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Q4 2021 Galapagos NV Earnings Call

EVENT DATE/TIME: FEBRUARY 25, 2022 / 1:00PM GMT

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to Galapagos Full Year 2021 Financial Results Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Sofie Van Gijsel. Please go ahead.

Sofie Van Gijsel ***Galapagos NV - Head of IR***

Thank you, and welcome all to the audio webcast of Galapagos Full Year 2021 Results. I'm Sofie Van Gijsel, Investor Relations, representing the reporting team at Galapagos. This recorded webcast is accessible via the Galapagos website homepage and will be available for download and replay later on today.

I would like to remind everyone that we will be making forward-looking statements during today's webcast. These forward looking statements include remarks concerning future developments of the pipeline and our company and possible changes in the industry and competitive environment. Because these forward-looking statements involve risks and uncertainties, Galapagos' actual results may differ materially from the results expressed or implied in these statements.

Today's speakers will be Onno van de Stolpe, CEO; and Bart Filius, COO and President. Onno will reflect on the operational highlights, and Bart will go over the commercial and financial results. You will see a presentation on screen. We estimate that the prepared remarks will take about 20 minutes, then we'll open it up to Q&A with Onno and Bart joined by the rest of our management Board.

And with that, I will now turn it over to Onno.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Thank you, Sofie. Yes. This is the hallmark moment as I will be presenting for the last time, the financial numbers of Galapagos. After 22 years at the helm, I'm handing over the baton to Paul Stoffels. It's clear that Paul is one of the most prominent individuals in our industry, and he is somebody that I'm very pleased to hand over all the responsibilities to. I've known Paul for the whole period that I've worked at Galapagos.

He has been -- he is one of the founders of the company, been on my Board in the early years. And we have kept in very close contact since then, when he moved on from Tibotec to rise within the ranks of Johnson & Johnson, being responsible for bringing a whole range of drugs to the market in his role as Chief Medical Officer at J&J. And he has now decided to join Galapagos as Chief Executive Officer, starting April 1.

So a little over a month from now, and I think Galapagos is in extremely good hands with him for a number of reasons. He is a very strong

leader with strong scientific roots. He also has an incredible network around the world at every level, and he is extremely dedicated to bring innovation to patients, new medicines with a high medical need to address that. And I think this really fits into the DNA of Galapagos. He has known Galapagos all those years. So he will also be very close to the organization and its culture, and therefore, will be very well received by or has been very well received by everybody in the company.

Actually, many of our employees have worked in earlier days at Tibotec or at J&J and have worked with or for Paul in that role. So his appointment has been very well received by everybody. Also internationally, we've had a whole range of congratulations that we were able to get Paul as our CEO. I think it's a big step forward for the company. But it also shows that I'm leaving behind a company that is clearly of a value that a person like Paul is joining it as a CEO.

There is an organization that has developed Jyseleca from target all the way to the market, to the patients and is actually marketing that throughout Europe. It's an organization that has now the cash, the infrastructure and the individuals to bring multiple products to the market. We have had our disappointments over the last 1.5 years, but it's a solid organization with a fantastic culture that I'm sure that under the helm of Paul, will be able to bring a number of new drugs to the patients. I wish him all the luck and I'm sure he will be very successful there.

If we look at the year-end review, clearly, positive and quite some negative activities there. We had to hold our trial in idiopathic pulmonary fibrosis with ziritaxestat, ISABELA trial, which was in a Phase III because of lack of efficacy and a safety concern. So this product has been completely stopped.

We also had disappointing clinical activity of our first SIK program, GLPG3970. Although we saw clinical activity and new mode of action in psoriasis and in UC, the level of activity was too low to really make a route forward for this specific molecule. So we're drawn back -- we are back at the drawing board to come up with more potent, more effective SIK molecules.

We also have positive news. Clearly, the approval of Jyseleca. You see in the U.S., the EU is a big one. Of course, that is not going to be approved in the U.S., is clearly a negative there. We also had positive news of Jyseleca in Crohn's disease where the full recruitment is now there, and we'll get the data early '23. So that's the third indication that we hope Jyseleca will reach the market.

So quite some news on clinical trials. Based on the setbacks in Jyseleca in the U.S., the clinical activity of '3970 and ISABELA, we have resized the company and reprioritized the R&D organization. And I think we are now well set for the next step, the next step that Paul can fill in and adjust to what he thinks is the right things to do.

So if we can go to the next slide. The investment case is very strong. It has been strong for quite a number of years, and since we did the deal with Gilead. And clearly, the future from that point of view is bright. We have a very strong target discovery platform. The pipeline is, although early, it's solid. We're moving forward in a number of programs. Jyseleca or filgotinib molecule is now fully launched in Europe in RA and starting to get launched in UC in certain countries. And by the summer, we should be up and running for UC in Europe in most countries as well. And therefore, that franchise is gaining ground, and Bart will discuss this in more detail. But we are quite positive about the early results of the sales of Jyseleca in Europe.

The Gilead collaboration is alive and kicking. It's clear that, of course, we both -- both companies had hoped more success with ziritaxestat as well as with the SIK results. But we -- this is a long-term relationship for another 8 years, and we both believe that this collaboration will ultimately show the value to the patients and also to the investors.

We are very lucky with a very strong cash balance, EUR 4.7 billion, which is in euros, so close to $5 billion in dollars, which secures our future. And in the deal with Gilead, we also secured our independence for another 8 years, which means that we can rebuild our pipeline over the years to come and show the investors that Galapagos is there to stay.

If you look at the portfolio, you can see that except for our filgotinib JAK1 inhibitor, the rest of the pipeline is quite early. Filgotinib is approved for UC and RA. And as I said, it's fully recruited in the Crohn's Disease trial, but the other programs are in Phase I or Phase II. So there's clearly a gap there, a gap that we need to fill. Doing that through our own development work is taking too long. So we are very

active to see if we can find molecules that can fill this pipeline and bring products to the market and feed our commercial organization that we have in Europe in the coming years. Therefore, M&A is high on our agenda.

Last slide I would like to discuss is around the collaboration that we have with AbbVie and cystic fibrosis. We had a long-term collaboration with AbbVie that ultimately we decided to end in 2018 where we handed all rights to AbbVie at the time for a onetime payment milestones and a royalty. It now looks that this program within AbbVie is getting traction. It's -- they have announced that we can expect data in the first quarter and later in this year around dual and triple combination therapy for CF potential competitor to the Vertex portfolio.

If AbbVie reaches the market there, we get a single to low double-digit royalties on global sales in CF. So that's very attractive for us, and we get some additional milestones up to EUR 175 million. But especially the royalties are, of course, attractive, especially as it looks like 2 of the 3 molecules in the triple combination might originate from the Galapagos research, which would mean that we would get double-digit royalties of the sales. So we'll see how it all turns out. And if AbbVie makes it to the market with the triple combination therapy, but hopefully, we can harvest from this collaboration that's been part of Galapagos for a very long time in the past.

So with that, happy to hand it over to our President, Bart Filius. Bart?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Thanks, Onno, and good morning, everyone, in the U.S., good afternoon here in Europe. Indeed, a memorable moment all now because I think we've done this together for about 30 times now. So it's -- and I think all of those 30 times went pretty okay, at least from a technical point of view, except the 1 time when we hit the hang-up button instead of the mute button during the conference call, but the other 29 events were, I think, successful. So thanks very much for the...

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes. That one time was not the best one. Right.

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes. That was a bit of a miss. So thanks for that collaboration, Onno. Happy now to take you through an update on the commercial and on the financials for full year, and I'll start with Jyseleca. Obviously, our first marketed products. We're extremely proud here that we've got this product on the market now approved in RA, but also in ulcerative colitis. In the fourth quarter, we got the final approval there as well.

And we're also proud to be the marketing authorization holder for Jyseleca. We've taken over the product from Gilead and all the transfer activities regarding the marketing authorizations have been completed now. So we're happy to be the sole commercial partner on Jyseleca.

A few words on Jyseleca, the business case maybe to start off with. As a reminder, I've shown this slide to a few of you before. We think that this is a product with peak sales potential of about EUR 0.5 billion. And actually, we think it could be a 50% contribution margin products when we are at peak. So that's a very decent profitability profile.

As of this year, we have the full commercial structure in place in all of the countries with RA and IBD staff active. And we think we can bring this to a breakeven product contribution in the course of 2024. And then we have another 11, 12 years of patent exclusivity. So hence, we believe that's benefiting from those years of profitability, provides for a good NPV business case for Jyseleca in Europe itself.

Maybe a quick word on the launch itself. This is a graph that I've shown also at the end of Q3, but now we've included the month of October to December. So full year sales is landing at a little short of EUR 26 million, of which EUR 15 million is booked on the Galapagos side. This is the last year where we have this dual booking because Gilead was still the owner of the product in Germany and the U.K. in the beginning of the year as colored in gray here and the U.K. for until the end of the year. And then in orange, it's all the other countries that are marketed by Galapagos.

So we're quite pleased with what we see in terms of trajectory. It's a pretty linear evolution, except for the months of June and July, where we've had this transfer in Germany, the stocking, destocking effects. But in terms of in-market performance, it's a pretty linear line upwards towards about EUR 4 million monthly in December of last year. And with that, we think that we should be able to achieve sales in the course of 2022, that ranges between EUR 65 million and EUR 75 million.

We're rolling out in RA and in UC throughout Europe. We're now reimbursed in 14 countries, amongst which all the big 5 countries are included and process is ongoing in the rest of Europe. We're launched in Germany and the Netherlands in UC since November. And like we did for RA during 2021, also in the course of the year 2022, we'll get additional indications reimbursed in the other countries as well. And we've signed a partnership with SOBI for the Eastern European countries for Portugal and for Greece, and they will be seeking reimbursement and launching in those countries in the start of '22, first in RA and then also subsequently in UC.

We were notified by the EMA of a safety review procedure that is ongoing, where they're reviewing all of the JAK inhibitors that are in inflammation. We are expecting an outcome of this procedure in Q3, probably in the September time frame. And we look forward to interacting with the EMA on the various data points that we have. It should be noted that actually the data that we have on Jyseleca has been extensively reviewed as part of the UC process quite recently. So they are, and we're already in possession of all the safety data around Jyseleca when they designed the label in UC in the second half of last year.

If we go to the market share of the class, which is an important driver, obviously, of the potential of Jyseleca, we see now that the market share is about 18% at the end of last year in the total market in RA, but more importantly, the dynamic market share. So that's the market share amongst patients that are either switching from other therapies or are naive to advanced therapies. And there, we have a market share of about 26%, clearly increasing from the 21% that we -- that was there a year before. And here, you see the impact of the launches of both Jyseleca and Rinvoq playing an important role. So basically, the switch market share is the market share that we think is the target that we can go for as an out of market share of the class, and we hope to grow this further together with the other players in the markets.

Then a quick word on the UC itself. There's a clear need for novel treatment options there. Currently, still remission is suboptimal. Still a few patients are actually getting to full remission. And if they do so, there is still a significant number that are remaining corticosteroid dependent with the associated safety concerns, obviously, therein. And on top of that, it's still complex treatment with injectables, and there's really only except for XELJANZ, now with Jyseleca, an oral treatment available in this market.

We think it's a market of currently about EUR 1 billion with potential to grow further. And therefore, we think this is an indication which is very attractive for us as well for Jyseleca to be successful. As a quick reminder, maybe the data that we have obviously shared with you before because this is the data from the selection study first on the induction. And on the next slide, I'll show a bit of maintenance.

So on induction, good to note the rapid response already in Week 2, both in the naive and in the refractory population. We were able to see statistically significant difference between active and placebo, and we have clinically meaningful declines after 10 weeks as well in both of those populations as measured by the partial Mayo clinical score. So we're happy with the induction data. And we're also quite proud of the remission data that we've seen at Week 58 at the end of the maintenance period of that study.

If you take 3 variables here, on clinical remission, a delta between active and placebo of 26 points, highly statistically significant. The same for histologic remission, 25 points in delta between active and placebo. And then also and very importantly, 6-month corticosteroid-free clinical remission. So patients that are able to stay in remission without using corticosteroids is a delta of 21 versus active and placebo. So we have -- we believe, a very strong proposition.On efficacy side, we have a strong proposition because of the oral treatment, and we have a benign safety profile, we believe, for patients to offer as well. So we're looking forward to bringing this to other markets in Europe throughout 2022.

Then if I move to the financials, this is a slide that shows the evolution of our cash position between the end of December 2020 and the end of December 2021. Our cash burn is ending at EUR 565 million in orange. And that's within the guided range between EUR 530 million and EUR 570 million that I gave back in November at the announcement of our Q3 results and is a clear lower number than what we were anticipating at the beginning of the year as a result of the restructuring program that we implemented.

Other variances that affected positively to our cash position were the proceeds of the disposal of Fidelta, our subsidiary that we sold in the beginning of 2021. And we had a positive impact on currency effects, that's mainly the dollar position improving over the last 12 months that has led us to also a EUR 67 million improvement on our cash balance. Overall, EUR 4.7 million at the end of 2021.

On the other financials in the P&L, total revenues and other income combined EUR 539 million, of which about half is connected to filgotinib development and half is connected to revenue recognition for the platform. So those are both accounting entries. Noncash items, as we know and date back from the 2 transactions that we've had with Gilead, first on filgotinib and then on the larger collaboration in 2019. And then also EUR 50 million of actual sales in Jyseleca, out of the EUR 26 million total that we had in the markets in Europe and some royalties as well.

Operating costs are flat versus full year 2020, which is a combination of increases in SG&A as opposed to declines on the R&D front. And our net loss is about EUR 100 million, which includes a gain on the disposal of Fidelta as well as the positive impact on the currency as was also the case in our cash overview.

Then maybe looking forward with a couple of years ahead, and this is a slide that we've also shared before. The way to look at the cash burn at Galapagos is really the 2 components on one hand, what I would call the recurring component, which is the R&D burn in orange, which is between EUR 300 million and EUR 350 million.

And if we look at the other parts, that's actually the burn that's connected to Jyseleca. This is both the development costs that we're still incurring on Jyseleca and most notably the Diversity study for Crohn's Disease is still ongoing, as you all know, and is an important factor therein and as well the cost of commercialization of the products. This is not a recurring item. We think if we can get to breakeven position in 2024, this will then fall away and our actually underlying recurring burn will be all things being equal around the EUR 350 million mark. And then if we go to later years in this decade, Jyseleca will actually contribute positively to our overall cash burn.

Our guidance for the year 2022 is between EUR 450 million and EUR 490 million. So that's a further significant reduction of about EUR 100 million compared to where we were in 2021. And if you take a look back at where we were before we announced the restructuring in the beginning of 2021, we are about EUR 200 million lower than what we were planning to be in the early months of last year, first part being already realized in the course of 2021 and a further EUR 100 million achieved in 2022.

Now let me conclude with the last slide that highlights the key components of our strategy and the foundations for future growth. Of course, R&D remains core to our company and our novel target engine is continuing, and we will deliver new preclinical candidates for clinical exploration on novel targets in the years to come.

We have our targets regarding commercial to make sure that we get the rollout of Jyseleca in RA and UC correct. We have also announced that we are interested to do BD. We've announced that earlier in the year. And we're sure that also with the incoming new CEO, Paul Stoffels, we'll be in a position to execute on some BD opportunities, hopefully in the course of this year.

And then finally, to reiterate the 2 elements that we give specific guidance on, first Jyseleca, between EUR 65 million and EUR 75 million of sales and cash burn between EUR 450 million and EUR 490 million.

With that, I'd like to conclude and hand it back to Sofie, and perhaps you can lead us through the Q&A, Sofie.

Sofie Van Gijsel ***Galapagos NV - Head of IR***

Thanks very much, Onno and Bart. So this concludes the presentation portion of today's audio conference call. I would now like to ask the operator to open the line for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question comes from the line of Jason Gerberry from Bank of America.

Jason Matthew Gerberry ***BofA Securities, Research Division - MD in US Equity Research***

So my question is just, was there anything new or unique from the post-marketing data from TOFA or baricitinib that triggered the EU scrutiny on the deck? Or is it just more of the same issue that the FDA has stretched up in the past? And if you can just talk about some of the potential scenarios that could emerge from the CHMP opinion, I imagine that this is mainly a labeling consideration, but just curious if you guys can clarify on that, I'd appreciate it.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Jason, this is Walid. So I'll take that question. I'm not sure everybody is calling from Australia at this point. So no, I think the information that we got from PRAC was very specific. It's about some data that came from post-marketing studies that I believe were with baricitinib. It's nothing new. I think it's -- what they saw was a higher risk of thromboembolic events, VTEs, I think is the term that specifically that they use. And if I'm not mistaken, MACE as well. So nothing new there. As you guys know, this has been an area that we've been following for some time for the class, and we've been reporting on our data on a regular basis with regard to filgotinib.

In terms of the process and what this will -- what will be the scenarios -- outcomes, it's really very early to tell. I think CHMP and EMA have the responsibility to monitor the ongoing safety of these compounds that are approved. And in this case, since there is Article 20 that was run actually previously on tofacitinib, now there's new data that came out on baricitinib. I think they're going through the due diligence and asking the other 3 JAK1 in the inflammatory space, so that would be upa, filgo and the new compound from Pfizer for atopic dermatitis to CIBINQO to just -- to get the data on these adverse events of special interest that we've been monitoring and there's nothing new in terms of signal. And then based on that, they will decide what is the next course, but it's really premature for us to make any assessment at this point.

Maybe I'll take this as an opportunity to reiterate our strong conviction about the risk benefit profile for filgotinib. We've been communicating on this for a long time right now. We believe that the JAK1 preferential activity that we've seen with our compound plus the judicious choice of doses that we've taken forward in Phase III and ultimately approval give us the -- what we believe is the best risk benefit profile, and you've seen it in a number of the data that we've been showing on thromboembolic events, on zoster, on serious infections and so on and so forth. And so we look forward to working with EMA on this topic, and we are hoping that we will be able to convey our message clearly, and at the end, be able to end up with information that will be best helpful for prescribers to use these very important compounds and particularly filgotinib in the patient population who need it the most.

Operator

The next question comes from the line of Dane Leone from Raymond James.

Dane Vincent Leone ***Raymond James & Associates, Inc., Research Division - Research Analyst***

Just 2 questions for me. Firstly, I guess, in terms of the guidance for Jyseleca, the results of MANTA seem very helpful. But for the commercial infrastructure that you've built out, how fungible are the calling points between the rheumatologists that you're working on with RA to the touch points that you expect for ulcerative colitis? And what's in place now versus what would have to be built there? And how do you factor in the contribution from ulcerative colitis in terms of the longer-range forecast that you now have for Jyseleca? And then the second question, which, obviously, I would have never thought I would have to ask you, but is there any expected disruption from the ongoing war in Ukraine?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Dane, this is Michele here. Good afternoon and good evening also from my perspective. I'll take the first question on Jyseleca. So well, we already clarified our expectation to have a EUR 500 million peak sales in the second half of the decade and that, of course, includes the infrastructure for commercializing RA and commercializing the 2 indications in IBD, so UC and Crohn's.

As we got approval for UC in Europe and then subsequently in Great Britain, November and January, recently, we have been building or expanding our infrastructure in the countries to account also for that indication. So to say that, so the bulk of the organization is already

in place and was already in place for RA. So everything to do with, of course, distribution more of the backbone operationally, but also the market access, the negotiation at a national level and subnational level is the same infrastructure we have for RA. And actually, it was a good continuation of work after we got a very successful RA reimbursement to then continue immediately and go further for UC as well.

In terms of field force or salesforce and also MSL medical, we have different approaches country by country very judiciously to understand how much really it's needed incrementally. And in some countries, actually not too much because the prescriptions happen in hospital. So we managed to get also into some type of hybrid roles that maximize efficiently the detailing capabilities on also the gastroenterologists. In some other countries, actually, it pays off, and it's better to have dedicated employees in both commercial and medical roles to then communicate to gastroenterologists. But all in all, where we assess the business case to be positive -- consistently positive for UC, considering the incremental resources that we have to put in place.

And considering as well then the reimbursement cycle, so typically in Europe, about 12 months from central regulatory approval, we are building up those capabilities in the countries as we go. And I've indicated earlier, we launched already in Germany and UC, so we are pretty structured and organized there in the countries that take typically longer, like Italy and Spain to get central reimbursement. We are building that up in these times in the next months. Also considering the impact of COVID and how much the face-to-face connections and calls will be needed versus more of a centralized digital approach.

I can't give a sense on the second question about the tragic situation in Ukraine. Not directly on this part of the organization besides, of course, the tragic humanitarian political setup there. As this is not a region that we are commercializing in where we have people there. I might then pass the boat to Walid maybe on something that is related more to R&D or studies.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Yes. Thanks, Michele. And thanks, Dane, for that question. Yes. No, we've definitely -- of course, this didn't come out as a surprise. It's been building up for a few days. So we've been looking into this and try to evaluate whether there will be any disruption. And I also can speak on behalf of sort of all aspects, not just clinical studies, but across R&D as well as drug supply and so on and so forth. So we don't see any major disruptions there.

From a clinical study perspective, of course, the most important part are the safety of our patients. To some degree, we dealt a little bit with this with the COVID situation and tried to focus on how do we balance between maintaining safety of our patients and then having access to the medications that they need from our studies at the same time and making sure that they're going to be safe.

So far, the numbers in Ukraine, from our studies, are very low. And we don't expect to have any significant disruptions. Well as you can imagine, this is something that we are monitoring very closely. We have a sort of core team that's formed that's going to be monitoring this on a day-to-day basis and adjusting as a result. But as of today, I can say with confidence that we don't see any significant disruption.

Operator

The next question comes from the line of Peter Verdult from Citi.

Peter Verdult ***Citigroup Inc., Research Division - MD***

I have a question on business development, please. Just Onno and team, how would you characterize the general environment to execute BD in light of the biotech sector selloff? And if I may squeeze in one extra addendum. Specifically, when we met last month with the announcement of Paul as the new CEO, you mentioned at that time that the Board was assessing a deal. I realize this is not the floor to go into details, but can we assume Paul has had a chance to assess that deal and in theory, could Galapagos act quite quickly once he starts in April?

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes, let me answer this. Clearly, to have cash in the current market is a clear benefit, if you are on the hunt for a deal in this sector. Clearly, the capital markets are quite negative on biotech at the moment. So yes, that's clearly in our favor. And with the announcement of Paul, we actually have received a lot of inbound calls regarding companies that would like to collaborate or do a deal one way or the

other. Clearly, the network of Paul is tremendous, and we can benefit from that.

Paul is already quite active in discussions with the Galapagos team. Although he starts in a little bit over a month, he is already not continuously, but regularly involved. And so we are moving forward in the process of selecting potential interesting candidates.

Operator

The next question comes from the line of Brian Abrahams from RBC Capital.

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

Just my congratulations to Onno on all your accomplishments over these last several decades and best wishes going forward. Just on the Toledo program, can you give us an update on the status of the next-generation compounds? I guess, how far along you are some of the key similarities and differences as you work through the chemistry there? And then maybe just a quick follow-up on the business development side. Just wondering, I guess, how you and Gilead are working to align on overall strategy there?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Brian, this is Walid. I'll take the first question. I'll turn it over to Onno. So on Toledo program, we currently have the SIK3 inhibitor '4399 finishing Phase I. And then once we get the results of that study in healthy volunteers, we will have data on pharmacodynamic effects as well as PK and safety. And this will put us in the right place to decide on what would be the most appropriate next step for this compound.

At the same time, what we have been doing, actually, we're not done with this is to look at the totality of the data both from safety as well as efficacy and biomarker from the large number of compounds that we have developed through various stages in discovery and 3 of them right now until now in the clinic to be able to have a much better idea as to the appropriate next step.

So today, our working hypothesis is that going after selective compounds for SIK2 and SIK3 is the right approach. And it's working with compounds that have a higher target engagement with -- and as a result, being more potent with higher target engagement in the clinic will be what would be needed. These are the lessons learned from our experience with '3970.

So we expect that 1 or 2 of such molecules will be coming into the clinic in the next, I want to say, 6 to 12 or so months so that we can advance these forward and have an assessment as to the differential activity between SIK2, SIK3 and what does a combination of SIK2, SIK3 bring forth.

Having said that, I'm very confident that our know-how in the space of inflammation with this novel pharmacology and the fact that we were able to demonstrate evidence of clinical activity in psoriasis with a molecule that probably did not inhibit the target as much as we would have wanted to, but clearly showed evidence of clinical activity in psoriasis, not competitive, but still unequivocal.

And some evidence of biologic activity in ulcerative colitis, that to me bodes well for the future of this class of compound and inflammation. And I think Galapagos is well poised to be the leader in that space because we have truly developed a wealth of information that's going to put us in a great place to capitalize on this and figure out what is the true potential of this class of compounds.

And so stay tuned. We'll keep you posted in the next several months as for the development. I'm very positive where it's going to go. But at the same time, I'm very careful. I don't want to be overpromising and get ahead of myself. With that, I'll turn it over to Onno.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Thanks, Walid. Thanks, Brian, for the question. Yes. So for everybody who's not so aware of the situation we have in the deal with Gilead, Gilead has an option on all programs that Galapagos develops or in-licenses after conclusion of Phase II. After that, they have an option for the non-European rights. There's a license fee of EUR 150 million per program. And then we jointly -- after the option is exercised, jointly develop Phase III 50-50. So for programs that we develop internal, this is a very clear cut and a very good relationship.

If we acquire programs or companies, it gets more complicated, if the acquisition sum is substantial because it doesn't make much sense to do an acquisition of EUR 0.5 billion or EUR 1 billion and then opt out the non-European rights for EUR 150 million. So Gilead understands that and accepts it and has multiple times indicated that they're interested to jointly do an acquisition with Galapagos and pitch in for the -- for an upfront payment and milestone payments.

So that's something we need to, on a case-by-case basis, discuss with Gilead. And we exchange ideas on potential acquisition candidates on a very regular basis and licensing candidates. And yes, I hope to see this year, clearly, a deal where Gilead joins Galapagos in getting a product into our pipeline, of which Gilead then has the non-European rights or other or less rights than that, but definitely the American rights and they would participate in the acquisition cost.

Operator

The next question comes from the line of Laura Sutcliffe from UBS.

Laura Sutcliffe ***UBS Investment Bank, Research Division - Equity Research Analyst***

A quick question on the TYK2, please. You've mentioned of evaluating this in the context of a competitive landscape. But what are the parameters you're working with here? Does it have to be best in class for you to want to keep pursuing it? Or at the other end of the spectrum, are you essentially committed to keeping it going if it looks safe, no matter what? And then maybe just a quick follow-up on the Gilead piece. You restructured your agreement before. Are you in a position if both sides want that to restructure it again? Or is there anything that would stop you doing that?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

I'm sorry, was the first question on the TYK2?

Laura Sutcliffe ***UBS Investment Bank, Research Division - Equity Research Analyst***

It was, yes.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Yes. Sorry, you broke up a little bit. Yes. So for the TYK2 program, look, I think we are -- we're finishing Phase I, as we've indicated before. I think at the end of that, this will give us a sense of the sort of the safety data and tolerability that we get from that Phase I plus target engagement as evidence of some pharmacodynamic endpoints that we're looking at and also PK. And this will tell us truly what is the promise of this compound going forward.

At this point, we cannot ignore some of the regulatory environment that is operating, particularly around the JAK class in the U.S. When you have the situation in the U.S. with the JAKs being relegated to second line or third line after biologic IR and the fact that TYK2 signals through the same pathway as the JAKs, we think that going into indications like psoriasis might be a bit too risky for us, at least, at the stage of development that we're in.

Ulcerative colitis was another indication that makes sense to pursue with TYK2 inhibitors just because they block signaling through IL-12 and IL-23. And we know that these pathways have been clearly demonstrated to be involved in ulcerative colitis and inhibiting them actually produced clinical benefit. However, the data from deucravacitinib, which was recently released at ECHO and shed more light on the fact that they've used a total daily dose of 12 milligram and that the data were difficult to interpret in that biologic naive patients seem to be doing worse on drug versus placebo and maybe because there's a higher placebo response. But nonetheless, we need to take note of that.

And there were some numeric potential difference in biologic IR, but we need to take into consideration the totality of the data and compare it with the data that we have on our compound and see whether there's a way forward in ulcerative colitis. To me, it does seem like the bar is high and the level of inhibition of the target that was achieved with deucravacitinib, obviously was not enough to have a competitive therapy over there.

Having said that, TYK2 inhibition actually plays an important role in a number of diseases. We're evaluating potential indications in

diseases that are driven by interferon alpha, things such as dermatomyositis and polymyositis, lupus as well is one of those indications. And we expect that we will finish our evaluation in the first half of this year, and we hope to be starting a study towards the end of this year in one of these indications and the data support that. And I believe I'll turn it to Onno for the other question if I am not mistaken.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Bart, maybe you can answer it better because it's looking forward regarding a potential of the restructuring of the Gilead relationship.

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes. Look, Laura, I'm happy to say a few words. I would -- at the moment, we're not discussing with Gilead to restructure that contract. We are quite pleased actually with where it is. This is a contract that allows us to have a strong collaboration partner for programs that we bring to the end of Phase II. And it also is a collaboration partner for earlier programs in terms of exchange of knowledge. So there's no need or intent on our side to have any type of renegotiation of that contract.

The only case where -- and that's what Onno was alluding to before, where we probably need to sit around the table, will be a situation where we do a BD transaction which is something that we would collaborate on jointly, and we might need to alter the terms here and there to make that work. But the framework of the contract is quite proper, we believe.

Operator

The next question comes from the line of Matthew Harrison from Morgan Stanley.

Unidentified Analyst

This is Charlie on behalf of Matthew. I guess I have 2 questions. For the IPF fibrosis, can you talk about the Phase II kind of study design, its potential trial size? And do you think it can be large enough to see a signal? And then my second question is regarding the competitive landscape in the kidney disease program and what you need to achieve in 2023?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

I'll take both questions. It seems like you are referring to a particular study for the IPF fibrosis, and I'm not sure we are there yet. I think -- but maybe I can speak in general, IPF is really a very tough disease. There's huge unmet medical need, and we actually invested a lot of time and effort and built a great relationship with the community and frankly ran one of the largest Phase III programs with ziritaxestat.

So we've developed a lot of know-how, and we're still actually analyzing the data and looking into it to try and better understand essentially, can we identify certain patient population or sub populations that would be, have maybe less variability or have a -- would be at a rate of a higher rate of decline so that you can detect a signal a bit faster. At the end of the day, that is truly what defines your sample size that you would need.

So the way it is right now, you find that if you really want to power studies to detect a difference between drug and placebo for the Phase IIb study, you're talking about 200 to 250 per arm or maybe 200. Let's put it that way for about a year. And often, this is not the case. Often, companies go after smaller studies, something along the lines of maybe 80 per arm for 6 months and try to estimate what the slope might be and try to get at that point. It's a difficult disease.

And as a result, you will go forward into Phase III carrying a bigger risk because you haven't fully estimated your effect size during Phase II. And I think that's the nature of the development in this area. It's almost close to how we do it with Alzheimer's disease and other longer-term illnesses that you need to get after. And I think that's probably what I could say about IPF and fibrosis. We will be able to communicate more once we get better data from our ISABELA trial so that we can discuss more whether there are ways by which one can improve the signal detection method in those trials.

Regarding the ADPKD program, currently, really the field is quite open. There's a huge unmet medical need. The only drug approved is Tolvaptan. Our understanding is that there are significant challenges with that compound leading to the fact that in minority of patients, actually, with that disease, use it.

So there's -- we find that there's a very large room for unmet medical need to be addressed there. Our study is -- our first foray in that space, it's a 60-patient study, 40 on active and 20 on placebo. We're looking at total kidney volume by MRI at the end of 1 year. This might be a bit more sensitive as an end point to look at the size of the kidneys, and we estimate that we're going to reduce the cyst size. So as a result, we will have a reduction in kidney. But ultimately, approval will be driven by EGFR, and that is usually a much longer endpoint, maybe beyond 1 year, in many cases, 2 years to detect a stronger signal as well as a much larger sample size. And you might be able to estimate whether we're heading in the right direction from our trial, but our trial is really very small, and we need to be reasonable as to what we would expect from it.

From a competitive landscape, we're seeing some companies going into difficulties getting approval in that space. And I think that, at the same time, tells you that the development is difficult. But also there's a high unmet medical need because there's not much out there for these patients. So I think with that, I'll stop. And hopefully, I addressed your question.

Unidentified Analyst

Yes.

Operator

The next question comes from the line of Phil Nadeau from Cowen & Company.

Philip M. Nadeau ***Cowen and Company, LLC, Research Division - MD & Senior Research Analyst***

Onno, let me add my congratulations on your tenure. A question from us on the cystic fibrosis royalty. Can you talk a bit more about how that is calculated? Would you get the royalty rate that you mentioned on the overall revenue from AbbVie's cystic fibrosis franchise? Or do you get a royalty specifically on the Galapagos molecules, and therefore, for example, as currently constituted, royalty would be calculated off 2/3 of the revenue?

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes. Thank you for the nice words. It's a royalty on the total global revenue. So what we negotiated at the time is that if AbbVie would develop a product without any of our molecules in there, we would get a basic royalty. And if there was 1 component of the triple that originated from Galapagos, we would get a higher royalty and 2 out of the 3 would be the highest royalty, which is the [low] (corrected by company after the call) double digit. So that -- and it's all global sales.

Operator

The next question comes from the line of Jeroen Van den Bossche

Unidentified Analyst

I wanted to -- I have a question on Jyseleca, a little bit more in both rheumatoid arthritis and also in ulcerative colitis. Do you have any idea or can you give some more color as to potential patient populations for which the drug appears to be ideal, especially from a competitive point of view?

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes. Michele, do you want to take that?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes. So I'll start with that. So yes. So what we are seeing from the actual, I would say, actual use in the first data there is really about the fact that Jyseleca is being used in actually a broad population from treatment sequencing where we have the richest data from insurances, which is Germany.

We see, for example, that Jyseleca is being used in rheumatoid arthritis approximately by 1/3 of advanced treatment naive patients, so ahead say of anti-TNFs or biologics or other drugs, 1/3 is used after TNF inhibitors and 1/3 also after JAK inhibitors. So which indicates there is unmet need actually in all these different populations.

You see in terms of real use, it's very early, it's early days. So we had a very satisfactory launch in the first months in Germany and in the

Netherlands. But of course, having received approval in end of November, we don't have a depth and length of data to take any conclusions. I would add that we have running some also real world evidence studies, but of course, they are running that, and those would possibly provide interesting insights on the use of Jyseleca, especially in RA. But they will be then communicated and published at the appropriate scientific conferences in the future.

I don't know, Walid, if there's anything you want to add?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

No, I think that's what you've covered it.

Operator

The next question comes from the line of Peter Welford from Jefferies.

Peter James Welford ***Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst***

Just 2 quick follow-ups, if I can. Firstly, just coming back to the TYK2's '3667. Should we infer from the commentary with regards to your pursuing in healthy volunteers, a Phase I study with dose range finding that you're looking to get to doses well above those that they studied in the original psoriasis followed this study to potentially then assess whether or not there are -- there is a dose level where there is acceptable tolerability and I guess, better target engagement? And is it really a higher dose at the required outcome for them be able to consider pursuing further with that mechanism?

And then if I could just come back to the comments on business development. You mentioned that you're very active to find molecules and feed the commercial organization. I'm just curious, where is the need do you think greater or more urgent? Is it on the rheumatology side or is it on the gastro side? I appreciate the comments that Michele made with regards to synergies between the two. But just trying to understand, given those two footprints where you think the -- which part of the commercial organization is most in need of leverage?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

So very quickly, Peter, I'm conscious of the time. So no, for the '3667, the plan was to finish Phase I and allow to explore the full dose range so that we can have the -- we can go into Phase II with exploring the full dose range. It wasn't as a result of seeing certain observations or adjusting to certain limitations. Simply, we completed the preclinical studies, which allowed us to increase actually our dose-limiting margins, then we were able to go back and explore higher exposures there, and that will allow us also to demonstrate target engagement and on to whoever is going to take the IBD question next.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes, Peter, it's Onno. Yes. I think in general, we believe that in gastrointestinal, the opportunities are bigger. The unmet medical need there is higher. Clearly, less competition in RA, probably the most competitive field to play in. So yes, if we can find interesting opportunities in the IBD space, then that clearly has the priority.

Sofie Van Gijsel ***Galapagos NV - Head of IR***

Thanks, everyone. That's all we have time for on today's call. Please feel free to reach out to the IR team, if you still have questions. Our next financial results call will be our Q1 2022 results on May 6. Thank you all for participating, and have a great day.

Operator

That does conclude the conference for today. Thank you for participating. You may all disconnect. Have a nice day.