Q1 2022 Earnings Call

Company Participants

- Caroline Litchfield, Chief Financial Officer
- Dean Li, President of Merck Research Labs
- Peter Dannenbaum, Vice President, Investor Relations
- Rob Davis, President and Chief Executive Officer

Other Participants

- Andrew Baum, Citi
- Chris Schott, Analyst, J.P. Morgan
- Chris Shibutani, Analyst, Goldman Sachs
- Colin Bristow, Analyst, UBS
- Daina Graybosch, Analyst, SVB Leerink
- Edwin Delfin, Barclays
- Louise Chen, Analyst, Cantor
- Mara Goldstein, Analyst, Mizuho
- Mohit Bansal, Analyst, Wells Fargo
- Seamus Fernandez, Analyst, Guggenheim
- Umer Raffat, Evercore ISI

Presentation

Operator

Good morning. My name is Grace Lakra, and I'll be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co. Q1 Sales and Earnings Conference Call. All lines have been placed on mute to prevent any background noise. And after the speakers' remarks, there will be a question-and-answer session. (Operator Instructions) Thank you.

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

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Grace, and good morning. Welcome to Merck's first quarter 2022 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 have excluded these items 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 2021 10-K identify 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.

Rob Davis {BIO 6955931 <GO>}

Thanks, Peter. Good morning, and thank you for joining today's call. Before I get started, let me take a moment to speak about the ongoing crisis in Ukraine. We are hopeful for an immediate and peaceful resolution to the Russian invasion of the country and we support the Ukrainian people and stand with them and recognize what a terrible tragedy this represents. Merck is making every effort to protect the health and safety of our employees and to ensure essential medicines and vaccines continue to reach patients. In addition, we are dedicating meaningful resources to address the humanitarian crisis in the country, through multiple channels.

Turning to our business, we continue to deliver across our key strategic priorities in the first quarter. We're sustaining the strong business momentum we delivered in 2021 with robust top and bottom line growth. We've also achieved significant clinical advancements across our research pipeline and successfully integrated Acceleron.

Now moving to our results. We've had a strong start to 2022, achieving very strong top and bottom line growth. Commercially, we continue to execute well across a broad set of key growth drivers. Most notably, KEYTRUDA, GARDASIL and Animal Health. Our performance reflects robust underlying demand for our derisked innovative portfolio and reinforces the importance of our science-led strategy.

LAGEVRIO, our COVID-19 antiviral treatment was a significant contributor as well. But even excluding these sales, our top line growth was still a very healthy 19% versus last year. On LAGEVRIO, we've accelerated broad global access and is now established as an important tool for patients and healthcare providers to address the ongoing pandemic.

Since receiving emergency use authorization in December, we've delivered approximately 6.4 million courses to more than 30 countries. The success we are achieving is reflected in our updated 2022 guidance, which demonstrates our expectation for another year of strong growth and overall business momentum.

Our oncology business is benefiting from the continued rollout of new and important indications, including in earlier lines of therapy. Global demand for GARDASIL still remains strong and growth will benefit from increased supply as a result of the significant investments we are making to expand manufacturing capacity and our Animal Health business remains positioned to grow at above market rates.

Longer term, we remain confident in our ability to deliver strong revenue growth and operating margin expansion through 2025. We're preparing for the post KEYTRUDA LOE period by continuing to strengthen the levers we have and building upon them in order to deliver long-term growth. In oncology, we remain committed to building on the foundational position that we have achieved with KEYTRUDA and we aim to expand our presence in this key therapeutic area and to establish an enduring leadership position.

In addition, we'll continue to maximize the opportunities we see for our durable growth drivers, such as GARDASIL, our pneumococcal portfolio and Animal Health through our proven commercial execution. Beyond our existing portfolio, business development remains a key priority. We remain highly focused on our pursuit of the best external innovation and will be appropriately aggressive when great science and value aligned. We have a strong track record of business development, but we know we need to do more and we believe we are well positioned to quickly deploy capital towards the right strategic assets as they present themselves.

And finally, we'll continue to advance our broad pipeline across key therapeutic areas in order to deliver medically important innovations to patients. We've taken important steps to provide increased transparency into the opportunities we see in our portfolio and our business, including through two recent investor events.

Earlier this month, we provided a detailed description of our growing cardiovascular portfolio and pipeline. And Merck, we're focusing our efforts where the needs are greatest and where we have the best opportunity to positively impact patients' lives, including heart failure, pulmonary arterial hypertension, thrombosis and atherosclerosis.

We made significant advancements across our CV pipeline and believe our broad differentiated portfolio can have meaningful impact on patients' lives with at least eight potential new approvals by 2030. We're confident that these important innovations have the potential to be meaningful growth drivers for Merck well into the next decade.

And in February, we hosted our inaugural ESG event, which highlighted our activities in our four priority areas of access to health, employees, environmental sustainability and ethics and values. Our ESG efforts are grounded in our Company's values and we look forward to building on Merck's legacy of operating responsibly going forward.

Before I close, I'd like to take a moment to recognize Dr. Roy Baynes, who has announced his retirement after eight years of Merck. Roy has been instrumental and helping Merck become a leading oncology company, particularly through his leadership and the development of KEYTRUDA. We wish we were the best in his future endeavors and we're confident that he leaves behind an outstanding team and program.

I'm pleased to report the Dr. Eliav Barr was appointed to succeed Roy. Eliav not only has deep experience having served in several research capacities throughout is more than two decades of Merck, but also has an unwavering commitment to patients consistent with Merck's purpose to save and improve lines.

In summary, we've begun 2022 with strong operational momentum and I want to express my sincere thanks to our employees worldwide for their continued focus and commitment. We remain confident in our fundamental strategy, our growth prospects and in our ability to deliver significant benefits for patients and value to shareholders well into the future.

With that, I'll turn the call over to Caroline.

Caroline Litchfield {BIO 20934609 <GO>}

Thank you, Rob. Good morning. As Rob highlighted, we have had a very strong start to 2022 with exceptional performance in both revenues and earnings. These results further demonstrate that our focus on science and innovation at the core of our strategy enabled by excellent execution of our dedicated colleagues across the globe. It's delivering value for patients, customers and investors

Total company revenues were $15.9 billion, an increase of 50%. LAGEVRIO contributed $3.2 billion in revenue. Excluding LAGEVRIO, the base business delivered very strong growth of 19%. The remainder of my comments will be on an ex-exchange basis. Our Human Health business continued its strong momentum excluding LAGEVRIO, the Human Health business grew 21% driven primarily by our key pillars, as well as the reduced impact of the pandemic.

Our Animal Health business also delivered above market performance with (inaudible) increasing 9% driven by growth across both companion animal and livestock segments.

Now turning to the first quarter performance of our key brands. In oncology, KEYTRUDA grew 27% to $4.8 billion, reflecting continued robust global demand and the expansion into new indications. In the U.S., KEYTRUDA continues to demonstrate strong growth across all key tumors and is benefiting from recent launches in earlier stage cancers, including triple-negative breast, renal cell carcinoma and melanoma.

KEYTRUDA is currently approved to treat five indications in earlier stage cancers and we are excited about the potential opportunity to expand into adjuvant lung cancer based on the encouraging data from KEYNOTE-91. We continue to be confident, the KEYTRUDA's robust clinical data combined with physicians familiarity and experience with the product will support expanded use and patient benefit in early stage disease.

In the metastatic setting, KEYTRUDA continues to maintain its leadership position in non-small cell lung cancer, capturing 8 out of 10 eligible new patients. Outside the U.S., KEYTRUDA growth continues to be driven by lung cancer and the ongoing launches in head and neck cancer and renal cell carcinoma. Lynparza remains the market leading PARP inhibitor. Our alliance revenue grew 20% driven by uptake in metastatic breast cancer, we are also excited by the expanded opportunity in early stage breast cancer following the recent FDA approval based on the OlympiA study.

Further, we look forward to potentially reaching a broad prostate population based on the PROpel study. Lenvima alliance revenue also had very strong growth, driven by uptake following the launch of the KEYNOTE-581 in advanced renal cell carcinoma and KEYNOTE-775 in metastatic endometrial cancer, where we are seeing encouraging new patient share trends across each of these tumor types. Lenvima growth also benefited from increased demand in hepatocellular carcinoma in China and certain one-time items

We are also excited by the launch of WELIREG, for patients with certain VHL-associated tumors. WELIREG continues to generate strong interest among scientific leaders, providers and patients. Although still early in its launch, WELIREG has had uptake providing a treatment option to the significant unmet need for these patients. We are working to potentially extend its reach to broader RCC indications in the future.

Our vaccines portfolio again delivered excellent performance led by still GARDASIL, which increased 60% to $1.5 billion. Outside the U.S., significant growth was driven by strong underlying demand across key geographies, particularly China, as well as increased supply. In the U.S., sales increased due to the timing of CDC purchases. Global demand for GARDASIL remains robust supported by strong clinical and real world data as well as efforts to increase the recognition of GARDASIL as a vaccine that can help prevent certain HPV-related cancers in both females and males.

In our hospital acute care portfolio, BRIDION sales grew 20% driven by the ongoing recovery in surgical procedures during the quarter and continued strong leadership of the neuromuscular blockade reversal agent class. Our Animal Health business delivered another quarter of robust growth with sales increasing 9%. Companion animal sales increased 13% driven by global demand in parasiticides including the BRAVECTO line of products, as well as vaccines. Livestock sales increased 7% due to higher demand in ruminant and poultry.

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 70.7%, a decrease of 5.9 percentage points driven primarily by higher LAGEVRIO sales. As a reminder, we share profits from LAGEVRIO equally with our partner Ridgeback, which is reflected within cost of sales and reduces our gross margin percentage. Gross margin this quarter also reflects the favorable impact of product mix, offset by higher manufacturing costs.

Operating expenses increased 7% to $4.8 billion, as we continue to prudently invest behind our growth drivers and pipeline. Other expense was approximately $140 million. Our tax rate was 14%. Taken together, we earned $2.14 per share.

Turning now to our 2022 non-GAAP guidance. As a reminder, at the request of the SEC, certain companies in our industry, including ours have made changes to non-GAAP reporting. We will no longer exclude significant expenses for upfront and milestone payments related to collaborations and licensing agreements as well as transactions accounted for as asset acquisitions from non-GAAP results.

As a result, $1.7 billion of R&D charges primarily related to the acquisition of Pandion are now included in our recast 2021 non-GAAP results. This increased R&D expense by $1.7 billion and decreased non-GAAP EPS by $0.65. There was no impact to the first quarters of 2021 and 2022. Our 2022 guidance does not assume any significant transactions that would have previously been excluded from non-GAAP.

So this could change in the future quarters, if we execute business development, which is a strategic priority. The underlying strength of our business, enables us to raise and narrow our full year guidance. We now expect revenues to be between $56.9 billion and $58.1 billion, representing growth of 17% to 19% or 11% to 12% excluding LAGEVRIO and the impact from foreign exchange.

The projected impact from foreign exchange includes an incremental headwind of approximately $200 million using mid-April rates, resulting in a full year negative impact with just over 2%. We are increasing our gross margin expectation to between 74% and 74.5%. We expect operating expenses of $20.3 to $21.3 billion. At the midpoint, this is consistent with what was implied by our prior guidance. We expect other expense of approximately $350 million. We assume a full year tax rate between 13.5% and 14.5% due to an increase in estimated U.S. taxes to be paid on foreign income.

We assume 2.53 billion shares outstanding. Taken together, we have increased our expected EPS range to $7.24 to $7.36, representing pull-through of the operational strength from our key pillars and operating expense leverage. Offset in part by a slight reduction in the top-end of our LAGEVRIO sales assumption, the increase in our tax rate and an incremental 1% headwind from foreign exchange using mid-April rates. As you consider your models, there are a few areas to focus on. First on LAGEVRIO. We are narrowing the range of our full year guidance to $5 billion to $5.5 billion.

We have entered into supply and purchase agreements for approximately 10 million courses of therapy. Since authorization, we delivered 6.4 million courses of therapy, including 5 million in the first quarter. We expect approximately half of the remaining full year revenue from LAGEVRIO in the second quarter. We continue to expect strong annual growth for GARDASIL, especially in ex-U.S. markets including China.

Finally, as a reminder, our other revenue line contained several items including supply sales to Organon, which we began recording upon the completion of the spin-off last year and to Johnson & Johnson for its COVID vaccine also included our revenue hedge and royalties. Other revenue in first quarter also benefited from approximately $100 million in receipts relating to out licensing agreements.

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 will continue to be appropriately aggressive in augmenting our internal pipeline through strategic business development 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, we remain very confident in the growth of our business, driven by the global demand for our innovative medicines and vaccines. We are in a position of financial and operational strength and our continued execution will enable us to deliver value to patients and our shareholders well into the future.

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

Dean Li {BIO 21985278 <GO>}

Thank you, Caroline. It is good to be here to provide an update on our progress. In the first quarter, we continue to demonstrate progress in our pipeline. We made advances across multiple therapeutic areas including oncology in both advanced and earlier stages of cancer as well as in cardiovascular disease and vaccines.

I will also provide an update on LAGEVRIO. In oncology, we continue to build upon our strong position and execute on our strategy to expand, deepen and expand benefits patients and diversify our imprint on cancer. This past quarter, we achieved milestones in several tumor types as well as different stages of disease.

Notably, we continue to expand our treatment impact in earlier stages of disease, where we now have six approval from the FDA, five for KEYTRUDA and one for Lynparza. At the European Society for Medical Oncology Virtual Plenary session last month, data from the KEYNOTE-091 or PEARLS trial, evaluating KEYTRUDA for the adjuvant treatment of patients with stage IB to IIIA non-small cell lung cancer, following surgical resection for war presented. At an interim analysis, KEYTRUDA significantly improve disease free survival in all comers, one of the studies dual primary endpoint.

The trial will continue to analyze the other dual primary endpoints of disease free survival in patients whose tumors express high levels of PD-L1, which did not meet statistical significance at the time of the planned interim analysis. These latest data provide a strong signal for the benefit of KEYTRUDA in the adjuvant treatment study.

Additional ongoing studies in earlier stages of non-small cell lung cancer include KEYNOTE-671, which is evaluating new adjuvant therapy for patients with respectable II, IIIA and IIIB disease. KEYNOTE-867 which is studying stereotactic body radiation [ph] therapy with or without KEYTRUDA in adults with unrestricted Stage I or II disease. And KEYNOTE-012 where we are studying KEYTRUDA in combination with Lynparza in Stage III disease.

Following the approval of KEYTRUDA for the adjuvant treatment of patients 12 years and older with Stage IIB or IIC melanoma following complete resection based on KEYNOTE-716. We announced that at a pre-specified interim analysis, the study also met its secondary endpoints of the spin metastasis-free survival and showed continued improvement in recurrent free survival compared to placebo. The data from KEYNOTE-716 reinforces the evidence for KEYTRUDA as adjuvant therapy for appropriate patients with Stage IIB and IIC following surgery to help prevent recurrence of disease.

Now similarly, in the earlier stage setting along with AstraZeneca, we announced Lynparza was approved by the FDA for the adjuvant treatment of patients with germline BRCA mutations with HER-2 negative high risk early breast cancer, previously treated with chemotherapy either before or after surgery based on the OlympiA study. Further, in women's cancer, we received FDA approval for KEYTRUDA for the treatment of patients with microsatellite instability-high or mismatch repair deficient advanced endometrial carcinoma based on new data for KEYNOTE-158.

Now this approval is the fourth gynecologic cancer approval for KEYTRUDA and mark the fifth approval derived from the KEYNOTE-158 trial and innovative trial designed to evaluate the use of predictive tumor biomarkers in patients receiving KEYTRUDA for that solid tumors.

Next, the prostate cancer. Along with AstraZeneca, positive results were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium for the PROpel trial evaluating Lynparza, combination with abiraterone as a first-line

treatment for patients with metastatic castrate resistant prostate cancer, with and without mutations and a group of homologous recombination gene.

At a planned interim analysis, results showed an improvement in radiographic progression-free survival versus the standard of care. These early results also showed a trend toward improved overall survival. The trial will continue to discuss its key secondary endpoint and we plan to engage with health authorities to discuss the findings with the aim of bringing this important option to appropriate patient. Prostate cancer represents a significant unmet need and we are continually gaining important insights into the biology of the tumor. We are keen on making impact for patients with late stage disease.

Last month, we announced the discontinuation of the KEYLYNK-010 study, evaluating the combination of KEYTRUDA and Lynparza for the treatment of metastatic castrate-resistant prostate cancer. At an interim analysis, the study showed no evidence of superiority to abiraterone or enzalutamide with respect to overall survival and radiographic progression-free survival. Our attention in metastatic castrate-resistant prostate cancer now shift to KEYNOTE-091, a study exploring the combination of KEYTRUDA and chemotherapy and KEYNOTE-641, which is evaluating the combination of KEYTRUDA and enzalutamide.

Outside of the United States, we continue to deliver on our regulatory strategy, notable actions include the positive CHMP opinion for cervical, MSI high and early-stage breast cancer in Europe and approvals for the combination regimen of KEYTRUDA plus Lenvima for advanced renal cell carcinoma in Japan. And finally, to coincide with ASCO, in early June, we are planning to host an investor event in Chicago.

At our recent cardiovascular investor event, we showcased our growing portfolio of programs targeting a range of conditions, including atherosclerosis, heart failure, pulmonary arterial hypertension and thrombosis.

Following the completion of our acquisition of Acceleron Pharma, we are making strong progress in advancing the development of sotatercept, our potential first-in-class valuable Activin receptor Type IIA fusion protein. We recently completed enrollment for the STELLAR trial ahead of schedule. STELLAR is the first of four ongoing Phase 3 studies evaluating sotatercept. This progress reflects enthusiasm from investigators regarding this novel investigational mechanism.

For the first time, the 2022 American Heart Association, American College of Cardiology and Heart Failure Society of America guidelines for the management of heart failure, including Verquvo which we collaborate on with our partner Bayer. As a Class IIB recommendation for the treatment of stage C heart failure with reduced ejection fraction. The guideline highlights this mechanism of SGC such as Verquvo and the potential benefits of stimulated soluble guanylate cyclase and increasing cyclic GMP.

Based on evidence from the pioneering VICTORIA. Verquvo is the first drug specifically study and approved for patients with worsening heart failure. And the only drug recommended in the new guidelines for these patients. Our ongoing VICTORIA study is designed to expand on the evidence to date by evaluating Verquvo in patients with chronic heart failure and reduce ejection fraction, we have not experienced a recent worsening heart failure event.

Merck is uniquely positioned to meaningfully impact the treatment of patients with cardiovascular disease with at least eight potential approvals by 2030 including Verquvo and stable heart failure and sotatercept as well as our pipeline of candidates including an inhaled soluble guanylate cyclase stimulator, the Factor XI inhibitor and an oral PCSK9 inhibitor.

Next, the COVID-19 and LAGEVRIO. As the pandemic evolves, there continues to be regional surges in infection rates with the emergence of new COVID-19 variant. Some of these strains are resistant to specific monoclonal antibody regimens and appear able to vague some vaccine production highlighting the importance of testing and availability of antiviral option. At the recent European Congress of Clinical Microbiology and Infectious Diseases, we presented Phase 3 virology outcomes data from move out, adding to the growing body of evidence for the antiviral properties of LAGEVRIO.

The Panoramic trial evaluating novel antivirals for early treatment, which is being sponsored by the University of Oxford and funded by the UK government and the MOVe-AHEAD trial evaluating the LAGEVRIO for post exposure prophylaxis are both ongoing. We are working collaboratively with the European Medicines Agency to provide additional data from these trials in order to secure an approval. We remain confident from the safety and efficacy of LAGEVRIO in appropriate patients. In particular, we believe it's low propensity for drug-drug interactions makes it an important option for patients.

Next on our pneumococcal program, earlier this month, the FDA extended the PDUFA date for the supplemental Biologics License Application for VAXNEUVANCE, our 15-valent conjugate pneumococcal vaccine in infants and children to July 1, 2022. The agency requested additional analysis of data, which we provided importantly no new studies were requested.

Also in our pneumococcal program, we received breakthrough therapy designation for V116, our investigational PCV that is designed to target serotypes responsible for approximately 80% of the residual invasive disease and the older adult population and include eight unique serotypes not in currently license vaccine. We look forward to providing future updates.

In closing, I would like to think Roy Baynes for his many contributions to Merck over the past eight year. As we build upon his legacy, I'm constantly reminded of Roy's wisdom and teaching and I am grateful to work with a remarkable team he is trained and mentored. One of those mentees of course is Eliav Barr. Eliav experience and

commitment to Merck's purpose of saving and improving lives makes him the ideal leader of our global clinical development program. Eliav has a wealth of experience, holding leadership roles across an array of therapeutic areas during his 27 years at Merck, including vaccine, infectious disease and oncology. I look forward to continuing to partner with Eliav to build upon Merck's legacy of innovation and breakthrough science.

And now, back to Peter.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Dean. Grace, if you could please begin the Q&A and we requests that analysts limit themselves to one question each today to get to as many analysts as possible. Thank you.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from the line of Carter Gould from Barclays. Your line is open.

Q - Edwin Delfin {BIO 22285348 <GO>}

Hi, good morning. Thanks for taking our questions. This is Edwin Delfin for Carter. We wanted to ask about GARDASIL, if you could talk about any impact you're seeing in China either from a demand perspective or disruptions to manufacturing. And in the context, should we think about cadence over the year being notably different than in the years past, there's is just a lot of different crosswinds in place or any color there would be helpful. Thank you.

A - Caroline Litchfield {BIO 20934609 <GO>}

Carter, this is Caroline. Thank you very much for the question. GARDASIL continues to be a great growth driver for our company, globally including China. Specific to China, we saw strong performance in the quarter and we expect continued strong performance as we go through this year. We have significant demand in China and as they're off flares as a result of COVID and potentially lockdowns in one part of the country. We have the ability to ensure that we're supplying more of the GARDASIL doses to other parts of the country.

So we're, therefore, not anticipating a significant impact to our GARDASIL performance in China as a result of what we're seeing in Shanghai at this moment in time. I think pertains to our supply chain, our company has a very robust supply chain and we have plan A and plan B, if there are any interruptions in the supply chain. So we again have no concerns for the reliability of our supply chain, but we remain vigilant and focused on the situation at hand.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Carter. Next question please, Grace.

Operator

Thank you. Next up we have Mohit Bansal from Well Fargo. Your line is open.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great, thanks for taking my question and congrats on the quarter. So one question you're getting a lot is, how do you feel about potential challenge from a competitor for PD-L1 and TIGIT combo potentially looking better than KEYTRUDA in first-line PD-L1 high lung cancer. Do you see this as a major threat especially looking at the Phase 2 data from that competitor digit. Thank you.

A - Rob Davis {BIO 6955931 <GO>}

Hi, thank you for that question. So I just want to emphasize, the question focuses on the addition of another checkpoint inhibitor TIGIT on top of PD-1 and this is a strategy to sort of deepen the response to PD1 and PD-L1. I think it will be very important to see that data and look at the contribution of components. And really where we have a TIGIT program that we are also advancing in non-small cell lung cancer and small-cell lung cancer.

So the field will have to sort of see as the data evolves, how much this TIGIT add to PD-1 in the lung space. But I do want to make a broader sort of comment, which is you'll see movement and TIGIT that was recently movement and PD-1 and CTLA-4 and PD-1s and LAG3. What you recognizes each of those combinations? What they do is, if you able to show a benefit of the additional agent. It doesn't have as broad of an impact as PD-1 has in many different tumors. And so one of the things that I think it's important to highlight is, our strategy is not to just be invested in LAG3, not to be just invested in CTLA-4, not be just invested in TIGIT, but to be invested in all three and to focus from in specific tumor types.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you, Mohit. Next question please, Grace.

Operator

Thank you. Next up we have Seamus Fernandez from Guggenheim. Your line is open.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Great, thanks for the question. So just really wanted to focus in on sotatercept in the six-minute walk test as the primary endpoint. Just -- if you guys could just help us understand, what is being done in the clinical trial to really manage closely the risk that sort of a subjective endpoint represent. Or is your confidence that the

magnitude of the difference that you saw in the Phase 2 will comfortably cover the challenges of the six-minute walk test that we've seen in some other studies given some placebo responses that raise levels of concern. So just love to get your thoughts there. Thank you so much.

A - Rob Davis {BIO 6955931 <GO>}

Yes. So thank you so much for that question in relationship to sotatercept. So just to reemphasize, we have three different trials all driving towards somewhat different outcomes. The six-minute walk, which is the STELLAR trial. There is also time to clinical worsening and then up there is obviously been harder outcomes past that. And as you point out, each one of those is sort of ratcheting up what sotatercept can do. In relationship to the first one, which is STELLAR which is related to what you said the six-minute walk test, where we saw actually quite impressive data in relationship to the Phase 2.

We have very committed patient groups as well as sites who are very well trained in how to do these trials. And the Phase 2 was really nice data and the fundamental issue is that we are confident that many of those same sites that we're involved with the Phase 2 RMB [ph] of with Phase 3. So I think we're confident we'll see what that data is, but the best predictor of how well we can manage those trials is really the best indicator is the Phase 2 and we're using there are many of the same sites in the investigator. So we have great confidence in them.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great, thank you, Seamus. Next question please, Grace.

Operator

Thank you. Next we have Chris Schott from J.P. Morgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much for the question. I made just two partner around kind of corporate structure. I guess, first business development landscape, I know you talked about the SIP priority. I guess, it's been another kind of quarter of weak equity market performance in the biotech side. So I guess, are you seeing any change in willingness on the part of some of the targets to engage or any resets and valuations that could enable some of these business development kind of activities to move forward.

And then Rob, just to kind of a -- maybe tangential question on that is broadly across the Pharma Group, I think we've been seeing asset divestitures of non-traditional pharma businesses. I know you viewed Animal Health is more core to the company. But have your thoughts evolved at all, I guess, as your time as CEO and when you look at your implied kind of core valuation given where some of the Animal Health multiples trade, so incremental perspective there would be appreciated. Thanks.

A - Rob Davis {BIO 6955931 <GO>}

Chris, thanks for the questions. On the BD landscape question, the short answer is, we are not seeing a fundamental shift and seller expectations as of this point. I think as time continues, if we see the market reset to become more permanent and more importantly, if the IPO market continues to be challenged to for biotech companies that might change over time. This company has become more cash constrained. There are some some smaller players that do you have cash challenges. So I think that's where you could see the movement first, but fundamentally, we've not seen a change in the landscape yet. We'll have to continue to watch.

With regards to the Animal Health business, our view continues to be that the Animal Health business, as you said is core to the company, it's core to our strategy as part of our as part of the growth driver for the company. But as we've always said, we look at this regularly, we always are challenging ourselves to ask what is the long-term value creation opportunity of this business in our hands relative to what would it be outside of the company. And on a long-term view, we continue to believe it is best in our hands as part of the company. But if that situation evolves, we obviously will continue to be objective and how we analyze that, but we are -- we do not look at the short-term arbitrage opportunity for us, it's more about the long-term value creation and that has not changed as of now.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thanks, Chris. Next question please, Grace.

Operator

Thank you. Next up we have Chris Shibutani from Goldman Sachs. Your line is open.

Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you. Good morning. If I could ask a question on KEYTRUDA. The strength, particularly out of the U.S. this quarter, if you could help us with some of the underpinnings there and relatedly longer term 2025. I think you framed how KEYTRUDA your objective is to have. I guess, the wording changed slightly, you were previously looking for 30% coming from adjuvant with your focus framed around the U.S., if I'm reading it correctly, you brought in the framework here to now think about it as 25% on a global basis. Maybe update us on where you feel you are in terms of making progress towards achieving those objectives of the adjuvant revenue contribution. Thank you.

A - Rob Davis {BIO 6955931 <GO>}

Yes. So, Chris, this is Rob. Maybe I'll take the first part of the question and Caroline can can jump in for the second part. On the strength of the growth we're seeing in the United States, this is really a testament to what we've been talking about all along, which is as we continue to rollout new indications. We are continuing to see our share grow as the leading IO agents, and importantly, I would highlight that the growth we saw among other things in the quarter continuation of our position in renal cell carcinoma, continuation of the growth we're seeing in head and neck. In RCC, obviously, being a first-line treatment in the metastatic setting as well, all of now having adjuvant therapy as well. We cover pretty much the waterfront of RCC

and we have the opportunity to continue to grow there. But the stand out frankly for the quarter and it's -- I think really important to understand is triple-negative breast cancer.

Both in the metastatic setting and in the adjuvant setting, we are seeing incredible growth in that space, and it's something that we feel very proud of, because I think we're going to have a meaningful difference there. Reason I highlight that is both, if you look at the adjuvant opportunity there and the growth we're getting, as well as I mentioned in adjuvant RCC. I think it just reinforces what we see in the future, which is the growth contribution from the earlier lines of therapy long-term, but with that maybe Caroline can be specific to some of the guidance we provided.

A - Caroline Litchfield {BIO 20934609 <GO>}

So to Rob's point, we are extremely excited about the opportunities we have for adjuvant and the impact that has on patient. We initially shared that we expected 50% of our growth to come from adjuvant, representing 30% of the U.S. business. We have now extended that to say 50% of the growth will come from adjuvant, representing 25% of global business in the year 2025. And to Rob's point, early introduction into the earlier stage cancers with five indications now in KEYTRUDA are putting us on a very good course to have this impact.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you, Chris. Next question please, Grace.

Operator

Thank you. Next we have Umer Raffat from Evercore ISI. Your line is open.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi guys. Thanks for taking my question. Maybe let me touch upon Molnupiravir quick. I think the total utilization to date is about 200,000 courses through mid-April. And it looks like at least based on third-party data sets that, the Pfizer regimen is getting used 8x to 10x more than Molnupiravir. So I guess, my question is, if only a couple of hundred thousand courses have been used through mid-April and 3.1 million courses were contracted the U.S. Is there any recourse for U.S. to return a chunk of these courses back and I'm asking because some of the sales have been recorded in P&L. I just want to make sure their permanent sales.

A - Rob Davis {BIO 6955931 <GO>}

Yes. I'll let Caroline maybe address this.

A - Caroline Litchfield {BIO 20934609 <GO>}

So thanks for the question. First, let me start with proud of Molnupiravir, LAGEVRIO and the impacts of it can have on the world. And it has impact to the comments that Dean made given its importance especially in patients that have drug-to-drug interactions. The data that we have access to suggest that we have actually had

utilization by 500,000 patients globally at this stage. We have shipped 6.4 million courses as of now.

Those shipments represent expectations for utilization over a period of time. And we're actually seeing extremely strong utilization, especially in ex-U.S. market verses statistics few quote are actually reversed in some of the market. We have a very strong market share. So as we sit here today, we've guided on the $5 billion to $5.5 billion based on the contracts that we have been and we are confident in that in our financials.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you, Umer. Next question please.

Operator

Thank you. Next we have Daina Graybosch from SV8 Leerink. Your line is open.

Q - Daina Graybosch {BIO 20659414 <GO>}

Hi, thank you for a question. I have another one on KEYTRUDA and early stage. Could you please talk to how the success of Opdivo plus chemotherapy in neoadjuvant lung cancer, changes your expectations or strategy for the early stage opportunities and lung cancer and in the other tumor.

A - Dean Li {BIO 21985278 <GO>}

Thank you very much for that question. In relationship to sort of just earlier stage in lung cancer, I think it's really important that emphasize. There is a series of different ways to approach it, one is neoadjuvant, one is adjuvant. And I just think all of these signals just demonstrate throughout a variety of different studies. Just the impact that PD-1s can have. So our point of view of that, it shouldn't change our strategy, it should just make our strategy pretty comprehensive.

The fundamental thing is we have KEYNOTE-091, which is in the adjuvant. So that's post-surgery and that's usually given by a medical oncologists, the disease-free survival was positive in all comers regardless of PD-L1. There was a trend the CPS greater than 50% but not statistically significant. And unless there was a favorable trend regardless of PD-L1. So won't be flooding that data mature as we continue to discuss with the FDA. But getting going to your point, it's not just one KEYNOTE-091, it's KEYNOTE-671, it's KEYNOTE-867, it's KEYLYNK-012.

It's all in the earlier stage. So our desire to really push that earlier stage is going to be -- if anything our commitment towards that is even greater. The one thing I would just add in relationship with some of the comments that Caroline and Rob made is that I think it's very important that think about melanoma, renal cell carcinoma and triple-negative breast cancer, where at least my experience being in the hospital, there is a concept that really looking at that earlier stage.

I think uptake maybe sort of built-in the medical system. I think all of us including us and other companies as well as patient advocacy and medical centers are going to have to require diligent investment to really, really maximize the important scientific impacts of KEYTRUDA and PD-1s and PD-L1s in the early lung space.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you, Daina. Next question please, Grace.

Operator

Thank you. Next we have Andrew Baum from Citi. Your line is open.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. I'd just like to thank Roy for all the contributions and insights over the years. The question is on your Factor XI monoclonal. Given your background in cardiology and I'm sure familiarity with hemostasis. That's clearly been a number of indications, where the DOACs were unsuccessful compared to warfarin for both efficacy and safety. Potentially speaking to different underlying mechanisms for thrombosis in the different indication is I'm thinking about -- I'm thinking about mechanical heart valves. Given what you know about Factor XI biology and the intrinsic pathway nature of the inhibition. What indications would you actively avoid or be somewhat cautious about taking a Factor XI inhibitor into bit yours or someone else's.

A - Dean Li {BIO 21985278 <GO>}

Yes. So let me just step back for just a moment. The benefit risk of whether it's platelet or coagulation factors in terms of cladding is something that's actually very topical in the news. I would just emphasize for years for probably a decade or more aspirin has been just everywhere and recently people realize the benefit risk one have to be very careful. There has been a major change in the guidelines. So that impacts how I think about it. The other sort of thing that impact is if you look at Factor XI the fundamental advantage of that is that you can get blockage of the coagulation cascade with by genetics very little impact in relationship to adverse effect.

And so for me, the critical thing is to prove that as quickly as possible. So we immediately go where is the problem, we have thrombosis and bleeding is both impacted there. And so that's why we ran to end stage renal disease. But I could see in the future, mechanical devices with one of my favorite sort of things is left ventricular assist device. I think those will continue to need to be monitored in the future. So that's place where the risk of bleeding and the risk of thrombosis is really high.

Where we have chosen to be a little bit careful. It's, for example, broader sort of things such as atrial fibrillation and the risk of relationship to stroke, because we look at the Factor X a very effective. There are bleeding complications, but to make a space the argument for it, you're talking about a very, very large trial. So we are

raising to places where the benefit-risk of thrombosis and clotting and bleeding where that differential would make something like a Factor XI have the biggest impact.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Andrew. Next question please.

Operator

Thank you. Next we have Louise Chen from cancer. Your line is open.

Q - Louise Chen {BIO 21301405 <GO>}

Hi, thanks for taking my question. I wanted to ask you about your pneumococcal conjugate vaccine and how you think you're more targeted approach will be competitive advantage versus the one size fits all that we're seeing now. And is there any precedents to what you're doing with V116 and V117? And maybe just lastly, how would you make that message clear to physicians since of everything goes as planned you will have several PCBs on the market? Thank you.

A - Rob Davis {BIO 6955931 <GO>}

Yes. So first of all we need to get the data to demonstrate that we have an advantage in the different patient populations. But I think you point out a really important point, which is essentially what we're trying to do is for lack of a better word where you want to call it precision targeted vaccination. Right. So the fundamental thing is V114 as adult approved and we're driving towards a pediatric approval for the 15-valent. And so that will be in the pediatric population. In the V116, where we have a breakthrough designation, board trying to demonstrate that we can target 85% of the residual serotypes and I would just sit there and say it would be eight unique serotypes of -- in relationship there, all of the different currently approved ones.

And I think that patient population, I reflect a little bit about COVID, but it's -- that older population that especially as the risk factors who will do really want to make sure that whole population -- that adult population is covered. And so I do think the the fundamental thing is we'll have to have the data, but our concept is the adult have a different set of serotypes and they need to be protected and we'll have to get the data to demonstrate that. But I think if we can demonstrate that the uptake will be quite good.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Louise. Next question please.

Operator

Thank you. Next we have Mara Goldstein from Mizuho. Your line is open.

Q - Mara Goldstein {BIO 2458369 <GO>}

Thanks for taking the question. I'm just hoping maybe we can return for a second back to the question of novel targets in combination with KEYTRUDA. And maybe if you could just give us a very high level perhaps rationale for which targets you're looking at and which indications a number for you here obviously two things like TIGIT, LAG3, ILT-3 and the like.

A - Dean Li {BIO 21985278 <GO>}

All right. So let me just sort of separate. So we always talk about expand deepen and extend and when we talk about deep and we're trying to get a deeper response with PD-1. And there is a series of things that we do with what I call non-IO agents, which is chemotherapy. We're doing stuff with many other people as well as ourselves with ADCs, there are RAS programs that are advancing. So we think that sort of combination there is large precedent throughout our portfolio, already and they will continue to be. And that's also true with Lynparza. The specific question, I think you're driving to is combinations of IO with IO agents and LAG3, CTLA-4 and TIGIT.

So at least in our mind, we do recognize that there was demonstration of LAG3 adding to PD-1 in melanoma. And I think that's an important signal for us, where we focused our efforts to LAG3 is in MSS CRC. So we know that PD-1 worked in MSI high and no one's really been able to crack MSS CRC. So that's very important. And also in classic Hodgkin's. I would say, in relationship to CTLA-4, there was recent data with HCC. I would make a comment that I think would make some of the people from Merck smile a little bit, we were the ones who actually did the study with PD-1 and CTLA-4 in relationship to lung. And we could not show a clear contribution of component of CTLA-4 over PD-1.

So that is not a place that we think is an important place for patients and that is not a place that we're going, because we have -- we did study to demonstrate that, where we think there could be is clearly other people have recently released HDC. We're focused in, for example, in renal cell carcinoma. And then PD-1 and TIGIT, our initial focus is in non-small cell lung cancer and also small cell lung cancer. And we're advancing a series of trials in that. So I hope that they have a comprehensive view of LAG3, CTLA-4 and TIGIT in relationship to ILT4 other checkpoint inhibitors such as CD27 or in relationship to cytokines, I think the data that we're doing in earlier stages will have to play out for us to be able to answer that more completely

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you, Mara. I think we have time for one more question and Rob will have a few closing comments.

Operator

Thank you. Your last question comes from the line of Colin Bristow from UBS. Your line is open.

Q - Colin Bristow {BIO 17216671 <GO>}

Hey, good morning. Congrats on the quarter and also wanted to say all the best. Roy, it's been really great working with you and also congrats to Eliav. So I just wanted to piggyback on a GARDASIL question, could you maybe just give us a little more detail on how you expect the GARDASIL supplies increase. And then maybe just help us into what is the supply demand mismatch right now, some of your prior comments suggested that there may not be such, but I know you said supply has been an issue over the past sort of couple of years. So we'd love to get your expanded thoughts there. Thanks.

A - Caroline Litchfield {BIO 20934609 <GO>}

Thank you for the question. This is Caroline. So let me start first with the supply demand. There is significant demand for GARDASIL. This cancer preventing vaccine in the HPV area has only reach today 9% of the global eligible population. So there is significant runway ahead of us to protect lives and to drive growth for Merck.

Indeed, we stated that we expect the revenue in the year 2030 to be double the $5.7 billion we achieved in 2021. So we have significant opportunity ahead of us. In order to achieve that opportunity, we are building new facilities that will be coming online from 2023, 2024 and 2025, so we're going to have a step-up in the level of supply to the market that will happen over that period. Specific then to this year, we will see a continuation of the supply into the market as we did in 2021, albeit not quite at the same step-up that we achieved in 2021. So we remain really confident in our ability to drive strong growth for GARDASIL both in 2022 and the years to come.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you, Caroline. Rob?

A - Rob Davis {BIO 6955931 <GO>}

Well I just wanted to say thank you for your time and your interest today. And I'd just like to conclude by, again, thanking the Merck team globally for their focus and commitment and really in driving the results, you've heard about today, but in continuing to ensure we keep the purpose of the company front and center, which is to deliver for patients.

Hopefully, you get the sense, we are very confident in the business momentum we have and I'd like to say as well, we are feeling better and better about the evolution of our pipeline in the things you've heard today. We're starting to expand. We're doing all of the things we need to do. We have more to do, but we're making great progress and that's why I have such confidence in the sustainability of our business long-term. So we look forward to continuing to share these results with you to deliver for the patients that count on us and in turn bring value to the shareholders. So with that, I'd say, thank you and have a great day.