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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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CORPORATE PARTICIPANTS

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Mark Wildgust *Johnson & Johnson - VP - Global Medical Affairs, Oncology*

CONFERENCE CALL PARTICIPANTS

Vamil Divan *Guggenheim Partners, LLC - Analyst*

Edouard Mullarky *Guggenheim Partners, LLC - Analyst*

PRESENTATION

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

All right, I think we're ready to get started. Thanks, everyone, again for joining us at the Guggenheim Inaugural Healthcare Innovation Conference this year. I'm Vamil Divan from the Guggenheim side, one of the biopharma analysts, for those who I don't know. Edouard's also up here from the Guggenheim side. I'm pleased to have next in this room Johnson & Johnson. Next to me, Biljana Naumovic. I hope I'm saying that correctly, as well as Mark Wildgust from the oncology side.

We're going to keep most of our conversation focused -- or all of our conversation, focused on the oncology side of things and certainly plenty to discuss in 25 minutes. So we'll try and hit some of the highlights at least. And then obviously if people have questions in the room please raise your hand and we can work those in as well.

QUESTIONS AND ANSWERS

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

So I think three main areas I want to sort of touch on, and I think there's obviously more we could go into. One is your work in lung cancer; second would be the progress you're making in the bladder cancer side; and then third, your sort of dominant position in myeloma and the steps you're taking there. So let's start with lung cancer first.

I think that's the one of the three where I feel like there might be -- bladder, we could argue too. But I think lung where I think you guys have some interesting data, but I think definitely a disconnect between how Johnson & Johnson is seeing the opportunity and where the Street is seeing things right now. So maybe just the progress you've made with RYBREVANT so far, any updates on the sub-Q and the sort of the tolerability, patient experience side of things. And then we have a couple of detailed questions after that, but I'll let you kick it off.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

Cool. Thank you so much. Hello, everybody. Great to see some of the familiar faces. Let me start with this. The whole eGFR space has been fairly dormant for the past 10 years. You had one pill. The pill was used. It was fairly easy. Your average survival is three years. We're talking about mostly middle-aged women that have eGFR.

We have brought this year a plethora of data. We went at speed in the combination with RYBREVANT, RYBREVANT and LAZCLUZE, or RYBREVANT combinations with other things, across multiple tumors of the eGFR space, whether it was Exon 20 that we started the year with PAPILLON, or with a common eGFR mutation with MARIPOSA and MARIPOSA-2 studies.

So three Phase 3 studies that we presented on ESMO last year. We've registered everything this year. In parallel to that, we also presented PALOMA-3 data with the switch from IV to subcutaneous formulation, received for the first time ever FDA-designated priority review for formulation change.

And we submitted in June, so with some good math, you'll understand that very fast we will have a subcutaneous formulation on the market. We're absolutely, manufacturing wise, ready for that.

Why is this all important? The front-line space for RYBREVANT and LAZCLUZE, where we see the majority of the benefit of this combination, is the space where we want to bring the overall survival benefit for the patients. And we think that overall survival is going to be -- efficacy is going to be the dominant driver for the physicians in this setting.

Why? Because the majority of patients, around -- up to 45%, actually, when you look at the databases in the US, never received the second line. So what we did, we already launched MARIPOSA. We launched MARIPOSA-2 and PAPILLON. We're extremely, extremely pleased with the uptake. I can tell you that we have patients in the front-line setting and the combination across the United States, not just in the academic setting, but also in the community oncology.

And the beautiful thing about it, because Mark will certainly talk more to it, we have brought in also the studies that show how to manage the immediate adverse events, whether it's infusion-related reactions with SKIPPirr study that was presented on World Lung, or the COCOON study that is talking about prophylactic management of rash, we are already implementing in the order sets these specific protocols that are supporting patients. So overall, it's just the very beginning, but it's a very good beginning of our lung cancer franchise in the US.

Mark Wildgust - *Johnson & Johnson - VP - Global Medical Affairs, Oncology*

Yes, I think -- one of the disconnects, I think, in the investor community on the Street -- I think this has been questioned. Can RYBREVANT, LAZCLUZE really supplant TAGRISSO, right? I think our answer is resolutely yes. I think that the marketplace is looking for a survival benefit. I think we showed you what that's going to look like at World Lung.

We showed you the data set that FDA and EMA asked us for, showing that we extended survival. And while that wasn't alpha-powered to test it statistically, you can already see the hazard ratio of 0.77 and a p-value of 0.019. And you'll see the final survival data from the MARIPOSA study next year. So survival's coming.

As Biljana said, one of the things that we've been working on is how can we further improve tolerability. In the short term, the SKIPPirr data has shown that just using a simple dexamethasone regimen, you can see a three-fold reduction in infusion-related reactions with the IV formulation. But most importantly, you don't see Grade 3 infusion-related reactions and no hospitalization, which means that you have an immediate solution for that IV formulation for the IRRs.

We showed at ASCO that the subcutaneous formulation reduces the rate of IRRs by fivefold. You turn that five-hour infusion to five minutes, and it had a better tolerability profile than the IV. And importantly, you also see that we saw what was on the J&J side, really, an unexpected outcome too, where we actually saw superior efficacy too, both in terms of progression-free survival and survival.

And then the last piece is that we're really working to improve or address this question about rash. And so I'm happy to share with you, we've been running a Phase 2 study looking at the comparison of prophylactic rash management versus normal standard of care. That's a 200-patient Phase 2 study. I'm happy to share that that study is now complete. It enrolled rapidly in eight months, much faster than we had anticipated, I think reflective of the interest and excitement of using RYBREVANT, LAZCLUZE.

And we're hopeful that we'll be able to present the primary results from that study next year. And as Biljana said, we already know that that there are proven rash regimens to address rash. There's about 13 or 14 studies that have demonstrated how to manage that, and our US colleagues are already implementing that into practice. And so you already have, really, I think, a profile of coming of RYBREVANT, LAZCLUZE with a survival benefit, subcutaneous formulation, management of IRRs, and management of rash. You really do have that preferred standard of care that's coming.

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

So maybe one quick follow up on some of the comments. So the uptake you're seeing so far, can you describe it in any way? What patients or what -- it sounds like it's a pretty broad community and academic center. So who's making the decision to use this over the other options that are available?

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

It would be very interesting to talk about the patient profile if I could give you one patient profile that they're using it on, but they're not. It is used really broadly. I've seen patients who were in their 80s being given the combination. I've seen also very young patients in the early setting. It's not a pick.

I'll tell you what's very interesting. The physicians and the nurse staff who have had experience with RYBREVANT and the support in knowing how to manage it are very free in using it in the front-line settings. So this is something that we're supporting across the United States, these first experiences with giving RYBREVANT and LAZCLUZE in the front line. There is no specific profile that we have identified.

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

Okay. Let me turn to Edouard to kind of dive into the bladder cancer side.

Edouard Mullarky - *Guggenheim Partners, LLC - Analyst*

Yes, on the non-muscle invasive bladder cancer side, you've got your TERRACE platform that we've been quite enthusiastic with, TAR-200, TAR-210. And you're actually potentially filing, I think, for the first indication early next year. But I guess there are some also other players in the space and some competition -- potential competition. So how do you see TAR-210 and TAR-200 fitting in and differentiating with these other players in the NMIBC space?

Mark Wildgust - *Johnson & Johnson - VP - Global Medical Affairs, Oncology*

So listen, first of all, I think you didn't mention disconnect again, right? So it seems like we've got a lot of signs coming, and there's disconnects with the Street, right? It's good to just talk about the size of the opportunity, I think, for a second, in bladder cancer. When you think about bladder cancer, there are about 600,000 newly diagnosed patients with bladder cancer a year. But there are another 400,000 patients who are recurrent.

So there are about 1 million patients in play every year for bladder cancer. And when you think about bladder cancer, actually, 75% of that is in the non-muscle invasive bladder cancer setting. And of that, about 55% to 60% are in that high-risk non-muscle invasive bladder cancer setting. So really, the opportunity is in that non-muscle invasive setting where we've got our SunRISe-1, 3 and 5.

Now talking about differentiated profiles, we have the highest single-agent CR rate that's been seen in that high-risk BCG unresponsive patient population at 84%. But one of the things, I think, that differentiates TAR-200 versus the other options that are out there is it's a simple-to-use drug device. It takes two minutes to put it in. It's an in-office procedure. It can be taken out within 45 seconds. It can be done by a nurse. It can be done by a physician. It can be stored in a regular room on the shelf.

In contrast, you have some of those other offerings that are out there that are considered biohazards. Those patients need to be put in a separate room for the administration of it. They need a nurse to stand by the patient's bedside for a couple of hours as that is delivered. And plus, there are concerns for when that patient goes home. They need to use bleach when they go to the bathroom. They can't have intimate contact with their family members as well.

And when you're doing that every week for six weeks, it really becomes very problematic. And it is not easy for the practices too. TAR-200 can be used anywhere where a urologist can use a cystoscope, which is everywhere. Those other products really have some restrictions in terms of -60 degree refrigerators. They need to have special setups to be able to manage that. They're complicated. Urologists want something that's easy, and TAR-200 offers a couple of things: unsurpassed efficacy, tolerability, and ease of use.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

In preparation of the market that we have been doing since the first results have been presented beginning of this year, There has been enormous excitement across the urology practices. I'll give you one latest discussion we had with OneOncology when they just purchased the UroGPO to go under their helm. I was with them on that day that it was announced, and all they wanted to talk about was TAR-200.

The beauty of the asset that we're bringing is not only that from the efficacy standpoint that they have not seen anything like this, but it fits so perfectly in their practice. They understand how to buy and bill. They understand where on the shelf to put it. They're already putting in their head how the patient flow is going to go when you understand that within 30 minutes you will have a patient with non-muscle invasive bladder cancer come in, sit in your office, have a cystoscopy. Within a minute, your device is in the bladder and you're releasing them home.

And the ease with which that can happen and the speed at which we have recruited the remainder of the studies that we have in bladder cancer has been truly phenomenal. So we know we have something that is fit for the market, US market, but we absolutely believe the rest of the world as well. And it also fits perfectly well with what FDA is expecting in terms of efficacy. When you look at how we designed the trial, FDA wants to see three-month complete responses without re-induction. That is a mandate for studies like this. This is what we did.

Edouard Mullarky - *Guggenheim Partners, LLC - Analyst*

Okay, maybe just a follow up on the commercial opportunities. So you talk about this recurrent population that's often neglected. Do you think that the TAR-200 could be used after in these recurrences, or would you potentially have to show data? And how does that maybe would impact -- go with the other emerging products?

Mark Wildgust - *Johnson & Johnson - VP - Global Medical Affairs, Oncology*

Yes, when I talk about recurrence rate -- actually, in the SunRISe-1 patient population, they've had recurrent disease. These are patients that have had multiple prior treatments. They are BCG unresponsive, so they've failed BCG. Actually, their next step is to have their bladders removed.

And so what TAR-200 is doing is really offering them that hope of being able to have efficacious regimen with long durability with tolerability that actually allows them to save their bladder. So that's one of the places when you hear me talking about newly diagnosed and recurrent. This group of patients is that recurrent group.

You also have those patients for TAR-210 in that intermediate risk setting as well. Those are patients who have a disease that comes and you see it. You clean it out with a TURBT, which is essentially scraping the walls of the bladder to get rid of that. Those patients typically then go home and come back again in three months, and they've got the disease back again. Those are recurrent as well.

We've got our MOONRISE 1 study ongoing looking at TAR-210 in that patient population, where we know that in that intermediate-risk non-muscle invasive bladder cancer setting, about 65% to 70% of those patients have and FGFR alterations. Unlike TAR-200, TAR-210 offers the delivery of a targeted therapy with a sustained drug delivery system once every three months for those patients. We really believe that we're addressing that patient population that's very much in need.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

So when you look at the opportunity overall, your recurring patient population is SunRISe-1 and SunRISe-5. Your new patient population -- new indicated patient population is going to be SunRISe-3. We will be covering the entirety of the non-muscle invasive high-risk bladder cancer space very fast.

Specifically in 2025, even though we will not have SunRISe-5 data registered yet, we will have Cohort 4 of SunRISe-1, which is actually identical patient population in SunRISe-5. And that is a 55-patient study that we will be reporting out. So there will be plenty of it. It's ideally an NCCN-guideline-informing study. So there will be plenty of opportunity to treat tens of thousands of patients in 2025 and 2026.

Edouard Mullarky - *Guggenheim Partners, LLC - Analyst*

Okay. Maybe last one for me. And then just on the -- I guess, it's sort of a complicated space because there's the CIS, there's the high-risk papillary, and you've talked about it. It's a very large commercial opportunity, but how do these different sort of subtypes -- if you can help us sort of size the opportunity by these different subtypes which is where you'll actually be getting the labels for.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

I can start with that. So we are first starting with SunRISe-1 on that it is CIS population, and this is going to be the registered population. That is a smaller subset of patients, of the high-risk patients, that majority are papillary. Our papillary registrational trial is going to come with SunRISe-5. But right after the registration of SunRISe-1, we will have the data sets from the Cohort 4 that is actually papillary set. So in essence, you will have the data next year for the entirety of the high-risk patients.

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

Let me see if there's any questions in the audience. Otherwise, we'll shift gears over to the myeloma side. Obviously, tremendous success that Johnson & Johnson's had there. I'll stick to a few of the key questions we've been getting from investors, one around CARVYKTI.

Nice sequential growth we're finally seeing here, with the manufacturing capacity picking up here. I think a little bit of questions on the sort of competitive side of things, especially with ASH coming up. So just if you can talk about, obviously, the profile you've built up for your products so far to date, but also I think questions around the safety and kind of how that might hold up relative to competition. Just your perspective as we head into ASH in a few weeks.

Mark Wildgust - *Johnson & Johnson - VP - Global Medical Affairs, Oncology*

Yes, so listen, from an efficacy perspective, CARVYKTI now is the only multiple myeloma CAR-T that has a proven survival benefit. We just presented that data at the International Myeloma Society meeting in Rio, showing a proven survival benefit with a 45% reduction in the risk of death. It's the first myeloma CAR-T to show that, and that's in that early lines of therapy as well in that second line setting.

I think there's some kind of questions popping up right now I think as people prepare for ASH, and they in particular see some of the anito-cel data that's coming out. I think there are questions coming up again about Parkinsonism and CNS toxicity. So let me kind of put that a little bit to bed, right?

We already addressed this question around Parkinsonism and the CNS toxicity before, right? We already demonstrated that when you actually use it in early lines of therapy, and when you use the mitigation strategies that we put in place and established at J&J with effective bridging therapies, with early monitoring for those types of tolerability issues, actually you fundamentally address that CNS toxicity issue.

And actually, we published and presented that a couple of years ago. We see less than 0.5% in terms of that. Now I think there's some questions coming up from some of the anito-cel folks saying they have a better CNS profile than we do. I'm not sure that's necessarily true. Let's take a look at the data when we see it at ASH. But their data doesn't suggest it has a different profile. They're just comparing apples and oranges there in terms of how they're doing that.

I think there's some other questions too about efficacy. I hear people talking about anito-cel having better efficacy than CARVYKTI. I haven't seen any Phase 3 head-to-head studies to prove that yet. I think they're extrapolating from small datasets. And I think there's a danger when you do that. But let's kind of walk through that for a second, right? I think the anito-cel data was in earlier lines of therapy, and then they're comparing that to later lines of therapy with CARVYKTI.

But actually my math says their median PFS was 30 months, and ours is like 35 months in a later patient population. When you look at safety, ours was an unselected patient population. My understanding is that the population within the anito-cel study is very highly selected, particularly taking out those patients with CNS considerations.

I think when you then compare, and you're comparing apples and oranges, you can start to kind of make conclusions that don't really exist. So for a medicine that's been out there with 56 patients versus CARVYKTI that has a proven survival benefit, Phase 3 study, treated in more than 4,000 patients, I think there's only one standard of care, and that's CARVYKTI.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

One of the things that I can say from the execution perspective in the US, you have seen quarter-on-quarter growth of more than 50% Q3 to Q2. We talked about with some of you in past years around our ability to ramp up manufacturing to make it sustainable in order to get to these numbers, and we're doing exactly that.

So we have now ability to manufacture at larger scale. We're opening facilities in Europe. We're ramping up at the speed that FDA is allowing us here in the US. We're making our lentivirus production, bringing more yield. We're reducing the out-of-spec and with CARTITUDE-4 and the move to the second line, the penetration in the second-line segment, and the referrals from the community to the academic centers is really tremendous.

One thing that I should also add is we have now seen in almost every interaction with major community oncology practices that they're building up spaces for them to apply cell therapy for their practices. So this is going to be something that people are going to move forward with in order to treat multiple myeloma patients. And with the data that CARVYKTI has, I do not foresee that, at least with everything that we have seen so far that, anito-cel is going to come even close.

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

So then, kind of talking broader portfolio here. You obviously have the bispecifics now on the market as well. Another common question we get is how does this all sort of fit in together? How do you sort of personalize there? How are you sort of thinking about which patients might be best to get the bispecifics versus -- than CARVYKTI? How does TECVAYLI and TALVEY sort of fit together? So maybe we can just talk about the bispecifics, their uptake so far, which patients tend to be maybe preferring that approach over the cell therapy approaches, and how do you see that as they're evolving going forward.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

Well, maybe I can start with this. Multiple myeloma is not one disease. It's a multitude of diseases. And the way we see it is we have regimens with the combination of therapies that we have brought to market to address basically every single patient with their needs to treat multiple myeloma.

DARZALEX is and will remain the backbone. We're just entering the front-line space. You've seen us bringing the data on the triple and quad combination, transplant-ineligible and transplant eligible patient population. We have maintenance therapy that we are also -- we have also presented and we are expanding the use in the frontline setting, adding also to the maintenance.

But worldwide, there's also a wide opportunity for DARZALEX to do even better. That work we have done with CARTITUDE-4 tells you that we're moving into the second line with absolute confidence that this is the space for CARVYKTI. CARTITUDE-5 and -6 are the studies that are bringing CARVYKTI to the front-line setting. This is where we really think CARVYKTI is going to make the biggest mark.

So we see CARVYKTI as the therapy of choice for the frontline patients, whether it's transplant eligible or ineligible. And then we have the multitude of opportunities, whether it's in the frontline setting with a combination of our bispecific TECVAYLI and TALVEY that work really well in extramedullary disease, or as sequence for after CARVYKTI or the patients who progress.

How is it going so far? It's going really well. When we look at the penetration across the US in terms of number of patients and the expansion in the community setting, we're very satisfied both with TECVAYLI and with TALVEY. We look at the -- even currently register the drug outside of our portfolio that is not really gaining even single-digit shares across the US because there is no need.

We have the most efficacious therapy. We have one REMS for TECVAYLI and TALVEY. And initially, we started with initiation of therapy in the academic setting for both of these drugs with the maintenance therapy that is being given in community setting. But now we're expanding more into initiating therapy in the community setting as well. And major community practices like the Texas Oncology or OneOncology or FCS are building their capabilities in order to initiate. So we think the 2025 will be the year for even massive uptake for TECVAYLI and TALVEY.

Vamil Divan - *Guggenheim Partners, LLC - Analyst*

Okay. I think just in the interest of time, we could always go much longer and deeper with everything going on in the oncology business. But thank you for the time. I think we'll have to leave it there, and we'll continue to follow the progress.

Biljana Naumovic - *Johnson & Johnson - President, Solid Tumor US Oncology*

Thank you for the great questions.

Mark Wildgust - *Johnson & Johnson - VP - Global Medical Affairs, Oncology*

Thanks a lot.
