seeing that data in a meeting but we'll be getting enabling safety work with all of them as we speak over this calendar year.

Operator

Thank you. We have reached the end of our question-and-answer session. I'd like to turn the floor back over to Mike for any further closing comments.

Michael Booth - *Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

So thank you all for your time today and for your questions. Of course, the IR team will be available throughout the day for any follow-up questions you may have, and we look forward to talking to you at investor conferences in the coming weeks. But for now, though, we thank you again for your participation in the call. Stay safe, and have a good day.

Operator

That does conclude today's teleconference webinar. You may disconnect your lines at this time, and have a wonderful day. We thank you for your participation today.