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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

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PRESENTATION

Asad Haider - *Goldman Sachs Group Inc - Analyst*

All right. We are just about time, so we can get started with our next session. My name is Asad Haider. I'm the Co-Head of the Healthcare business unit here at Goldman Sachs and the US pharma analyst. I'm very excited to be joined by Tom Cavanaugh, Group Company Chairman of North America Innovative Medicine over at J&J. Tom, thank you for being with us.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Thank you.

QUESTIONS AND ANSWERS

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Say again. So just maybe just to kick off very exciting times for J&J. You have multiple new products sprouting across the Innovative Medicines business. Joaquin made some comments last week saying again that The Street is continuing to underappreciate a number of these new products, both on the immunology side as well as in oncology.

So before we start to unpack some of the specific products in which I have a number of questions I'm going to hit you with. Maybe just make some high-level comments on what you've been most excited about.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Absolutely. Look, first and foremost, as we said last year and over the last year, STELARA was a thing of the past. We're going to grow through the loss of exclusivity of STELARA, something that many companies have not been able to do with their biggest asset and really look at that 5% to 7% compound annual growth rate over the next five years. And we're well on track to really go for that upper end of that, I would say.

Just looking at our Q1 results, we delivered $15.4 billion. This is our fourth quarter in a row delivering over $15 billion. We have 7% growth. In the US, we had roughly 10% growth and it excludes STELARA, it's 17% growth operationally and in the US, 22%. So we're really excited about the momentum that we have coming into 2026. It was described as last year as a catapult year, but this year, we said '26 is going to be better than '25 and '27 is going to be better than '26.

And we're well on the way to do just that. I think first and foremost, we had 10 products over double-digit growth in Q1 and some exciting product launches, which I know we'll get into. So I'll maybe leave it to you to ask some questions, and we can go from there.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Well, let's go right into some of the exciting product launches, starting with TREMFYA. It grew 64% in Q1 with leadership in new patient stuff in IBD, we look at weekly scripts, the momentum seems to be continuing. So just give us an update on what you're seeing broadly speaking in terms of overall market dynamics and really where the share gains are coming from?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yes. Yeah. So first and foremost, with TREMFYA. It's the only dual-acting IL-23, so it's CD64 and IL-23, CD64 is the source of inflammation. Why I say it, it's very important. We like to say tissue is the issue. If you can penetrate that tissue and hit at that target, you're going to see differentiated results, and we are seeing that. But if we just take a step back and we just think about IBD, we're just in the early phases of that launch. In IBD, the IL-23 class is the fastest-growing class in IBD, both in UC and CD.

And I would say it's barely penetrated. So it's about 20% to 25% penetration. So significant opportunity ahead of us in IBD and in psoriatic disease, whether it be psoriasis, psoriatic arthritis, a little bit more penetration, but still the fastest-growing class. In IBD, we're the fastest-growing product. In IBD, we are now the -- what we call the induction share leader in IBD with TREMFYA. And we're just about a year into launch, full launch with both CD and UC.

And I can tell you the excitement is really profound. And the team is executing across all measures. But I would say we're seeing a differentiation from our customers and from the uptake. A lot of it is that we talked about and highlight a little bit of the molecular structure showing that results. It's the only with subcutaneous induction, both in UC and CD. Highest endoscopic remissions in UC.

And then just recently coming out of DDW, we're really excited about this new data. It was the FUZION trial. It's basically perianal fistulizing Crohn's disease, represents around 25% of the population. And it's a population that really is not getting treated by IL-23 is typically being treated by REMICADE because REMICADE is the only product 20 years ago that has demonstrated success in this population. So this is the first time product TREMFYA has shown to differentiate in this population, similar to the way REMICADE did, which we're quite familiar with.

So we're really excited about that opportunity. It really can untap there. It also leads to the differentiation why we're so excited and feel confident we're going to be over $10 billion. And the last thing I would just say is as we think about psoriatic diseases, we'll get to it. I'm sure with ICOTYDE, as tides rise. And we're seeing significant growth also now an acceleration in psoriasis and psoriatic arthritis. And a lot of it is off the APEX data has shown that TREMFYA is the only IL-23 that shows the inhibit structural damage. That 30% of the population in psoriasis that have underlying joint disease.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Before we get into ICOTYDE because that is my next question, maybe just -- you talked about the subcu. AbbVie is going to be in the market at some point in the next several months with their subcu version. Just how do you think sort of from a competitive dynamic perspective, things could change that?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. I think we need to understand both in UC and CD, if there's any differences there, in dose and efficacy, in, I would say, longer-term results. But look, they're a formidable competitor. We feel very confident we have broad access. We have significant momentum. We have a molecular differentiated product, and we're here to compete to win for patients.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Fantastic. All right. Well, let's go right to the ICOTYDE launch. This is obviously something that's very much in focus. It's probably one of your most in-focus new launches. And on the mid-April earnings call, you provided some really helpful early metrics on the launch. I think you said 1,500 patients with prescriptions have been written over 1,000 unique prescribers shortly after the approval. So I guess any updated thoughts on how the launch is tracking? It seems like IQVIA may not be capturing all the channels right now. So any new metrics to share in terms of how things are going would be helpful.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

I would say some of the new metrics we're going to have to wait for our earnings call to release those. But I will share some qualitative and early insights that we have in the launch. I think it's important because I do think we're, one, incredibly excited about the launch of ICOTYDE. You heard from the earnings call, some of the early indicators, I can tell you we have roughly 4,500 prescribers now.

And the data that you were -- you quoted is our hub services. So we have fully dedicated hub services where we're able to get this information in. And quite honestly, if the patient has commercial insurance, some sort of commercial insurance is diagnosed with it and is of age, they can get the product in 24 hours. So they can get it through our hub services and then there's samples obviously available as well. I bring this up because ease of access is very important, and that's where they're getting the trial and able to understand is this product, what's right for them.

And it is really the sweet spot. ICOTYDE and we're hearing it from our customers. I've been able to engage with many of our providers at either AAD or a conference, CCD that was down in Florida just recently. And the insights, what we're hearing intent to prescribe and awareness in just two months has jumped 20 points. So you're seeing intent to prescribe and unaided awareness similar to what you see with current market products. We're fully focused from a commercial perspective, obviously, from a sales and marketing perspective, that's without even a DTC campaign.

So there's still huge opportunities ahead of us once we engage the patient and create awareness there. The provider base is -- typically what we're seeing is some of those that are treating in the earlier diseases. First-line systemic is where it's beautifully positioned, but advanced practitioner providers, some primary care and I would say, obviously, dermatologists.

And a lot of that is because, one, there's the ease of access, complete skin clearance. Safety is fundamental when they're looking to just switch from, say, a topical to a systemic treatment, placebo-like AEs. And then last but not least, that became quite exciting for many of the providers, no mandatory TB testing.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

When does the DTC campaign start?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Soon.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. And what can you tell us about the patient profile? I mean treatment naive versus existing oral [TCs]? Is there any sort of from -- impact from -- on the current injectable biologics, like where are the patients coming from?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. I'd say roughly, I would say, 60-40. 60% predominantly what we call systemic naive and about 25% of that sourcing probably from -- 25% sourcing from the orals.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

And I guess, how should we think about ICOTYDE's opportunity in IBD in the context of rapidly involving market combinations, emerging orals, ABVX, et cetera? Like how are you thinking about that?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. So we're obviously aggressively looking to accrue the trials in both UC and Crohn's disease. Coming off of our Phase II data, we've been very confident about the target and the product as well as the dose that we're going to be delivering and see truly being a unique opportunity for us to first really targeted oral therapy that has the trifecta: efficacy, safety, and convenience, that I do believe is going to hit an untapped marketplace right now. So those that are moderate to severe that may not be receiving treatment or subtherapeutic treatment, again, similar to psoriasis as an opportunity.

And in future, there's definitely combinations. I mean we are the first one to look at combinations in IBD with 4804. I'm sure you probably have some questions around that. But I'd say that absolutely in select populations. The ultimate goal here is remission. And that is truly what we need to do in IBD is really get to the highest level of remission. And most of that will be in combinations in the future. ICOTYDE is a wonderful product to be able to combine with because of everything I just said.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

And I guess when you make the statement and Joaquin has made the statement that this could be one of your biggest drugs ever, any high-level quantitative framing on either the math on how to get there, or is that purely based on PSO and PSA? Does it require additional indication expansion into the IBD indications?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. I think our current development plan will get us there. And a lot of it is kind of I alluded to. If you think about a population, let's take psoriasis. You have roughly 3 million to 5 million patients suffering from moderate to severe psoriasis. 75% of them are cycling through therapies that are not on advanced systemic treatment. 25% are.

So if you just think about the total size of the marketplace, that 25% is the ones that we're competing in today with TREMFYA and the likes. This true untapped marketplace is that first-line systemic treatment. So that just opens up a large opportunity. And you take that same mentality or approach in IBD.

And IBD, they're a little bit more aggressive. They are really trying to treat and really hit that underlying disease. But I do think the systemic treatment of an IL-23, such as ICOTYDE, truly will unlock that opportunity. So sky is the limit.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

And when can we expect to see the data for ICOTYDE head-to-head versus STELARA?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

We should be getting the data in this year and then read it out at an upcoming congress.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Let's move to 4804, you set me up for that. So you had the results of these recently presented DUET trials. I guess they fell short in the overall treatment population, but there was a pronounced effect in the subpopulation of highly refractory patients who cycled through treatment.

So how should we be thinking about this program and the size of the opportunity in the context of -- I think Joaquin framed this as a third blockbuster in your immunology stack on top of the dual powerhouse of TREMFYA and ICOTYDE. So maybe just with that framing, talk to us about this program.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah, absolutely. We're very excited about 4804. Really co-antibody targeted both IL-23 and TNF. And you mentioned the data like it's really important to do this trial so that we can understand the data in the population by which it is the most effective. And this is what we found.

I think if you think about it, the population, let's call it, refractory IBD. This is a patient population that -- roughly at this time, there's roughly 20% of the patients have seen two lines of therapy already if you just take the market today. So right there, it's close to 1 million patients of an opportunity.

If you think about it, truly high unmet need where they really need to have high endoscopic remissions or high response rates. That patient population, high unmet need, and then the data supports really that market opportunity. And that allows us also as you think about the marketplace, typically, eventually, longer term, I do believe it's going to be like oncology, use the best first and get the highest remission.

But in these chronic diseases, I do think you're going to start with a product, see if that product works, they're going to cycle through it. And if they're not getting the treatment they want, they might move on to another one and then probably get more aggressive. And that's where a lot of the KOLs are doing it. Sometimes, I would say, off label. They're looking at combination therapies already in the clinic. I think that's where 4804 is beautifully positioned looking at as co-antibody therapy in that line two-plus in heavily refractory population. I do think that value recognition will be there globally as well.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

So let's unpack that a little bit. First, just in terms of just the long-term coexistence of this compound with TREMFYA and ICOTYDE. Where does this live?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yes. I think if you just think kind of how I described like the patient journey, patients diagnosed with IBD, CD or UC, they're coming in, they're probably going to get depending on what -- when they get diagnosed, it could be ICOTYDE, it could be TREMFYA. If they're not getting the results they need, they might cycle through another alternative mechanism of action and then maybe then -- or not maybe, that is beautifully positioned in where 4804 will be.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

All right. Let's jump talk about nipocalimab. That's another potential new product cycle that we certainly are very excited about. You've had the launch in MG, you had a priority review in wAIHA. You recently presented very good data in lupus, numerous readouts in 2027. So help us frame the opportunity for this compound unfolding and from which indications you see the largest contributions.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. I think IMAAVY , as we've highlighted before, we do believe it to be molecularly different. We do have the fastest and the deepest IgG reduction. And why I bring that up is that's why I do think it's translating into many of these other diseases that we're looking at, whether it be, as you just highlighted, we're in hemolytic anemia, Sjögren's disease, lupus, MG and then if you look at maternal fetal, highly differentiated. It's basically from a safety perspective.

So if you think about MG, we're well on the way of the launch. We just received full J code at the beginning of the year. We're seeing definitely uptake, the fastest-growing biologic in MG. So we're well on the way there.

wAIHA is a unique opportunity. Nothing has proven or approved in that population. It's roughly 7,000 patients in the US highly unique population, and we're quite excited about the priority review and the recognition from the agency on just the medical need, also shows differentiation. I do believe really some of these room disease is where it's going to really unlock the potential and why we do believe it's a $5 billion-plus asset.

If you think about lupus, lupus, roughly 500,000 patients in the US, really nothing that's available there. It could be the first FcRn antibody to show demonstrated an effect in lupus and the data that you just saw at EULAR is pretty amazing. You take that as an opportunity. We have -- I believe we have a fast-track designation for lupus. We then looked at Sjögren's disease as well, the most prevalent. And if you think about that, that's breakthrough therapy designation that we have already.

So the excitement is there that we do believe the data will play out, and that just taps a huge opportunity for us as we think about just in those diseases. Highly prevalent diseases of women, of child-bearing age, so that's why I brought up maternal fetal approaches that we have in HDFM, and it just truly differentiates the product and the safety side of things as well as the efficacy across the other indications.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Terrific. Looking forward to seeing that program progress. I want to move to oncology, but before we do that, I just want to take a pause and see if any questions on the immunology side.

All right. Let's keep moving. So oncology, I guess, First, just starting with RYBREVANT, Joaquin called this out as one of the products that still remains underappreciated. You had some good data at ASCO. Recently, consensus numbers still have this regimen, RYBREVANT plus LAZCLUZE doing about $4.4 billion in 2030, peaking at about [5%] and change. So where do you see the disconnect there?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah, I think a couple of things. I think first, if we just think about lung cancer, we're still in the early phases of the launch. And in the US, I mean, we're literally -- we received approval for FASPRO, our subcutaneous formulation at the end of last year. So we should receive a permanent J code July 1. So if you think through that from a reimbursement perspective.

And as well as we've come to understand and have the data now that support and ASCO was part of that is really looking at the long-term survival that we see in exon 20, which really differentiate RYBREVANT in a population that's undertreated and really, there's not much for those patients.

And then in a common EGFR, we're looking at significant uptick in share growth that we're seeing already globally and then in the US as well. One in four patients are seeing RYBREVANT-LAZCLUZE in that setting. So really now, we're anticipating the five-year survival next year, that will be differentiated as well. We do believe to support where we're seeing it.

But also the absolute necessity of using RYBREVANT. I think that is actually coming across with our provider base. Especially, and I'll get to some of these follow-on indications, really looking at changing the underlying biology of the disease. And that is something that I think is differentiated.

We can't just say use chemo or not. No, it's RYBREVANT should be essential for the treatment of EGFR non-small cell lung cancer and it's in combination with LAZCLUZE in the frontline setting because you have to use your most effective and really look at change the course of the disease, and that's when you can look at it as a RYBREVANT-LAZCLUZE combination in that frontline setting.

Now I bring up just recently, we presented the data for head and neck and have submitted already or -- and received priority review from the agency for line two for head and neck cancer. And I'll tell you the feedback that we have from the providers, especially, I mean, they have not seen anything like this as a single agent showing a 42% response rate, a third of them being complete remission. So I do believe, and if you talk to some of them, they see the tumor essentially melts very quickly.

So highly effective in head and neck as well as in colorectal cancer, two high unmet medical needs from an oncology perspective and cancer perspective. And then we have already started and are well underway to the frontline trials on both of those and are aggressively pursuing those and accruing to those. So I do believe the totality of all that combined $5 billion-plus easily.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Let's maybe talk about ERLEADA that had another very promising plenary session at ASCO the discussion called the data practice changing. Congratulations on another successful trial there. So I guess what does this mean in terms of the revenue opportunity for ERLEADA? Like -- and how do you see the ramp from there? How can J&J make the most of the opportunity given the composition of matter expiry in 2030?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yes. So a couple of things. I think, first and foremost, we'll take the PROTEUS data that you're highlighting aside currently with ERLEADA, we're showing double-digit growth already. And some of it is based on most recent real-world data that we have, showing that ERLEADA either combined to the other ARPI showing overall survival irrespective of which ARPI that you're comparing to. And I do think that is really resonating in the community and with the practitioners saying, all right, this is different, and I need to use ERLEADA. So we're seeing an uptick there in the current indications.

Then you now have PROTEUS, which was in high-risk localized disease, those who look into intended to receive radical prostatectomy, so before and after surgery, and this is where it's shown. It was the plenary session highlighted at ASCO, the number one abstract, and they do believe there to be practice changes. The first time in an earlier line setting, if you use ERLEADA 12 months before surgery and then 12 months after you're showing a magnitude of effect of 20% risk reduction, which has not been shown to date.

I do believe that will have a halo approach across the brand overall, but also really change practice, and that's what -- why we do these studies and -- it was -- a lot of the feedback is it was the belle of the ball. It was great to see it was a long time coming, and we're quite excited that we're able to demonstrate that. I don't allude to loss of exclusivity assumptions, but we do foresee there's still a lot of runway left with ERLEADA.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Let's move to INLEXZO. This is another product that -- it's getting a lot of attention. It's a very in-focused product launch in oncology. It was highlighted on the sell side call that was done last week. I'm not going to press you on quantitative metrics because I know the answer to that. But qualitatively, give us some sense of how the trajectory is going on the back of April 1 J code. You provided some metrics on the first-quarter call. But just high level, how are things progressing in terms of the overall launch and the feedback?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah, very nicely. Just to remind everybody, launching INLEXZO, it's truly transformative. 82% complete remission rates. Half of those patients still out after a year on therapy in a very high-risk population. It's a fairly niche population,high-risk non-muscle invasive bladder cancer with carcinoma in situ. It's roughly 3,000 patients in the US. So if you just think about it that smaller niche introducing the marketplace and the receptivity has been pretty profound.

The intent to prescribe, unaided awareness, highest ever in bladder cancer. The other thing I would say is there is I would say, especially with the urology provider base, they're waiting for the J code, a lot of them are.

Post J code, you saw a 50% increase in providers utilizing it, there's almost like a 90% increase in insertions. So there's a little bit of a wait for it. And those are that -- it's still a smaller niche population. We just recently received NCCN Guidelines Category 2a for papillary disease. Papillary disease, just to remind you, we have a robust program for INLEXZO, and we can get to others, which is our erdafitinib intravesical drug release system.

But with INLEXZO, you have SR-5 , which is the papillary SunRISe trial, which is the papillary. So BCG exposed. Roughly 15,000 patients in that population. So much greater opportunity there. That's that NCCN guidelines. So that will be spontaneous until we get the approval for SunRISe-5 or the data readouts. Then you have SunRISe-3 which is a much broader population. This is the first time anybody that's ever gone head to head against BCG in bladder cancer. And this is a population around 40,000 to 50,000.

So those are two step changes. I think there is the disconnect with The Street with regards to the greater opportunity for INLEXZO, will bring $5 billion-plus. And then you add in Erda-iDRS, which is erdafitinib in this drug release system. And that is looking at it in non-muscle invasive bladder cancer for intermediate risk with the FGFR expression. So roughly 70% of the population has FGFR. So targeted use in FGFR. So I can say -- I can tell you there's significant opportunities ahead there and co-positioned quite nicely that the totality of that is going to be well above $5 billion plus.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

So I guess it sounds like, Tom, as we think about how quickly this product can sail, these additional population expansions from the SunRISe trials that you mentioned, but also the MoonRISe trials, maybe give us a quick update on that?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yes. So they're enrolling, and we're just awaiting the results on two of them, I think. But I do believe that the intermediate risk population, two of them, different types of intermediate risk and then one that goes a little bit over into the Erda-iDRS population, but targeted FGFR alterations. So that's where you'll see the differentiation. So Erda is also every three months. So it's 4 times a year. Okay. So a little less frequent insertions.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. All right. Let's talk about TECVAYLI. You had some data at ASCO just showing continued support to use as early second line. Maybe just zooming out from a big picture perspective, can you just frame how J&J is thinking about the broader treatment paradigm in multiple myeloma and specifically the coexistence of your BCMA targeting agents, [CARVYKTI] and TECVAYLI.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. I think we remain committed to search for the cure. And our development program, our investment will always be put around that. And I do think the patients will ultimately win with regards to that. I think first and foremost is what you're seeing. And even with the TECVAYLI data, DARZALEX is absolutely the foundational treatment and backbone therapy throughout the continuum. From the very beginning, all the way through the end.

It's one of the best combination of immunotherapies on the marketplace in multiple myeloma. And what you saw in the combination with TECVAYLI, truly unprecedented results. I mean I've been in myeloma for quite some time. I've never seen anything with a hazard ratio of 0.17 and the flat lining of the Kaplan-Meier curve.

And that's what we're hearing back from the feedback from our providers. What has also said is that data is in earlier lines of BCMA. Absolutely need to bring BCMA earlier in the treatment, whether it be CARVYKTI or TECVAYLI. And that is the mindset. Right now, where the setting is line two is available. So you do the quad in line one, you might have transplant or non-transplant and then if they're progressing, then you either based on patient preference, site of care, availability, things like that.

You either go to a CARVYKTI or TECVAYLI-DARA, and that sometimes becomes that I would say the shared decision-making with the patient and the provider. But right in and there, you have two incredible choices. And then post that, you'll see at EHA, we have the [TAL-DARA] data that will be presented at the plenary session at EHA. So that's TALVEY in combination with daratumumab, DARZALEX.

So that allows us then you have that position, bringing BCMA up for it, hit the best immunotherapy. If once they progress or if they progress, then you can go on to additional therapies. And that's our whole commitment. And each line of therapy, we want to be along the step of the way.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

What about your trispecific program? Maybe give us an update on how that's going and then also your involvement in vivo CAR T, been a topic.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yes. Yes. So it's trispecific, ramantamig. We're very excited about different molecule engineered by our scientists. And I'll tell you, so one of the benefits of being in myeloma so long with the team. We have the insights. We have the science, so we have the expertise and the external engagement to help shape this.

We -- you guys have followed us as well. You know all along step-up dosing, what's required for co-administration with either TECVAYLI or TALVEY needs some education, I would say, practice. What we understood also from a community to get expanded and really get the patient populations, how do you make a community-friendly targeted treatment that can be administered in the community by the community with less AEs. And that's what we did when we engineered ramantamig.

And also, as we think about either antigen expression or release the availability of having this trispecific targeting both GPRC5D and BCMA could prevent even further relapses and really looking at that curative intent. It's a different CD3 binder offers of CRS is looking a little

different as well as the GPRC toxicities. We're being able to dial those down. So really taking it and saying, all right, we've built very incredible combinations, but how do we improve even more so. and that's the ability that we're able to do with ramantamig. So we're going to be looking aggressively in line two and bring that in frontline as well.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. You mentioned --

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

So obviously, in vivo CAR Ts were -- obviously have some programs in-house, and we have a partner products with Kelonia, but we haven't disclosed any of the targets. So I'll just leave it at that. But we're quite excited about following that science as well. And we're looking across all modalities, anywhere we can look for cure and cancer to become the number one oncology company.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Looking forward to that. I'm going to take another pause there. Any questions on oncology before we pivot?

Okay. Tom, let's pivot to milvexian. That -- you've got this AF trial coming up from the Librexia program at the end of the year. You guys are running that trial along with your partners, Bristol-Myers. Just maybe give us your latest update and framing of your level of confidence on the success of the trial and -- is it still expected at the end of the year, I believe.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

It's an event-driven trial, but we're anticipating around that time. It could be before after, but it's on an event-driven timeline. But I would tell you, we're very excited. And we do believe milvexian will be another $5 billion-plus asset for us and working with our partner, BMS on this one. I do believe there's a significant unmet need still when you think about [claudication] and -- are they being not treated or undertreated.

So I do believe AFib, obviously, a significant opportunity ahead of us. We do believe the molecule and the dose we got right. We had modeled it appropriately. We've taken the data from the Phase II and really helped us inform on the Phase III. It's where we feel confident, really looking at similar efficacy to, say, an Eliquis or apixaban, but superior safety profile. And if you can reduce the risk of bleeding, we do believe that's going to untap a significant opportunity, both in AFib and obviously secondary stroke, which actually from a proof of concept have already been established.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

What -- on the bleeding side, what's the expected magnitude of bleeding superiority that you think would be needed to drive a meaningful displacement of ELIQUIS?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

I think from the research that we have from our providers, 30% to 40% risk reduction is absolutely significant.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

And how should we think about addressable submit populations, elderly renal, et cetera?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah, I think we -- when we get the data, we're going to need to identify that and see if there's enrichment strategies or subpopulations that might benefit versus others.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. And then maybe just on launch and access and pricing, anything you can share in terms of just color on how you're thinking about those metrics, the commercial opportunity really in the world of generic apixaban.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah. So I'd say, obviously, we're going to be working in close partnership with BMS. We won't disclose our strategies. But I would tell you, if you think about both ourselves, XARELTO, as well as our partner, ELIQUIS, when those products came into the marketplace, you were dealing with generic warfarin and we found a significant unmet need, and we're able to identify the value and ensure access and success.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Terrific. Let's move to neuroscience. This is an area that Joaquin has talked about an ambition to be number one in that segment. Do you feel that J&J is positioned to achieve that with the current portfolio?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Absolutely. I think what's helped us reinforce that was the acquisition for CAPLYTA intracellular. And I do think it not only for CAPLYTA actually intracellular in totality. I think CAPLYTA, obviously, we're well underway of the biggest indication for adjunctive major depressive disorder. We're seeing significant uptake already new to brand share surpassed REXULTI.

We're well on our way to look to become the number one atypical antipsychotic for branded. We just recently have data -- there are two studies, network meta-analysis that shows CAPLYTA is the most effective treatment across all branded atypical antipsychotics. So you have CAPLYTA, the momentum that we have there. We also got 1284 through the acquisition. We're looking at general anxiety disorder as well as agitation with dementia --

Asad Haider - *Goldman Sachs Group Inc - Analyst*

1284?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

It's another compound. It's a derivated CAPLYTA essentially -- it's unique.

And then coming back to our current portfolio, SPRAVATO, we're seeing significant growth, over 45% growth, still very little penetration in treatment-resistant depression, significant unmet need, opening up treatment centers and having utilization productivity to the treatment centers.

So we still see significant runway with SPRAVATO, our INVEGA baseline business as well as what I would say is seltorexant that we are looking to have read out this year, looking at major depressive disorder with those with underlying insomnia.

So I think in totality of that we are and will be the number one neuropsychiatry company. And then we're going to continue to look, as we think about neurodegeneration. Obviously, we have IMAAVY, but we continue to look there in other spaces.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

On the orexin 2 agonist that you mentioned that -- you said it's going to have Phase III data this year, I believe?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yeah.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

What -- level set us on what we should be looking for that?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Positive trial.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Any -- like what would define a positive trial?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Significant improvement in MADRS, of course. And then some of the endpoints that we're looking at with regards to insomnia.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Questions?

All right. Maybe just in the last couple of minutes, Tom. We've covered a lot across the enterprise, across your portfolio, like what haven't we talked about anything else you want us to be double-clicking on.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Yes. I think a couple, I would say, you touched on ERLEADA, but I would say our prostate cancer pipeline. We just recently did the acquisition of Halda at the end of last year with RIPTAC, we have our portfolio of products. I like to compare it now to our myeloma portfolio and how we're looking at myeloma. I think we have the ability, we have the science and the expertise.

We have the only KLK CD3 redirector, targeting KLK, we have the ADC KLK. We have co-stim. So there'll be data that's going to be presented at ESMO that's looking at our KLK CD3 plus co-stim in prostate cancer. So we have the ability to really target prostate cancer across all lines of therapy and different modalities really looking at curative intent. And I do believe what you're hearing, like the KLK2 data is pretty remarkable.

I mean, think about it, it's fit right nicely with the urology practice oncology practice. You don't necessarily have the step-up dosing and things that you have from bispecifics. Then if you can bring co-stim into there and really show even greater efficacy. And forget about it when you bring in RIPTAC, we do believe that's really going to transform the treatment of prostate kits.

So I do believe, as we think about our prostate cancer portfolio, we have significant opportunities to really help to look the curative intent there. And then that RIPTAC technology is not just prostate cancer, it's a platform that we can look across all other tumor types as well.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

And at the end of this year, you guys are going to be hosting an enterprise business review day after a few years. Maybe in the last 30 seconds, give us a little bit of a preview on what we should be looking for from your enterprise?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Significant growth.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Okay. Well, I think that's a great place to leave it. Thank you very much. In that time, we covered a lot.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, North America Innovative Medicine*

Appreciate it very much.
