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# **EDITED TRANSCRIPT**

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**OVERVIEW:** 

Company Summary



#### CORPORATE PARTICIPANTS

Tom Cavanaugh Johnson & Johnson - Group Chairman

#### CONFERENCE CALL PARTICIPANTS

Asad Haider Goldman Sachs - Managing Director

#### **PRESENTATION**

Asad Haider - Goldman Sachs - Managing Director

Terrific. We're just right about at time, so let's get started. Tail end of day 3 of our conference, saving the best for last. Very welcome to Tom Cavanaugh, Company Group Chairman, North American Innovative Medicines for Johnson & Johnson. Tom, welcome. It's great to have you with us.

Tom Cavanaugh - Johnson & Johnson - Group Chairman

Thank you. Pleased to be here.

#### QUESTIONS AND ANSWERS

Asad Haider - Goldman Sachs - Managing Director

So we have about 35 minutes on a lot of topics. Cover and you know maybe just to kick off just a high level question just to sort of tick the box because we've been asking all of our companies just, on the external environment in the context of all of this uncertainty on drug pricing and MFN any updates on sort of like the vibe in DC and you know what you're hearing and what might how that might emerge and the range of outcomes that you're thinking through for the innovative medicines business.

## Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, I would say as probably with many of our peers, there's ongoing discussions with the administration, obviously we take it very seriously, not literal all the time, at times we want to make sure we're understanding what ultimately we want to have, and I think we all share the same goals, and that is really to reduce health care costs for patients in America and we are front and center, wanting to work with the administration.

And there's areas that I would say organizationally and from an industry perspective that I think we could have a substantial impact, and some of it we're encouraged by the administration recognizes that some of them the middlemen focusing on the PBM reform, 340B reform, areas where we can bring, the cost and drive it down to the patients so they actually see it at the pharmacy counter.

So those are areas I think we want to continue to work with the administration on fixing. And that's where I think we stand today. But the discussions are going weekly, as you probably know.

#### **Asad Haider** - Goldman Sachs - Managing Director

Yes, certainly. All right, well, maybe we can just dive right in then again sort of staying big picture. Tom, talk us through the strategy in the innovative medicines business, unpack for us some of the drivers behind this growth trajectory framing of 5% to 7% growth, and what are some of the major catalysts that we should be watching?



#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yes, I'll be happy to, I think, as you probably remember in 2023 we had our enterprise business review at the end of the year and we laid out a strategy in innovative medicine really to focus on three pillars immunology, oncology, and neuroscience with some other selected disease area strongholds. And we also said we were going to hit \$57 billion by 2025. I'll say as you look back, we did that in 2024.

And are on track to continue that momentum into 2025 as you saw in the first quarter. I think if we stick with the strategy as we think about an oncology, substantial growth in oncology still on the backbone of many of our assets, whether it be DARZALEX, ERLEADA, some of the new entrants that we're launching RYBREVANT faspro and RYBREVANT LAZCLUZE there's one area that I would say of significant growth opportunity for us. We declared that a \$5 billion plus asset or combination asset, and we're well on track to achieve that.

I think you know based on if you just talk about that product or the combination of those products really substantial impact in EGFR non-small cell lung cancer, really displacing the standard of care as you think about the overall survival advantage that we highlighted at ELCC, really showing at least a one year advantage of survival over osimertinib. That is an area of truly transformation. There has not been an innovation over 10 years in this area that has demonstrated that.

We developed that product and that combination fairly quickly. We learned along the way. We learned that we also need to look at some of the AE management. So we did additional trials there to mitigate some of the AEs associated with the combination and have released that data as well.

So if you think about the survival advantage, the AE mitigation, as well as some of the other areas in which we can expand into, we definitely see substantial opportunity and growth. Immunology as well and neuroscience just with the acquisition of intracellular that we did not know at the EBR just gives more confidence to be able to deliver that five to seven growth and in Q1, you look at it, we had 4.2% operational growth. That's despite loe with Stelara, basically about 810 basis points of headwinds from an LOE perspective.

If we take that aside and move that aside, you're looking at an underlying operational growth of roughly 12%. So significant momentum, 11 products grow in double digits. So, we're very confident in delivering that 5% to 7% growth.

#### Asad Haider - Goldman Sachs - Managing Director

Perfect framing. Let's start double clicking on some of the things you said there. You said a lot. So I want to start, with immunology, just maybe just Stelara, I guess it's been a few months now since the biosimilar launches.

How is that erosion curve playing out and I'd be interested in hearing about what you know you're seeing in terms of switches to TREMFYA, if any at all, as the compound compressors?

#### **Tom Cavanaugh** - Johnson & Johnson - Group Chairman

Absolutely. I would say we were quite pleased and proud of the progress that we did and the impact Stelara has had on many patients worldwide. We reached peak year sales of roughly \$11 billion and as you highlighted, we lose an exclusivity of Stelara biosimilar entrants have taken place within the first quarter of this year, many of them in February, so you didn't really see a significant impact.

You'll probably see a little bit of acceleration. But I would say we still believe, year two of Humira is a good proxy as we think about the erosion curves for Stelara with obviously a little bit of the Part D on top of that from an impact perspective. If we think about Stelara though in TREMFYA now is what we really believe TREMFYA is going to overcome that LOE and really displace STELARA. Not only have we proven head-to-head superiority in psoriasis, that was communicated years ago.



But most recently we demonstrated with the CD trials for a GALAXI that Stelara was inferior. TREMFYA was superior because Stelara had many endoscopic remission end points. So that's one area that we do believe it's going to displace. We're quite excited about the launch of TREMFYA in IBD most recently, we launched first an ulcerative colitis, and with that launch we do believe we have one of the best in disease assets.

Based on the efficacy, one of the highest rates of endoscopic remission, as well as the sustained remission that you see there and what we saw is significant uptake. It's quite impressive to see you talk about STELARA, but IL-23 is the fastest growing class in ulcerative colitis.

And now within the first 6 months we've seen that has actually taken about 50% of that new share from an induction perspective. So, we're off to I would say the races with the UC indication. And then now just recently we got the approval in the US for CD.

That's the head to head data that we showed against Stelara and with CD also, the one thing that was different that is really a game changer we're hearing it from the providers is the subcutaneous formulation for induction. It's the only IL 23 that has a subcutaneous formulation and ease in administration and use and simple procedure at home. It's really a game changer and we're hearing that from, a lot of the early reception from many of the providers.

So Stelara, I mentioned, had \$11 billion peak year sales. 75% of it was IBD. So, if you just think about from 5, we delivered about \$4 billion in that trade sales off of the psoriatic indications. Now with IBD, there's no reason why you don't see it to exceed what we saw with Stelara.

#### Asad Haider - Goldman Sachs - Managing Director

And that launch, like you said, certainly does seem to be firing ahead. I mean, you beat the first quarter consensus by about 6% and like you said, Crohn's just got approval at the end of the first quarter. So, I'd just be, curious and just high-level framing on what you're seeing on the ground, particularly as it relates to receptivity between UC and Crohn's disease?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Absolutely. I think you know we do market research obviously and we have the voice of the customer. I think some of the things that we think about from leading indicators intend to prescribe unaided awareness, how we're getting in the marketplace.

And we are really hitting all the parameters and all the metrics, exceeding what we see from a competition standpoint. The other IL 23s in the marketplace on UC, and we're already seeing that on the CD perspective as I highlighted some of the early feedback, whether it be the subcutaneous formulation and administration for CD. We're anxiously awaiting the approval of that for UC, which we do believe we have another inflection point and see a rapid uptake.

One of the other things that we did was invest heavily into the fulfillment. So how can patients be helped along the process to get the product post prescription, and we invested heavily there, and I will tell you the fulfillment journey and some of our patient services, many of our customers are saying it's best in the industry now and that's something we're quite proud of now that we have the ability to deliver the product at home, if a patient has commercial insurance, is an adult. They can basically receive this treatment within 24 hours.

These are some of the things that I would say are leading indicators, but also receptivity from the customer that they see truly differentiating.

#### Asad Haider - Goldman Sachs - Managing Director

That's perfect, very helpful. Let's just maybe stay within that and talk a little bit about the oral IL-23 icotrokinra.



#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

It's a test, isn't it?

#### Asad Haider - Goldman Sachs - Managing Director

It's always a test, and you know I'm going to have to just keep practicing and saying it over and over. How about to going to be filing soon for plaque psoriasis, and I believe you know this is the first time that an oral pill is going to have the efficacy and tolerability of a biologic, and you have framed a tremendous amount of enthusiasm.

For this opportunity which we, share to some extent, so maybe just high level start framing the opportunity for us and then also talk about how you see this fitting in with the injectables like TREMFYA and why wouldn't there be, why wouldn't it potentially cannibalize some of TREMFYA opportunity along its launch?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, so we are incredibly excited about icotrokinra, our first targeted oral peptide targeting the IL-23 pathway.

One, we obviously released the data on psoriasis against placebo, truly looking at, the perfect combination that you see our perfect product if you think about just complete skin clearance, safety, and the convenience of once a day oral administration.

As you think about it, we have 125 million patients suffering from autoimmune diseases just in, IBD and psoriatic diseases, roughly 5 million patients should be on an advanced therapy or a biologic that are not on. So, there's significant opportunity from just a market expansion. You talk about positioning. There's this group of patients that may not want to go on to a biologic, but need to receive treatment, whether it be in psoriasis or inflammatory bowel disease.

So if you think about that market opportunity, that's there. And then within the space where those who want a treatment, 75% of patients believe they would like to switch to an oral therapy that are already on a biologic.

So you have some that may be on a biologic, they may want to go on to an oral therapy. We don't believe it just to be a convenience play though. We do believe the safety profile and we soon will be releasing head-to-head data against deucra later this year. We do believe this will be the first line systemic treatment for patients with autoimmune diseases.

#### Asad Haider - Goldman Sachs - Managing Director

And then would you, I know you haven't commented, but just sort of high level framing in the context of where we started, MFN drug pricing, just any early thoughts on how you would think about sort of the pricing strategy for this compound?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, we don't talk about future pricing strategies for any of our investigational drugs. I would just tell you we know the marketplace very well. We know the innovation that it's bringing, we're going to continue down our pricing principles of how we deliver that to the market.

## Asad Haider - Goldman Sachs - Managing Director

Let's segue to multiple myeloma. A little bit more complicated in some than immunology, I think you know there's some debates on the margin and a few different things that I want to talk to you about.



Number one, just on DARZALEX, I guess that has been the subject of some debate around IRA price negotiation inclusion, just maybe talk about J&J's position regarding when it could be potentially up for negotiation and sort of what gives you the confidence that if it's not up for negotiation by the, what gives you that confidence?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yes. So, I think first and foremost DARZALEX, what a remarkable product and such a significant innovation that it's taken place within multiple myeloma. We're quite proud of the progress we've made. We're not satisfied until we reach cure across all patients from a J&J perspective, we've delivered now half of the 11 products that are approved in multiple myeloma, so we know the space very well.

Getting to your point with regards to IRA or the draft guidance, for interpretation and under comment for you right now looking at, fix those combinations or you know different subcutaneous formulations, we do believe based on the current draft guidance and our interpretation of that, our stance remains the same. We do not foresee to have an impact from negotiations any sooner than 2034.

Because DARZALEX is an innovative fixed dose combination that delivers clinically meaningful benefits to patients versus the IV. A significant reduction in IRRs and AEs associated with the subcutaneous versus the IV formulation. So based even on the draft guidance, we feel very confident that we won't be up for negotiations prior to 2034.

#### Asad Haider - Goldman Sachs - Managing Director

So they're truly clinically different. Yes, what you're saying in terms of different modalities. Yes. And when does when does that patent expire?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

We were looking for, based on the Current guidance of IRA, we wouldn't look for negotiations until 2034

#### Asad Haider - Goldman Sachs - Managing Director

Negotiated in 2034. Okay, let's talk about anything else on DARZALEX that you'd want to.

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Look, I will tell you DARZALEX, has significant growth year over year, as quarter 1, roughly 23%. We still see significant growth in the future. I think if you think about it, we're awaiting in the US the additional quad indication for the transplant ineligible population. And we believe DARZALEX is the foundational treatment of multiple myeloma.

So there's significant opportunity in many markets to continue to grow share in the front line, duration of response or duration of therapy also growing as you go in the earlier lines, but also being the foundational backbone of all investigational drugs, even our own that are coming into the marketplace, are in combination with DARZALEX so we can get better a standard of care. So, we see significant opportunities ahead of us still with DARZALEX and then obviously our portfolio products with multiple myeloma.

#### Asad Haider - Goldman Sachs - Managing Director

Perfect segue into CARVYKTI then, continues to show some pretty remarkable data on the efficacy side. I mean, coming out of ASCO this Cartitude-1 data that you saw, the five year data that was suggestive of a cure potential cure in a subset of patients, it's really remarkable efficacy, but you know within that there's also the subtext of this lingering debate with respect to Parkinsonism.



And neuro-toxins and whether this could actually impact J&J's position in an increasingly crowded landscape where everyone is battling to go into earlier lines of lines of treatment. So just speak to the pushes and pulls on the growth trajectory for CARVYKTI in this backdrop.

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Absolutely. You touched on it already up front. I mean we are quite impressed as well as the community out there and hopefully patients, the opportunity or hope for cure. In the Cartitude-1 data that was released at ASCO and then actually the most downloaded publication in JCO showing that really a third of the patients, or 33% of the patients are disease free after five years, and those are patients that have blown through five lines of therapy.

It truly transformative. You take the Cartitude 1 data, and we went in Cartitude 4 and released that data and showed a substantial survival advantage over standard of care in lines 1 through 4, so prior line therapy. If you take that, that's really where you got to start with, overall survival is key and cure even keyer. So that's a relative benefit risk ratio that you need to look at right there you're saying overall survival advantage. So, we do believe CARVYKTI is going to be a mainstay, especially as you go in earlier lines of therapy.

In fact, half of our utilization is in earlier lines now. As we think about the utilization, so there's already adoption and receptivity. You touched on potentials AEs, neurotoxicity. Yeah, we did see some of that in the later lines as we're thinking about and see in the earlier line settings less than 1% as you go into earlier lines. So that relative risk benefit ratio is already leaning towards benefit.

And we learned a lot through the development as with other products in our portfolio, as with any other company in oncology. You start with a single arm trial, and you go to Phase 3 trials, you start to characterize the profile of the product and understand from a safety standpoint how you can mitigate that. Many of the sites are already looking at that bridging therapies we understand a little bit better and educate around the proper bridge bridging therapies, as well as looking at ALC counts.

So there are mitigation factors to even delay the neuro-tox further if it is. So, we feel very confident in our ability to deliver CARVYKTI and being a \$5 billion plus asset as well and the totality of our multiple myeloma profile, we feel very confident, as we said at EBR of \$25 billion by 2030.

#### Asad Haider - Goldman Sachs - Managing Director

Very clear. Thank you for that. Let's stay within oncology, let's talk about bladder cancer and the TAR 200 program.

Your team has made some comments about how you want to make bladder cancer the next multiple myeloma, so sort of a good segue into maybe unpacking this opportunity, and that's a big statement, in terms of like what we just discussed on DARZALEX and even CARVYKTI.

And when I look at the landscape thus far, bladder cancer is still sort of commercially unproven in some respects. So, walk us through your thinking on how you're getting to this sort of numbers that are getting framed?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Absolutely. I think first and foremost. Bladder cancer still is a high unmet medical need. I mean there are roughly a million patients globally, whether it be, early diagnosis to recurrent disease, so significant unmet need still exists in the marketplace. We have the ability to deliver two products, TAR 200 is the first product they all get to. TAR 210 is another one. TAR 200 has gemcitabine into the intravascular drug delivery system.

And erdafitinib is the product for TAR 210. I'll talk about the difference of those two products, but if you think TAR 200 right now is under review with the FDA and the real-time oncology review, which we did receive priority review for that, and we do anticipate that approval later this fall, and that is in high risk non-muscle invasive BCG unresponsive bladder cancer, so a pocket of non-muscle invasive bladder cancer.



And in the data that we shared at AUA showed over an 82% CR rate for half those patients are disease-free after a year, so truly differentiated, true innovation, and this isn't a device or a drug delivery system that It's a simple procedure in a practice, in a urology practice. It was made by a urologist for urologists, so locally administered AEs, minimal AEs when it's locally administered, and every three weeks go to an administration to have it removed and then insert it back in.

So substantial opportunity ahead of us, easy the supply chain as well as you think about storage, easily supplied within the urology office, so. We do see that to be transformative and as we go into further indications or expansion in the marketplace going head to head against BCG as well as we're looking at muscle invasive bladder cancer.

So across all of bladder cancer we do believe it to be a \$5 billion plus opportunity. TAR 210 is now targeted towards FGFR. So FGFR has a higher expression in earlier stage bladder cancer, 40% to 60% expression. So, you now have a targeted approach in a similar device or a delivery system with similar profile. So again, you have two combinations, two products that you can look at the targeted approach and then another depending on the patient population. So significant opportunities if you think about a portfolio play.

#### Asad Haider - Goldman Sachs - Managing Director

And how are you thinking about, the emerging Competition from CG Oncology, just maybe just talk to us about the competitive landscape, the emerging competitive landscape?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, we do believe that we have what we believe to be the best in disease product. Let's just talk TAR 210. TAR 210, not only the indication that we're initially seeking, but also as we think about in the future indications. One of the things that we are going head to head against and nobody else has is RCG.

So BCG is, an old therapy, toxic therapy as well, hard to administer, if you talk to patients, they believe it's like a tiger clawing at your bladder. We're going head-to-head to displace BCG. Many of the others are combining with BCG.

So if you just think from a patient perspective here you now are able to remove a therapy that they do not want to have administered to them, and the complexity of administration is even more so. To go into a urology practice and have it inserted in your bladder, TAR 200, and deliver the CR rates with the durability of CR rates is truly going to be differentiating. So, we do believe that the future will be looking at TAR 200.

#### Asad Haider - Goldman Sachs - Managing Director

And Tom, you mentioned timelines. I still get the sense that there's some investor debate about whether this actually will get approved this year, and you said you seem pretty confident by the fall we'll see approval.

I know you have priority review like you mentioned. I believe you also have a brand name now.

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

**INLEXZO** 

#### **Asad Haider** - Goldman Sachs - Managing Director

Yes, that's been thrown out, which is obviously very encouraging. So just maybe zone in on the. You know what's giving you confidence that you'll get timeline approval by the fall?



#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, I think you touched on it. I think we obviously are in frequent discussions with the FDA through our real-time oncology review. We have the appropriate data that they're looking for and they have provided us priority review, so we anticipate fall okay.

#### Asad Haider - Goldman Sachs - Managing Director

And how should we be just high level thinking about the early launch out of the gates?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, I think we know the space very well. We've been in urology for prostate cancer. We know the buy and bill practice as well in the US. We do believe we're going to be able to quickly penetrate the marketplace and then obviously with many other buy and build products, J-code comes a little bit later and then you'll see an inflection with the J-code as well.

#### Asad Haider - Goldman Sachs - Managing Director

Okay. Alright, let's talk about RYBREVANT LAZCLUZE. You talked about, this in your opening remarks already. I do want to drill in a little bit further and magnify and double click on some of the comments that you made. So, consensus estimates for '27, '28 are about \$2 billion.

And I think you guys have said it could be twice that in that in that time frame, so \$4 billion by 2028. In the first quarter you did \$140 million so the ramp that that sort of opportunity is assuming is pretty steep. So, help us understand how you're getting to those numbers.

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, I think if you just focus on EGFRs, non-small cell lung cancer, first and foremost, we're approved front line, second line, exon 20, so 3 indications. EX-US, we have the sub-q formulation available. In the US we're anticipating that later this fall as well.

So currently in the US as we think about the IV formulation, so not only do we have these three indications, we also have, and I highlighted earlier, an overall survival advantage for pertinent. So that is critical. I mean, survival trumps everything, when we were doing market research with many of our physicians, they said what would be substantially different and differentiated would be a 6-month advantage.

What we have highlighted and already communicated at least a 12 month projected advantage over OC. So right there you have the opportunities now truly high efficacy. Patients, on average live 3 years in this setting you can give them another year. That's truly substantial.

We also made developed this product pretty quickly. We had to understand the safety profile of it as well, the administration, the burdensome of the administration. So, if you think through that, we also did two other trials what we call cocoon and Skipper. Cocoon data was released that we were able through a simple prophylactic regimen to reduce dermatologic AEs by 50%. SKIPPirr as well reduced IRRs substantially.

Now we also did the Paloma trial which showed the sub cu versus IV. Significant reduction in IRRs which we were anticipating, but we weren't anticipating was this overall survival advantage and durability of response that we saw in the trial.

So if you just think about EGFR non-small cell lung cancer, you have a front line overall survival advantage with a subcutaneous formulation that demonstrates that response and that ability to have an impact on patients. And then if they're already on a treatment, they're able to get RYBREVANT in combination with chemotherapy, so you have immediate play on all lines of therapy.



We're also doing a trial, so we didn't just rest there. We're doing a trial called Copernicus. Copernicus, this is a trial in the frontline setting, our Mariposa one data, the frontline data was with IV.

Now you're bringing in the subcutaneous formulation with all the benefits that we just demonstrated with Paloma. With four-week dosing, so ensuring that the patient as well as the provider, have a seamless experience. So we do believe that's going to be the regimen of choice as we learned a lot about the compound.

The other thing that I'd like to highlight that we've shared data already and we're going to share a little data later this year for RYBREVANT, we also have colorectal cancer, significant unmet need, high number of patients on, innovation has not happened in colorectal for some time now.

Head and neck is another area that we're going to release some data. So not only are we looking at EGFR non-muscle lung cancers, we also have colorectal and head and neck, two huge tumor types with significant unmet medical need.

#### Asad Haider - Goldman Sachs - Managing Director

Very good, thank you. Maybe just sticking with lung, I do want to ask you just on your views on the PDF, PD1 measure bispecifics just given, all of the activity and excitement. About this modality as a potential disruptor in large oncology indications. So, what is J&J's appetite to participate in this opportunity?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, we obviously consult with our R&D colleagues who follow in the space quite closely as well, and some of this is drug development. I touched on the magnitude of benefit that RYBREVANT LAZCLUZE has provided to patients with overall survival advantage. What you saw in some of these trials that you just highlighted was you saw a PFS advantage but also not a survival advantage. So, we need to really understand the biology of the disease and why that's the case.

As you're going to really need survival advantage to really make an impact. So, we continue to monitor it. We do believe we might have some other immunotherapies in our pipeline that we're more excited about and want to invest in, and many of our R&D colleagues.

#### Asad Haider - Goldman Sachs - Managing Director

Some of them were released, I would say maybe not in lung cancer. In prostate cancer we had we had our KLK2 CD3 redirector in prostate cancer or metastatic prostate resistant prostate cancer, really showing early signs of efficacy, but also a safety profile really for the community urologist oncologist to be able to administer. So, we do believe that's an exciting one. Some other ones will be disclosed, I'm sure at other times.

We'll keep an eye on it. Let's talk about Nipocalimab. Just maybe just color on how is that launch going.

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

It's early. It's early. We're definitely excited finally to bring IMAAVY

to the marketplace nipocalimab. It's the first and only FCRN blocker for a broad population of both pediatric as well. Adult and ACR positive antimusk positive patients. So, it's early in myasthenia gravis, but we do believe the profile of the product, the safety profile, as well as the dosing and efficacy is truly differentiated. We're already hearing early signals, I would say anecdotal from many of our customers that are excited about it. Some of them are switching from previous FCRM blockers and some are just naive to it. So that's your first entrance into autoantibody driven diseases, then obviously we look at.



Rare autoimmune diseases as well, autoantibody diseases, maternal fetal, which we do believe is truly differentiated, as well as rheumatic diseases such as Sjogren's and lupus, and many of these diseases, you think about the safety profile of the compound where we're studying it, if you just think maternal fetal, so female with childbearing potential really demonstrating truly a safe product in this patient populations.

There's a high prevalence of females and Sjogren's, lupus, and some of these other autoantibody driven diseases. So truly having a differentiated safety profile and a sustained efficacy, and that's one of the things to our dosing and knowing biology is what we're trying, we're showing it's going to be differentiated.

Asad Haider - Goldman Sachs - Managing Director

What Do you think is going to lead to the inflection in that?

Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, I think obviously how we're going to launch the myasthenia gravis, but then the secondary indications that I would say that are untapped that it's going to be a major inflection point.

Asad Haider - Goldman Sachs - Managing Director

Okay. Let's maybe move to neuroscience as Spravato. That's also early ish, but it's been a very exciting launch and certainly doing better than expectations. So, give us, sort of updating framing of that opportunity.

Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, I would say take a step back in neuroscience, it's one of our three core pillars for development from end to end as we think about our resources and investment. We're focused on neuropsychiatry and neurodegeneration.

In neuropsychiatry, we have Spravato on the marketplace today, truly innovative for treatment resistant depression, the only one that I got priority review for both the adjunctive as well as the monotherapy that we just received approval this year for truly shown a differentiated profile. I mean, you have complete significant reduction of depression symptoms within 24 hours, as well as the safety. A resolving within 24 hours. So, something that's truly differentiated to any of the antipsychotics in the marketplace.

We have seen rapid advancements in the acceleration of treatment centers, so where they can administer the product has to be administered under the observations of a healthcare provider. But we've seen, as you've seen highlighted, it's already a blockbuster. We perceive this to be a \$1 billion to \$5 billion asset, really penetrating into earlier lines right now.

Many of the usage of Spravato is like in fifth and sixth line. We think if you can bring it up into earlier line, maybe three, fourth, you're going to see significant inflection point and continued growth and momentum, and that's where our strategy is to do just that. I also have to highlight, a recent acquisition for intracellular.

Asad Haider - Goldman Sachs - Managing Director

I was going to go there, but please go



#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

and think about neuroscience. We do think if you think about multiple myeloma.

We now have, we're just excited to welcome intracellular to the organization and it's truly what we do believe is the best in disease product for depression. Caplyta, already approved for bipolar 1 and 2, the only one approved for bipolar 1 and 2 depression, as well as schizophrenia, and we have a pending SNDA with the FDA for AMDD. If you think about the data for AMDD, it's truly the best in the disease asset.

The consistency between two trials and the reduction of the MADRS scores. Two times what you see on the marketplace today. So and with a profile that can be delivered, none necessarily change in weight gain, EPS, and some of the safety signals in my baggage, I would say that you see with some of the other antipsychotics.

I absolutely believe this to be a \$5 billion plus asset. So, if you think about line of therapy, you have Caplyta, earlier lines of major depressive disorder, and then for treatment resistant depression you have Spravato. In the pipeline we have Seltorexant and then aticaprant

#### Asad Haider - Goldman Sachs - Managing Director

How's the integration of the ITCI acquisition going?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

It's going really well, yeah, I would tell you, the more and more we look behind the curtain, the more excited we are. I have to highlight also the pipeline 1284 that we acquired from them also a highly differentiated asset in GAD and Alzheimer's disease. So we have a portfolio of products that we're able to play with and at the end of the day it's truly going to be important because significant unmet need and depression and neuros.

## Asad Haider - Goldman Sachs - Managing Director

We have a couple of minutes left and there's two more things I want to talk about. Number one, is there anything else in terms of pipeline opportunities, Tom, that we have not touched on?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Oh wow, I mean you could talk, I talked about neuropsych, neurodegeneration. We have their [tau] protein for Alzheimer's disease and then in oncology I touched a little bit on prostate cancer. I will tell you we have a pipeline of other products, myeloma. We just released data, our tri-specific antibody.

So I would say as we're leaders in multiple myeloma, I do believe we're also leaders in bi specific antibodies. We've learned a lot about the chemistry and the biology, the engineering of our R&D organization and early discovery, I mean really, we believe might have made a best-in-class asset with this tri-specific. Early data is out there but truly can be transformative.

So we are leaders. We're going to shoot for that cure and we're just excited and reaffirm our commitment to be able to deliver well above their five to seven that we've said.



#### Asad Haider - Goldman Sachs - Managing Director

Okay, and I guess maybe just to wrap then in the last couple of minutes, where do you from where you sit, Tom, see opportunity to build out the portfolio within innovative medicines and I guess what I'm asking is that where would you, where do you think you're still subscale and there could be an opportunity to lean in?

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

I would say they're still within the three therapeutic areas. We didn't touch on it. We've done some BD deals as we think about atopic dermatitis, another area in autoimmune diseases, maybe some other cancers within oncology as we highlighted the EBR, we believe we're going to achieve \$50 billion in oncology alone, non-risk adjusted. We could do well beyond that by our expertise as well as our commercialization.

Asad Haider - Goldman Sachs - Managing Director

Okay. All right, well, any questions from the audience?

## **Unidentified Participant**

(inaudible)

#### Tom Cavanaugh - Johnson & Johnson - Group Chairman

Yeah, we continue as you continue to see growth across both assets Opsummit, Uptravi, , as well as the recently launched Opsynvi, and we are anxiously awaiting one of the other studies that we have ongoing. It's our Maci 75 program that's comparing Maci 75 to Maci 10 and PAH.

We anticipate a read out that eventually soon, and if that hits, that's going to be another growth opportunity for us from the PAH perspective. Outside of that, we'll continue to explore any other BD opportunities. But we want to maintain laser focus on the three core areas that we've highlighted.

## Asad Haider - Goldman Sachs - Managing Director

Alright, we're just about at time. Tom, thank you very much for that discussion. It was very helpful. It was great to have you here and I think that's a good place to wrap.

Tom Cavanaugh - Johnson & Johnson - Group Chairman

Glad to be here. Thank you.

Asad Haider - Goldman Sachs - Managing Director

Thank you.



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