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MRK.N - Q4 2021 Merck & Co Inc Earnings Call

EVENT DATE/TIME: FEBRUARY 03, 2022 / 1:00PM GMT

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## PRESENTATION

### Operator

Good morning. My name is Grace Lakra, and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co. Q4 Sales and Earnings Conference Call. (Operator Instructions) Thank you.

I would now like to turn the call over to Peter Dannenbaum, Vice President of Investor Relations. Please go ahead, sir.

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### Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Thank you, Grace, and good morning. Welcome to Merck's fourth quarter 2021 conference call. Speaking on today's call will be Rob Davis, President and Chief Executive Officer; Caroline Litchfield, Chief Financial Officer; and Dr. Dean Li, President of Merck Research Labs.

Before we get started, I'd like to point out a few items. You will see that we have items in our GAAP results, such as acquisition-related charges, restructuring costs and certain other items. You should note that we've excluded these from our non-GAAP results and provide a reconciliation in our press release.

I would like to remind you that some of the statements that we make today may be considered forward-looking statements within the meaning of the safe harbor provision of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1A in the 2020 10-K, identified certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statements.

During today's call, a slide presentation will accompany our speakers' prepared remarks. The presentation, today's earnings release as well as our SEC filings are all posted to the Investor Relations section of Merck's website.

With that, I'd like to turn the call over to Rob.

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

Thanks, Peter. Good morning, everyone, and thank you for joining today's call.

2021 has been a year of significant achievement and meaningful progress for Merck in the face of what has been a challenging environment for all of us. We deliver on our strategic priorities and took important steps to set a foundation for success in 2022 and beyond.

We achieved strong operational performance, accelerated our broad pipeline, including molnupiravir, completed the spin-off of Organon and acted on key strategic business development activities. We enter 2022 with strong momentum and are pleased to reflect this in our initial revenue and EPS guidance.

We continue to evolve with a more focused, more efficient and faster growing company, with an increased urgency to bring forward innovations to address critical unmet needs. This remains the core of our strategy to benefit the patients we serve and, in turn, create long-term value for all stakeholders, including our shareholders.

Our business achieved strong revenue and earnings growth. Total revenues increased 24% in the quarter and 17% for the full year.

Commercially, we have executed extremely well across all of our key performance drivers, including KEYTRUDA, GARDASIL and Animal Health. We delivered initial molnupiravir shipments to customers around the world, and following the FDA emergency use authorization that was granted in late December made meaningful progress towards our commitment to the U.S. government.

Our dedicated teams worked diligently, including through the holiday season, to deliver 1.4 million courses of therapy to the United States, United Kingdom and other countries by year-end.

Throughout 2021, we invested in the discovery, development, production and commercialization of medicines and vaccines, furthering the long-term sustainability of our business, all while delivering meaningful operating leverage and strong EPS growth.

In total, 2021 was a year of strong execution of our strategic priorities across all fronts: operationally, commercially, clinically and financially.

As we look at 2022 and out to 2025 and beyond, we expect to achieve continued strong growth. Our oncology portfolio will benefit from the uptake of numerous recent approvals and the expected launch of many additional indications, including in earlier lines of therapy.

Underlying global demand for GARDASIL remains robust, and further growth will be realized through the investments we are making to increase manufacturing capacity. And our Animal Health business remains very well positioned to grow faster than the market well into the future.

Overall, we expect another year of strong revenue growth in 2022. While we will continue to make investments on our pipeline, we are confident that we can achieve a leveraged P&L and significant long-term operating margin expansion.

Longer term, we are intensely focused on successfully navigating the headwind created by likely biosimilar competition to KEYTRUDA at the end of the decade. We aspire to grow through and beyond this period. But at the very least, we will look to minimize the headwind and shorten the time it takes to return to strong growth. We have multiple levers to achieve this task, driving sustained growth well into the next decade.

First, we intend to strengthen our leadership in oncology broadly and leverage that position for sustained long-term success. We've done an excellent job of establishing KEYTRUDA as a foundational therapy, and we intend to maximize its opportunity and patient impact. In addition, we

have an expanding portfolio of commercial and developmental oncology assets beyond KEYTRUDA, which offer meaningful growth opportunities beyond 2028.

Second, we have many important franchises beyond oncology that we expect can drive durable growth into the next decade, including GARDASIL, which we believe can potentially double by 2030, as well as our pneumococcal portfolio and our Animal Health business, to name a few.

Third, we expect to generate very strong cash flow, which we intend to deploy into value-enhancing business development to augment our pipeline and bring additional drivers of longer-term growth.

And fourth, we will advance our internal pipeline and the opportunities we see in vaccines, cardiometabolic, neuroscience and other disease areas. We are making extensive investments in discovery research as well, which we believe will be the source of longer-term innovation.

As part of our commitment to provide more transparency into these efforts, we will host an investor event focused on our cardiovascular portfolio and pipeline in the spring.

In addition to accelerating our internal pipeline, as I noted, a key part of our strategy will be to deploy our cash flow towards value-enhancing business development. We will continue to be appropriately aggressive in pursuing compelling external innovation, and we will supplement our pipeline with an approach that is science-led, but portfolio informed. Last year's acquisitions of Pandion and Acceleron are good examples of our approach.

We are taking calculated risks, and we'll continue to focus on creating value in areas of unmet need. We have the operational capabilities, financial capacity, scientific prowess and sufficient runway before the end of the decade for business development to play an important role in our goal of achieving long-term sustainable growth. While we have a strong track record of business development, we know we need to do more.

Finally, we've taken further steps to integrate important environmental, social and governance goals into the core of our business. In December, we completed the inaugural issuance of a \$1 billion sustainability bond. We intend to use the net proceeds to support projects and partnerships in the company's priority ESG areas and to contribute to the advancement of United Nations Sustainability Development Goals.

We've also acted to accelerate global access for molnupiravir through our groundbreaking access strategy, including a recent agreement with UNICEF for up to 3 million courses of therapy to supplement supply available for distribution in low- and middle-income countries.

In addition, this morning, we announced plans to host our initial ESG investor event on February 23. We believe that strong performance across key ESG metrics aligns well with Merck's core values and mission, and we look forward to providing insights into our commitment to this space.

Now before I turn the call over to Caroline, I want to take a moment to recognize Frank Clyburn. Following 14 years of significant contributions, Frank will be leaving Merck to become CEO of IFF. I want to thank Frank for the strategic vision and operational excellence he has provided in helping establish Merck as a global leader in oncology and for his strong leadership of our Human Health business.

We wish Frank and his family all the best as he embarks on his new endeavor. While Frank will be missed, we are well positioned to continue our strong momentum with the deep and talented team we have in place, and we expect to announce new leaders shortly.

With that, I'll pass it over to Caroline to provide details into the performance of our business as well as our financial results and outlook. Caroline?

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**Caroline Litchfield** - Merck & Co., Inc. - Executive VP & CFO

Thank you, Rob. Good morning.

2021 was a year of exceptional performance for our business. We drove robust top line growth of 17% and bottom line growth of 33%. Our teams performed with agility and executed with excellence, despite challenges from the ongoing pandemic.

We are also very proud of the significant efforts to bring monotherapy to patients worldwide. These results reinforce the confidence we have in our science-led strategy and in our outlook for strong growth. We will continue to invest in our portfolio and pipeline as well as in business development to maximize growth over the near and long term and to create value for patients and shareholders.

Now turning to our fourth quarter results. Total company revenues were \$13.5 billion, an increase of 24% or 23% excluding the impacts of foreign exchange. Molnupiravir contributed \$952 million in revenue or 9 percentage points of growth. The remainder of my comments will be on an ex-exchange basis.

Our Human Health business continued its strong momentum, growing 23%, driven by our key pillars and contribution from molnupiravir. Our Animal Health business also delivered robust performance, with sales increasing 8%, driven by companion animal products.

Now turning to the fourth quarter performance of our key brands. In oncology, KEYTRUDA grew 16% to \$4.6 billion, reflecting continued robust global demand. In the U.S., KEYTRUDA continues to demonstrate durable momentum across all key tumors and is benefiting from the recent launches in neoadjuvant and adjuvant triple-negative breast cancer, renal cell carcinoma and in cervical cancer.

KEYTRUDA continues to extend its strong IO top leadership and maintain its position in non-small cell lung cancer, capturing 8 out of 10 eligible new patients, despite competition. Outside the U.S., KEYTRUDA growth continues to be driven by lung cancer and the ongoing launches in head and neck and RCC.

We continue to expand our reach into earlier lines. We were very pleased to receive 2 additional adjuvant approvals this quarter in RCC and in melanoma. With these approvals, KEYTRUDA has now received 5 indications in earlier-stage cancers.

If approved, we also look forward to expanding into adjuvant lung cancer, following the encouraging top line results from the KEYNOTE-091 trial. We are confident that, along with strong clinical data, KEYTRUDA's reputation and familiarity among physicians will be a benefit as we move into early-stage disease.

Lynparza remains the market-leading PARP inhibitor. Growth of 33% was driven by our breast cancer indication and continued uptake of the most recent indications, including prostate. Our expected launch in a broader prostate population based on the PROpel trial represents a significant opportunity.

Lenvima sales grew 31% driven by RCC and endometrial cancer in the U.S. We have seen very encouraging early trends in new patient share following the launch of KEYNOTE-581 in first-line RCC.

We are also excited by the recent launch of WELIREG for patients with certain VHL-associated tumors. WELIREG continues to generate strong interest among scientific leaders, providers and patients and is off to a promising start. We expect to extend its reach to broader RCC indications in the future.

Our Vaccines portfolio again delivered strong growth driven by GARDASIL, which grew 50% to \$1.5 billion and nearly 40% for the full year. Outside the U.S., robust growth was driven by strong underlying demand across all key geographies, particularly China as well as increased supply. This growth more than offset the decline in the U.S. due to timing of CDC purchases as well as the replenishment of the CDC stockpile in the fourth quarter of 2020.

Also impacting HPV immunization levels was the prioritization of COVID vaccinations in younger age cohorts. Underlying global demand for GARDASIL remains strong, as it is increasingly being recognized as a vaccine that can help prevent certain HPV-related cancers in both female and male.

In our hospital acute care portfolio, BRIDION sales grew 24% driven by increased usage of neuromuscular blockade reversal agents and BRIDION's growing share within the class.

Our Animal Health business delivered another quarter of strong growth, with sales increasing 8%. Companion animal sales increased 26% driven by global demand in parasiticides, including the BRAVECTO line of products, as well as vaccines.

Recall that we experienced changes in distributor purchasing patterns, which negatively impacted last year's results. Livestock sales were flat, as strong global demand for poultry and swine products was offset by a difficult year-over-year comparison due to the recording of an extra month of sales relating to Antelq in the fourth quarter of 2020.

I will now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis. Gross margin was 74.8%, a decrease of 0.2 percentage points. As a reminder, we share profits from molnupiravir equally with our partner, Ridgeback, which is reflected within cost of sales and reduces our gross margin. This impact was largely offset by favorable mix and lower discards.

Operating expenses increased 3% to \$5.3 billion as we continued to invest behind our growth drivers and pipeline. Other expense was approximately \$50 million.

Our full year tax rate was 11.2%, which is lower than our prior guidance due to a more favorable mix of income and expense than previously estimated. The effective tax rate for the fourth quarter of 4.3% reflects the impacts of the lower full year rate as well as foreign tax credit. Taken together, we earned \$1.80 per share.

It is worth noting that our underlying operating results were toward the upper end of our expectations and the contributions from molnupiravir, and the favorable tax rate resulted in EPS that exceeded our prior guidance.

Turning now to our 2022 non-GAAP guidance. We believe the strong underlying momentum in our business will continue, and we will also benefit from increased molnupiravir revenues. We expect revenue to be between \$56.1 billion and \$57.6 billion, representing growth of 15% to 18%, including a negative impact from foreign exchange of approximately 2% using mid-January rates.

Our gross margin is expected to be approximately 74%. We expect operating expenses to grow at a mid- to high single-digit rate driven in part by the addition of R&D expenses related to the Acceleron acquisition.

In other income and expense, we expect expense of approximately \$350 million. We assume a full year tax rate between 13% and 14%. We assume 2.53 billion shares outstanding. Taken together, we expect EPS of \$7.12 to \$7.27, reflecting growth of 18% to 21%. This range includes the negative impact from foreign exchange of approximately 1% using mid-January rates.

As you consider your models, there are a few areas to focus on. First, on molnupiravir, we are excited by our regulatory authorizations to date and believe molnupiravir will be an important treatment option to combat the ongoing pandemic. We have announced a number of supply and purchase agreements, providing approximately 10 million courses of therapy. Based on agreements now in place, we are confident in our ability to achieve \$5 billion to \$6 billion in revenues in 2022, weighted to the first half of the year.

Next, we expect continued strong growth of KEYTRUDA, which should benefit from increased expansion in ex-U.S. market and the continued ramp of recent launches globally.

On GARDASIL, we continue to expect robust demand, along with increased supply to drive strong year-over-year growth, albeit not at the same pace as in 2021. In the U.S., increased uptake in the mid adult cohort as well as catch-up from missed doses due to the pandemic will drive growth.

Outside the U.S., we continue to expect strong demand across regions particularly in China and from a relaunch in Japan. Global HPV vaccination levels remain low, and we continue to believe GARDASIL's opportunity for growth is significant.

In pneumococcal, we are excited by the recent launch of VAXNEUVANCE in adults and the potential opportunity for approval in pediatric, which represents a larger portion of the pneumococcal market. We expect some offset however from the impact to U.S. sales of PNEUMOVAX 23 as the market continues to shift towards newer pneumococcal conjugate vaccines.

We also expect to experience modest LOE pressure on JANUVIA in the second half of 2022, as we lose exclusivity in some of the larger ex-U.S. market.

For Animal Health, given our broad and innovative portfolio, we are well positioned to again drive above-market growth in 2022 and beyond.

Finally, as we look out to 2025, we remain confident in our ability to achieve strong revenue growth driven largely by our derisked portfolio and operating margin in excess of 43%. Our capital allocation priorities remain unchanged.

First, we will continue to prioritize investments in our business and pipeline to drive near- and long-term growth. We also continue to augment our internal pipeline through strategic business development. We were active in 2021, including the acquisitions of Acceleron and Pandion, and we intend to pursue additional value-enhancing opportunities.

We remain committed to the dividend with the goal of increasing it over time. To the extent we have excess cash, we will return it to shareholders through share repurchases.

To conclude, our growth in the fourth quarter underscores our confidence in the underlying strength of our business and in the global demand of our innovative medicines and vaccines. We remain in a position of financial and operational strength, and our continued execution will enable us to deliver on that promise now and well into the future.

With that, I'd now like to turn the call over to Dean.

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**Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories**

Thank you, Caroline. Good morning, everyone. I will provide a brief summary of notable achievements in 2021 and then report on progress since the last earnings call.

In 2021, we made meaningful advancements across our broader pipeline with approvals for new molecular entities, including VAXNEUVANCE, VERQUVO and WELIREG, and an EUA for molnupiravir. We also made strides in women's cancers with U.S. regulatory approvals for KEYTRUDA in cervical, endometrial and triple-negative breast cancer.

In total, we received more than 30 approvals and filed more than 20 NDAs and SBLAs in the United States, EU, Japan and China. In 2022, we look to build on this progress and momentum.

I will now cover notable regulatory milestones and clinical updates for our molnupiravir, oncology, pneumococcal, HIV and cardiovascular programs. As we enter the third year of the pandemic, the Omicron variant continues to reap havoc on our communities and health care systems. In the United States alone, we are now seeing approximately 2,000 deaths a day. Vaccines and treatment options have the potential to help combat this pandemic.

Since the first authorization for molnupiravir by the U.K. in November, we have received authorizations in 9 additional countries, including an emergency use authorization in the United States and a special approval for emergency in Japan. In addition, other countries have provided authorizations to our voluntary license holders.

Findings from the MOVE-OUT clinical trial published in the New England Journal of Medicine at the end of last year showed molnupiravir significantly reduced hospitalization or death in adult patients most in danger of progressing to severe disease. Importantly, for physicians and patients, approximately 90% fewer deaths were seen in those taking molnupiravir. These results reinforce that molnupiravir provide an important oral treatment option for certain adults at high risk for severe illnesses.

The Director of the United States CDC has indicated the need to prioritize therapeutic interventions for people with the highest risk of progression, such as those with certain comorbidities. We believe molnupiravir has a low propensity for drug-drug interactions, make it a meaningful and

important option for appropriate patients with COVID-19 who are receiving treatments for underlying conditions, such as heart disease, hypertension and diabetes, and for those with impaired liver or kidney function, consistent with local recommendations.

To date, this pandemic has consisted of successive waves of SARS-CoV-2 variants, most recently, Omicron. Last week, we announced data from multiple independent studies indicating that molnupiravir is active against the Omicron variant in vitro.

Each surge comes with distinct public health and disease characteristics and corresponding treatment and prevention challenges. The potential threat of rapidly emerging variants reinforces the need for treatment options with high barrier to resistance that target ever solutionarily conserved aspects of viral biology.

Recognizing the importance of an oral antiviral, we committed to manufacturing molnupiravir and have it ready for supply to patients within the U.S. upon emergency use authorization. As Caroline noted, we were able to fulfill that promise and ensure delivery of this important treatment. We are working with governments and partners around the globe to stay ahead of the curve and to further Merck's contribution in fighting this pandemic.

Next, we continue to fortify our position in oncology. Several recent milestones highlight our strategy of targeting earlier-stage cancers where there is potential for improved outcomes by reducing risk of recurrence. We received FDA and European Commission approval for KEYTRUDA in the adjuvant setting for renal cell carcinoma and FDA approval for certain stages of melanoma.

In RCC, approval was based on KEYNOTE-564. KEYTRUDA is the first and only immunotherapy treatment option for certain patients at intermediate high or high risk of recurrence in the adjuvant setting.

And in melanoma, the approval was based on KEYNOTE-716 and provides for the adjuvant treatment of patients 12 years and older with Stage IIb and IIc disease following complete resection. Both approvals provide patients with important new options shown to help reduce the risk of recurrence.

Similarly, we recently announced a positive finding from the KEYNOTE-091 or PEARLS study, evaluating KEYTRUDA as adjuvant treatment for patients with Stage Ib to IIIa non-small cell lung cancer following surgical resection. At an interim analysis, the trial met one of its dual primary endpoints, demonstrating a statistically significant improvement in disease-free survival in all [corners] when treated with KEYTRUDA compared to placebo.

The trial will continue to analyze DFS in patients whose tumors express high levels of PD-L1, the other dual primary endpoint, which did not meet statistical significance at the time of the planned interim analysis, as well as overall survival, a key secondary endpoint.

We are continuing to make progress in women's cancer based on data from the Phase III OlympiA trial. The FDA granted priority review for Lynparza for the adjuvant treatment of patients with BRCA-mutated HER2-negative, high-risk early breast cancer previously treated with chemotherapy, either before or after surgery. We anticipate FDA action during the first quarter of 2022.

Moving to the broader portfolio. The FDA issued a complete response letter for the new drug applications for gefapixant and have requested additional information related to the measurement of efficacy. There were no safety concerns for gefapixant, and we will continue with the FDA to discuss next steps as we look to address the significant unmet need in patients with chronic cough.

In Japan, we are pleased to announce the Ministry of Health, Labor and Welfare approved Lyfnua, the trademark for gefapixant, for adults with refractory or unexplained chronic cough.

Momentum continues in our pneumococcal disease program, following the U.S. approval in July 2021. The European Commission approved VAXNEUVANCE in individuals 18 years of age and older in December. Also in December, we announced the FDA granted priority review of our supplemental application for VAXNEUVANCE in the pediatric setting.



Importantly, VAXNEUVANCE incorporates serotypes 22F and 33F and provides robust response on other key disease-causing serotypes, like serotype 3, therefore, offering the potential to prevent additional invasive disease in children. We anticipate regulatory action in the spring of this year.

Merck has a proud legacy of HIV research, and we remain committed to those impacted by this virus. Following the announcement of the FDA clinical hold for ongoing trials evaluating islatravir, we are working to understand the data and the principles of the finding. We believe in the potential of the nucleoside reverse transcriptase and translocation inhibitor mechanism for both the prevention and treatment of HIV, and we intend to share updates in the future.

Looking across our broader pipeline. As Rob noted, in the fourth quarter, we completed the acquisition of Acceleron. Its lead candidate, sotatercept, is an excellent complement to our pipeline and has the potential to provide a novel approach to treating pulmonary arterial hypertension. The integration is proceeding according to plan, and the Phase III program is on track. We plan to provide further details on our cardiovascular pipeline at an investor event in the spring.

In closing, 2021 was a tremendous year where we demonstrate our ability to advance both our internal and external pipelines. We are well positioned to continue our momentum into 2022 with a dual focus, becoming the leading oncology company by 2025 and sustaining that position beyond 2028, while also extending our impact across other therapeutic areas. I look forward to providing further updates in the coming year.

Now I turn the call back to Peter.

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

Thank you, Dean. Grace, would you please start the Q&A? (Operator Instructions) Thank you.

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) Your first question comes from the line of Geoff Meacham from Bank of America.

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

I guess, one for Dean or for Rob. How strategically important is molnupiravir? Is the goal to maximize the revenue this year, assuming that resistance doesn't emerge? Or are you guys making investments in a potential combination to turn this business into maybe a longer contributor?

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

Yes. Geoff, thanks for the question. So as we look at molnupiravir, obviously, you heard from Caroline the guidance we're giving for this year, but I think you've hit upon an important point, which we do see the potential for molnupiravir beyond the current situation with COVID-19 and the pandemic given the fact that it does have such good activity more broadly in RNA viruses.

And as we believe, it can be pan-coronavirus effective. And as we showed recently with 6 preclinical studies, working well against the Omicron variant, and we believe we'll continue to work against future variants.

But maybe I'll turn it over to Dean to expand upon what we're thinking about from a developmental perspective for longer term.

**Dean Y. Li** - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So if I may, let's just frame how many deaths we have a day in the United States. I mean, it's quite staggering where we are at this point. And I would just emphasize, molnupiravir is an oral drug as all know. It's effective in reducing hospitalization and death.

And I really think, when we think about the death rate in the United States and throughout, having access to medicines that can reduce mortality greater than 80%, 85%, 90% is going to be really important. And molnupiravir is one of such drugs that can do that, and I think that needs to be sort of emphasized throughout.

Now in relationship to molnupiravir directly, those people who we have to be concerned about drug-drug interactions or renal insufficiency or liver insufficiency are often those people at the highest risk. And the fact that molnupiravir has a profile that is really useful in those patients is important.

I do want to emphasize that by first principle, the whole mechanism and the molecule is designed to be as variant proof as can be theoretically possible. And what we've seen with the Omicron and potentially what we will see with other variants is that theoretical becomes real. With Omicron, for example, all of a sudden, there's a series of antibody treatments that are no longer effective.

And then the other point that I would make is when we sent our EUA in October, we also held hands that we would be able to produce, supply, distribute this drug immediately. And I think that's been shown that when we sent our EUA in October, we were in that position. And we demonstrated when we got an EUA in late December how fast we could distribute.

And I just want to emphasize that I think that when one looks at the death rate when we sent in our EUA and what the death rate now is, it's threefold higher. So I just want to emphasize that.

When you think about the future, I suppose there is different bookends with one can think through. And the different bookends would be, okay, maybe we could get a really lethal sub-variant. Then that issue of us having a resistance profile that we're very confident about could be really important.

The other possibility of a bookend is that this becomes sort of more endemic. So it's everyone's getting it. It's not necessarily that lethal for healthy people. But in that situation, like in flu, it is the most vulnerable patients are the ones who need to get treated, and that most vulnerable population are often those people you have to worry about drug-drug interactions, renal and liver insufficiency. So in that context with just COVID-19, that's how we think about molnupiravir.

In relationship to your question about eventually does the [field] have to really think about combination, I do think. And I do think it's important that we have an arsenal of multiple mechanism of actions because in every viral disease that I know, the virus is pretty good at evading different mechanisms of action.

And I think we may have to think about this combination issue that you've talked about. And we have invested both internal resources and other mechanisms of action. And we're in conversations with other people with different mechanism of action.

So the fundamental thing is, I think, we need to have a view, that we need to be prepared, that we're going to need multiple options, and molnupiravir is an important part of the arsenal that this -- the United States and globally will need to have.

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**Caroline Litchfield** - Merck & Co., Inc. - Executive VP & CFO

And if I may, this is Caroline. We have guided to \$5 billion to \$6 billion of revenue this year. That's on the basis of approximately 10 million courses.

To Dean's point, our company remains focused on ensuring there is enough supply, depending on how things move forward. So we are still committed to the 10 million courses we did manufacture in 2021 and more than double that in 2022. So we will have in excess of 30 million courses to support how the pandemic and how the use of molnupiravir progresses.

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**Operator**

Your next question comes from the line of Chris Shibutani from Goldman Sachs.

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

On KEYTRUDA, important parts of that leadership strategy is the adjuvant opportunity as both combinations. With the adjuvant, can you just comment a little bit more in terms of what you think you're seeing so far and how that's progressing?

And with the combinations, it looks like the data is scheduled to read out more in the '24, '25 time frame. Dean, perhaps, is there an opportunity that we might potentially be able to get a look earlier than then on any of the combination efforts?

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**Dean Y. Li** - *Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories*

Right. So I just want to emphasize. There are 2 types of combinations that we have. We have an IO-IO combinations, and I think that's what you're referring to in relationship to KEYTRUDA, whether it's with our TIGIT, LAG-3, CTLA4 and that. And you're right, those readouts are event-driven and the [fact sheet], and that will be -- we'll see where it is, but I think your timing is a reasonable sort of timing in terms of Phase III readouts.

In relationship to other combinations, I want to draw your attention to the combination of KEYTRUDA with chemotherapy, with other ADCs that we've worked with other companies with. But I would also focus your attention also on the readouts of KEYTRUDA with Lenvima that continue to spool up, and KEYTRUDA with Lynparza. And the reason why I think that's important is we think about how to raise the immuno-oncology profile of KEYTRUDA with other IO agents.

But also as we see Lynparza and LENVIMA, they are -- they give us readouts of how to think about DNA repair and with combination in second and third generation of different sort of compounds in that place. And also in relationship to Lenvima, where you're looking at blocking vascular endothelial growth factor, RTKs, it gives us a thought as to how to think of drugs such as WELIREG, which also plays in that sort of same sort of play.

And so we're very interested in seeing how WELIREG plays out in sporadic renal cell carcinoma. And then we will ask ourselves outside of renal cell carcinoma where else should it play where an anti-angiogenesis agent has been shown to be effective.

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

Yes. And maybe, Chris, just to answer the first part of your question how are we seeing the adjuvant space, obviously, we are very excited about moving into earlier lines of therapy. We think this is a real area of growth.

Obviously, the strength we're seeing in KEYTRUDA is about how we're able to expand into new indications and continue to broaden. If you look, we had just in 2021 alone 21 approvals of new or expanded indications for KEYTRUDA. Three of those were in the adjuvant space, with adjuvant triple-negative breast cancer, adjuvant renal cell carcinoma and moving into a Stage II cancer in adjuvant melanoma.

So important growth there. And if you look at that, combined with the remaining other indications we already have and the other ones in adjuvant mel and what we hope to have soon with KEYNOTE-091 in adjuvant non-small cell lung cancer, we're looking at movement into the earlier spaces, driving approximately 50% of the growth for the drug for KEYTRUDA through 2025. And we think by 2025, it will be about 30% of our total revenue coming from the adjuvant indications we have.

So this is an area where we're starting to put runs on the Board. And I think we're going to show that the breadth of what KEYTRUDA could do, both in maintenance as well as in the metastatic space, is going to be very important as we build the leadership for the long term.

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

And to be clear, Rob is referencing the U.S. markets.

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**Operator**

Your next question comes from the line of Steve Scala from Cowen.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

I'd like to ask about a more obscure pipeline agent. Sanofi believes that there is no discernible evidence of benefit of the Merck RSV monoclonal antibody versus the Sanofi monoclonal antibody, and that Sanofi is so far ahead that Sanofi unquestionably will dominate.

So I'm wondering what Merck thinks. And if you disagree with Sanofi, then why is your antibody better than theirs?

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**Dean Y. Li** - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. I want to be a little bit careful that I'm answering questions about another company's drug. I think that having a monoclonal antibodies that can treat RSV in a really important patient population is critical.

We have data that will be coming out, and we'll have to see what that data looks like. But we do think that there is opportunity to have a really effective drug, that really is easier to provide to that patient population.

So I'm a little bit hesitant to comment directly, but we are very confident in the profile of our RSV antibody studies. And we will just have to see what the clinical data looks like as the clinical data comes through.

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**Operator**

Next, we have Umer Raffat from Evercore ISI.

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**Jonathan Miller** - Evercore ISI Institutional Equities, Research Division - VP

This is Jon Miller on for Umer. On islatravir, is there -- obviously, the long duration and the long PK here is the major selling point. But is there any chance to avoid CD4 monitoring or maybe to get around some of the potential product issues that you've been looking at or evaluating?

If you stick to sub milligram daily dose rather than trying to push for the weekly or monthly doses, is that a potential path forward for islatravir in the HIV franchise?

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**Dean Y. Li** - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So let me take that. So we are evaluating a considerable body of data. You mentioned trends of lymphocytes that have been observed in different trials that we've had.

I would point out that our Phase III with islatravir and doravirine demonstrated the efficacy and just the highly efficacious nature of islatravir in that combination, which is Q day. We will have a near-term evaluations of the future options, but we are still very committed to this longer acting sort of point of view as well.

So to get to your question, we have data in relationship to Q day islatravir, doravirine, and it's highly efficacious. We are going to look at the body of data in relationship to other ways to continue to make that long sort of resident time, be able to have a less frequent either PrEP or treatment. And we're evaluating that data as we speak.

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**Operator**

Our next question comes from the line of Mara Goldstein from Mizuho.

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**Mara Goldstein** - *Mizuho Securities USA LLC, Research Division - MD of Equity Research Department*

I'm wondering, in the last couple of weeks, there have been a number of comments made by some of your competitors around valuations in M&A. And since you did discuss acquisition as a part of strategy, I'm wondering if you could maybe opine as well as to where you think valuations are relative to the overall strategy of continuing to supplement the company's pipeline.

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

Yes. Thanks for the question, Mara. So as you pointed out, we are seeing in the biotech space valuations have pulled back quite a bit of late. I think it's too early to see whether or not this is a permanent rebasing in the market or if it is just a temporary change in the marketplace. We need to see how that plays out.

And the other thing, this could be important is what happens with the investment flows into the space. You are seeing IPOs start to slow. And it would be interesting to see if cash investments start to also slow down as people look to invest into the space with a lower valuation in the market, as you point out.

Whether or not that drives to sellers being willing to see the restatement of value that will allow us to do deals at different levels, we'll have to see. But it doesn't change the importance we see of doing business development for the company.

And obviously, we're very focused, first and foremost, on driving and accelerating our own pipeline, but we know we have to augment it. And we are going to continue to focus in this area. And I'm confident that we're going to find the opportunities where the scientific opportunity match to our capabilities and where we see good value will allow us to do value-enhancing deals, regardless of the market situation.

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**Operator**

Your next question comes from the line of Tim Anderson from Wolfe Research.

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**Unidentified Analyst**

This is [Adam] on behalf of Tim Anderson. On your oral PCSK9 program, you say that you're going into Phase II in 2022. Assuming that this takes 2 years to wrap up, what would a Phase III trial look like in terms of lengths and comparator? Guessing that this might not take until the late 2020s to report out.

**Dean Y. Li** - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. Thank you for that question. So the question is about our oral PCSK9 drug. We presented the Phase I sort of readouts in relationship to that. The Phase II readouts will be very important.

As everyone recognizes, cardiovascular risk is just a tremendous risk throughout. It's actually -- you could view it as an epidemic that continues, and there will be two sort of important considerations to take.

One is, as we advance the oral PCSK9, the biomarker of reducing LDL is a powerful biomarker that has been established as an important biomarker that has provided a path for registration based on that, even prior to having sort of readouts in terms of cardiovascular outcomes, in terms of death and heart patient endpoint.

So we believe that we're going to have to do both, but we're very eager to see how well this agent works in our Phase II trials in driving the levels of LDL down, and that will give us the confidence to really advance this for patients. But again, driving the LDL down will be an important registrational point that has been a path for other drugs as well. But we will also have to do outcome study in addition to that.

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**Operator**

Next up, we have Matt Harrison from [Eres].

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**Unidentified Analyst**

This is Charlie Young for Matthew. Can you provide, in terms of your launch expectation of VAXNEUVANCE this year and perhaps even next year, especially after the pediatric indication approval?

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

Yes. So obviously, we're very excited about what VAXNEUVANCE and the opportunity to just present starting with, as you point out, the adult indication, which we received. And as you probably know, we did do the [NMWR] come out and validate the ACIP recommendation. So we're at a point now where reimbursement is established in the marketplace, and we are beginning to ship product.

As we look at this, we see a real opportunity because if we look at what is the profile of VAXNEUVANCE in combination with PNEUMOVAX 23, you're looking at an agent that has the broadest coverage. Between the 2, we have 15 serotypes in VAXNEUVANCE. We're adding 9 additional serotypes, 4 which are unique to PNEUMOVAX 23.

And as we look at the coverage, obviously, in things like serotype 3, we showed with VAXNEUVANCE that we are very competitive, if not superior to the competition in the marketplace. And we know that serotype 3 is an important contributor and driver of disease, as is serotypes 22F and 33F, which are in ours as well.

So as we look at it, you've got very broad coverage, you've got important coverage in high disease-causing serotypes. And we have important data showing how the drug works in at-risk and immunocompromised patients, which will be in the label -- is in the label.

So we're well positioned. We're going to have to obviously fight it out at the commercial level, but we think we're well positioned to do that. And we already are starting to look forward to what we see in the pediatric space.

Right now, hopefully, we're going to see -- with the PDUFA in April, we're going to see hopefully the opportunity to get that drug into the marketplace. But obviously, we're going to build on the momentum from the launch in adults to then carry that forward into the pediatric setting. So far, all have started well, good contracting underway, and we're off to a good start. Thanks.

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**Operator**

We have Andrew Baum from Citi.

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**Andrew Simon Baum** - Citigroup Inc., Research Division - Global Head of Healthcare Research and MD

A question on islatravir. Are you in a position to disprove mitochondrial toxicity as a cause for the lymphocyte compression? Or would you file for approval for the once-a-day combination if you have no clear line of sight on a longer dosing period formulations?

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**Dean Y. Li** - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

You broke up just a little bit. In relationship to the mechanism by which the lymphocyte trends that we've disclosed is going down. We're looking at the mechanism of action.

I would say just two brief points. One is there's a question of whether or not there are ways to get around it by looking at the dose that was provided. And then the second sort of question is the mechanism. The mechanism, we're still evaluating.

I believe your question was in relationships with mitochondrial toxicity. That does not list as the first place that we would go in relationship to the data that we have right now. But I don't want to rule out anything right now as we're evaluating all the data as we speak.

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**Operator**

Next, we have Louise Chen from Cantor.

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**Louise Alesandra Chen** - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

So I want to ask you if the headlines about the logistical obstacles for oral antivirals, how accurate are they? And if they are, how are you working through them?

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

Yes. I appreciate the question, Louise. So if you look at the situation, and I think you're probably focused mainly in the United States, we are in a situation where we did deliver to the United States doses of courses of therapy before the end of the year, a little over 900,000 courses of therapy were delivered to them.

Since then, we continue to add to that. And by the end of this week, we should be to the full 3.1 million courses delivered to the distribution hubs that they have.

Obviously, at that point, it's us working with the government, but it's up to the government on where and how they distribute it from the hubs out into the pharmacies and the local markets.

I think the real thing we're focusing on in discussions with the government is how do we increase the messaging to help people understand how they can find out, where they can go to get to antivirals. And there's locator sites that the government has on the web. And we're trying to make sure as much as we can to help people know to go look there because the drug is in the marketplace, you just have to be able to find out where to go find it. And we will continue to partner with the government any way they need to ensure we can get access as quickly and as broadly as possible.

Obviously, we're very focused beyond the U.S. as well, and I feel very good about what we're doing. You probably saw we announced that we had a deal with UNICEF for 3 million courses. That really is us trying to help make sure we could accelerate access to the low- and middle-income countries as we wait for the generic manufacturers.

So we had the licenses with as they ramp up production. So hopefully, that will help fill in the gap in those markets as we wait for the generics to be able to ultimately come online.

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**Operator**

Next, we have Daina Graybosch from SVB Leerink.

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**Daina Michelle Graybosch** - *SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst*

I'm going to go back to KEYTRUDA in oncology and the IO combination. So we're going to see this year, I think, multiple randomized readouts of TIGIT from Roche. And I think, as somebody mentioned earlier, you guys have multiple trials of TIGIT and LAG-3 coming in the future.

I wonder if you could talk to how your development strategy could be differentiating for these IO-IO combinations. In particular, can you highlight anywhere where your base position of KEYTRUDA may give you an advantage?

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**Dean Y. Li** - *Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories*

Let me take the scientific question in relationship to that. So thanks for that question. I would emphasize just the general principle that we have, which is we believe that there are ways to improve the immuno-oncology sort of access of PD-1 by adding another checkpoint inhibitor.

We believe that, that is going to be potentially a different checkpoint inhibitor or a different addition to PD-1 given a different tumor cut. So we're not so sure that there is one additional checkpoint inhibitor that you could add to PD-1 that would have as broad of an impact as P1 has itself.

So our strategy has been to invest in CTLA-4, to invest in TIGIT, to invest in LAG-3, to invest in ILT4. I think the strategy of some of our other colleagues is to place a larger bet on each of those combinations more broadly. So I think that's something that I think is really important.

The second point that I would also emphasize is you want to show contribution of components, and you want to show that what you're added on to the PD-1 is really better than the PD-1. And the reason I want to emphasize that is that one should also look at what the base of our PD-1 response is compared to others in relationships. So it is my belief that targeting the PD-1 axis is, in general, more effective than, for example, a PD-L1. So that gives us a distinguishing position as well.

And then the third issue is, especially in lung, where physicians are very comfortable in relationship of where we stand in relationship with PD-1, with our PD-L1 monotherapy sort of differentiation as well as PD-1 plus chemo in relationship. And also we're driving our PD-1 into earlier stages of cancer, for example, in lung and others. I think that gives us sort of a leg-up as well.

So three things. One is how we think strategically about IO-IO combinations. And then the second sort of thing is in relationship to PD-1 versus a non-PD-1 sort of position, so PD-1 versus a PD-L1. And also our ability to sort of paint the whole from adjuvant all the way to later stage is something that I think gives physicians enormous comfort in our base drug.



**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

Great. Thank you, Dean. Thank you, Daina. And thank you all for your good questions today. We realize there is a peer call starting right now, so we want to be mindful of that. If you have any follow-ups, please reach out to the IR team at any time, but we appreciate the good questions today and your interest. Thank you.

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

Thank you.

**Operator**

Ladies and gentlemen, this concludes today's conference call. Thank you all for joining. You may now all disconnect.

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