EDITED TRANSCRIPT

JNJ.N - Johnson & Johnson at SVB Securities Global Biopharma Conference (Virtual)

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Great. Good afternoon, everyone, and thank you for joining us for this next session with JNJ. My name is Dave Risinger, and I cover diversified biopharmaceuticals. It’s very much my pleasure to welcome 2 senior leaders at Johnson & Johnson. So that is Biljana Naumovic. She is Worldwide President of Global Oncology; and also Peter Lebowitz, who’s Global Therapeutic Head of Oncology R&D.

So I thought we’d start off with a high-level question for Biljana. Could you discuss -- well, first of all, congrats on all of the phenomenal progress and momentum for your organization and what you’re leading. I thought we’d start off with asking you to discuss your vision for capitalizing on the tremendous success that you’ve already had and driving further success in multiple myeloma.

Biljana Naumovic

Thank you, David. And it’s really a pleasure to be with you here. So look, our leadership in multiple myeloma is rooted in a really focused scientific strategy that has been shaped by Peter and the team. And once you have a strategy like we do for multiple myeloma, understanding that the regimens are going to be the way forward, plus that the best curative intent can happen only when you have the most efficacious regimens being delivered first, it is really an obligation to shape the market in a way that is going to support that’s coming to life.

So the -- how we have approached it that DARZALEX is our -- currently the backbone of myeloma therapy, and we can talk about that a little bit more. Last year, we had 2 approvals, one of CARVYKTI, best-in-class cell therapy for multiple myeloma and of TECVAYLI, first off-the-shelf BCMA therapy for the patient. This year, we expect the approval for talquetamab as well. Now what does that do for the community of multiple myeloma patients and physicians? Well, it puts an obligation for all of us to educate and shape the system in a way to support the administration of our medication.

And what we are foreseeing is on one side, deep connections with our academic institutions, to be able to get to the first patient treated in a way that is going to show how the combination therapies work. On the other side, we’re working with the community setting to really understand what they need for the outpatient setting for the utilization of all of these medicines that we have.

And for some of them, the key will not be in building capacities for hospitalization, the key will be in finding a way to develop safe administration of our drugs that we’re doing right now and finding ways to administer and manage the safety profile in a way that it can be easily administered in -- or easier administered in the outpatient setting. So this is how we see the combination of the signs that we already brought to market, but also shaping of the market to be able to support all the patients and physicians who will be using it.
David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

That's helpful. And just a follow on. So what role can JNJ play in helping management of the safety profile? So I would assume that would involve a lot of nurse education and, I mean, you obviously can't hire nurses for providers. But help us understand what you can really do when the system is stretched and the nurses aren't educated and necessarily highly attuned in the community setting to deal with safety issues with some of your therapies.

Biljana Naumovic

Thank you, David. So there is -- I can mention 3 things that we're doing in parallel to make sure that we're supporting the first part of the treatment, but also supporting the longevity in the long term. On one side, you mentioned that it’s education. And it’s education that we’re building with our nurse teams. We do have -- we can’t support all the nurses in the hospitals, but we can support the education through our nurse teams to the entire community, and we’re taking a very tailored approach as to how to come very broadly to the centers, not only community centers, but to academic centers as well to make sure that everybody understands how to manage it.

So that's one approach from our side. We’re also coupling that with the peer-to-peer education that we're bridging between the physicians and the nurses who already have experience with administration of TECVAYLI, whether the ones that will be using it soon. So that's one part of the approach.

The second lever of that is management or the utilizing data to really showcase the safety management, both in terms of infection rates, but also the CRS rate that we are doing, both with the community physicians within the United States, but also with the patients and physician association in some of the major European markets.

Some of this data, we will be presenting in the congresses that are coming ahead of us.

And the third part is really building the guideline. As we are first-in-class therapy of the cell therapy to come to market, we really are working very closely with the U.S. and international organization for multiple myeloma to shape the guidelines on how this is done. So that we can continue the education and the appropriate management for TECVAYLI moving forward.

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Let me just add one more thing, David, because it's very important is that whenever a new therapy comes along, it does -- it often takes some time to understand exactly what the safety profile looks like over time and how to manage it the right way and how to dose that therapy the right way.

So we believe -- we moved this program very fast because there were patients in need but we believe that there is more that we can do, and it's ongoing right now, to mitigate the CRS with producing data showing how you can mitigate CRS as well as device regimens where we can minimize the infection risk that we're seeing with extended dosing. So both of those things are things that we believe we can affect with further clinical trial.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Excellent. That's very helpful. Perfect. And then one more commercial or high-level question. Biljana, it would be helpful to just understand penetration. So JNJ is already leading in multiple myeloma. It already has an extraordinary position. Could you talk about opportunities for broader market adoption and just sort of where we are in terms of opportunities for expansion in myeloma for JNJ?

Biljana Naumovic

Thank you, David. So look, we are the leading multiple myeloma company, which by no means, means that there is no opportunity to expand and help more patients in it. If I could start with DARZALEX. We have penetrated extremely well the relapsed/refractory setting of multiple myeloma.
We have introduced DARZALEX FASPRO. We now have more than 85% of patients who are treated with FASPRO. We have around 360,000-plus patients who have been treated with DARZALEX so far. We are, having said that, growing as well last year of 33% with DARZALEX. We are only scratching the surface of the frontline setting.

So we are nowhere near to penetrate the half of the population in the frontline setting. The data that is coming out with MAIA regimen with PERSEUS that is -- that are going to be our registrational studies with GRIFFIN that already read out, and those were the things that were highly highlighted in the ASH are going to also open the opportunities additionally for us in the frontline setting in the U.S. as well as the major European market.

On the other side, there is a population in the rest of the world that is only now getting DARZALEX in the relapsed/refractory setting. So frontline setting in that vast majority of markets is still going to be open. So that's only one drug. With CARVYKTI, we're just scratching the surface. You have seen CARTITUDE-1 data. We have announced the positive results of CARTITUDE-4 data that will be presented later on. And we are moving CARVYKTI into frontline therapy. We believe that will be best-in-class and best option for cure for patients for multiple myeloma. That is a huge opportunity for us to expand.

And then additionally, TECVAYLI that we just launched and talquetamab that we will be launching or entering in the 4-plus lines of therapy with the combination that we're bringing forward, and like we said at the beginning, building regimen that Janssen can do, unlike other companies, will expand our penetration in multiple myeloma in the next decade.

Peter Lebowitz
- Janssen Pharmaceuticals, Inc.
- Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Biljana, why don't you start and I can add on because we haven't released the actual results. We've released a very brief assessment of the trial, but we will release that fairly soon. But Biljana, you can comment on the commercial part.

Biljana Naumovic

Very well. So look, we know that patients drop off very fast in the outer lines of therapy. And the benefits of cell therapy, especially because we have to count on the viability of the patient, is really in the early line setting. So when we think about CARTITUDE-4 and the result we will be releasing this year, we certainly see the opportunity to get best-in-class therapy, so the standard of care, if I can call it that way, for the second frontline setting for all the patients who can receive cell therapy.

So in essence, we believe that, that will -- the magnitude of that opportunity is huge. And we want to make sure that we're able to serve as many patients there as we possibly can with CARVYKTI. But knowing that the expectations of the multiple myeloma community and what we already have seen in CARTITUDE-2 data cohort B of these patients, we really expect that this will be standard for cell therapies.

Peter Lebowitz
- Janssen Pharmaceuticals, Inc.
- Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Just a couple of things to add, David. The interesting thing here is that when you go into that -- first off, we're really excited about the results, and we're really looking forward to presenting them. But when you go into that earlier line setting, you overcome a number of barriers with providing CAR-T. One of them is that those patients come in with a bridging regimen.
And so you have more time to make the CAR-T, and the patients are more stable when they get the CAR-T, and they have less of a disease burden. And so that's the setting where CAR-T, we believe, CAR-T becomes even more effective because you're actually dealing with a patient population where you can get them the therapy in a reasonable time, and they have less burden of disease. So our hope was when we started that study, that it would be -- that we would see improved safety as well.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Excellent. And then, could you just frame in the U.S., I don't know, how stretched the treatment centers are today in terms of providing CAR-T therapy? So if you had all the supply in the world, how much will you be limited by the major academic institutions' ability to deliver CAR-T to patients?

Biljana Naumovic

Well, maybe I can start on that. Look, currently, around 400 centers around the world have been educated on various cell therapies, not just ours in multiple myeloma, but in other hematological malignancies that existed before. We are very much aware that the capacity and the experience is going to play a major role once we -- especially if we unlock the production and opportunities for patients to be more broadly treated.

So we're taking a very tailored approach and making sure that, on one side, we understand where that capacity lies, what the restraints are and how we approach it with the centers. And we're opening the centers in a way that will allow for broader experience with not just one-off experiences with CARVYKTI. On the other side -- so that's one piece that we're really doing in a tailored way without opening the gates too wide.

On the other side, we also believe that it is important to save the capacity for the best cell therapies that exist. So bringing our clinical data to prove the best-in-class and show what we can bring to patients will certainly open more opportunities for patients to be treated with CARVYKTI versus anything else.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Right. Okay. And so Peter, could we talk a little bit more about TECVAYLI in terms of chronic use and infection risk? And how would you frame that for us?

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Yes. So I think I mentioned a few things about this before that as we're developing drugs, we often find -- with longer treatment, we'll find emerging toxicities. And so there is, in the current regimen as it's approved in some of our trials, we do see this issue of infection risk with extended treatment. And as I said, I think there are things that we can do around supportive care as well as potentially altering the regimen that we can give in order to reduce that infection risk. So that's what we're working on now. And I have a lot of confidence that we'll be able to get there.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Excellent. And so when should we watch for additional disclosures on updates to potentially alter the regimen?

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Some of that work in clinical trials is ongoing, so it's hard for me to say exactly when those updates will be. But it's not work that's theoretical, it's work that's ongoing.
Okay. Very good. And then how do you see competitive threats from various BCMA bispecifics in development?

Well, I mean, number one, you always want to be first and the strategy that we always take, and we've taken it with IMBRUVICA and DARZALEX and ZYTIGA and others, is to be first, which we've achieved with this. But then the next step is to build the best regimens in earlier line settings. And so that is the core strategy of what we're pursuing now to be -- to keep the lead as the BCMA CD3. If you look at the other BCMA CD3s, you see little variations in things all the time in studies, but to us, there isn't that much that differentiates these BCMA CD3s that are behind us that would impair our competitive position.

And look, what I can add to that, David, as well, we're very cognizant of all the data that is coming and we're looking very, very tightly to understand what the comparisons are to our research, even though they can't be compared and we do believe that we have the first in class -- best-in-class BCMA [that shows] bispecific.

So the one other thing that I would add, David, is -- and it's not something I'm going to go into now because it's too early to talk about and it's a real competitive piece for us, but we have some unique approaches and combinations to create regimens that aren't necessarily available to other companies, and we are actively looking at those with some early interesting data.

Well, you teased us a little bit there. So when might we expect updates on that? Later this year? Or not until '24?

I expect that we'll report on some of these regimens absolutely this year, yes.

Excellent. Okay. And then maybe we could talk about new modalities in immunotherapy. So it may be too early for you to talk about it. But I guess it would be helpful for you, Peter, to just discuss different modalities. ADCs are seeing a little bit of a renaissance. Obviously, there's a lot of focus on NK cells and NK engagers, but anything that you would like to highlight would be helpful.

Yes. So look, there are many different platforms -- the amazing thing now is a number of these platforms are expanding and advancing in ways that we feel really increase their activity and their promise. ADCs is one of them, right? ADCs have been around for a long time. But there are new platforms of ADCs and we've learned how to make these ADCs better and very focused around what target we're going after and what we then need in the toxin and the linker and all these other pieces, that we now have really engaged with ADC platforms. We did a deal with Mersana last year. We did a deal with Hangzhou DAC last year as well. and we have the binders to bring into those ADC platforms. So we like ADCs a lot.
We also, as you know, have a big CD3 platform, and that continues to move on. And you should expect to see trispecifics around CD3 as well as some other approaches. And then the other thing that we've invested in is iPSC CAR therapy. That comes in an NK cell format, but also now in a T cell format, and that's some work that is ongoing as well. So I think as things progress, these 3 major platforms are ones that we're going to end up focusing on. And I think all of them have a lot of promise, and they may be used in different ways, different places. Often people like to say which one is going to be the best, but it usually ends up being that you need all of them.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Right. Okay. So maybe we could just pivot back to a commercial opportunity or two. So assuming MARIPOSA shows superiority versus TAGRISSO at the interim this year, what is the TAGRISSO sales run rate that could convert to JNJ? And how quickly could JNJ affect that change?

Biljana Naumovic

Look, for lung cancer, we absolutely understand that it’s already become, past decade, a place where if you bring something that is transformational, people want to use the best opportunity in the frontline therapy. Now we have -- with that in mind, we have been developing RYBREVANT and lazertinib as a combination and have MARIPOSA study that compares RYBREVANT-lazertinib versus osimertinib directly versus lazertinib and I can talk to 3 things there. On one side, we've seen already the lazertinib monotherapy data in the refractory setting and the combinability, the efficacy that looks stunning as well as the safety profile that looks very compelling versus osimertinib is something that we will be utilizing as monotherapy as well as knowing that, that will work in combination.

Second thing is we will be presenting very soon the updated information from the cohort of 20 patients from CHRYsalis-1 study. These patients have been osimertinib-naive. So this was the frontline therapy for them. And the results are truly impressive. And we are -- based on that, we think that if we bring the therapy that will be transformational versus osimertinib in a way that osimertinib or even better than osimertinib was versus previous TKIs, we should be able to replace osimertinib in the way that osimertinib replaced the previous TKIs.

So the magnitude of the efficacy effect and the impact on the patients in the frontline setting really tells us that there should not be anything to prevent us to work on getting this combination as primary choice for the patient in frontline setting -- we give for our patients in frontline setting. That’s what we want to do.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Excellent. And I received a question from the audience. When will the CARVYKTI capacity issues be resolved?

Biljana Naumovic

Maybe I can start with that. Look, we're very -- we have been approaching the unlocking the capacity for CARVYKTI for the longer-term period. You've seen -- now we've talked about the opportunities for the second plusline setting. We talked about the fact that we are going into early or frontline setting with transplant-eligible and ineligible patients. So what we’re doing is making sure that on one side, we have capacity ramp-up within the Raritan site already that we have opened within United States. On the other side, we're opening capacity in Belgium to be able to cater for that and have that facility for long term, so for decades, in order to build the capacity.

We are automating and building the capacity to not have lentivirus shortages once we have the patient demand that will require more. So we're building everything that we can in place to unlock the opportunity. The fact is that the challenges with autologous therapies are happening for all autologous therapies that are currently out there. And we are -- as we are learning ourselves, we’re learning also from the others that have been a bit longer challenged with this than us. So there are 3 approaches that we're taking. I've just laid them out. When we will fully unlock the capacity for CARVYKTI, we will be updating that -- the community, but we're working on all the levers that we can actually pull.
David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Got it. Okay. And I received another question, which is, is your iPSC T and NK cell work an internal platform given the Fate collaboration was discontinued earlier this year?

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

We did a lot of work with Fate and unfortunately, we had to terminate that. We do have some internal work there, but it's also a matter of looking at other things on the outside and other platforms.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Got it. Okay. Perfect. I wanted to bounce around and cover a couple of other topics. We've only got a few more minutes here. I guess, actually, Peter, we should focus on the TARIS bladder cancer platform. That seems to be a little bit of a sleeper because there's -- there hasn't been data recently, and we're still waiting for the pivotal results in coming years. But I think the platform is a lot more validated than maybe people on the outside appreciate. So could you talk about that and then discuss the key readouts ahead?

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Yes. So it's a timely topic, David, but we are really enthusiastic about the TARIS platform generally and the results that we've seen internally that we haven't yet presented. There are presentations at ASCO GU, which is just starting now. And so I'll leave that to when those are presented.

But that's sort of the first look at Janssen data with the TARIS platform. And the platform is really pretty remarkable and unique. It allows us -- more importantly, it allows us to really begin to expand out how we treat localized bladder cancer in a completely different way. The way it's treated now is the same way it's been treated literally for decades with BCG, and we believe we can put together regimens and even maybe even single-agent TARIS platform that can completely change the standard of care. So -- but the first part is going to be -- is, very soon, ASCO GU presentations.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

And remind us, pivotal trial results and potential filings in coming years?

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Yes. So pivotal trials are already started. And they're in muscle invasive bladder cancer as well as non-muscle invasive bladder cancer versus BCG. So those are started now, and we expect to file before 2025.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

And it seems like you're alone in market here, but maybe I'm incorrect about that. Could you just talk about if you're successful, how significant of an opportunity this will be? And I mean, clearly, the platform offers transformational potential, as you just mentioned, for both regimens and maybe even single agent. But if you could just expand on that a little bit more, that would be great.
Yes. So look, there are other competitors in this space. And -- but localized bladder cancer is a patient population of over -- 500,000 patients need therapy for their localized bladder cancer every year. So it's a massive, massive opportunity. And as I said, the standard of care hasn't changed that much. PD-1s are entering into the discussion with clinical trials that are ongoing. And then there are some other small company efforts out there in localized bladder cancer. But I think we're the only company that's really assembled the right platforms and drugs to start bringing that all together. Biljana, I don't know if you want to comment on the commercial opportunity.

Biljana Naumovic

I just wanted to add to what Peter has said. What we think we are bringing completely transformational is becoming a partner in interventional urology. And we know that localized bladder cancer is mainly treated by urologists across the world and we're bringing the assets where we are alone that is going to be completely localized and attacking it in a way that they approach how they treat bladder cancer, ultimately aiming to be the partner where they know that they can, in an interventional way, bring the therapy that is going to be very convenient for them and for the patients.

And in that sense, we want to be the treatment of choice for the physicians when they think about how they approach the localized bladder cancer with both TARIS options. So we’re -- like Peter said, we have several ongoing trials, both with GemRIS and ErdaRIS and we will be presenting them very soon to the community.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Excellent. And then one final question, Peter. So could you talk about the actual application of the treatment and physician experience with it, just so we have an understanding for how easy it will be for physicians to adopt it, assuming launch?

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Yes, yes. So this is something that urologists are used to doing because in patients with localized bladder cancer, they have frequent cystoscopies where they administer therapy. And it is BCG as well as other therapies. Sometimes they’ll give intravesicular chemotherapy. So it’s something that they are accustomed to.

It's on a schedule that they're also accustomed to. And potentially, we can improve that schedule with these TARIS depots that actually have even further extended release. On our latest TARIS drug depot, this is a 3-month distillation of drug. And so that spans things out longer than what most treatment regimens look like. So we believe we can improve the treatment paradigm in a way that urologists are very used to giving.

David Reed Risinger - SVB Securities LLC, Research Division - Senior MD

Excellent. Well, we are past time. This has been super helpful. I appreciate you both joining us. And thank you again for participating in our conference.

Peter F. Lebowitz - Janssen Pharmaceuticals, Inc. - Global Oncology Therapeutic Area Head for the Janssen Pharmaceutical Companies

Great. Thank you so much, David.

Biljana Naumovic

Thanks, David.
All right. Thanks, again.