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PRESENTATION

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Here we are. And welcome back from lunch, everybody. I hope everyone enjoyed that last panel discussion. Always informative to hear from the dark side. The opportunity now is to have the afternoon session kick off.

I'm very pleased to have Johnson & Johnson with us once again. And this is a very timely discussion, especially given all the changes that are happening with the company in terms of the rising prominence of the pharmaceutical division and we're especially pleased to have 2 of the leadership here from the oncology division, which is, I think, really the division of the business that really moves the needle here.

Biljana Naumovic who is Worldwide Vice President of Oncology, with a particular focus on commercial operations. We've had discussions with you previously, and you're probably familiar to a bunch of some of the investors as well. And then Mark Wildgust. Mark is an oncology specialist as well, medical affairs. And we're glad that you could come in here and pitch it to make sure that we had full representation across our discussion.

So both of you welcome, and thank you for joining us.

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

Thank you.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

We're coming on the heels of ASCO in particular. And I think we're going to talk all about really the multiple myeloma franchise and how enveloped that it's been. But I want to actually begin in particular -- and I consider these firesides a discussion amongst the 3 of us. And while you are here with the face and the name of J&J, it's important for us to understand who you are, where you're coming from and how to interpret what you say.

So Biljana, if you can give us a little snapshot of what your professional journey has been.

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

That's a good way to start. So, I'm a physician by training, and I started my practice as a physician in a country that fell through war in Eastern Europe. I'm Serbian. And I went into the pharma business very early on in my career when targeted therapy came to oncology. And I was excited by the prospects of it, started in Roche, building things in HER2 setting across majority of Eastern Europe. And I fell in love with -- what the opportunity in pharma is, to change the landscape. And I'm still very fascinated on the impact we can make, but I'm also very committed into what we can do together. And apart from that, a global nomad. I've been living in 3 continents, many, many countries, and worked in amazing organizations that are bringing innovation to patients in our health care, and Johnson & Johnson is the most amazing place to be.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Yes. And the international background is no surprise and which is why when you said, when we were talking before about jet lag, I was thinking versus what time zone. So New Jersey is not that remarkable, but Mark, tell us about yourself.

Mark Wildgust

Yes. So Chris, I grew up in the United Kingdom. I'm a hardcore scientist by training. Did my PhD in the United Kingdom, my postdoc here in the U.S. But I spent 25 years in drug development, really spent most of my time on the oncology side. I've worked at J&J for almost 18 years, but I've also worked at other big pharma as well. But most of my career I've spent really developing new innovative oncology drugs, really pretty much across all of the disease areas, whether that's heme or solid tumors. And really the last 10 years or so, I spent a lot of my time at J&J really developing what I think Biljana and I agree is one of the best-in-class portfolios in the industry.

But for me, I'm a dad. I've got 2 kids, grownup. Both of them are no longer -- they have no interest in science. Ones in cybersecurity, The other one's an artist. So I'm not sure where I went wrong there as a hardcore scientist, but they're certainly doing some great things in the world today. But great to be here with you, Chris.

QUESTIONS AND ANSWERS

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Thank you. It sounds like you inspired them either way because we need all of those functions a little bit as well. We all can't do cool jobs like ours. So what can we say? The pharmaceutical business, as I mentioned at the outset, is going to become clearly more prominent with the consumer functionally and explicitly now, being separated as a corporate entity. Is there anything a little different in sort of like mindset, timbre of the air, just conversations at all?

It's been such a global organization and everyone is really focused on exactly what is center point for their efforts. But I'm just curious to know, is this -- this is a transformational year for you and particularly as a member of the leadership there. Is there a couple of pixels of awareness about that change that's happening or not so much?

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

Look, we're absolutely internally aware -- not only aware but excited -- about the change that is happening. And the change that will bring, Kenvue as the new company, the opportunity to do what they do best and the opportunity for us as the pharma and med tech business to kind of coordinate things better.

What's the impact of that change? There's a lot of focus on what we do in terms of research. We have just come out of ASCO. We're going into ESMO. We'll go into ASH. All of our senior leaders are with us. Every single congress we're in, we're discussing with our Board of Directors the strategy we want to take, especially around oncology and the progress we do there. So there's focus and depth that is imminent to happen with a transformation like that. And we're also very much aware that if we do it well as a med tech and pharma business, there's a lot of coordinated efforts we can do to really be a company that others might strive to be.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Okay. Now that totally makes sense. And I think that investors are going to be looking now with a little bit greater focus on that. I think pharma typically carries a larger percentage of the revenues and often the discussion here, but now it's going to be very explicit and intentional, so buckle up. So that sounds terrific.

Let's talk about multiple myeloma and ASCO and EHA and all of these meetings that are coming through. And as a disclaimer, one of the things that's always interesting to talk to you guys is that you're kind of everywhere. And so it's just like whenever people in the analyst community ask you questions about this, it's like, "Oh, CAR-T before biosimilars." And you're like, "Yes, maybe we win either way," because you kind of have this wraparound presence there.

So I'll ask you to try to be discerning about sort of picking a favorite child, to a certain extent. But let's talk about perhaps the highest profile result that came out, results at ASCO on CARTITUDE-4. Maybe highlight for us the key takes on the data there, in your opinion.

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

Yes. Well, Chris, first of all, I will come back to the philosophy in multiple myeloma, why we think we have a winning strategy. But I want to let Mark start with our excitement at CARTITUDE-4, sort of what we're bringing there.

Mark Wildgust

Yes. I mean CARTITUDE-4 is our first Phase III study for cilta-cel. And I think that while the data for CARTITUDE-4, I think maybe a sneak to peek out with some leaks beforehand, we're great to be at ASCO to be able to really showcase it. First Phase III study, we've seen a hazard ratio of 0.26. So for those of you who aren't into hazard ratios, that's the lowest hazard ratio or the best outcome for a Phase III study in multiple myeloma that we've ever seen. And so it really sets the standard now. That cilta-cel has really -- showing that it's really transforming outcomes for patients.

When you look at the 176 patients that were treated with cilta-cel, 175 of those had a clinical response. 99.4%, it's hard to get much better than that. A clinical response rate of -- a complete response rate of 84%, and 90% of those patients are progression-free at a year. Some of those data are the best we've seen out there.

When we look at CARTITUDE-4, as we go earlier, tolerability improves. As we go earlier, it looks like the efficacy improves as well. And so I think the CARTITUDE-4 study really kind of consolidates what we believe that cilta-cel is really the best-in-class BCMA CAR-T. And we followed up with longer-term data at ASCO as well and EHA on the CARTITUDE-1 data. We're now seeing, at 3 years, a progression-free survival really at that 3-year time point for the median progression-free survival.

And we also presented long-term data from Legend, too. And that showed, at 5 years, there is a plateauing now in that progression-free survival. About 20% of patients are still progression-free. And at 5 years, almost half of them are alive.

So the combination of those 3 studies really help us understand the potential for cilta-cel. One, it's transforming outcomes in that first line or first relapse setting. We're seeing transformational data. We're seeing long durability in those follow-ups from CARTITUDE-1. We're also seeing the potential for cure. As we go earlier, knowing the data gets better, I think there's even more of a potential as well. So I think cilta-cel is going to be groundbreaking. We're excited that we submitted it now with the European Health Authority and the U.S. FDA. Now we're going to be running to get that into the hands of physicians so they can start giving it to their patients.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

It's that clinical data, the profile, the report card in essence that is so impressive. And yet the decision that's being made by the clinicians often has more ingredients to it, comfort with the data that's there. Because often, kind of the measuring stick that we have complete response after certain periods of time, you're always going to get someone who perhaps is looking for a little bit more confidence with longer-term data, existing comfort with some very outstanding existing therapies where there's DARZALEX. And then you throw on top of that the logistic realities of actually manufacturing, supplying CARVYKTI.

And so when you think about that, what would you say is the right way for us to think about where CARVYKTI will fit in relation to DARZALEX. And obviously, we're going to go treading into discussions of where the biosimilars intercept this kind of this XYZ axis that's kind of a bit mind-blowing. But let's start with in and around DARZALEX.

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

Yes. So maybe there's -- when you look at the reality of the data and the complexity of autologous cell therapies, the promise with CARVYKTI is amazing. Is every single center going to be able to apply autologous cell therapies? Not really. And in that context, what we want to make sure that we have is a solution for multiple myeloma as a disease because being a multi-myeloma company and bringing a lot of research in it, what we want to do is, within this decade, start seriously talking about cure.

And how do you bring cure in a very complex disease like multiple myeloma where it's not one size fits all or one drug fits all? We have a combination of -- DARZALEX is a backbone of any combination therapy, primarily moving into the frontline setting where coming out of MAIA and the GRIFFIN data and PERSEUS data for the quad therapy that will come out very soon, we want to solidify the effects and the benefits that DARZALEX combination will bring.

CARVYKTI in the frontline setting, which is where we want to take it, not in the second plus lines, but with CARTITUDE-5 and CARTITUDE-6 data, that will prove CARVYKTI - ideally prove CARVYKTI when data comes out in transplant-ineligible and then directly versus transplantation and transplant-eligible, which we are the only ones researching that way and will help bring CARVYKTI to the setting where we think will bring the most benefit.

Is that going to be for all? Not necessarily. Some patients cannot wait for autologous cell therapy. Some patients have very bulking disease. Some patients have soft tissue disease that will require many things. And then post CARVYKTI, you will need to -- post refractory in CARVYKTI, you need to bring therapies that are going to be meaningful, be it TECVAYLI, talquetamab in monotherapies or in combinations, one with another. We have presented a lot of data on ASCO from RedirecTT-1, with the first data of the combination of our bispecifics as well as TRIMM-2, the combination with talquetamab and DARZALEX, we have combinations of TECVAYLI with DARZALEX. So we have the ability to actually tailor to the needs of the physicians, the centers and the patients so that for any eventuality of multiple myeloma we have a solution at Johnson & Johnson. And that's something that really gives us the true power to bring regimens and not talk about treatment to progression but really treatment to cure.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

We're kind of this intermediate stage where the adequacy of supply is defined as kind of a rate-limiting factor in terms of making that decision separate from the data, right? So could you update us in terms of where you are in terms of your current status of manufacturing scale-up and different aspects of building the efficiency yields and whatnot?

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

No, absolutely. That's a great question and very pertinent to this time. So there are 3 things that we're doing in parallel to make sure that we can scale up and cater for the need for CARTITUDE-4 and think beyond to the frontline setting. On one side, it's the lentivirus supply. So we have internalized the lentivirus, and we are scaling from 20-liters to 50-liters to eventually 200 liters, so we can have more lenti and better yield. And we're doing that. The 50-liter should be coming very soon and being functional. So that's one bit. We have internalized this, so we don't depend on anything that is outside.

The second part is making sure that we can ramp up our manufacturing. And it goes in 2 ways. One, we already have a facility that is within the United States in Raritan where we are ramping up according to the FDA regulations. We have increased 50% to date our daily manufacturing slot numbers versus the beginning of the year. We want to do another ramp-up by the end of the year. We are limited there by what the regulations say and how we can do it. And we're working hand-in-hand with the FDA to do certain things in parallel, but that takes time. And we are, as I said, ramped up once already. We will be doing that another time later on this year.

The second part is we're building manufacturing capacity in Europe, and that will be coming out of our Ghent facilities, hopefully, by the end of this year. This is the plan. And in it will have much more scalability within Ghent and different regulations that will require -- that will be required for the ramp-up. So that's our internal capacities are going to be heading to the state where we can serve way more patients incomparably more patients than today.

And then, of course, the third side is we have great results. CARTITUDE-4 came out and everybody would love to use it, and we're just limited by our own supply, correct? So, we are going outside in a smart way to make sure -- you've seen our collaboration with Novartis. We want to go where people have the manufacturing capacity and internal capabilities that people have already produced cell therapies because ultimately, with cell therapy, it is -- the process is the product. So, you want to make sure that, again, we have to go through the process of verifying the clinical supply through Novartis first, which we want to do as soon as possible and then move into commercial supply.

So, these are the levers where we're pulling to make sure that our ramp-up is going to be satisfying what the market is going to need.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

So all the elements appear to point you in the right direction. But then here on Wall Street, for better or worse, we have this thing called 2025, that year, for which the pharmaceutical business has had an identified sort of revenue objective. Within that, the building blocks, CARVYKTI is quite important. And so when we think about being able to get a narrowing of the gap between where I think the J&J team envisions based upon backing up of data but also some of the uncertainties of can we get the product through and the Street's expectations that we all tend to be kind of skeptic and grumpy.

How do we close that gap? And do you feel as if the opportunity to move into those earlier lines is going to be something that we're going to have confidence that it's going to be part of that 2025 equation to get that number for the total revenues because CARVYKTI is so -- such a significant potential opportunity there.

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

It is. And I mean, look, CARVYKTI has absolutely significant potential opportunities, and we have called it out as a \$5 billion potential asset. If you just do the math on the frontline setting and only in the U.S., you have 37,000 patient incidents every single year, capturing a fraction of that will bring much higher than \$5 billion potential. And we are aiming to get as much as possible from the manufacturing to be able to serve as many patients as possible. That will be closing -- that is aiding to the 2025 ambition, certainly. And we will be, like I said, doing everything that we can in that time frame as the opportunities in the Ghent facilities in Europe and with CMOs outside in this short term allow us to serve more patients.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Okay. That makes sense. Let's transition to bispecifics here. TECVAYLI, the launch there. Can you share any takeaways specifically about the launch progress to date. We're trying to think a little bit about sort of how physicians are adopting to use and the realities of the clinical dynamic because there's the element of learning curve and some of the issues there in patient management, complications, et cetera. Perhaps Mark, you can talk to that.

Mark Wildgust

Yes. I think that we're seeing a really good uptake in the U.S. market and also outside the United States. I think we're well over 4,000 patients now treated with teclistamab and we're seeing it really being picked up quite quickly. I think that the physicians are getting increasingly comfortable. Just here at ASCO just a couple of weeks ago, we were presenting new data on how to manage CRS to be able to potentially support outpatient management using prophylactic tocilizumab.

But we already know in the United States, in particular, that we're seeing practices starting to figure out how to be able to do outpatient management. And we're anticipating large academic centers really starting to go fully outpatient soon. And we have an ongoing study that we're going to be starting with a large U.S. network soon for them to be able to help to figure out how to be able to do outpatient as well.

But I think that the receipt and acceptance of teclistamab has been really strong within the U.S. market and overseas as well. These patients have run out of treatment options. These patients are responding rapidly. They're seeing their M proteins go down very quickly and seeing these patients get into complete responses. They're seeing what we saw in our clinical trials. They're seeing that highest CR rate that has been seen in any bispecific, and they're seeing long durable remissions as well.

And just at ASCO, we also presented now that patients can switch to an every 2-week dosing of teclistamab as well. And we're seeing that already translating into the community, too. So teclistamab has almost been on the market getting close to a year now. They're getting comfortable with it. They're very happy with it. But one of those elements of that I think they're also happy with is that personalized weight-based approach that we have for the dose. It allows them to really tailor teclistamab to that patient individually to optimize the efficacy and safety, and they're seeing those similar types of responses that they saw in the clinical trials, too. So I think the acceptance and the reception to it has been really strong so far.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

The first year is often a lot of adaptation and learning curve, so end of the year from now, 2 years in, can you hazard a range of perhaps a portion of patients that might be able to be receiving it on an outpatient basis?

Mark Wildgust

Yes. So Chris, it's really interesting, right? Because the U.S. FDA said patients should be treated in the inpatient setting. Should, not must. But actually, outside the United States, prescribing information is silent. And if we went to say, for example, France, for a second, at least half of those patients are being started in the outpatient setting already in countries like France where that prescribing information is silent. And we're seeing increasingly more coming in for one infusion in the academic center and then going out to the community setting. So I anticipate that more than half of the patients in the future, in the next year or so, will be treated outpatient.

And as I said, watch the space, you'll see some large academic centers soon announcing, "Here's how to do it." And as you said, they're figuring that out, but we're also contributing to that too, by saying, "Hey, here's the data to show the lowest rate of CRS seen in any BCMA bispecific by using prophylactic tocilizumab," "Here's how you can manage infections as well." We just presented data looking at usage of IVIG to be able to reduce those rates of Grade 3, Grade 4 infections, too. So we're contributing to that, but they're also learning and growing. And I think we're seeing teclistamab really being adopted in a very quick and fast way.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

It also seems to be perfect for thinking about combinations, which is just the inherent for multiple myeloma treatment. You have a combination study TECVAYLI with talquetamab as well. Can you talk to where the areas you think might be most applicable for the data that could come from that?

Biljana Naumovic - Johnson & Johnson - Worldwide VP of Oncology

So look, we presented at ASCO the RedirecTT-1 trial with a combination of TECVAYLI and talquetamab exactly in the historic patient setting. So patients that were heavily pretreated previously. And we have had overall response rate that range on the level of CARVYKTI, so they're in the 90-plus setting. And what we're seeing specifically with this combination, on one side, it is very tolerable when it's given together. So physicians know how to manage it. There is no surprises in the adverse event profile, and it's being loved as a concept of 2 immunotherapies being able to be given together.

But then on the other hand, the number of patients that had extramedullary disease for patients with soft tissue disease that is really aggressive and super hard to treat, especially also for autologous cell therapies, results are remarkable. And we have seen the data and the individual patient data where 80-year-old patients with massive comorbidities receiving TEC and talquetamab, had their disease disappear within months. So what we want to make sure is that we're bringing it earlier in the treatment paradigm that we're defining also well who can benefit the most from it and then seeing how we can set it in the frontline space for the patients who need fast responses to therapies like this.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Okay. Let's talk about another high-impact area that you're very much in the midst of: Rybrevant, lazertinib. And certainly, there's a tremendous interest from investors about the ultimate readout for the MARIPOSA study given the challenge to the throne of TAGRISSO. And building blocks for that, which we love to make -- read across analysis from, is the CHRYSALIS data. Longer-term data was recently presented at ASCO. Talk about the key areas of focus in your point of view to help make us smarter as we think about MARIPOSA as well.

Biljana Naumovic - Johnson & Johnson - Worldwide VP of Oncology

So I can start with our vision for lung cancer. And this, I think, is a vision that is shared by all the community that treats lung cancer and by many pharmaceutical companies as well. We want to push chemotherapy out of frontline setting and ideally push chemotherapy out, bringing the combination of targeted therapies or biologics ultimately. And what you have with CHRYSALIS data, so this is 20 patients, and we have followed them in a Phase II trial for 33.5 months. In this combination, after 33.5 months, we have not reached progression-free survival. And what it looks like is that for those 20 patients, the progression-free survival will be in the ballpark of osimertinib's overall survival.

The adverse event profile is managed perfectly well by the physicians. And what we have been discussing with patient associations is this amazing desire to have the most efficacious therapy as soon as possible. So it gives the opportunities and gives us hope for MARIPOSA. We don't have the results yet. We originally had the plan for final analysis Q2 next year. We have moved it forward by 6 months at least to the end of this year. We'll probably move it forward even further and have the data, hopefully, events allowing, to present at some of the congresses that are coming later on in the year. So, we are very optimistic about the opportunity.

The most important thing about the MARIPOSA study is that really the combination of the best. According to data, we have seen Yuhan 201 data, third-generation TKI, that numerically has impressive results versus osimertinib while, at the same time, having absolutely no issues with cardiac toxicity, which is the issue with the other third-generation TKI as well as low levels of diarrhea. And that combinability with RYBREVANT that brings then ultimately the combination of the depleting eGFR extracellularly as well as intercellularly and bringing macrophages too to the space where you can expect a longer-term effect of adding RYBREVANT there is something that is scientifically very plausible and we're so excited about data coming up and, in that sense, setting a new standard for what we should be looking at in the frontline setting and expecting from our therapies.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Can you share your thoughts in terms of the level of benefit or anything else with MARIPOSA, powering assumptions, that can help frame what you think is a balanced expectation?

Biljana Naumovic - Johnson & Johnson - Worldwide VP of Oncology

So look, we don't talk about our powering. But what we are -- the MARIPOSA study is powered for PFS, and we want to bring statistically significant PFS immediately. We want to also bring the benefits in terms of side effect profile, the convenience, the trends in overall survival. Ultimately, that will be the real goal when you look at the frontline setting is looking at the overall survival benefit. And what you can do as subsequent therapies post RYBREVANT and lazertinib.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Terrific. Let's move on to ERLEADA. It's another one of the important opportunities here as part of the building blocks to get to that oncology team driven model to get the pharmaceutical revenues in 2025, et cetera. Talk about your expectations for the ATLAS trial: efficacy, safety, particularly this metastasis-free survival end point. And talk about its efficiency in terms of presenting this for regulators.

Mark Wildgust

Yes. So Chris, I think that in the localized disease setting, we know that there's a group of patients with local disease but have high-risk features. And really today, patients with localized prostate cancer are treated in 2 ways, either with radiation therapy or with surgical therapy. And we have 2 studies that are ongoing: ATLAS, which is really looking at apalutamide or ERLEADA combination with radiation therapy over a 30-month period of time; and we have a second study, the PROTEUS study, looking at it with surgery as well, both neoadjuvant and adjuvant.

The primary end point for ATLAS is metastasis-free survival. And one of the reasons we picked MFS as the end point is that we know MFS is correlated with overall survival. And so we're confident. And I think we've seen recent data coming out looking at abiraterone in the same setting too, showing really beneficial clinical improvements and outcomes. And I think we're really confident that with the ATLAS study, we're going to see something very similar as well.

Now we saw earlier this year some data that came out from the Alliance Foundation looking at apalutamide or ERLEADA in that BCR space, that biochemical relapse space, again, confirming its efficacy in that earlier space. And I think between ATLAS and PROTEUS, I think apalutamide or ERLEADA is going to provide that opportunity to combine either with radiation or with surgery to be able to improve outcomes. So I think hold the space, I think you'll see ATLAS and PROTEUS in the near future.

And I think that's important because when we think about reaching for cure, one of those places that we need to reach to is that localized disease setting where we are starting to talk about improving outcomes and getting towards cure for these patients.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

So my appetite for catalysts is always a decoder ring. In the near future, is there hope for potential news on the trial in the 2023 time frame? Can you just help us a little bit in sort of the Wall Street vernacular of when are we going to learn what?

Mark Wildgust

I think we're thinking about it next year.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Okay. No, that's helpful there. TARIS, yes, the platform. I mean actually, Jess and Raychel were all very excited to host. And there have been some very helpful dialogues and conversations to get a little bit sleeves rolls up and to spend some time thinking about this. This is almost kind of pathognomonic of J&J, the ability to sort of be agnostic to therapeutics with device and delivery, right? I mean it goes back. The heritage is very deep here and, hence, the open-mindedness about this. But maybe for everybody, just outline sort of what we should know about the platform itself.

Biljana Naumovic - Johnson & Johnson - Worldwide VP of Oncology

That is your sweet spot. You love talking about that.

Mark Wildgust

Yes, let me tell you about it. So we actually have 2 of these devices, one called TAR-200 and one called TAR-210. TAR-200 is just really remarkable. It looks like a pretzel. It's actually a silicon-based tube. And we actually use this osmotic pump where we actually have urea inside of it and gemcitabine. When we put it into the bladder, it forms as a pretzel shape, floats around and it then elutes gemcitabine over a period of time. Now gemcitabine today is used for many patients with bladder cancer. Where we put gemcitabine into that bladder, we ask the patient to hold it, hold it, hold it, until they expel it. That's painful for them but it's also only giving them a short exposure.

And we've just reported out the data from SunRISe-1, looking at patients with non-muscle invasive bladder cancer. Non-muscle invasive bladder cancer is your earliest form, really on that surface of the bladder. And we know at that time point that patients typically get a therapy called BCG. But for those patients who are BCG unresponsive, really the therapies at that point are really limited. We're talking about removing that patient's bladder. And at that point, there's really not a lot more.

And so we just reported out the SunRISe-1 data with this TAR-200 pretzel, and we saw a 72% CR rate at 3 months. Now the currently approved regimen in that setting is KEYTRUDA of 40%. So those numbers really are quite different when we think about the SunRISe-1 data. But most importantly, we're seeing durability. For those patients who retained the CR, they haven't lost that CR. Whereas when we look at KEYTRUDA, I think it goes down from about 40% to about 16% over the year. So we're seeing high rates of CR and we're seeing durability of CR, too. So hopefully, later this year, we'll see some more data on the SunRISe-1 data.

But then the other pretzel that we have is called TAR-210. And this is where you're actually taking a novel -- really a tailored therapy erdafitinib, a targeted therapy that targets FGFR alterations. And we know patients with intermediate risk non-muscle invasive bladder cancer, about 70% of those patients have FGFR alterations. So we're putting erdafitinib into this pretzel and using zero-order kinetics. We're actually having permeability over a period of time. Put that pretzel in. Leave it for 3 months. And the data that we presented at ASCO on erdafitinib in the metastatic setting showing an overall survival should really give us even more confidence with that new drug device as well. So we are really excited this is really transformational for patients with bladder cancer.

Biljana Naumovic - Johnson & Johnson - Worldwide VP of Oncology

To add to that, what is beautiful about TARIS and why we get very excited about it is the fact that with a device like this, you're going into urology practices and you're asking them to do what they generally do, and that is put something -- put the device in the bladder. It is so well tolerated. For the gemcitabine pretzel, we're having a 3-week device. So after 3 weeks, you take it out and put it in again. For the TARIS with erdafitinib, it will be a 3-month device, so the practicalities of this for the patients.

And if you look at the results we presented on AUA that Mark just said, the SunRISe-1, BCG did not have 17% response rate in BCG naive. And the drops that happened in the first year are half not just for KEYTRUDA but for everything else. In real life, patients who are in BCG, they never stay on the protocol for BCG. It's not even in the single-digit percentage in the real world. So in that sense, not only we are excited by the data that we've seen, but the community is excited because it's going to be easy, it works, and it will give a lot of hope to a lot of bladder cancer patients.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Yes, BCG has been foundational to medical textbooks going into the prior century. So in that standpoint, that magnitude of innovation step change function I think is going to be very material. SunRISe-2, -3 and -4 are additional studies aiming to move into other realms, expand the opportunity because TARIS is one of the \$5 billion-plus club. Remind us what -2, -3 and -4 are like and when we're going to learn from those?

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

So for -2, -3 and -4, we're going into metastatic space with -2 and -4 and non-metastatic space replacing BCG. So SunRISe-3 is the direct replacement of head-to-head comparison with BCG and SunRISe-2 and -4 our Phase II and Phase III studies for the muscle invasive bladder cancer. So what we want to bring is something that will, like you said, use the opportunities that we have, unique opportunities as a biotech company, meaning MedTech and pharma company, and bring that to a space that didn't see innovation for decades seriously, the implementable innovation, let me call it that way.

And in that sense, when you look at the 600,000 patients per year that are being diagnosed that have bladder cancer, the majority of them sit in the non-metastatic space. In the non-metastatic space, nobody wants to use systemic therapy. Then the possibilities of a pretzel, be it with gemcitabine or with ERLEADA, erdafitinib is going to become standard of care. If we can deliver the results that we are seeing in SunRISe-1 and some extremely promising results that we're seeing in other settings that we see internally, we really believe this is going to revolutionize how bladder cancer is treated and be a bladder-sparing company.

Mark Wildgust

Hashtag pretzel.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Okay. Well, we're out of time here. Thank you so much for providing thoughtful updates across the oncology platform, Biljana and Mark. Appreciate it. Thank you.

Biljana Naumovic - *Johnson & Johnson - Worldwide VP of Oncology*

Thank you so much. Much appreciated.

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