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Full Year 2022 Galapagos NV Earnings Call

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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos Full Year 2022 Financial Results Call and Webcast. (Operator Instructions) Please note that today's conference is being recorded.

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

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

Thank you, and welcome to the audio webcast of Galapagos full year 2022 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 Paulus Stoffels, CEO; and Bart Filius, COO and President. Paul will reflect on the operational highlights of the year and provide an update on our oncology and immunology franchise. 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 Paul and Bart joined by Michele Manto, Chief Commercial Officer; and Daniele D'Ambrosio, Head of Immunology.

And with that, I'll now turn it over to Paul.

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Good morning and good afternoon, and welcome to our 2022 annual results reporting. So thank you for joining. It goes without saying that 2022 was an eventful year at Galapagos. We made significant progress with good sales performance and further rollout of the commercial organization. We entered a new therapeutic area with oncology with the acquisition of Abound and CellPoint. We made significant progress in the regulatory review with Jyseleca on both on the testicular safety with the MANTA CHMP positive opinion as well as with the adoption of the PRAC regulation -- recommendations.

In our Capital Markets Day, we shared with you our vision on 2028 and our new strategy focused on immunology, oncology and accelerating time to market for drugs. But we also disclosed to you the further optimization of our organization with restructuring of 200 people out of the organization and a new organizational structure. And then later in the year, we were able already to highlight the first good data of our ongoing trials with our CD19 in NHL, and I'll also give you an update on the more recent data on CLL.

Galapagos remains and positions itself for strong growth in the future. We focused the pipeline on immunology and oncology, going in first-in-class to best-in-class, adding into that business development new opportunities, external opportunities, and accelerated our entry in oncology with CAR-T and with new modalities. We now have the ability to do cell therapy and also, on top of the small molecules, we can do now biologicals in our modalities. We continue to build on a long-term Gilead collaboration, both on the R&D side, but also on BD with multiple interactions and exchange of information between the 2 companies on the future for our collaboration.

At the end of 2022, we had a cash position of EUR 4.1 billion, and that gives us a strong basis to continue to work for an accelerated path to market with many several drugs in our pipeline.

Here, you have a top line view of our current pipeline. In filgotinib, unfortunately, Crohn's disease was taken out as we missed the co-primary endpoints in induction. We are excited to announce the start of a Phase III in AxSpA, and more of this will follow later in the presentation.

Also in our immunology portfolio, we added a CD19 CAR-T program in refractory lupus. And then in onco, as I early indicated, we made good progress on our CD19 programs with NHL and CLL as well as we are initiating imminently a study with BCMA in multiple myeloma program early this year.

In our oncology road map for 2028, as we showed on the Capital Markets Day, our short term is to validate decentralized CAR-T delivery models. We generated very encouraging initial data already in NHL, CLL as well as a very solid production method to be able to do this CAR-T production as point-of-care in hospitals.

In the medium term, the focus will be to further enhance our pipeline with best-in-class cell therapies, where we are looking both internally with the Abound research team as well as with business development opportunities and further scale up the decentralized CAR-T platform globally with launching this year at several centers in the United States.

In the longer term, we can further leverage the capabilities we are building today in small molecules, antibodies and also in CAR-Ts and continue to address unmet medical needs, most likely including CAR-Ts in solid tumors. This is a top line of the more recent data on the EUPLAGIA CD19 CAR-T Phase I/II in the refractory -- relapsed/refractory CLL. And what you see on the slide is the Phase I/II design in CLL with point-of-care, which we presented at the recent EBMT-EHA meeting in Rotterdam 2 weeks ago where we have 2 dose levels, which are currently being tested.

If you look at the slide, you see we have 3 dose levels tested in the dose escalation study, and that is then followed by dose expansion when -- of particular doses we select to do that for. We aim to present the top line data around mid of this year.

Next slide shows you the encouraging results we have. Overall, the response rate of the first 7 patients, 6 out of 7 had an objective response rate and had a complete response. And 6 out of 7 had a complete response. On the right scan, you see a patient with Richter's transformation that is in complete remission at day 28 after treatment with 1 dose of CAR-T. This is based on a PET scan evaluation, which can be done 28 days after start of therapy.

Going more in details of these results. Here, you can see that the swim lane plot, where 4 patients out of the 7 with CLL had Richter's transformation. And Richter's transformation is manifested as an aggressive lymphoma with a very poor prognosis. It are mutational alterations, where CLL transform into a more aggressive DLBCL. And today, the unmet need remains very high, and there are no currently available treatments. And overall survival is between 6 and 12 months when patients receive this diagnosis.

What you see here in dose level 1 and 2, that 4 out of 4 patients with Richter's transformation got a complete response within 4 to 8 weeks that is in -- 1 out of the 7 patients with CLL got a CD19 negative escape. Overall, this is very encouraging and gives us good hope that we can progress this '5201 CD19 into further clinical expansion cohorts as well as into pivotal studies later in the year.

If you go to the safety, then you see that so far, safety-wise, we see a very encouraging profile. No CRS above Grade 2 and no icons were

observed. And this is in line with the safety data for the CD19 in NHL, where we saw similar data as we presented last year.

Now going through the Crohn's disease diversity study. Unfortunately, in the induction phase, the 2 cohorts missed the co-primary endpoints of clinical remission and endoscopic response at week 10. Maintenance looked much better. Filgotinib 200-milligram achieved the co-primary endpoints of clinical remission and endoscopic response at week 58. Safety was generally consistent with the known profile of filgotinib with no new safety effects. But based on the data, we decided not to submit for approval with regulatory authorities in Europe. We remain fully committed to filgotinib in the approved indications, RA and UC, and now to the development of AxSpA.

On this slide, you see a progress in AxSpA, well, first of all, the data, the positive data from Tortuga, the Phase II trial in AxSpA, which was published in The Lancet in 2018, where we saw an immediate response starting from week 1 with a very good continued response up to week 2 and at the endpoint of the study. The AxSpA is an indication in spine and sacroiliac joint, a very heterogenous clinical feature. It's a high medical need. Only 15% to 20% of the patients get into remission, and limited options are available as well as no new mode of actions are expected in the next few years. So there is a real opportunity for us to expand filgotinib into that area.

You see the design of the study. It's going to be a study in radiographic and non-radiographic AxSpA comparing filgotinib 200-milligram with placebo. 238 patients will be enrolled and either treated with active or placebo. The endpoint, ASAS40, will be scored at week 16, and there will be in an open label up to week 52. The start is anticipated in Q2 this year, and top line data are expected in 2025.

This concludes my remarks on the clinical side. Bart, I'll leave it to you for the financials.

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

Thank you, Paul, and good morning, everyone, in the U.S. Good afternoon in Europe. Happy to be with you for the annual results, and happy to also give you some color to the numbers that we've completed the year with.

So let me start off with something that we're extremely proud of at Galapagos, which is the European performance of our commercial teams with Jyseleca. As you can see here, we are landing now the year at EUR 88 million in terms of sales in -- of Jyseleca in Europe. And as you remember, we've been able to increase our guidance twice during the year, and also this number is at the top end of that of that guidance range. And that within a year, where there was the Article 20 review of the entire class, we are extremely proud with this achievement. We're treating now 18,000 patients across Europe, and that number is increasing.

Two noteworthy events in addition. First of all, we got the feedback from the EMA or the CHMP opinion on the MANTA/RAy studies and how we can adjust the label for that. And that opinion was positive, and we'll be able to, with the course of this year, update the label accordingly. So we're very pleased with that. That point is off the table for the European markets. And secondly, we've also seen the outcome of the Article 20 review process, and it has confirmed that Jyseleca remains available for both biologic refractory and biologic naive patients and that any limitations are indicated for high-risk patients. So we're also pleased with that outcome for the entire class because we believe the class is a very strong Class IV patients with RA and UC.

And I'll give a bit further detail on guidance in a few slides in a few seconds. But indeed, next year -- this year, I should say, in 2023, we anticipate sales to go up again between EUR 140 million and EUR 160 million as a range is what we're forecasting.

Then a couple of words on the next slide on the actual financial results, and let me start off as usual with the cash position. As you know, we focus on cash burn, and our guidance was between EUR 480 million and EUR 520 million. We've landed at EUR 514 million, which you can see here in dark green. We always exclude from the cash burn -- cash out from acquisitions. The EUR 150 million here reflects the acquisitions of CellPoint and AboundBio earlier this year. And we also exclude currency effects from cash burn, which was a EUR 50 million positive. Compared to the Q3 results, obviously, that number is a bit lower. We've seen the dollar fluctuate quite a bit during the year very positively in the first 9 months, a little bit in the other direction in the last 3 months of the year. But overall, still a positive EUR 51 million contribution to our cash balance from the dollar-euro exchange rates. So we're landing the year at EUR 4.1 billion of cash on our balance sheet, which, as a reminder, reflects a good EUR 62 a share.

Then on the next slide, a couple of words on the P&L. We focus always on product sales and cash burn because we believe that these are

the strong metrics to focus on to evaluate Galapagos. A lot of other things are going on in the P&L. Some of these are accounting. For those of you that are following the story longer, you see a couple of these things coming back every quarter.

We always assess the development cost for filgotinib until the end of the development period. And based on that, we recognize the income that we received from Gilead over the last couple of years. And we recognize that, let's say, over that period, and that has generated EUR 174 million of revenues in the year 2022. And also the remainder of the Gilead transaction from 2019 is a recognition that we see every year coming back in our numbers, EUR 230 million on a straight-line basis. And as a reminder, there is still in our balance sheet about EUR 2 billion of revenues still to be recognized over the next couple of years, EUR 1.5 billion on the platform and EUR 0.5 billion on Jyseleca.

Then the product sales we discussed. On top of that, we have also royalties coming from the Japan business and a couple of sales milestones from our partnership with Sobi.

On the operating cost side, we've seen an increase in operating costs. There's a couple of things happening under the hood, if you like. As part of the discontinuation of some of the programs in fibrosis and kidney, we've also taken some impairments in the last quarter. Total impairment charge for the year is about EUR 55 million. Some of this was already in previous quarters, but that's a, what I would call, cleanup of the intangibles on our balance sheet from some of the discontinued programs. What also is happening here is that we've put some restructuring costs into our P&L for 2022. As Paul was alluding to before, we've downsized our organization quite meaningfully. And as a result, we've taken a charge in the 2022 P&L for this.

And finally, another important one, and that's been already noted several times during the previous quarters, is that, this year, 2022, we've had for the first time no cost share with Gilead on the commercial and medical affairs expenses. So that is no longer part of income or reduction of operating costs. As a result, you see sales and marketing costs going up a bit from year 2021 to 2022.

Net loss then comes at EUR 200 million negative, which includes the FX income, as I pointed out before.

Then guidance for the next year. I already spoke about sales. So between EUR 140 million and EUR 160 million, we believe, is feasible. That does reflect, I think, the current growth trends year-over-year that we've seen in 2022 and also now coming back in 2023. It also does include further launches in some countries in Europe. We know that UC has been launched in quite a few countries, but there are still a couple to go or a couple are also very early days in the launch. So we anticipate also some further UC launches throughout Europe to help us achieve that number.

And then on the cash burn guidance, obviously, this has been a big focus for us to make sure that we spend our cash wisely. When we did the R&D Day, I indicated that we would be reducing our cash burn compared to 2022. And actually, I'm happy to report that we're actually going to be able to reduce it by more than EUR 100 million to land at, if I take the midpoint, EUR 400 million of cash out for the year. And that's a result of the program discontinuations that we highlighted, also the Jyseleca performance, obviously, the organizational restructuring. We have a bit more friendly interest rate environment. And on the other hand, we're also investing in the other direction in the oncology buildup. Net-net, we should be able to significantly reduce our cash burn in '23 compared to 2022.

Then a few words on the overall business case for Jyseleca. Obviously, we were very disappointed with the readout of the DIVERSITY trial. And therefore, we have had to take out Crohn's from our peak sales estimates. And we now believe that we're going to be landing around EUR 400 million at peak, and that includes RA and UC, which are already in the markets, but also axial spondyloarthritis, which we plan to launch in a couple of years' time. So EUR 400 million is the net-net outcome of taking out Crohn's, adding AxSpA, but also taking into account any impacts from the Article 20 outcomes of the review that was done last year.

We still believe that the contribution margin can stay at 50% or even a bit better than that. So net-net, if you look at the peak year, previously, we were estimating EUR 500 million at 50%. We're now guiding for EUR 400 million at 50%. So the net-net impacts of losing Crohn's in Europe from our business case is about EUR 50 million at peak.

Full commercial structure is in place. Breakeven product contribution, we're shifting it with 1 year backwards. It's quite a small

adjustment. But in full transparency, we're just not going to be there at breakeven in 2024. We're losing a milestone on Crohn's in 2024, which was foreseen. And we're also paying a little bit higher royalties to our partner, Gilead, as a result of the loss of diversity. So net-net, we're going to be slightly negative in 2024 still, but we should be positive in 2025, and that gives us then an additional 10 years of patent exclusivity to benefit from the proceeds of Jyseleca to our company.

Then I'll conclude with an outlook on the clinical side for 2023 before we give it over to Sofie for Q&A. So key top line results that we're anticipating are the results in NHL and CLL with our 2 CD19 programs at the point-of-care. We've had some initial results there already. We will be excited to look at the full top line results later this year.

In terms of regulatory process also in the oncology space, we plan to have a submission for IND for the CD19 program, but also clinical file approval for the BCMA program. And trial initiations, quite a few. The AxSpA first patient first visit is anticipated as well as for '3667, our TYK2 inhibitor in dermatomyositis and lupus. Then we're also excited to start a program with our CD19 in lupus, and we'll initiate that trial also in the course of this year. We'll initiate the expansion cohorts in NHL and CLL. And then finally, the BCMA program will also get off the ground in the course of 2023. So a lot going on, on the clinical front.

And I'm sure that we're going to have a little bit of discussion of that in the Q&A as well. We're still very much looking out for additional business development deals both for clinical programs and preclinical programs. And we believe that, that's going to be an important part of the transformation journey that Galapagos is on currently.

With that, I conclude the opening remarks and suggest to go to Sofie and the operator for the Q&A. Thank you very much.

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

Thank you, Paul and Bart. That concludes the presentation of today's audio conference call. I would now like to ask the operator to open up the lines for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We are now going to proceed with our first question, and the question comes from the line of Matthew Harrison from Morgan Stanley.

Wenjiang Ma ***Morgan Stanley, Research Division - Research Associate***

This is Wenjiang from Matthew's team. So I am curious about the potential efficacy bar of the CAR-T program. So what would you see a potential response rate in a larger cohort and the potential duration of response that could beat the current SOC?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Well, I think from a -- what we can say based on the very small numbers, 2 times 7 patients, which we have today, fast expanding in clinical that the initial response rate and complete response rates are very high. That probably has to do with a good quality of cells and a very good expansion of the cells. What we don't know is the duration because most of the time, the failure is happening because of CD9 (sic) [CD19] escape. The fact that we have very good complete response rate is predicting that we might expect a good overall durability, but the clinical trials have to show that.

So I think so far, so good. The clinical trial results midyear, where we'll have the full dose finding as well as some of the expansion cohorts, will give a good indication on duration. For now, we stay with the response rates we see in the small cohorts, what we have observed in NHL and CLL.

Wenjiang Ma ***Morgan Stanley, Research Division - Research Associate***

Just a follow-up with the CD19 program. Can you talk about the case to use the CD19 in lupus? And are you looking at other autoimmune indications?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Yes, there was a study, which was done by a German group which was published, and I think that's very well known in 5 patients, where to many of our surprise -- to many of us who are very surprised with a very positive outcome of that study with full responses in these people with very advanced lupus.

And so it's an exploratory study, and so we are going to try to repeat those results with our drug. There's a good chance that this type of medicine, this type of indication can be tackled with the CD19 CAR-T, but to be confirmed. So far, we know of 5 patients with good results, 5 on 5. Not our drug, a drug developed by Erlangen, a university in Germany. But it's an initial study exploring efficacy in lupus with CD19.

Operator

The next question comes from the Phil Nadeau from Cowen.

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

Congrats on the progress last year. Sticking on the theme of the CD19 CAR-Ts, can you discuss what you think the regulatory requirements will be for CMC for point-of-care manufacturer? Is there any visibility on what the regulators will require in terms of, let's say, visits, inspections or verification in order to get the CD19s approved?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Yes, it's very early, of course, to explain full CMC requirements. But what we see in the clinical trial today, we are able to do a CD19 in point-of-care, fresh cells, 7 days vein-to-vein with all the necessary quality controls and quality release to make the release happen in the clinical trial environment. We are further automating and simplifying the quality control testing. We have a combination of a point-of-care system combined with a digital data system, which records all of the quality control testing as well as the manufacturing parameters. And under the clinical trial agreements with the government, today, we can do this in point-of-care.

What is required is a GMP environment because certain handlings have to be done in a GMP environment. We select, at the moment, the centers based on GMP capabilities, and that works really well. They are -- at least in Europe, they are expected by the authorities. So there, I think we are safe. We are in a good position.

In the U.S., most likely the strengthening of GMP capabilities in hospitals need to happen. That's not that a big step. It's doable. So from that perspective, I think it's important that GMP capabilities are there.

What we'll have to discuss with the regulators at the time of approval is the release criteria on potency, on sterility and also in our Phase III critical -- clinical trials on what will be required to release in point-of-care testing. So we're -- this is all in the making. But currently in clinical trials, we are able to do it in a very practical and pragmatic way with approval of the authorities.

Operator

And the question comes from Peter Verdult from Citi.

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

Pete Verdult from Citi. Two questions, please. Paul, just wondering if you've done any, earlier in the team, early post mortem on diversity and reasons for the failure. Anything you could share there? Any thoughts there would be helpful.

And then secondly, just on BD. Would you like to -- I mean, we're approaching a year of your tenure. Would you like to do more? Or could you characterize the environment for doing BD, how conducive or not is it in terms of finding the sort of assets you're looking for?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

I missed on the first one.

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

Do you want me to repeat the first question?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Yes. No, that's too early. We went into a deep dive. It's very recent. We went into a deep dive on the data to be able to come to the conclusion. We are now looking at what happened in the study, why negative, why the induction was negative, but also the maintenance was positive. And more to follow on that. More work to be done on the details of the data before coming with the conclusion there.

On the BD side, we have done and we are doing very extensive evaluations. First, as you know, we have done CellPoint and Abound already back in June in the -- when we brought them onboard. They are now fully integrated. We are building on that capability of cell therapy to get to next-gen cell therapy potential, where we are evaluating multiple opportunities in the world. I think that's one. But on top of that, we are evaluating multiple opportunities in other modalities in oncology as well as immunology.

The team is very busy. The environment is good for us, I think, but it's also how much can you take on with the company in a very short time with going through a restructuring as well as bring on-boarding significant new teams. I think it's going well. More to follow. The next year will be a year of on-boarding, acquiring and on-boarding more assets.

Operator

We are now going to proceed with our next question, and the question comes from the line of Brian Abrahams from RBC Capital Markets.

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

I was wondering if you could expand a little bit more upon like what we should be looking for from the full NHL and CLL top line CD19 CAR-T data this year in terms of maybe a little bit more in terms of the dose levels, patient numbers and duration of follow-up.

And then what's the latest on how you guys are thinking about a potential registrational path? Is there still an opportunity to accelerate development and perhaps a more niche indication? Or do you plan to go broad?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Well, the 2 studies, CLL and NHL, are progressing in parallel. Each of them go with a study of 15 patients in the dose escalation, where we study a low, medium and high dose. And then depending on the doses we choose, 30 patients per cohort in the expansion. So you could expect around in the range of 45 patients. If you have one in each of the different -- in the 2 spaces, that is what we could expect. .

The studies -- the first NHL study is ongoing from, let's say, mid this year in -- sorry, for last year 2022. So there, we'll have up to 1 year response. The CLL started somewhat later, but at the same time, I think 9- to 12-month response time data you can see. So in total, between each of the 2 disease areas, CLL, NHL, we will present that type of top-level data mid this year.

What we see with the use of the point-of-care is that it allows physicians to treat very sick, very advanced patients with very short life expectancy. And that is an area where many of the centralized produced CAR-Ts don't have an answer for because of the time the patient doesn't have any more to receive their therapies.

And so we are going to discuss with the regulators to see what is the -- what can we -- what type of study do we need to do in the really urgent need, high medical need, where there is no good solution anymore for patients. We see patients with 1, 2, 3 months of life expectancy still getting good outcome with a 7 days vein-to-vein therapy in the hospital. So that's where the first step of our programs we'll focus on, is the extreme high medical need where we have a differentiated product, which we can bring with life-saving prospect.

What is very particular in the CLL is that this Richter's transformation is a disease today, which is not solved by any therapy. And that gives us an ability to look into, is that an indication we can pursue for accelerated review -- breakthrough designation accelerated review with authorities to be discussed. We are not yet there to submit the data, but that could be an opportunity to go fast and bring something to patients, which is really transformational, life-saving and addressing a very high medical need. So top line, mid next year, we'll have a good answer on all of the things I just lined up here in the discussion.

Operator

We are now going to proceed with our next question, and the question comes from the line of Jason Gerberry from Bank of America.

Unidentified Analyst

This is Chi Fong for Jason. I guess first one, Jyseleca. I'm hoping you can provide a bit more color on the guidance change on peak sales. Earlier in the call, you mentioned old guidance made EUR 50 million peak sales for Crohn's and new guidance factor in impact from Article 20. Could you help us understand your assumptions on the contribution of parts among these 3 indications?

And then second, on the '3667. Arguably, the TYK2 landscape has evolved quite a bit over the past 6 to 12 months following the deucra label. Could you talk about the potential point of differentiation with '3667? Does it have any distinctive molecular features, say, selectivity, potency or PK, that you think could stand relative to competitive programs?

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

Yes. So Michele will take the first question on Jyseleca, Chi. And then Daniele, you can maybe chime in on the question on the TYK2.

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

Yes. So sure. So on the Jyseleca model, I think first, the changes from peak sales, EUR 500 million to EUR 400 million, and that's a difference of EUR 100 million. And then the contribution margin at peak is 50%. So that's EUR 100 million sales transfers into EUR 50 million contribution. I think that's the EUR 50 million that Bart mentioned before, so to give the context of the EUR 50 million.

Then, of course, we move from EUR 500 million to EUR 400 million. The moving parts are -- I mean, the big blocks are Crohn's going out, AxSpA coming in and I would say some marginal adjustments because, of course, of the impact of Article 20. So let me give some colors on these 3 components.

Crohn's going out. We did not give specific details on the composition of the EUR 500 million before. But as a reference, we also shared that we see the market of EUR 3 billion for RA, EUR 2 billion for Crohn's and EUR 1 billion for UC. So Crohn's basically accounting from 1/3 of that market, so that gives us a sense of direction of how much Crohn's was part of the EUR 500 million. So that's what we lose by not approving in that indication.

On top, we come with the AxSpA. In Europe, AxSpA, we can forecast at the time of launch will be a market worth about EUR 1 billion. And then there also, we remain with the previously mentioned 8% to 12% market share to capture in that market. So that's a positive that comes in.

And well, the last part is, of course, Article 20. That came in, and it's now the label about to be approved. The outcome is ultimately a positive outcome because it doesn't bring the limitations that the FDA, for example, brought in the U.S. But still give some attention to patients with risk factors, and that, of course, has a marginal impact on our potential in our RA, UC and ultimately AxSpA. So that gives the negative further adjustments that ultimately lands on the EUR 400 million. Daniele?

Daniele D'Ambrosio ***Galapagos NV - Senior VP & Head of Immunology Therapeutic Area***

Thank you. Yes. So on '3667, yes. So of course, as you said, we were very encouraged by seeing the outcome of the label with deucra with -- for TYK2, which differentiates clearly from the German JAKs.

On our compound itself, we have a kinase domain inhibitor therapy for TYK2. So that's different from some of the other allosteric inhibitors that, of course, have been developed now by Nimbus or by Ventyx. But what's interesting is when we actually profiled our compound in relevant biological systems. And particularly of cells and looking at cytokine signaling, we do see a unique cytokine inhibition profile with our compound and where we see a very strong inhibition of interferon alpha at the doses and the exposure that will correspond to our clinical dose, which was -- which performed very well in our initial clinical study in psoriasis.

And we were encouraged by that. And basically, based on those data, we felt that the best indication, the best fit for the profile that we

have in our hands are diseases, which are driven by interferon alpha. And basically, when you look at basically dermatomyositis and lupus, we know -- we understand that interferon alpha plays a very important role in the photogenesis and the development of these diseases.

And that is why we decided to focus on those. And we believe that, of course, we have to understand it. But we believe we have a very good profile to fit, and we'll -- that's why we're going to run the studies soon to have the first patient in, hopefully in dermatomyositis first and then followed by lupus.

Operator

We are now going to proceed with our next question, and the question comes from the line of Rosie Turner from Jefferies.

Rosie Turner ***Jefferies LLC, Research Division - Equity Analyst***

Maybe just following up on Pete's question around business development. Can we just clarify, are you still looking at kind of very much earlier stage assets? Or is there a potential that it could be something kind of mid-stage?

And then thinking about your Richter's transformation patients, was it a conscious decision for targeting that population within these kind of 2 early-stage trials? And are you aware of anybody else who is -- I mean, I appreciate there's nothing currently on the market for these patients. Are you aware of anyone else that is looking at this area?

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

Yes. Rosie, let me first take the question on BD and then, Paul, you'll take the question on the Richter's patients. So I think it's unchanged compared to focus what we've expressed before. So we're very much interested to do either licensing or M&A in a stage of development where there's still value creation to be made by Galapagos. So you'll not find us very quickly in a major competitive bidding process for a late-stage asset at high values. We think we should be more on the early clinical.

I would not rule out mid-stage, as you say. So I think Phase II is definitely part of the equation. Ultimately, what also matters here is time to market and not just the actual precise stage of the molecule. We do also want to make sure that we have some assets in our pipeline that still can get to approval stage within the decade like is the case for our existing pipeline. So maybe that helps.

So all in all, still early stage Phase I, Phase II. Definitely, still be on the agenda. We're also looking at preclinical opportunities because in some areas, that's definitely also interesting. And lastly and finally, also the European, let's say, assets for, let's say, leveraging our commercial infrastructure are very much also part of the focus of our BD teams.

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Yes. On the Richter's transformation, what we observe is that because of the point-of-care and the availability of a 7-day vein-to-vein, at the moment in the studies, people are brought to the hospitals where the -- where we are able to treat those. So that is, first, an observation.

If you ask, would we only target Richter's? Most likely not. But it would be the aggressive form of CLL, whatever that definition embraces as well as Richter's transformation to have a -- those people who have a short-life expectancy with very aggressive disease who can benefit from the point-of-care advantage of having a 7-day vein-to-vein in the hospital available.

Currently, we are not aware of anybody focusing on Richter's. Maybe with our data, some other companies would start doing that. But I think the very important thing is the 7-day vein-to-vein, the very short time access for very advanced people, which is difficult to match with centralized production. That is where we -- good product, combined with the decentralized and 7 days vein-to-vein, fresh -- using fresh cells is probably the combination which gives the benefit to these patients.

Operator

(Operator Instructions) The question comes from the line of Dane Leone from Raymond James.

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

Congrats on all the progress. I just want to follow up on the TYK2 question. I know there's been some questions earlier in the call, but let me pose the question this way. Clearly, there's a growing investment in the space as a drug class that might be a better oral solution in certain autoimmune inflammatory disorders. What was able to be achieved with JAK inhibitor class? Later this year, we'll get proof-of-concept in Crohn's and ulcerative colitis from the deucravacitinib effort over at Bristol. And clearly, Takeda is going to put a lot of investment behind the Nimbus asset that they've recently acquired.

So the question for your team is, currently, we're waiting on the start of the dermatomyositis study, but there really has not been a lot of messaging on how that program would expand around that. Is your view that, one, it needs to be more of a measured approach to developing the Galapagos TYK2 inhibitor, maybe given the experience with filgotinib or is there going to be an approach where you're looking to go in indications maybe that the other 2 players are not going to be pushing into that might be a lower investment from both money and time to get to market? Any insight there would be greatly appreciated.

Daniele D'Ambrosio ***Galapagos NV - Senior VP & Head of Immunology Therapeutic Area***

Yes, thanks. Maybe I can take this question again. So as you said, there will be inflection points and information that will come during the course of the year. So we'll obviously look at that very carefully. But at this point, given the data we have in our hands and having seen the data from the competitors so far, we believe the best scenario for our molecule is the indication we are currently pursuing. That doesn't mean that we are not going to reevaluate potential other opportunities.

But we really see based on what we understand of the profile that we have in our hands and the competitors that the 2 indications have a very good benefit risk profile, very high unmet need. And I think, again, a good fit with the mechanism of action that we see with our molecule and the preferential inhibition of interferon alpha versus, for example, Interleukin-10, CD19 inflammatory cytokine, which we've seen differently inhibited by the other molecules. So we really feel this is the best home for this compound at this point in time. That might change, of course, with new data cue, but this is the current situation.

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

So maybe if I can add 1 or 2 words on this one beyond the clinical choices. I would say, Dane, that we're carefully selecting now the indication that we go after for the reasons that Daniele had just described. We believe going now, for example, after psoriasis, 5 years after deucra, given the stage that we are in today. It's not the most logical thing to do, but we are very keen, obviously, to first see the data in both dermatomyositis and lupus to understand exactly what we have in hand before we make final choices and further choices in terms of development.

So just to say, we're very keen and interested in this field. We like the asset that we have a lot. We welcome the fact that the big players are also stepping in to this field. And we'll make sure that we develop this wisely and make our choices over time. I hope that helps.

Operator

The question comes from the line of Sebastiaan van der Schoot from Kempen.

Suzanne van Voorthuizen ***Kempen & Co. N.V., Research Division - Analyst***

This is Suzanne on for Sebastian. First, regarding the mid-'23 data sets that you will present for NHL and CLL. Can you clarify what number of patients we should be expecting to be included in those data cuts? Should we expect that all dose expansion patients are included next to the dose escalation, even though there will be shorter follow-up for those?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Well, the final data of the dose finding will be presented there. And then whatever data we have on the dose expansion will be included on the safety side. We hope to be able to have already significant durability data from the dose findings. Mid in the year at the point where we had that towards the end of the year, we'll have more data on the longitudinal follow-up of the expansion cohorts.

Suzanne van Voorthuizen ***Kempen & Co. N.V., Research Division - Analyst***

Got it. Got it. And just to double check, should we also be expecting an announcement on the recommended Phase II dose for those 2 studies in between now and the mid-'23 data presentation?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Head of R&D & Member of Management Board***

Not between now and the mid-'23 data presentation. That will be part of the regulatory discussions happening later next year.

Suzanne van Voorthuizen ***Kempen & Co. N.V., Research Division - Analyst***

Got it. And then maybe a final question regarding your breakeven point being moved out to 2025 versus 2024 previously. Just to understand, given Crohn's was not expected to be a large contributor to 2024 per se. Can you elaborate on the dynamics that led you to adjust your forecast and if it's more relating to lower sales expectations or higher sales and marketing costs?

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

Suzanne, no, it's actually related to the fact that in 2024, we were anticipating also a milestone on Crohn's approval that we're not going to have. And we're also, as part of the 2021 agreement with Gilead, we're also paying slightly higher royalty to them now that the total market potential is a bit lower. So those 2 effects would basically dip us just below the breakeven, and therefore, we need to extend it to 2025. It's not big numbers. I would say up to maximum EUR 50 million negative for 2024. So these are, let's say, small adjustments. But in full transparency, we wanted to indicate that to the Street.

And by the way, this does not affect the overall cash burn perspective that I laid out back in November at the R&D Day in New York because we do believe that our actual cash spend on the rest of the business, as we've now indicated, the reduction of more than EUR 100 million for this year can definitely offset that extension of the breakeven point.

So overall cash profile for Galapagos is unchanged. Diminishing cash burn for the short and medium term up to a level where, ultimately, Jyseleca could contribute roughly EUR 200 million a year in terms of cash. And that number, as I indicated earlier, is a bit lower than what we had anticipated when Crohn's was still around. I hope that clarifies.

Operator

We have no further questions at this time. I will now hand the conference back to Sofie Gijsel for closing remarks. Sofie, over to you.

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

Thank you very much, operator. So that concludes today's earnings 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 2023 results on May 5. Thank you all for participating, and have a great rest of your day.

Operator

This concludes today's conference call. Thank you for participating. You may now disconnect your lines. Thank you.