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CORPORATE PARTICIPANTS

Frank Clyburn

PRESENTATION

Unidentified Analyst

(technical difficulty)

pharma analyst at Bank of America. I am pleased to be introducing our next company presenter. I'm joined by Merck & Co. and we've got Frank Clyburn, President of Global Oncology; and Peter Dannenbaum from Investor Relations. So thank you, gentlemen, for joining us here in Las Vegas.

Frank Clyburn

Great to be here. Thank you.

QUESTIONS AND ANSWERS

Unidentified Analyst

Maybe we can just get started. Frank, your role within Merck in the oncology area, obviously, this was a therapeutic category that was not a huge area for Merck a few years back. But you guys are fast growing in this space on the heels of a lot of successes with KEYTRUDA. So a very competitive category. Can you just talk about how you're leveraging some of the near-term wins around KEYTRUDA to build a sustainable leadership position in this category?

Frank Clyburn

Sure. So thank you. And it's great to be here. If you go back 5 years ago, we actually started to look at the opportunity that we had with KEYTRUDA and we had a chance to build out a business unit globally, pretty much from the ground up. And we now have several thousand people around the world focused on oncology. We brought in top external talent that are very oncology experienced. We have complemented that team with a very talented internal team. We think the global aspect of Merck, in particular, we're now approved in 80 countries around the world for KEYTRUDA. We have reimbursement in more than 50. So we think we've got a very strong team around the world to maximize the opportunity. In addition, in our clinical teams, we brought in great talent there as well. So we feel, as though, we are very well positioned for the future as we go forward.

Unidentified Analyst

Got it. So Bank of America had a Washington panel yesterday to discuss some of the recent administrative updates around blueprint and drug pricing proposals. And I think one of the things that was there was, as it relates to potential part B to Part D change that oncology was sort of sacred (inaudible) untouchable. As you guys have analyzed the blueprint, I'm just kind of curious as you think about just some of the general Part B dynamics, just kind of curious to get your perspective.

Frank Clyburn

Yes. So we acknowledge that pricing and affordability is a challenge for the U.S. and also around the world. However, we believe that Merck's focus really on investing in innovative research and development with a broad portfolio really helps us from a number of fronts. We also do believe that the administration sees the importance of an innovative pharmaceutical company that is developing innovative vaccines as well as therapeutics

and we think that will help us, and we look forward to working with the administration. I think it's too early to comment on specifics on the blueprint. Just know that we look forward to working with the administration and if you look at what we've done with KEYTRUDA, the amount of R&D investment with now over 750 clinical trials across 30 different cancer types, we feel as though we are positioned well, not only in oncology, but across Merck and other aspects of our pipeline. And then like I said, we'll look forward to working with the administration as things start to materialize. But I think it's a little premature to get into specifics as far as the blueprint.

Unidentified Analyst

Sure, sure. And one last big picture question before we jump into KEYTRUDA. But your general thoughts as you move into large tumors with the treatment like KEYTRUDA and over time simply more combinations and pricing models that could be deployed in this phase, particularly, in the U.S. we talk a lot about value-based and outcomes-based models. How far away do you feel like we really are from some novel mechanisms coming into the U.S. market and being utilized?

Frank Clyburn

Yes. So there are some pilots that have been done or underway looking at value-based pricing in the U.S. I think right now, the current health care system in the U.S. where KEYTRUDA is reimbursed in a Part B reimbursement regimen, we feel as though, there is a lot of work that may need to be done for that to actually change in any shape or form. So we think we're still a while off before you see any real change within the U.S. construct of reimbursement. But as I mentioned, I think regardless of how things may evolve, we think we're positioned very well for the future.

Unidentified Analyst

Got it. And shifting gears to KEYTRUDA and the lung cancer data that you recently presented at AACR, just sort of curious in the U.S. marketplace, you're already there in an accelerated basis. It sounds like you're pretty much in launch mode already even though there is a later full conversion event on the ultimate label. So can you maybe just comment how that's going since the data became available? And I think the commentary at AACR was PD-L1 negative was sort of the bigger opportunity of the U.S. where utilization was noticeably low and that the other segments are reasonably well penetrated, but maybe you can put that in your words.

Frank Clyburn

Yes. I want to maybe start and look back over the last 1.5 years because I think, it's important to put into context what is actually happening in the marketplace and then how do we see 189 coming into that. So we, right now, have in the U.S. market, about 80% of the patients are getting tested for PD-L1. In the patients that are high expressers with PD-L1 of -- and a tumor proportion score of 50 and above, that patient population predominantly is getting KEYTRUDA. Mostly monotherapy, but even some combinations in high-expressed patient population. We launched KEYTRUDA plus ALIMTA and carboplatin last year in May based off of our KEYNOTE-021G data. So you're right, the regimen is actually already approved in the U.S. and we were starting to see and we still are seeing in the PD-L1 the 49 segment penetration of that combination into that segment, where we see opportunity going forward and what we're hearing from customers expressing now based off of the outstanding results from KEYNOTE-189, when you have an overall survival benefit where you reduce the risk of death in half. We have heard from KOLs that this is now starting to establish the new standard of care for nonsquamous non-small cell lung cancer patients. So to answer your question when you look at where the segment opportunity or what opportunities we have still in front of us clearly still the 1 to 49s with the combination, the PD-L1 negative population, which is about 30% of the non-small cell lung, nonsquamous patient population has not really been penetrated with the combination and we think 189 really will help us there for adoption. And then there are still patients that are not being tested as well. So you have the untested population as well about 20%. So when we take a step back in one of the other questions that was really on a lot of oncologists' mind is they wanted to know not only the all-comers trial for 189 the benefit that you saw, but they were really interested in the PD-L1 negative population. And in that population, we show today AACR, we have a hazard ratio of 0.59 in that segment. So we think and what we're hearing from oncologists is that was very important to understand the magnitude of effect in that segment along with the overall population. So we feel like we're very well positioned

now with KEYNOTE-189 and because we had approval, our teams are out communicating the data from the New England Journal Medicine publication.

Unidentified Analyst

Maybe can you quantify on a trailing quarter basis, how well penetrated first-line lung cancer is with PD-1 or off-label chemotherapy? Just kind of give us a sense broadly in the nonsquamous how well penetrated in that market is?

Frank Clyburn

Yes. The class is probably anywhere from 35% to 40% penetrated in the frontline. If you think about frontline therapy, about 20% to 25% of the patients receive are either EGFR or mutated positive or out positive. So they're getting targeted therapies in that segment. And then chemotherapy is still predominantly used, as I mentioned, in the segments, especially the PD-L1 population. And then the rest of the segments or the other segments, as I mentioned, especially the high-expressed group is really well penetrated with KEYTRUDA, as we said today.

Unidentified Analyst

In Europe, you've got a separate regulatory process, and you don't have the all-comers yet technically approved. But both ALIMTA and KEYTRUDA are individually approved and reimbursed. So as we think about either in the near term or even there's typically a 1 year lag before pricing and reimbursement for launch. Do those sort of rules of thumb apply here or because you've got this amazing data and a real impact on patient's lives and survival that you can alter that sort of uptick?

Frank Clyburn

So our -- right now to your point outside the U.S., we really have approval that's probably in 40-plus markets now where we now have approved what reimbursement for our first-line nonsquamous and squamous high-express patient population based off of KEYNOTE-024. So today that is what is basically approved and reimbursed. And the good news there is, you could see from our Q1 results, we're starting to see good growth outside the U.S. because not only do we now have melanoma, but our first-line lung indication in monotherapy is starting to be reimbursed. As we think about KEYNOTE-189 outside the U.S., I just still do think even though both regimens are approved and both regimens are reimbursed, health technology assessments will still want to have an assessment prior to reimbursement. So we don't anticipate that it would be upon approval that you would see automatic use of KEYNOTE-189 or the combination. We still will want to go through some of the health technology assessments. We'll be working with payers around the world. We do feel with the positive data that we have that those discussions should go well, but we do anticipate that there will be a lag time between approval and reimbursement even though the 2 regimens are approved.

Unidentified Analyst

And broadly in those markets, the ability to get reimbursement is still gated by the PD-L1 status?

Frank Clyburn

Yes. In those markets today, right now, it's monotherapy today. And then as I mentioned, as 189 hopefully gets approval in those markets, we'll have to enter into discussions with payers. And our objective obviously is to try to accelerate reimbursement as we can, but there will be assessments.

Unidentified Analyst

Sure. Okay. And if you just -- as you think about some of the successes with KEYNOTE-189 near or medium term, but scientifically there is going to be a continued push to try to move away from chemotherapy. We hear about this in a lot of different markets and malignancies. So just trying to get a sense of how you sort of balance the near-term wins with that consideration and the urgency amongst the one of oncologists that ultimately move away from chemotherapy over time?

Frank Clyburn

Well, with regards to moving away from chemotherapy, I want to make sure we do emphasize, and Merck's approach really has been from always starting with the science to kind of drive our strategy. So if you think about it, we've explored monotherapy very broadly across many different cancer types. And as I mentioned, we have over 700 clinical trials, both in monotherapy and in combination. We have one of the broadest combination programs in the industry. We have been agnostic to modalities. So we have combinations, as you can see, with KEYNOTE-189, with chemotherapy. We have chemotherapy options in frontline of head and neck and other cancer types. So we think chemotherapy does play an important role. Physicians are used to using chemotherapy and I think with the overall results that you're now seeing with 189, the bar is raised pretty high. So that clearly is something that we feel positions us well. If you look towards the future and we've had a lot of discussions with our clinical and commercial colleagues is that we do want to make sure that we're exploring combinations with targeted therapies. We are building out our own internal pipeline. We have our anti-LAG-3 that we are now studying. We have our STING agonists. We have our anti-TIGIT molecule. So when I look at our overall approach and strategy, we feel we're positioned very well based on our early data with KEYNOTE-189. But as you look out both monotherapy and combinations across a number of different modalities, a number of different products, we think we're very well positioned depending on where the actual data goes. The last thing I will mention is, it is also very important, as we just talked about outside the U.S., chemotherapy is a very, not only is an important but as you have reimbursement discussions and as you think about payers outside the U.S., we think having our regimens with chemotherapy are also really important from an access reimbursement perspective today and in the future.

Unidentified Analyst

So one chemo sparing option is obviously KEYTRUDA monotherapy and you've got the KEYNOTE-042 data that will be presented in detail at ASCO. So as we think about the benchmark, I realized that Merck's message is this is a very much a patient-doctor discussion in terms of the trade-offs that they're willing to make in terms of efficacy versus the -- the tolerability benefits that you get with the monotherapy. So from your experience, in the high expressers, I don't know, can you help us what is sort of the typical magnitude of trade-off as we kind of think about it clinically meaningful benchmark or drop-off compared to -- say, the 1 to 49 subgroup data we saw with KEYNOTE-189? Just kind of curious if you can kind of put a little more meat on the bones in terms of what we should be thinking about as we go into ASCO?

Frank Clyburn

Well, as you mentioned, we're going to share the data and we have, obviously, announced that we have with KEYNOTE-042 just to remind everyone of the design where you looked at the 50% PD-L1 patient population with the TPS above 50 initially and we announced, obviously, that we have overall survival benefit not only at the 50% cut point, Michael, we have a KEYNOTE-024, but now all the way down to 1 and above. So that represents approximately 2/3 of the lung cancer patient population. We do believe that it will be more of a physician-patient choice. I think when you look at the magnitude of the fact that you see with KEYNOTE-189, clearly that is a significant benefit and result that is now in the marketplace. But for us, it will really then come down to physicians making the decision if it is a monotherapy option that they want to choose. Obviously, we have exploited or explored monotherapy pretty broadly. There are patients that have a performance status of 2 or 3 that you might want to continue to use monotherapy. They may have other comorbid diseases. So we think it's going to really depend on the physician's choice working with their patients. For us though, if you think about it with 189, with KEYNOTE-024, we'll be presenting obviously KEYNOTE-042 and then also KEYNOTE-407, which is our combination in squamous for lung cancer patients. We think that we have a very broad program in position across lung cancer and whether it's combination or in some cases, you might see monotherapy selected clearly because of the physician choice. We think that the KEYTRUDA regimens were well positioned across a number of patients.

Unidentified Analyst

And as we think about your strategy, how you maximize the value in lung cancer? Not all patients are going to get a complete response and patients will eventually move to second line. And so there still will be a meaningful second-line opportunity. But using PD-1 treatments are probably unlikely to follow a first-line PD-1 treatment. So your thoughts in terms of will you set to explore different treatment modalities in the second line? Or you're just going to focus on the frontline just broadening the range of response so that you can maximize the durability of the first-line population over time? Just kind of curious how you think broadly about that issue.

Frank Clyburn

Yes. I think, we have really been focused on moving to earlier lines of therapy. Obviously, our first-line trials, if you look now, we're thinking in exploring, obviously, adjuvant therapy, neoadjuvant therapy. We think those are very important for an agent like KEYTRUDA. As you get to later lines of therapy, there are questions being asked if you get an I-O upfront what happens in second or third line and clearly, we're thinking through some of those options as well. But our focus has been really monotherapy broadly, combination therapy broadly and moving into earlier lines of therapy.

Unidentified Analyst

And in the wake of AACR, just kind of curious your thoughts, the company started a CTLA-4 combination study. I believe it was mainly as a defensive strategy in case the market evolve towards that and perhaps it doesn't look like -- at the moment that it's going to go in that direction. But there are some other alternative approaches like triple combination with chemo and CTLA-4 more broadly. Have you guys been rethinking your strategy in terms of combination approaches with CTLA-4? Or just going to resume the pathway with the existing study and leave it at that?

Frank Clyburn

Yes. So for right now, we obviously have stood up our trial, which is comparing KEYTRUDA monotherapy because we think that is the standard of care today in that high-express population combining that with CTLA-4 plus KEYTRUDA in that segment. We think that it is an important question to be answered. And if there is a benefit from that combination, we think that may be the segment that you do see. The question is always with CTLA-4 plus KEYTRUDA or other agents is the efficacy benefit and the toxicity trade-off one may need to get. So we feel as though we're going to answer that question with our current study, but we also are clearly looking at a number of other combinations as I mentioned across a number of different cancer types. So we're really looking how we can continue to do everything we can to meet unmet needs for patients around the world.

Unidentified Analyst

One of the comment refrains from investors is that Merck has a stock, hasn't really appreciated or realized the value of the data that we saw in AACR. One of the comments that I hear is, well, there is potential for some fast follower chemo combination approaches that can get to the market and Roche or Bristol with their chemo combinations. And your general thoughts, do you typically -- when you think about the lung cancer market, do you think this is going to be a competitive market? Or how do you think about the threat from some of those fast follower strategies?

Frank Clyburn

So we do think, there is a lot of data to read out as you mentioned in non-small cell lung cancer. And we do think that the marketplace will evolve and be competitive. With that said, we feel as though and what we've seen is being first matters. In the first mover advantage that we have even with 21G as of last year and now with 189, we feel it positions us extremely well in lung cancer. So we think first is really important, and we think that the data that we now have with 189 really sets a very high bar for future competitors coming.

Unidentified Analyst

And just that -- I hear from some companies in terms of order eventually discussion, say, while 3 months doesn't matter, but a year or sort of the cut point where if you're a year or more ahead of your competitor, that's where this sort of order eventually advantage really sets the matter. Your thoughts on that.

Frank Clyburn

Yes. I don't have a specific time frame except to say that if you are there first with very strong data and oncologists start to use the product, we have found that, that does provide usually a competitive advantage long term. Typically, you'll see shares are much higher for the first mover than somebody coming in as a second or third or fourth entrant. So we feel as though we've seen it when we established our initial indication in melanoma, we've seen it as we have now moved into head and neck and clearly within our bladder cancer indication. We actually worked first in bladder. We were actually last, but we had a very strong dataset with overall survival. So the way I look at it is first matters as well as the overall data manages -- matters as well. And having overall survival with a significant magnitude of effect on patients really is what are the 2, I put together and say, when you have that, you're usually very well positioned.

Unidentified Analyst

And as we think about the next wave in lung cancer of combination approaches that -- where we have registration-enabling data, when you envision that to be? I mean, can you highlight some combination strategies that you will be first to read out? And are you altering your development strategy to go up against the KEYTRUDA-189 type regimen now as compared to...

Frank Clyburn

Yes. So we've announced and we have a number of, as I mentioned, internal assets that were now in the development or in the clinic with our anti-LAG-3, our STING agonists or anti-TIGIT molecule. We have done a deal where we've acquired an oncolytic virus. We have, obviously, now a very broad collaboration with Eisai with LENVIMA and you'll see a number of -- a lot of data reading out, I think, across 3 or 4 different cancer types LENVIMA plus KEYTRUDA. We also are working with our colleagues from AstraZeneca with LYNPARZA. So as I take a step back, we have a very significant amount of data flow that will continue to come. We are very excited about ASCO. I think, the abstracts go up today and there'll be a significant amount of data that you'll see for KEYTRUDA at ASCO. And as far as our combinations, as I mentioned, not only some of the products I mentioned, but our KEYNOTE-048 data, for instance, is chemo plus KEYTRUDA in first-line head and neck. We think all of that data would be very important for the future.

Unidentified Analyst

Any questions in the group?

KEYNOTE-407. There was a little bit of, I guess, an investor confusion on the earnings call, but ultimately the press released shortly, I think, a few days later and positive results on the first interim analysis. Maybe as we sort of think about the expectations at ASCO around this study, contraindications that they've been granted accelerated approval on the basis of ORR in other indications. Do you think that the ORR data is sufficient to drive an accelerated approval in your view in this setting?

Frank Clyburn

Yes. So on May 3, we did announce that our trial for squamous lung cancer patients met a prespecified, it was a secondary endpoint, actually of ORR in an earlier cohort of patients at the interim analysis 1. And based on that data, we did announce that we filed an sBLA with the FDA, and

you'll see the data for 407 here shortly. It's been accepted as an oral presentation at ASCO. And then we have announced that we have the potential that there will be an additional interim possibly before ASCO. And then we may be communicating additional data around 407. So I'm not going to really comment anymore on the FDA and our interactions there, but 407 is a very important trial. Obviously, it's an all-comer trial across squamous lung cancer patients. And squamous represents probably 15% to 20% of the patient population. So we think it's a very important trial, and we look forward to the data being shared at ASCO.

Unidentified Analyst

Got it. And thinking about the opportunities set for growth outside of lung cancer. We had some melanoma data recently. Where do you see sort of the biggest opportunities for growth outside of the lung cancer for KEYTRUDA over the next, call it, 2 to 3 years?

Frank Clyburn

Sure. So we have a number of different data readouts and we presented at AACR an update of the KEYNOTE-040. We presented, which is our second-line head and neck trial, we presented additional data at AACR around adjuvant melanoma. We think that's important, that was KEYNOTE-054. We have upcoming PDUFA dates in cervical and other cancer types. Head and neck, as I mentioned, we see is important. Gastric, we think is a very important opportunity for us in the future as well as all of the work that we're doing with our colleagues from AZ and Eisai with regards to LYNPARZA and LENVIMA as well. So we think for KEYTRUDA, there is a number of data readouts of registrational trials. And as I mentioned, some of the cancer types that we're looking forward to in the near term. And then as you look out the breadth of our program across, a number of different cancer types will continue to see a lot of data readouts in the future and we feel very well positioned there.

Unidentified Analyst

Frank, you mentioned that you're involved in business development discussions at Merck. As we think about the BD strategy, ultimately, to augment where you are in oncology, more broadly speaking, and getting ownership of assets that you think are strategically important. Could you talk a little about the criteria that you're looking at in terms of combination assets? What's the most important to you? And I guess, maybe just secondly, you are having some of the comments in the most recent earnings call, asset valuations might be viewed as a little bit prohibitive. So I guess, how does that alter your ability of Merck to be active in the M&A market this year?

Frank Clyburn

So we have business development as a high priority for us at Merck. And I think you've heard Ken, Adam and Rob and Roger speak about that, that we are looking at deals that really generate long-term growth and value for our shareholders. But it is extremely important to us, and I'll highlight a couple of examples and I think that LENVIMA and LYNPARZA are more recent examples of how we looked at business development. We saw an opportunity to participate with 2 very important targeted agents. We actually were very excited about the current development program of LYNPARZA as well as what it could mean in the future in combination with KEYTRUDA, the same with LENVIMA. It was a good way for us to have a derisked approach from a business development perspective, and we feel really good about those collaborations. As I mentioned, we've made some acquisitions with regards to Viralytics. We made acquisitions in our earlier-stage pipeline as well for RIG-I molecule. So BD is a very significant priority for Merck. And as I mentioned, we feel like that we're making very good progress, and some of the examples I mentioned here are just some of the highlights.

Unidentified Analyst

Great.

Frank Clyburn

Okay.

Unidentified Analyst

Webcast have time limit here but, Frank, thanks very much for joining us today.

Frank Clyburn

Thank you.
