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OVERVIEW:

Company Summary

CORPORATE PARTICIPANTS

Sarah Brennan *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Mark Wildgust *Johnson & Johnson - Vice President, Global Medical Affairs, Oncology.*

CONFERENCE CALL PARTICIPANTS

Vamil Divan *Guggenheim Securities LLC - Analyst*

PRESENTATION

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Okay. I think we're ready to get going here. So thanks, everyone, for joining us again for our second annual Guggenheim Healthcare Innovation Conference on day-2. I'm Vamil Divan, one of the biopharma analysts here at Guggenheim. Very pleased to have us joined for our next session in this room is Johnson & Johnson.

From the company, we have Sarah Brennan, Company Group Chairman, Global Commercial Strategy Organization; and next to her, Mark Wildgust, VP of Medical Affairs in Oncology. So obviously, tons to talk about. We had a great breakfast discussion for an hour. We have half that time here, and we didn't even get that far in the breakfast itself.

QUESTIONS AND ANSWERS

Vamil Divan - *Guggenheim Securities LLC - Analyst*

So let's just jump right in. I think we'll start on the oncology side. We have a lot of exciting stuff across the portfolio going on right now, but a big approval recently in the bladder cancer side for Johnson & Johnson. Maybe you can just talk about INLEXZO and the sort of early feedback you're getting from the field as this rolls out to the community?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. I'll start. Thanks for the question. Great to be here. We're super incredibly excited about the recent approval of INLEXZO. But just taking a step back, our approval is within the non-muscle invasive bladder cancer. But annually, you see about 600,000 patients that are newly diagnosed, another 400,000 that have their bladder cancer reoccur. There hasn't been innovation really in four decades, in 40 years.

So the approval of INLEXZO really represents a tremendous opportunity for patients to move away from BCG, which is a very challenging current standard of care as well as preserving patients' bladders because unfortunately, they lose their bladders as part of the treatment. So we have seen the highest complete response rates of 82% with this CIS population, which is a smaller, the first of several approvals that we expect to come.

And at 12-months, disease-free, which is incredible. We also see the sustained delivery that's really making a difference of gemcitabine over a three-week period. It's the ingenuity of our MedTech capabilities, coupled with our pharmaceutical ingenuity to really deliver the sustained release of gemcitabine. And the patient can go about their daily activities, which is a huge benefit.

And then it's practice changing, and we're seeing that firsthand in our early experience, fits right into the urologist practice, easy to administer and a procedure that they're very, very familiar with. So early experience, we got approval on September 9. Right out of the gate, we activated our supply chain team, our field force, our reimbursement specialists, and we're seeing incredible receptivity, a lot of momentum, excitement, not only from the urologists, but also from the patients. They truly see this as transformational.

Mark Wildgust - *Johnson & Johnson - Vice President, Global Medical Affairs, Oncology.*

Yes. And I think, Vamil, that first step for that first approval is phenomenal from that SunRISe-1 data, but we have more to come, right? We have two fully enrolled Phase III studies, SunRISe-1 and SunRISe-5. SunRISe-3 in that high-risk, newly diagnosed setting, head-to-head against BCG, 2 active arms. That's INLEXZO versus BCG and INLEXZO plus our own PD-1 versus BCG.

Really will be the first innovative BCG-free therapy in that newly diagnosed setting. And then we have our SunRISe-5 study, which is in those patients who are BCG exposed. Both of those are large patient populations. You can kind of get an idea of what that SunRISe-5 patient population data looks like from the cohort four of SunRISe-1. You're seeing high disease-free survival.

And then when you think about it, right, between SunRISe-3, SunRISe-5, we really cover kind of that whole spectrum in that high-risk non-muscle invasive bladder cancer setting, but we also have our TAR-210 sustained drug delivery system as well, both MoonRISe-1, which is in that intermediate risk setting, which is another 1/3 of patients in that non-muscle invasive bladder cancer setting and then also MoonRISe-3, which is in that same SUNRISe-5 patient population on BCG exposed using that FGFR targeting perspective too. So we really do cover the majority of patients with bladder cancer in that localized disease setting.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Okay. That's great. And you've obviously talked about this being a \$5 billion-plus type opportunity for Johnson & Johnson. We do get some questions on how to think about the initial sort of uptake and also the breakdown across different types of provider settings, whether it's academic, large groups or kind of more community-based urologists. So how are you thinking about sort of the profile across those three settings?

And then again, the sort of initial uptake as you're still rolling out, obviously, you got an approval in a small group, you have a lot more data to come. It's a long-term play here. So how should we think about the next year, a couple of years in terms of the initial uptake?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. I mean we are seeing adoption across academic, large urology practices, smaller deeply embedded into the community. As we mentioned, it's really seamless. It's very integrated into the urologist practice. So as they become very familiar with this first indication, it's just going to help accelerate as we continue. And we're just really, really excited about the platform, the TARIS platform in general, but specifically in non-muscle invasive bladder cancer.

And as Mark described, I mean, if you think about it, our development program covers the majority of non-muscle invasive bladder cancer. 75% of overall patients are in that non-muscle invasive bladder cancer and then 50% are high risk. And then we see intermediate about 30%. So end-to-end, we're really looking to bring this transformational innovation with subsequent indications.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Okay. So there's a lot of products I want to talk about.

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

There's a lot we can talk about. I want to touch on a few others that maybe I come back another time. Because RYBREVANT made a lot of great progress there. So maybe the latest around getting the subcu formulation approved here in the US. But then also, I think kind of any insights you can provide on the uptake you're seeing in the lung cancer space. It sounds like your commentary on recent earnings call has been pretty positive on the adoption even before the subcu formulation arrived?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. And maybe I'll talk a little bit around -- first of all, we're super excited about RYBREVANT and LAZCLUZE. We're seeing great momentum in the market. We are the first and only chemo-free regimen for frontline use. And we're really focused on that durable overall survival as well as preventing resistance. It's very important in lung cancer because patients do develop resistance with the current standard of care.

So we are really poised for this to become the new standard of care. What I can say, we're focused on changing that trajectory of that five-year survival rate. And what we see today with the IV in market, we are -- have the highest intent to prescribe. So the number one regimen intent to prescribe RYBREVANT and LAZCLUZE.

We have the highest unaided awareness and every one in four patients are on a Johnson & Johnson Innovative Medicine regimen for lung cancer, and we're penetrated across all of our key sites and centers. Now RYBREVANT subcu will be another catalyst for us and enable us to get even deeper and accelerate the utilization of RYBREVANT and LAZCLUZE. But we're now really talking about how the market is moving to combinations. Maybe Mark can build a little bit on that.

Mark Wildgust - *Johnson & Johnson - Vice President, Global Medical Affairs, Oncology.*

Yes, Sarah, it's a good point because you've really seen a shift, right? So the World Lung Cancer meeting happened earlier in September. And if you think about EGFR non-small cell lung cancer, single-agent monotherapy pills, TKIs have really been the standard of care for the last 15 years, and that's very, very much entrenched.

But coming out of the World Lung Congress, you now have two combination Phase III studies that have proven that you have a superior survival benefit versus monotherapy TKI. So I think the era of monotherapy TKI is over. I think we're really in that combination realm. And I think the question now is which do you pick? Do you pick two old treatments together or do you pick one new regimen?

Do you pick a regimen that changes the biology and changes the outcome, that targets EGFR prevents the resistance forming that enhances the immune system? Or do you use chemotherapy with a TKI. And I think that's where I think the marketplace is kind of readjusting. I think, one, I think you're going to have to see the marketplace say, the physicians are saying, do I really like easy and easy is a set of pills.

Easy is also an order sheet, which says, hey, nurse, please give my patient chemotherapy. I think there's a reshifting there of saying, okay, I really need to think about how do I optimize that outcome. I think that some of the initial feedback from RYBREVANT was, okay, I'm still learning how to deal with some of these infusion-related reactions. Okay, I figured that one out now. Oh, I see some skin-related reactions.

Now we've put out the COCOON regimen. So they're getting very comfortable with that. And I think importantly, with the subcutaneous administration, you now give a patient and the physician the simplest and fastest administration of a combination, which then harnesses that changing the biology and resetting the long-term outcome. So I think that's where we're seeing that shift in the marketplace of the moving away from what they did to what that new regimen is going to look like.

Sarah Brennan - Johnson & Johnson - Chairman, Global Commercial Strategy Organization

Yes. And we're seeing growth both in the front line as well as we see growth in the second line because we're seeing patients develop these resistance.

Vamil Divan - Guggenheim Securities LLC - Analyst

Okay. And then obviously, lung cancer is a focus now, but I thought very interesting data at ESMO from RYBREVANT. So maybe you can just touch on the head and neck data, the opportunity there and then colorectal is another you mentioned.

Sarah Brennan - Johnson & Johnson - Chairman, Global Commercial Strategy Organization

Yes, Vamil, when you think about EGFR, there are definitely other malignancies where EGFR is a really important driver. Head and neck is one of them. Most of those patients particularly HPV-negative patients, right? EGFR is a real driver for those patients. And really, it's a real medical emergency for those patients. And so we're really excited to present the OrigAMI-4 data, the cohort looking at just RYBREVANT alone subcutaneous in those patients with recurrent and metastatic head and neck cancer.

And you see more than 45% with objective responses and then more than 80% of those patients are actually having disease reduction. Put that into context for a second. Current standard of care in that second-line setting with therapy, you're talking about somewhere in about the 10% range. And when you think about durability, it's not very durable as well.

Then when you think about the current standard of care for patients with head and neck cancer, it's typically chemotherapy or chemotherapy plus PD-1 response rates are about 36% in terms of that. So to see a 45% response rate with RYBREVANT in that recurrent metastatic setting really sets the scene for us. We're going right after EGFR. We're blocking MET again. We're harnessing the immune system.

And so we just announced at the ESMO meeting our OrigAMI-5 study, which is going to be the new first-line study that we're going to be looking at in head and neck, looking at chemo pembro plus ami, head-to-head against chemo pembro, and we think that, that has the potential to kind of reset expectations there. But colorectal cancer is the same, right?

We have OrigAMI-2, which is our frontline study in left-sided wild-type disease. That study is enrolling incredibly fast across the United States and around the world. And then we also have our recurrent study in the second-line setting as well, the OrigAMI-3. And we know in colorectal cancer that EGFR is an important pathway as well. So it makes sense for us to go right after that.

But I think, Vamil, one of the other things, too, is that when you think about medical oncologists today, in the community setting, they're treating lung cancer, head and neck cancer, colorectal cancer. And so I think that broader kind of array of the portfolio for RYBREVANT is going to fit right into the pocket of those physicians, right, who are treating those EGFR-driven diseases.

Vamil Divan - Guggenheim Securities LLC - Analyst

Okay. That's great. So I want to shift gears again, still within oncology. But obviously, multiple myeloma is a massive area for Johnson & Johnson have to sort of talk about it. So a couple of areas I want to just get your thoughts on here. One on CARVYKTI, I think we're seeing nice sort of uptake. Obviously, manufacturing issues seem to be essentially behind you at this point. So how you see that sort of path moving forward?

And then we get some question on the bispecifics, what I think you've talked about being very bullish on, but the commercial uptake, I think, to date has not been maybe quite as much as we thought, and there's been some changes around the dosing intervals and stuff that played a role. So just kind of what you see for CARVYKTI and the bispecific portfolio sort of going forward?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. Maybe I'll start on CARVYKTI and then we can move to the bispecifics. So as you mentioned, CARVYKTI has been incredible in terms of what it's delivering for patients. We shared data on CARTITUDE-1, and we see that 30% of the patients are disease-free at five-years. So it's really incredible. We continue to grow with CARVYKTI. We've expanded our sites in the US. We've also launched in 14 countries.

We've treated over 9,000 patients worldwide, and we continue to see incredible growth. The team from a manufacturing perspective has done a phenomenal job. We are meeting the demand, the growing demand in the US, outside the US and seeing incredible growth. And really over half the growth is coming from the community setting. So we've really been able to offer this to so many patients on a worldwide basis.

And we are planning to launch in even more countries and continue to expand. So it's been a big success rate, and we continue to be seeing it be a very critical treatment option for patients. I don't know if you want to add anything on CARVYKTI, and then we can talk a little bit about bispecifics?

Mark Wildgust - *Johnson & Johnson - Vice President, Global Medical Affairs, Oncology.*

Yes. I think, Vamil, with CARVYKTI, right, we're resetting expectations, right? We're now starting to talk about cure for the first time and the potential for cure in the myeloma setting, and that is really coming from CARVYKTI. I would tell you on my side, right, I'm super excited about publishing in New England Journal of Medicines.

But actually, this summer, we saw a simultaneous New York Times article, which was kind of interesting, right? But you actually talked about that idea from hospice to hope, where you have -- you're really talking about these patients who had a median of six prior lines of therapy, 1/3 of patients with single dose are alive at five-years.

Just to kind of ground people again, median survival in that patient population before CARVYKTI was approved was 12-months. Now you got 1/3 of patients who are alive, no disease left at five-years. You see that plateauing of the curve that is indicative of cure. And I think we're resetting the expectations of efficacy when you think about CAR-Ts in myeloma as the curative potential. And I think anyone following us, anything on an efficacy perspective, cure is the benchmark.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Yes, the bispecifics?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. So I wanted to -- we are very excited about TECVAYLI and TALVEY. So TECVAYLI has been the most successful bispecific launch overall. So we're really pleased. We're obviously seeing continued momentum. We've seen over 20,000 patients being treated worldwide. We have the lowest rates of discontinuation. And we're continuing to garner additional experience in the community, and that's accelerating our momentum and our growth for TECVAYLI.

TALVEY is also growing nicely. It's actually the fastest-growing molecule in its approved indications. And you have the flexibility of using it before BCMA or after. So there's a lot of opportunity there. And again, we're garnering additional experience in the community and seeing that continuous growth. And we also obviously have some -- we recently announced some great anticipated data on a combination regimen, which is really going to accelerate the utilization of the bispecifics into the community. And maybe Mark can talk a little bit about that. It's very exciting.

Mark Wildgust - *Johnson & Johnson - Vice President, Global Medical Affairs, Oncology.*

Yes. Just a couple of weeks ago, we announced in a press release that we reached the primary endpoint for the MajesTEC-3 study, which is tec dara versus dara pom dex or dara VELCADE dex. We announced that we met the primary endpoint of PFS, but we also included in that press release that we also saw a survival benefit as well. So we now know that tec dara has a proven survival benefit in that early lines of therapy.

And I think the thing that I think is good to just kind of keep in mind with tec and dara, in that schedule, tec is dosed with dara. We use the dara schedule. It's a fully subcu regimen. And I think when we saw with TECVAYLI coming out, first of all, we saw people playing with the dose, playing with the schedule. And I think perhaps that's kind of had some impact on some of the usage.

But here, we anticipate that people know exactly how to use dara. It's going to be fit with dara, tec dara. It's going to fit right into that community setting. It's built for the community. It's built for the community that we now know how to manage CRS, which means that patients can get started without worrying about hospitalization. We know how to manage infections because we've seen how to use IVIG.

And so I think that, that regimen of tec dara is really going to fit perfectly into the community setting, and I think you're going to see that rapid uptake clinically because the data are going to be transformative.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Okay. In the last sort of 6 minutes here, I do want to move away from oncology because you have stuff outside of that, too. So the big one, I think, for us, at least icotrokinra. So now filed. Again, one of the big pipeline products that you're highlighting. Can you talk about how you see that sort of entering the market? Obviously, psoriasis is an initial indication but then IBD.

And is this a market expansion opportunity? Or do you see it sort of pulling from some of the other advanced therapies that are out there now?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. No, great question. And we are extremely excited about icotrokinra. It is really -- we've seen this become just an unprecedented combination of complete skin clearance in psoriasis, favorable safety profile in an easy once-daily oral pill. And we have a tremendous opportunity to expand the market for psoriasis. If you think about today, about 60% of patients are eligible and either not taking a systemic treatment or they're not on an advanced systemic treatment.

So when you think about this oral icotrokinra, where from market research, the majority of patients prefer orals and they're cycling through topicals and not necessarily on a systemic, you can imagine this can be truly the frontline systemic treatment of choice to expand that market in psoriasis. So it's truly an expansion opportunity, and we're really looking forward to delivering this product with this type of combination.

It's going to be a real game changer for patients with psoriasis. And then you mentioned IBD. So we also have data from a Phase II study that we're leveraging to initiate our Phase III programs in IBD, both ulcerative colitis and Crohn's disease, and we see tremendous opportunity to also expand the market with icotrokinra in IBD.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Okay. And then not to leave out another big approval you recently had was CAPLYTA, also \$5 billion opportunity for J&J. So this is for adjunctive treatment of MDD. So as you think about the \$5 billion, and I know you don't break it up by indication, but how important is the adjunctive MDD opportunity within the broader CAPLYTA?

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. It's -- first, we're very excited. We got the approval Wednesday of last week, and we were ready to go on Thursday. And it's very important. First and foremost, CAPLYTA already was approved and has an indication for bipolar I and II, both mono and adjunctive treatment as well as schizophrenia. So you add the adjunctive major depressive disorder indication on, it's just -- it's really important and incredible for patients and prescribers. In the US, there's 22 million people with depression.

Mental health is a major issue, not only in the US, but also globally. And one out of two patients that are on an antidepressant have residual symptoms and issues. So having this adjunctive treatment for major depressive disorder is very, very important, and it really resets the treatment expectations. We have data from a long-term study that shows that 80% of patients had a response and 65% of those at six-months are in remission. So it is an incredible opportunity.

And I think the prescribers really see the benefit of having all of these indications as they're treating patients with different types of conditions. So we couldn't be happier and more excited for patients, and we certainly see this as one of our \$5 billion-plus assets coming out of our Intra-Cellular acquisition.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

And maybe just one more follow-up on CAPLYTA. I think we've gotten some questions on -- you already have obviously these other indications. So is there a lot of work to sort of do with the payers to get access for patients in MDD? Or should it be relatively seamless because it's already out there.

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Yes. It's already been out there. So you can imagine it's really going to be integrated into what is already established, and we continue to be very confident in our ability to enable access for a broad patient population. And then looking to find opportunities to expand even beyond the US into other markets as well. So very, very excited.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Okay. All right. Great. I think we'll leave it there. Thank you so much again to the J&J team for joining us. And obviously, a lot of excitement led us to upgrade shares a few months ago, just given all the progress you guys are making on the pipeline here. So great to see and we'll be watching closely over the next year.

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Thank you so much for having us. We appreciate it.

Mark Wildgust - *Johnson & Johnson - Vice President, Global Medical Affairs, Oncology.*

Thank you so much.

Vamil Divan - *Guggenheim Securities LLC - Analyst*

Thanks.

Sarah Brennan - *Johnson & Johnson - Chairman, Global Commercial Strategy Organization*

Thank you.

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