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PRESENTATION

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Welcome to the afternoon sessions of the first day of the BofA Health Care Conference. My name is Geoff Meacham, I'm the senior biopharma analyst here at BofA, and Charlie Yang from my team is onstage as well.

So we're thrilled today to have Johnson & Johnson and with us on stage here is John Reed, who's Executive VP, Innovative Medicine from the R&D side. So John, thanks a lot for joining us.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Thank you, Geoff. Great to be here.

QUESTIONS AND ANSWERS

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

What we'll do is just if you want to give us a high-level kind of set up the stage here for what to expect here from a sort of a pipeline perspective and then we have lots of questions.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. Well, I have to say the pipeline has just been like a rocket ship. We enjoyed, last year, a 90% success rate across all stages of the pipeline; in the first quarter of this year, about 85%. So really kind of industry-leading success rate. And the momentum has just gotten so strong in oncology, immunology, even in neuroscience now.

We see a lot of opportunity just in the recently launched medicines. If you look in myeloma where we're #1, and we're #1 and #2 overall in hematologic malignancies, here you've got TECVAYLI, TALVEY, CARVYKTI, so first-in-class T cell redirector bispecifics as well as the best-in-class CAR-T cells that have recently been getting additional line extension approvals, building on our success with DARZALEX, the first biologic for myeloma, the CD38 targeting molecule. So really exciting momentum there as we move these into earlier lines of therapy and in combinations.

In prostate cancer, where J&J is also #1, recent data in the early space with adjuvant therapy that are looking really interesting and more readouts to come. But in the late stage in metastatic, we have 4 new mechanisms in the clinic: radiopharmaceuticals, T cell engagers, ADCs, CAR-T cells. So really exciting momentum there. And then in lung cancer with RYBREVANT, the world's first bispecific for a solid tumor indication, targeting 2 growth factor receptors, really what we think is the new standard of care for EGF receptor mutant lung cancer. So that's just in oncology.

And then in immunology, we'll be sharing next weekend our data in inflammatory bowel disease with TREMFYA, our selective IL-23 biologic. And then SPRAVATO, the first new mechanism for depression in more than half a century, continues to gain market share and acceptance. We just had a monotherapy set of data. They're beautiful, best effect size as seen in that space, so really transformational therapy.

So those are the things that have just recently been approved. And then the pipeline of new NMEs that are seeking their first approval has really been really exciting. So maybe we can get into some of that during the interview.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Yes, yes. Let's talk about myeloma first. So obviously, a huge contributor to you guys. Maybe I guess the question is like where are we for DARZALEX as a foundational therapy in myeloma and obviously foundational in your P&L? But give us a perspective on what's ahead in terms of share opportunities, life cycle management opportunities.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. DARZALEX continues to grow. It's actually now our largest-selling product, having displaced STELARA, which will soon go off patent. And we've been getting more and more traction in the front line setting as we released data like the PERSEUS study that we showed at the ASH meeting, American Society of Hematology, were added on to the most prevalent or common backbone regimen. We've had progression-free survival that's unprecedented. I think the hazard ratio was 0.3 something -- actually no, it's 0.42 so reducing the risk of progression by more than half. And so we're getting more and more traction there.

Plus in myeloma, there is this kind of precancerous, if you want to call it, state, smoldering myeloma, where patients have not yet met the diagnosis. So we're going to have data on that in combination with REVLIMID pretty soon that could open up that, which is a big space. And then going forward, we're doing combos of dar with tec and tal, our T cell engagers. So that's looking more and more promising, too, and even have collaboration with academic investigators who are taking those again into smoldering myeloma, trying to intercept disease early and even into MGUS, which is an even more prevalent, even earlier sort of preneoplastic state.

So I think there's still a lot of opportunity with dara. It's still the only sub-Q option for CD38 therapy out there, and it's become more and more a backbone almost every regimen out there.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Sounds great. Yes. And then the next conversation, obviously, will shift to cell therapies with CARVYKTI, so fantastic data in last line and then moving up the paradigm.

Maybe just help us, John, with where we are in the manufacturing capacity. That tends to be a rate-limiting step. But do you feel like is 2025 the year that you think we'll be more free and clear of capacity? And kind of what does that mean for the paradigm?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. So it's certainly been a journey. Autologous CAR-T is -- it's a steep hill to climb. But fortunately, I mean, CARVYKTI has been such an effective product that it certainly gives us the motivation to do what's necessary. If you saw in the second line where we just recently got the approval, the CARTITUDE-4 data, hazard ratio of 0.26, the best hazard ratio ever produced with any therapy in myeloma. I mean, my goodness.

So yes, we've been expanding the number of sites. We recently built and opened a new facility in Ghent, Belgium to supply the European market. We've been expanding our sites in New Jersey, partnerships with other companies to expand into their excess capacity to give us more slots.

On the lentivirus, which had often been kind of a rate-limiting component of these, we've really mastered that technology now and have now got an FDA clearance on a 50-liter scale. So we don't see that being a rate-limiting step anymore for us.

And then behind the scenes, we're working on all kinds of ways of automating and robotizing this process so that it can be even more high throughput and higher scale. We announced a partnership last year with a U.K.-based engineering company called Cell Origins (sic) [Cellular Origins]. And then we're leveraging all those scores of engineers we have in MedTech at J&J and have got them also in our labs helping us to figure out how to make more of this an automated closed system process that we can do at scale. So it's a journey, but feel good about the progress we're making.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

And as you move it, CARVYKTI, to earlier lines of therapy, I know the FDA recently updated guidance for MRD negativity that should help with trials and development. But what are the challenges of moving up the paradigm? And obviously, the benefits are a huge number of patients and long-duration therapy -- or long benefit.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes, I think so. Regardless of the therapy, indeed, as you move to earlier lines, you're going to have to wait longer for definitive clinical readouts. So the FDA pronouncement that they would allow the minimal residual disease as a potential approval endpoint is a really nice opportunity then to be able to, frankly, justify the investment of going into these really early spaces.

But that won't solve the problem in other countries unless they get on board with this at some point. At this point, they're still requiring the usual progression-free survival, overall survival types of endpoints. So our studies so far are still designed with those classic endpoints, but we are looking at whether MRD negativity in very, very early, like smoldering or things like this, could be a way to go in the future.

In terms of CAR-T in these earlier lines, I think that's really interesting because the standard of care for patients who can tolerate it is to go through an autologous bone marrow transplant, which is not trivial, right? There's a high -- there's a pretty significant mortality rate associated with that, high risk of secondary malignancies.

So if we can offer as an alternative to that, to try to get that residual disease under control with a CAR-T therapy, I think that could be a complete paradigm changer for early-stage myeloma.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

And I guess last question on myeloma. When you think about the bispecifics, lots of exciting assets that are coming up the paradigm at J&J. How does it all play out? Do you see DARZALEX maintaining its first line? And then you sort of have this wave of cell therapy, CAR-Ts, middle of the paradigm and then bispecifics. How do the -- how is it...

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

We're frankly trying to move everything in the front line so we're doing combos of dara with tec or tal and seeing if we could move that into the front line. And then as I said, as an alternative to bone marrow transplant in the front line, having the CAR-Ts then to sort of polish it off. So that would be the dream, is to bring these all into the front line.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Got you, okay. Charlie, do you want to...

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Can I follow up on that just quickly. Just in terms of kind of like the big sales potential you're thinking about for the bispecifics, right? Is the base part, the base case for them to be used in a front line setting?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

I think we see that as a potential for the future. We have to generate the data to prove it in the -- currently, it's more in the later lines. And for patients that maybe CAR-T is not the right solution for them, this turns out to be a very good way to come in and in a different way engage the immune system. Particularly popular outside the U.S. where CAR-T is not usually reimbursed in most countries. So we really see it as a couple of different ways to solve the problem for patients.

We also find some patients just have preferences. Like we talked to some patients who love the prospect of going in a CAR-T where then they could have long remissions and not have to worry about taking a medicine every day or every week. And then we have others who, when they've relapsed, they go, I don't want to wait. As the CAR-T cells take a few weeks to prepare, I don't want to wait. I want

something I can just jump to now and so they prefer the bispecifics.

So it's nice to have different ways of trying to crack the problem for patients depending on their preferences and their circumstances.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Got it. How about from like the competitive dynamics standpoint, just within your own account, bispecifics versus CAR-Ts or potentially kind of other CAR-Ts in place in terms of kind of taking out the best, taking out the infusion spot? How that's impacting your progression this year?

And then maybe just to follow up to that, think about other potential competitors coming up potentially in a couple of years, how is J&J thinking about that?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Well, it's certainly becoming competitive. J&J has the advantage that we were first-in-class with these mechanisms, first-in-class with CD38 dara, first-in-class with the BCMA targeting, first-in-class with PCR GPRC5D essentially an antigen we discovered in our own labs. Others, once they see something works, they try to copy it and come in behind you so it will be competitive.

But I think the combinations, the fact that we have such a diversified portfolio that we can bring combinations together that others maybe have one of the assets, but not all the assets.

And then we never stop inventing. Like we've got an early development right now, a molecule I'm super excited about, is a trispecific that gets BCMA and GPRC5D in the T cell engager. So you have the CD3 arm to grab the T cell and then 2 targets on the myeloma. In that way, if the myeloma becomes smart enough to try to down-regulate one of the targets to try to escape, the other one is still there. So much less resistance problems. The early data are still coming in, but -- so we just keep moving on. We try to disrupt ourselves rather than have somebody else do it.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Yes. Great.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

John, would you view J&J's capabilities and CAR-T and cell therapy as a broadly strategic advantage? I know in myeloma, clearly a partnership with Legend. But if you look at other liquid tumor types, is that something that you would rather -- a modality you'd rather go after or a bispecific? Or is it all of the above?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. I guess we've taken more of a multiple-approaches approach. If you look at what we're doing in B-cell malignancy where our kind of entry point there was the BTK inhibitor, IMBRUVICA, the first BTK inhibitor, which has been an amazing molecule. And we've even been building on that with the data we just shared at the last ASH meeting in front line CLL in combo with venetoclax. The new standard of care, IMBRUVICA plus venetoclax.

But we have in the clinic now a CD19/CD20 [bi-CAR] for lymphoma. And then we have a trispecific for lymphoma with CD20 and CD79b and CD3. And we have a co-stim with CD28 and CD19. So we're again building up both the multifunctional biologics and the kind of multifunctional CAR-Ts to see if we can break through to the next wave of innovation in that space.

And then we're trying to do some of this in solid tumors, in prostate cancer. We've got a CAR-T targeting a thing called KLK2, which is the most selective prostate cancer marker out there. It's expressed prostate only. Unlike PSMA and some of those, it's spilling to other tissues. We have a radiopharmaceutical targeting that, an alpha emitter. We have a T cell engager targeting that. And then we -- on the PSMA side, we've got an antibody drug conjugate and a CD28 bispecific.

So really using multiple approaches because it's going to take combinations to win the war against cancer. And so we're trying to bring all the weapons we can bring to bear for those areas where we really commit.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Just along those lines, I mean, let's switch gears to bladder cancer and the TARIS platform. So you guys had recent data at the AUA meeting. But maybe just take a step back and just give us a bit of a history here of what gives you the conviction and the platform? And what makes you excited about this as a new strategy?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. And I think -- so for those who don't know, this is a drug-device combo that is inserted in the bladder for early bladder cancer, which is a huge problem. 600,000 new cases a year of early bladder cancer. It's the most expensive oncology indication today to manage because it's kind of like whack-a-mole where they have multiple tumors popping up in the bladder. And the urologists are in there with the scopes, et cetera, and try to chop them out and catch them.

Most patients, though, end up losing their bladder, which as you can imagine, what that does to their quality of life that patients suffer through without a bladder. So to have a bladder-sparing option is really a game changer.

So by having the drug-device combo, we've been able to really achieve unprecedented levels of complete responses. Now the journey started with the acquisition of TARIS, which had made a prototype version of this device that releases gemcitabine, good, old chemotherapy, with a controlled pharmacology. So it just comes out at a nice steady rate and it can sit there for weeks.

But that was not optimized and they were building those one at a time by hand. So our engineers whipped that into shape, got it ready for mass manufacturing, optimized elements of it. We put that in the clinic and we got Breakthrough designation on that now. And the data we showed at the AUA, it's just single-arm data but it's so compelling with 83% complete response. Of the responders, 85% still in remission, best in disease activity. So we're going to file on that using the Breakthrough designation while we do more of advanced studies.

And then on top of that, again, the engineers with our process chemists came up with another one with a targeted therapy, erdafitinib, our FGF receptor inhibitor, and made an entirely new device, different technology, uses a barrier diffusion technology rather than an osmotic technology. That releases the drug with consistent pharmacology, not for 3 weeks but 3 months. And that has given 90-plus percent complete response rates in the clinic.

So it's just a completely transformational therapy that only a J&J could do with a device and a drug where we got MedTech and pharma under one roof.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Makes sense. Charlie, you want to?

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Maybe you want to talk about like some of the -- I know you mentioned the efficacy or the durability. What else do you think is the differentiating factor for the TARIS platform, especially in light of all these emerging therapies out there?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. I think the tolerability is outstanding and it's something that just fits so easily in the urologist's practice, right? So they don't like to give systemic therapies and IV infusions or things like this. What they like to use is the scope and the catheters.

It's an intravesical treatment. It takes about 2 minutes to insert it. It takes about a minute to take one out using standard technologies that the urologists use all the time. So we just feel it just fits so well into the practice. Well-tolerated, outstanding efficacy. So we feel like we've really got a winner here.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

And would you say that this is essentially all the HCP out there or at least nurses can also do these procedures as well?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes, that's right. And that's probably what will happen, especially outside the United States, but yes, a really trained nursing staff. It's quite simple. It's not much different than if you're doing a catheterization just to remove urine from the bladder or something, it's not much more complicated than that, frankly.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

You good?

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Yes.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

So let's switch gears to lung cancer, so the lazertinib-RYBREVANT combo. Maybe just take a step back in the recent MARIPOSA data. How does J&J look at this relative to, say, a standard of care like TAGRISSO? Can both parties win? Usually, these markets aren't a zero-sum game is kind of how we think about it. But I wanted to just get your perspective on the approach to moving up the paradigm and how you see yourself competitively.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. I mean, you make a good point that there's no shortage of lung cancer, right? It's extremely common, extremely deadly still. But in the head-to-head, the MARIPOSA study, for those who don't know, was osimertinib versus 2 different ways of attacking the EGF receptor pathway. One was a third -- lazertinib which is a third-generation tyrosine kinase inhibitor, oral small molecule that hits a bunch of the resistance mutations and is brain-penetrant. Important because very often when patients with lung cancers relapse or end up in dire straits, it's because of brain metastases.

And then RYBREVANT, bispecific antibody that gets the EGF receptor, yes, but also another growth factor receptor c-MET, which is often involved in resistance to EGF receptor. So we're anticipating the resistance mechanisms and trying to stay ahead of them. The molecule is also fully immune-competent, so the tail of it, the Fc region and recruits immune cells. And we think that's also an important part of the mechanism that is brought to bear that you would not get in a small-molecule EGF receptor inhibitor.

So with this multidimensional way to try to attack, we saw outstanding progression-free survival. The overall survival data are still maturing, but they look very encouraging. The PFS-2, which is sometimes used as a way of kind of predicting where OS might go, those data were outstanding as well, all this in the front-line setting. So those have been submitted on a global basis and we're waiting for the approvals.

But while we were waiting, we started further evolving the regimen. So we now have a sub-Q, so instead of IV. You'd see those data at ASCO, the pharmacology, the efficacy, everything beautiful. But you also have now the convenience of sub-Q, but also better tolerability because the IV preparation had some infusion reaction issues. This one now, very clean.

And then we also had, in the first studies, probably because we were inducing so much tumor cell lysis that can lead to venous thrombosis like -- so we now do prophylactic anticoagulants with our XARELTO for 4 months, takes care of that. And then EGF-targeting therapies always have some skin tox, but we now have a prophylactic use of skin treatments that are ameliorating that to some extent.

So all that work is helping to further optimize the regimen, make it more tolerable for patients, more convenient for patients. So we feel really good about that.

And then in the second line, we had great data in combination with chemo for a couple of different types of EGF receptor mutations. So all the data sets have just been really stellar on the progression-free survival.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

And the regulatory path for sub-Q, is it just sort of a bridging mechanism? Or do you have to run a...

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

We have efficacy as well, so we feel like we've got the package that allows us to submit sometime this year.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Okay. Perfect.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

And maybe just on the, I guess again, the competitive dynamics with the first-line versus TAGRISSO or versus TAGRISSO plus chemo, I know this is more of a chemo-free option, but kind of what's the feedback from physicians, from docs in terms of how you're thinking about the data that you have seen so far versus the patient convenience or...

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. As I said, I think the efforts we've been making to make the regimen we have with lazertinib and RYBREVANT, a chemo-free one to make it better, more tolerable, more convenient will really help there. I mean, chemo is no walk in the park, as you know. And I know most of the KOLs we talk to really like to have the chemo in their back pocket for when patients relapse, and they usually do relapse at some point.

So if you've already used that, you really don't have much to turn to in the second-line setting, which I think is why the PFS-2 data are informative, right, because if you relapse -- if the patients relapse after RYBREVANT/lazertinib, you still have chemo that you can turn to and buy some more time for the patient. If you're doing that upfront, you've kind of used all your ammunition and now you're left with nothing.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Yes. Are we going to expect to see OS data later this year as well or...

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Maybe. It's event-driven. It could be later this year but we can't promise because it's event-driven.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Got it. Yes.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

So oral IL-23, there's a lot to talk about at J&J so there's a number of programs we can ask about. So 2113, give us some context for how you think that shapes up to the standard of care today or an emerging standard of care, for example, for [take twos]?

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. No, maybe just a little background. So this is what we call a targeted oral peptide, so that binds to the IL-23 receptor and inhibits it. And that is really difficult chemistry. But the teams use these complex cyclic peptides that we got a starting point from a collaborator protagonist.

And then over, I think, a 3- or 4-year journey, just solve a problem after problem to we have now a well-behaved molecule. We can give it orally, it's very stable and very potent. So we're doing once-a-day dosing and have seen the Phase II data in psoriasis just beautiful efficacy, along with the pristine safety you've come to expect from IL-23 selective inhibitors.

So we're in the middle of the Phase III campaign for psoriasis while we've started Phase II studies in some other indications like ulcerative colitis.

But just to give you a sense, I think, of how much interest there is in having an oral option on the part of patients. We enrolled the Phase III psoriasis studies in 1/3 the time that it normally takes to do a Phase III study and that indicates patients are just flocking to the protocol. And as we know, when you look at the diseases like psoriasis, there's a, let's say, relatively low penetration rate in terms of the percentage of patients who are eligible for advanced therapy who actually take one.

And that's because of the resistance to some of the -- either there's a resistance to the injections or there's concern about safety, which you have with some of the other oral therapies where, instead of selectively targeting the receptor, you're targeting signal-transducing kinases that, yes, they play a role in your desired receptor, IL-23, but they also play roles in other receptors, too, and then you get this collateral damage in terms of the risk of safety.

So we've just seen an enormous enthusiasm for and the molecule has been behaving beautifully.

And then the final thing I would say, which is not trivial, is the manufacturing. So we're not making this like you would a GLP peptide where you have like a solid support, you add one amino acid at a time. This has been done with a completely nonsolid based, a completely solution-based chemistry using convergent synthesis. We've driven down the cost of goods by a hundredfold and have scaled this to multi-kilogram scale. So it's really a beautiful piece of process chemistry that the team has done as well.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

I think the last question here just to sort of tie everything together. You talked a little bit at the beginning about J&J's approach and top-down, but from, say, a BD versus a licensing perspective, there's a lot of in-house innovation that J&J can push forward, but there's also opportunities for partnering as well.

So how do you think about that going forward with so many companies and with sort of nifty technologies, but maybe not quite products, right? This is a perfect spot for you guys.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Yes. I mean, look, we have a broad partnering agenda and I think J&J has been known with that when we have these kind of unique approaches like innovation centers around the world and JLABS and things like this where we try to have scouts out in the four corners of the globe looking for interesting technologies and assets. And incubating companies usually will have like 50 companies per JLAB at different innovation centers around the world.

But we play in both the platform side and the product side, so some things are supplementing the pipeline. Like I just mentioned, the protagonist collaboration that led to the IL-23 inhibitor, 2113. Others are more on the platform side. On the CAR-T side, for example, we acquired a company called Serotiny, which has an AI-enabled high throughput way of optimizing the CAR construct. And then we partnered with Cellular Origins on the robotics and automation side for the manufacturing. So we're playing both the platform and the product side as part of our overall innovation agenda.

Geoffrey Christopher Meacham ***BofA Securities, Research Division - MD***

Got you. Okay. Well, John, thank you very much.

John C. Reed ***Johnson & Johnson - EVP of Innovative Medicine, R&D***

Thank you, Geoff. Thanks, Charlie.

Chen Yuan Yang ***BofA Securities, Research Division - Research Analyst***

Thank you.