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PRESENTATION

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Good afternoon, everybody. I'm Chris Schott at JPMorgan. And it's my pleasure to be introducing Merck today as we wrap up day 1 of the 40th Annual JPMorgan Healthcare Conference.

From the company, we have Rob Davis, the company's CEO; as well as Dean Li, President of Merck Research Labs. So Rob and Dean, Happy New Year. Great speaking with you today, and I look forward to the presentation.

Before I turn it over to Rob, I did want to mention, if anyone wants to ask a question during the Q&A portion of this, feel free to submit that through the Ask a Question button, and I'll work those into my Q&A as we go through.

With that, let me turn the call over to Rob to run through the presentation.

Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Well, great. Thanks, Chris, and good evening, everyone. I'm excited to be here with Dean to share with you our thoughts on why we're so confident about our ability to deliver short- and medium-term growth. But importantly, I'm also very confident that we have the right focus, scientific talent, financial resources and capabilities to deliver long-term sustainable growth well into the next decade. And obviously, before I get into the discussion, I do want to point you to the forward-looking statement I have here. But with that, let's go ahead and jump right in.

Next slide. We've made great progress in 2021, becoming a more efficient, faster-growing company. And in many ways, I would say we are a new Merck. As you can tell here from the slide, we've started to really accelerate important programs in our pipeline, we've augmented that pipeline through meaningful business development and we've completed the successful spin-off of Organon, enabling the simplification and focus, which we're now experiencing. And obviously, we've done all of this with very solid operational execution. And as a result, we've been able to achieve very strong top and bottom line growth. And as we look at the end of the year and start to move into 2022, we're going to carry this momentum forward as we really are, I think, a company that's going to be operating with speed, with urgency and with agility.

And as you can see here, as we look at 2021, it was a year of very strong financial performance. Each of the key growth pillars, oncology, vaccines, animal health and hospital, all contributed to our performance with strong execution across the board. This resulted in year-to-date revenue growth as of the end of the third quarter, [ex] exchange of 13% on the top line and non-GAAP EPS growth of 18%. Obviously, we believe the success of our science-led strategy has put us in this position of financial and operational strength. And we do expect this momentum to continue both into the fourth quarter and into 2022, where we do expect another year of very strong growth.

As we look out longer term, that momentum continues. We expect continued strong revenue growth through 2025, driven largely by our derisked portfolio of growth assets. And importantly, earnings should grow faster than sales as we drive meaningful P&L leverage, while also ensuring we fully support the key investments in the business and the pipeline. And in fact, as you can see here, we now expect operating margins in excess of 43% by 2025. While we continue to focus on growing and accelerating our internal pipeline, I also, as I know Dean does as well, fully recognize that we need to augment our internal efforts through the best external R&D opportunities, adding compelling science and innovation from outside

the company, that is a top priority. I'm confident we'll be able to successfully execute on this strategy given our track record to date of successful transactions across multiple therapeutic areas and animal health.

And as you can see here, we've made several important acquisitions that show up here as examples, whether it be Antelliq, Peloton, VelosBio or Pandion, just to name a few. And then in addition, we've executed value-enhancing strategic partnerships, including Gilead, AstraZeneca, Eisai, Seagen and Ridgeback. And we are very excited to now add Acceleron's great science and world-class scientists to Merck. Sotatercept is a potential multibillion-dollar peak sales opportunity that strategically complements our internal efforts in cardiovascular disease, and is a great example of the types of transactions we are going to focus on going forward. As we execute on business development, we'll be appropriately aggressive and we have the financial flexibility to pursue any strategic opportunity we identify both in their early and late-stage pipeline.

Finally, we will continue to be science-led, unbounded by therapeutic area, but mindful of the need for a more balanced portfolio over time. All of this is with an eye to ensuring we can successfully navigate through the period of likely biosimilar competition to KEYTRUDA late this decade. While we aspire to grow through the period at the very least, we are focusing our efforts to ensure we will be able to minimize the headwind and return to strong growth in short order. And we have multiple levers to help us do this.

I'm confident in our ability to drive success during this period for several reasons. First, we expect to be the oncology market leader by 2025, and we intend to leverage this position for lasting success in oncology well into the next decade. Dean is going to get into more of this in a moment, but this is an important element of our strategy. We're also continuing to benefit from a portfolio of durable growth drivers on top of oncology that will continue to grow into the next decade. If you think about it, we have GARDASIL, to name one of the most important assets, and I'd just like to point out, we believe that GARDASIL has the potential to double in sales by 2030. So that is still meaningful growth as we look out through the rest of the decade.

Other vaccines like VAXNEUVANCE and our pediatric vaccines also have the potential for long tails. And our Animal Health business also offers consistent sustainable annuity-like growth, which we think is something we will be able to sustain as we move into the next decade. Importantly, we also have the necessary cash flow we will generate through the products you see listed here over the next 7 years that we'll be able to deploy into that value-enhancing business development to augment the pipeline that we've just discussed.

And finally, we have world-class scientists doing amazing work across the breadth of key early and late-stage opportunities across therapeutic areas you see listed and as well as others, and this will be an area that Dean is going to get into in just a moment. But I continue to tell you how confident I am and what I'm seeing in our pipeline. We need to augment it, but we have a lot of great opportunities, and I'm excited we'll be able to share some of that with you today.

So to summarize, 2021 has been a year of tremendous progress, and we enter 2022 with really good momentum. As we look out to 2025, we expect to achieve strong growth in revenue with significant margin expansion. And finally, we are intently focused on the long term, and we believe we have multiple levers that will help drive our success later into this decade as well as into the next.

With that, let me turn the call over to Dean to provide an update on our research activities. Dean?

Dean Y. Li - Merck & Co., Inc. - EVP

Yes. Thank you so much, Rob.

Next slide. So it's critically important. We have a powerful research organization and we're focused, we're focused on 2 goals. One, as Rob said, to be the leading oncology company by 2025, but really to prioritize our programs and our capital and our pipeline assets in oncology to make that a durable and sustainable position in 2028, 2030 and into the next decade.

The second major focus that we have in relationship to moving forward is to accelerate and expand our focus to really move in other therapeutic areas, And we will talk about that just a little bit as we focus, for example, on cardiovascular, but it's not just cardiovascular. It's also increasingly important for me coming from that world, from the biotech world, that we really advanced new modalities and platforms and technologies, and

that we use BD, both to accelerate and enhance our clinical pipeline, but equally to use business development to accelerate and really advance our own internal pipeline, especially with modality and platform investments.

Next slide, please. So 2021 has been an important year, and I'll go through some of them. But I think it's really important to understand, it's not just the advancement in 2021 in oncology, where we've had really a movement last year in terms of women's cancers. We've really advanced that. And also a concerted effort in moving it into earlier stage. And it's not just KEYTRUDA, it's WELIREG, it's Lynparza, it's Lenvima.

It's also in vaccines. The V116 or VAXNEUVANCE. It's in the adult setting and really advancing that with FDA approval and ACIP. And clearly, that sets us up well for '22 and beyond in relationship in pneumococcal vaccines. As I spoke, it's really exciting to begin to have the resources to expand the focus to the broader pipeline. I lay out here some critical movement that we've had, the approval of VERQUVO, the advancement of a Factor XI inhibitor. But I'm going to just jump to the bottom, which is really our expertise in PAH, or pulmonary artery hypertension, and inhaled SGC and our MK-5475, really made us understand how important it would be to partner and acquire Acceleron, which we were successfully doing and advancing. And then clearly, in COVID-19, our ability to advance a respiratory antiviral response to this in molnupiravir. So these are evidence of our important sort of tasks in front of us, which is advancing oncology to a premier position in 2025 and beyond, as well as broadening our portfolio in other therapeutic areas.

Next slide, please. In oncology, I've often spoken of how it's important that we really are in a strong position. We're in a strong position. Even now, we're expanding into new tumor types: breast cancer, endometrial cancer, cervical, the many women's cancers that we were expanding into. We're being able to extend into earlier lines of therapy. Just today, we announced KEYNOTE-091. But really last year, it's the ability to show in breast cancer, in triple-negative breast cancer and melanoma and renal cell, that ability to extend into earlier lines. And we have multiple mechanisms, 20 mechanisms in deepening KEYTRUDA's response. And those mechanisms include other IL agents that can be coformulated with KEYTRUDA, such as TIGIT, LAG-3, CTLA-4, ILT4, and in the future, near future, cytokines. But it's also investing in other oncology assets such as antibody drug conjugates, KRAS, BTK inhibitors, bispecific and multispecific antibodies.

Next slide. So it's not just oncology, it's how we're set up for the future. So we've talked about VAXNEUVANCE, and really, the last year was focused on adult. But this year, it's really focused on pediatrics as we race to get our VAXNEUVANCE both approved in the United States, but also to advance it with the ACIP.

This also sets us up for future programs, for example, our program in V116, which we're also advancing with urgency and speed. Where we've got the RSV, we have dengue. And in the cardiometabolic, I've already talked about sotatercept and MK-5475, we have programs in thrombosis. We have multiple programs in clinical stage in relationship to NASH, but we also have 2 sRNA programs in relationship to NASH that is in the discovery stage. I really want to point out the lipid lowering [MK-0616], this oral PCSK9 inhibitor, which I think is a real contribution to the world. We have programs in clinical development in schizophrenia, treatment-resistant depression and Alzheimer's. And we've made meaningful effort in expanding our focus into immunology with the acquisition of Pandion, as well as continued investment in the HIV both for treatment and prep.

Next slide, please. Increasingly, we've always been a company that's focused on what the product is, what the biology is, what's the task. But I think it's very important that Merck, and we're really focused on this, is expanding our capabilities and modalities. We have active programs in all of these. But I just want to point out some of them. I've already talked about our rich pipeline in terms of monoclonal antibodies. We have multi-specific antibodies internally and in partnership with Dragonfly that will be important for oncology. We have multiple collaborations and partnerships and internal programs in terms of targeted therapy, either in antibody drug conjugates, or in engineered proteins as we have done with Pandion. And we are advancing programs in oligonucleotides or mRNA and sRNA. And I think we have a leading position in what I would call macrocyclic peptides, and PCSK9 is just the first of multiple programs that we'll be advancing.

Next slide. So I'm really, really excited that our clinical position and our clinical book of business and our knowledge is really translating in our ability to really focus on the most important human biology. We have distributed discovery centers that really we've invested in the last few years, and they are moving forward with over 120 programs throughout these type of therapeutic areas, broadly speaking. And we're excited to see those advance. We're tracking top talent. And I think it's very important as we attract top talent that, again, we get an increasing focus on platforms and modalities and technology. But we have a broad research program, and we're confident in our ability to drive these internal programs, which also are accelerated by business development.

Next slide. So in conclusion, I just want to reiterate that we have 2 tasks, and we're really confident about it. It is to build a leading oncology program by 2025, to be that leader and to invest and move programs forward that will keep that position durable 2028, 2030 and beyond. We are also extremely excited that we are beginning to show the movement and accelerating the movement in other therapeutic areas. In cardiovascular, which I've sort of highlighted here is just the tip of the iceberg. And we are confident in these 2 tasks as we chart our course to 2025 and to the next decade.

With that, I'd love it to turn it back over to you, Chris.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. Thanks so much. I think we're ready to open up the Q&A section of the discussion here.

QUESTIONS AND ANSWERS

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

So maybe the first one for me. KEYTRUDA concentration, and you addressed part of this in the slides, that is very helpful. But right or wrong, it feels like this has been kind of dominating the narrative on Merck shares. So I guess on one hand, what's your sense of urgency to kind of address this issue and give The Street more visibility on how the business evolves over time? And I guess as part of that, beyond just building out the pipeline, are there other levers that you think about or that could unlock value as we think about, at least to me, it feels like your shares are distinctly undervalued given this kind of large asset, LOE that we're facing over time. I was just trying to know how you think about solving for that and kind of driving the share price higher even in the face of this uncertainty.

Robert M. Davis - *Merck & Co., Inc. - President, CEO & Director*

Yes. No, Chris, thanks for the question. I'll start, and Dean can jump in. As I look at it, obviously, to your question, this is something we're intently focused on. I recognize, Dean recognizes -- While I'm confident we have the financial capability, the financial resources, we have the technical scientific capability and the operational execution discipline to handle this and to be able to successfully navigate the eventual LOE of KEYTRUDA.

We recognize we have to start now. And we're already doing that. In fact, I would say we've already started. We've started in the past. And I think if you look at a lot of the activities we were doing last year, it was positioning us for that. And you look at what we did with Acceleron, with Pandion. Those are examples of us moving more aggressively on the BD front to bring in the case of Pandion an early-stage asset in the immunology space. And then in Acceleron, a late-stage asset with sotatercept, and one that, frankly, given its exclusivity window that goes well into the 2030s is an asset with multibillion-dollar peak revenue opportunities that will be growing in that important time.

We need more of those, and I think you're going to see them coming not only from what we have inside our own pipeline, and that's why Dean tried to highlight a little bit of what he did. We think we have some exciting stuff coming out of our own pipeline. We're going to continue to focus it and accelerate it, but we're going to add to it. But the other reason that we continue to believe we're going to be able to do this, and we're confident is what Dean was hitting on around oncology. We keep focusing on this as concentration risk. We see it as leverage. And if we handle this the right way, it has the opportunity to be a position, as Dean says, if we deepen it, we extend and expand our position, there's no reason we can't find the opportunity to be a leader in oncology well into this decade. And that is one of our focuses.

So it's that, it's broadening the rest of our portfolio and doing everything we can do in the near term to ensure we deliver on the derisked growth we have between now and 2028. I think that's important as well, the opportunities to grow. So it's something we're very focused on I feel good about. To the broader question of are there other levers, right now, our heads are down, focused on accelerating the pipeline, augmenting the pipeline and delivering on the derisked assets we have. That to me is where we need to focus, and that's where our attention is going to be.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. And then just on the conversation around business development. I know you went through some of the priorities. But it does seem to me the company has done some smaller deals, we saw the company go a bit larger with Acceleron this year. It seemed like that was last year it was very well received by The Street. Are Acceleron-like deals kind of the sweet spot for Merck at this point? Is that kind of the message I'm hearing? And maybe just elaborate more broadly about the breadth of opportunities that you're considering right now.

Robert M. Davis - *Merck & Co., Inc. - President, CEO & Director*

Yes. Well, so clearly, I think the Acceleron deal is a good example of what we're trying to do, as is the Pandion deal. So that's why we use those 2, because they really are both what we're talking about. So it is more of those. The key is the science will drive us. It's where we see a scientific opportunity that matches our capabilities and where we think that with that, we can go after an important unmet need. And obviously, we're cognizant of what we have is the exposure late in the decade. And so we're with an eye towards that I want to leverage our oncology position, but I'm also mindful of balancing out the portfolio.

So if we can also continue to add things around oncology, as well as broadening inside of oncology, that's the goal. And that's what we've been doing between the deals we've done to broaden our position in oncology and then move into these new spaces like cardiovascular, like immunology and obviously, Dean highlighted, we've got a lot of earlier stuff in the neuroscience space. And some of that is developed in-house. Some of it is actually itself through partnered opportunities and smaller deals we've been doing. So it's the totality of all of those type of opportunities is where we're focusing.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. And I think when I look at that chart, in the last couple of years, you've been averaging somewhere kind of low double-digit billion, so to say, \$11 billion to \$14 billion of business development per year. Is that a decent proxy for the amount of kind of annual capital deployment we should think about over, let's say, the next 3 to 5 years? Or could you actually see that the company step up its level of M&A, given obviously, growth in the underlying business as we are closer to the KEYTRUDA LOE?

Robert M. Davis - *Merck & Co., Inc. - President, CEO & Director*

Yes. Well, as we have said in the past, we're less focused on the specific size of the deal as to a strategic fit, not wanting to obviously do deals that we see as disruptive or to do cost synergy deals. So saying it differently, yes, I'm more than open to go in deals that are larger than what we've done. But I think it's going to take a combination of a whole host of different size opportunities. It's less about trying to look at something based on its size, it's more measuring the opportunity and then asking do we have the wherewithal to execute on it, and I'm confident we have the capital to do it and the capabilities to execute. So that's really where we're focused.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Okay. And maybe just 1 final question on this. I know it's only a single asset, but the company seemed very excited around islatravir, and I know we'll talk about that asset a little bit more in the individual product side. But I guess, does the setback you've run into in the last few months changed at all how you think about prioritizing assets or transactions as you think about kind of some of the external opportunities that you're considering?

Robert M. Davis - *Merck & Co., Inc. - President, CEO & Director*

I wouldn't say it changes. Obviously, we were excited, we are excited about what potentially islatravir can be. Islatravir is a great asset. And if you look at some of the important characteristics it has, high potency, high barrier resistance, it plays well with other assets, and Dean can get more

into the science on that side here in a moment. But if you look at it, clearly, yes, do we wish we had the clearer path to the type of revenue potential that islatravir potentially we saw earlier on before we put the studies on hold? We do. We need to, frankly, run that to ground, because we're still not convinced that there's not a real opportunity with islatravir or with that mechanism in the NRTTI space. So we're not giving up on HIV. We're not giving up on that mechanism. And there's more work to be done, and Dean can comment on that. But it just highlights the difficulty of science and why we need a lot of shots on goal. So we are very focused on making sure we have enough opportunities that with those kind of setbacks, we still have what it takes, and that's where we're focused.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. And maybe a good transition over to Dean. That maybe talk a little bit about next steps for islatravir? I think we're obviously seeing the headlines, and I think we are trying to get our hands around to how much of a setback this was and when we could be in a position to get some more clarity on the path forward, I guess, for this one?

Dean Y. Li - *Merck & Co., Inc. - EVP*

Yes. The mechanism of an NRTTI is what we're interested in, islatravir is an example of that. We have other compounds of that sort of mechanism of action. But one of the things I would emphasize is we did do a clinical trial, a switch study in relationship with q-day. And one thing is very clear. In terms of efficacy, islatravir did quite well in that study, in the SWITCH study, that one with islatravir and doravirine. So that gives us some base as to why we're still committed in relationship to that mechanism and really understanding where we stand.

Clearly, we have all the benefits that we've discussed about that class in islatravir, and we need to run it to ground what is -- we need to sort of balance all the efficacious component parts and minimize what it might do in terms of reductions in lymphocytes and how we advance that in relationship to combination where there's other compounds and how we do it in monotherapy in a healthy patient population, but for a long period of time. So we're going to be looking through all the trials, both on our own in relationship to prep, but also in relation to the combination both for us and with our partners. And I would imagine over the next 3 months, 6 months, we'll be able to run it to ground to get some sense of what is the path forward, how do we crystallize the efficacy that we saw and how do we sort of minimize the effects that we're seeing in some of the studies in relationship to lymphocytes.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Just to jump around a little bit. Rob, I think in the remarks on GARDASIL, I think it seems like an asset The Street kind of consistently is underestimating the magnitude of the ex-U.S. opportunity. So I think in the presentation, you mentioned that GARDASIL could double by 2030. I guess, my question is, is that off of like a 2021 base, which I guess I think would imply a \$10 billion peak sales or larger type of assets? Is that the right way to think about this? So I think it would help if you put your hands around like how high in the scale, I guess, in terms of the peak sales.

Robert M. Davis - *Merck & Co., Inc. - President, CEO & Director*

Yes. So if you look at what -- it implies around of just a little over \$11 billion is really what it was.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Okay. Yes.

Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

And if you look at what's driving that confidence, it's -- this asset is still in an area of significant unmet need. It's amazing. If you think about it for as long as GARDASIL has been available, we still have only addressed less than 10% of the total potential population. So this is still in its infancy as far as its ability to have impact. And as you're seeing both the opportunities to move more into gender neutral, obviously, we've recently, for instance, gotten head and neck indication, other indications, as well as cervical cancer. So it's becoming more clear that this is a gender-neutral vaccination, not just for girls and for women. The fact that we continue to have important growth in markets like China, where this is the #1 drug in China and with still significant unmet need, We recently have received approval to relaunch within Japan. That's going to be a big market opportunity. And then obviously, as we continue to drive gender neutral globally, all of these are why we believe there's a lot there.

So the demand is real. The acceptance of this as an anticancer vaccine has crystallized. The question then becomes, can we meet the demand with the supply? And what we've actually seen, and part of the reason we were so successful in 2021, we've actually seen productivity improvements more than we expected in our existing assets. And we're still on track to add additional assets in that 2023 time frame that should allow us to double our capacity. So we have the supply and you see the demand, and that's why we're so confident and excited about what GARDASIL can be.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Yes. That's a pretty impressive opportunity ahead of you as for that one for sure. Another question maybe for Dean. I know you have had some data on adjuvant lung released this morning. I was trying to get your perspective here in that it seemed like we hit in the all-comers population, but it didn't hit in the greater than 50%. So just help us a bit near in terms of like what drove that? When can we think about another look here? And is there a filing pathway just based on the all-comer population alone? So maybe you can touch on those 3 topics a bit.

Dean Y. Li - Merck & Co., Inc. - EVP

Yes. So let me answer the last question first because that may actually be the most important questions. We are in conversations with the FDA. And I think both them and us see a path in terms of filing. But we also have to look in relationship to how the data sort of evolves. You were right. There were dual endpoints, and we hit on one, and it was clear and it was robust and it was positive. And that was in all-comers. What I would say in relationship to different subgroup analysis, if you look throughout those subgroups, there's a little bit of what we would call convergent validity. We understand why the all-comers was positive because when you look at the subgroups, we understand that all is reinforced. These trials and the data, we'll have to let that play out in relationship to statistical plans and events turning over.

I do want to emphasize, everyone's focused on disease-free survival. It is a secondary endpoint. But I think it's also important as the data comes out, that people look at to see what the trends are in overall survival, because ultimately, at some point, it's not the most critical sort of endpoint for an adjuvant study. But it is an important sort of view to look at. I just want to emphasize, this is not the only early stage lung cancer trial we have. It's KEYNOTE-091. We have other early ones, and I think it's really important. A company that has gotten the faith and the confidence of lung cancer doctors throughout the world, we have a very strong position in lung cancer that we need to be able to push it in early lung cancer and have multiple ways to deploy KEYTRUDA depending on how a physician wants to use adjuvant and neoadjuvant.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

So it sounds like good news here, it's sounds like path forward on the all-comers and kind of stay tuned on the data in terms of the details.

Dean Y. Li - Merck & Co., Inc. - EVP

Correct.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Excellent. And then maybe more broadly on the PD-1 side. I think there's been a discussion around some lower-priced PD-1s coming into market, whether that's U.S., Europe, I just want to see with some of the upcoming panels where -- what that exactly looks like. But maybe a question for Rob, just how do you think about a cheap PD-1 and what that could mean for KEYTRUDA? Do you think this is relevant from a competitive standpoint? Is this kind of just noise around the periphery? Just help us -- how are you thinking about the potential risk.

Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Well, we don't take the competitive landscape lightly. We take it very seriously. That said, I continue to be -- I know the team is very confident that we have a very strong hand. And I do not see a low-priced PD-1 coming in fundamentally disrupting our position. Oncology continues to be a market that is data-driven and one where the results matter. If you look at the number of studies, we're now at 34 indications, and this is just in the U.S. across 16 different tumor types. I think we have overall survival now we've shown in studies, in combination studies, in at least 10 studies and then as monotherapy across 7 studies.

So you have a product with a very strong position, very strong data. And not only is the data deep and strong, but it's so broad across so many indications and across so many uses. So that is going to definitely make it difficult. And as we know, this is a tumor-by-tumor indication-by-indication fight. This is not -- you can't look at a macro level. You have to look at the indication at the tumor level, at the specific cancer-type level. And we're not standing still. I think that's the important thing for people to understand.

While people are trying to figure out how do they move into metastatic non-small cell lung cancer, we're moving into adjuvant. While people are looking at how do they think about lung cancer, we're now starting to see growth opportunities in women's cancers, in prostate cancers. So by continuing to move, expand, deepen and grow, it's going to be hard for people to unsee this. So for all of those reasons, I feel our competitive position is incredibly strong. But I don't want anyone to think we brushed this off. We don't. We focus on it. But I think our strategy, driven by the data, driven by the investment in new indications and broadening KEYTRUDA and extending it and expanding it is going to put us in a great position as we look through the remainder of this decade.

Dean Y. Li - Merck & Co., Inc. - EVP

Chris, I just wanted to sort of emphasize, I think it was important that everyone look at, I think, the FDA and its leadership in the oncology division put out an important sort of piece in the New England Journal of Medicine to think about how PD-1s from -- which are only been sort of studied in a single country, how you would think about them and bringing them in. The other issue is you really shouldn't be doing single-arm trials. And the third thing that I would just emphasize is when we develop drugs and get it approved at the FDA. We must compare it to a standard of care. When these other compounds come in, it is important that they get compared with standard of care. We are often the standard of care through the breadth and depth of all these different cancers. And we would welcome the ability to -- if people want to bring those in, I think it's important to really do a comparison with standard of care, and we are that standard of care.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Absolutely. And Dean, maybe just another one on KEYTRUDA. Just as we think about combining KEYTRUDA with other agents. What are you most excited about there? It seems like TIGIT probably gets the most attention right now. I don't know if you'd agree with that, that being the most exciting. And maybe more broadly, what are the other programs you'd point us to that we should be watching closely?

Dean Y. Li - Merck & Co., Inc. - EVP

I think TIGIT is important. I think Roche's data, in relationship to their PD-L1 plus TIGIT, is an important data for us to look and compare it to our clinical data and preclinical. And when we look at their data and our data, we are advancing TIGIT with PD-1 in Phase III trials. So clearly, we're very enthused about this.

We also think TIGIT plus PD-1 in other cancers may be important. But I also want to emphasize that, at least for us, I don't know that there's a single agent that you can add from an IL agent onto PD-1 that has the breadth and depth of PD-1. So we're very bullish about advancing and exploring PD-1 and TIGIT, but we're also very interested in LAG-3. There has been readouts in melanoma, that's important. So we're advancing our LAG-3, we're advancing CTLA-4, we have other compounds and checkpoint inhibitors.

So we think that it's very important to have a broad stroke of checkpoint inhibitors to combine with KEYTRUDA, but to be very smart as to where you're going to advance it. Outside of checkpoint inhibitors, I think it's very important to look at what the future readouts in relationship to cytokines are, especially IL-2 and others. We are watching that. We have multiple programs in these cytokines in protein engineering that we have done with other companies. And we are advancing ours, and we're advancing others.

And then outside of -- these are all immuno-oncology assets. We have really expanded our focus on what I would call traditional oncology pathways such as belzutifan with VHL, RAS, MEK. We're very interested in bi-tri specifics. We think that's a very scalable and important technology. And clearly, a company that's advanced pembro chemo, we're very interested in next-gen chemo in the form of antibody drug conjugates. And we have announced partnerships that we've done that were announced today. But throughout that field with multiple companies, and we think those are important arenas to look at.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Just that we're running short of time. Just a couple of quick questions on molnupiravir, I'm getting a bunch of them on that front. Maybe first of all, just how do you expect the efficacy for this product to hold up against Omicron as a new variant versus the -- maybe some of the data we saw with the prior variance, maybe we'll start that one and then...

Robert M. Davis - *Merck & Co., Inc. - President, CEO & Director*

Go ahead, Dean, you can...

Dean Y. Li - *Merck & Co., Inc. - EVP*

Yes. So I would just reemphasize. This has an important effect in hospitalization and death, and had a 90% reduction in mortality in the trial that we did before there was Omicron. I would also emphasize that the mechanism and the molecule, the whole purpose of the mechanism and molecule that you can advance in preclinical studies indicates that this is a high barrier to resistance. What does this mean. Of all the mechanisms and all the molecules, if there is a mechanism and molecule that you would imagine would be variant proof in relationship to its ability to do it, it is this mechanism. Clearly, in in vitro experiments in this. We're very confident that it will -- it affects Omicron. But clearly, we are very confident in the fact that -- this is a mechanism that has a 90% reduction in mortality. This is a mechanism in a molecule that in every experiment that we've done that you can do in the nonclinical setting, this mechanism and molecule works for Omicron. And I would imagine most any variant that comes up.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. And then maybe just another final question on this one. Just latest in terms of capacity and -- basically, do you think it's a situation where you'll be able to pretty much sell out everything you produce of this? Or is it still to be determined in terms of the demand you're going to see out there with the product? So any color on that front?

Dean Y. Li - *Merck & Co., Inc. - EVP*

Rob, did you want to take that?

Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

I'll take that. Still, I would say that the last part of that is still to be determined. But maybe to give you a sense of where we are. As we entered 2022, we had produced 10 million courses at risk. So we had 10 million courses done by the time we finished 2021. We intend to be able to -- continue to believe we will add an additional 20 million courses in 2022. If you look at what we've seen to date based on contracts in place, we've given guidance a little while back that we expected revenues of \$0.5 billion to \$1 billion in the fourth quarter of this year or in fourth quarter of '21. And cumulatively, \$5 billion to \$7 billion by the time we get to the end of '22.

We continue to believe that guidance is the right guidance based on what we're seeing with the contracts we're signing. And importantly, we're delivering product. We actually delivered about 950,000 courses to the U.S. government in December shortly after we received final approval, and we're going to deliver in total 3 million courses, I think 3.1 million courses to the U.S. by the end of January. So we are moving product, And hopefully, we're going to make a difference for the patients that are counting on it.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Great. I think we're just about out of time here. Obviously, lots of exciting things going on at Merck so appreciate the time today. And look forward to seeing the continued internal and external kind of growth of the company as we go through the year. So again, thanks for the presentation.

Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Thanks, Chris.

Dean Y. Li - Merck & Co., Inc. - EVP

Thanks very much. Take care.

Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Good night.

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