OVERVIEW:
Company Summary
CORPORATE PARTICIPANTS
Caroline Litchfield  Merck & Co., Inc. - Executive VP & CFO

CONFERENCE CALL PARTICIPANTS
Geoffrey Christopher Meacham  BofA Securities, Research Division - MD

PRESENTATION
Geoffrey Christopher Meacham  BofA Securities, Research Division - MD
(technical difficulty)

Caroline Litchfield, CFO. Caroline, good to see you.

Caroline Litchfield  Merck & Co., Inc. - Executive VP & CFO
Great to see you again, too.

Geoffrey Christopher Meacham  BofA Securities, Research Division - MD
Thanks for joining. I know we have a list of questions, but maybe just kind of give us the post 1Q highlights and kind of how you see maybe the balance of the year, and we have a lot of product questions.

Caroline Litchfield  Merck & Co., Inc. - Executive VP & CFO
Okay. Good. So first, I want to say thank you to all of you for being here and for your interest and support of Merck. It is a special time at our company. We’ve got great momentum in the business. We’re executing well operationally, scientifically and financially. And we’re having impact for the patients and the customers that we serve.

In the first quarter, we posted good results. We had growth of 9% on the top line, and that really was driven by our performances in oncology with KEYTRUDA, in vaccines with GARDASIL as well as VAXNEUVANCE, in our Animal Health business as well as important contributions from LAGEVRIQ. As a result, we raised and narrowed our guidance on both the top line and the bottom line.

We’re proud of the progress that we’re making with our pipeline. And indeed, in 2023, we started more than 20 Phase III studies across 8 novel candidates, and we expect to do even more this year. So as we look forward in 2024, we’re focused on continuing to execute, execute on the products in our hands today, ensure an outstanding launch of WINREVAIR. We’re looking forward to the approval and launch of V116, and we look forward to continuing to progress our pipeline and augmenting that pipeline with scientifically focused, financially disciplined business development. So we’re confident in our future and the opportunities for growth.

QUESTIONS AND ANSWERS
Geoffrey Christopher Meacham  BofA Securities, Research Division - MD
Well, perfect. Well, you mentioned WINREVAIR, so let’s get right into that. So I know you’re not in a position to give any sort of intra-quarter update, but maybe any anecdotes on the initial experience? How is access going? How is the physician reception, patient awareness kind of thing?
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Right. So we are excited about the launch of WINREVAIR, first and foremost, because this is a meaningful product that's going to significantly impact patients with pulmonary arterial hypertension. So we've been planning internally to ensure we've got appropriate capacity to support the launch and to ensure we've got the appropriate commercial support and medical support for our launch.

The impressions that we've received from our customer groups have been very positive. Both the patient groups as well as the prescribers have been extremely positive around the data and the opportunity to use this important product. What we're seeing is, at the moment, prescriptions being raised by both prescribers in the COEs and prescribers outside of the COEs. And to remind you, in the United States, there's about 40,000 patients that have been identified with PAH, around half of them are treated in the COEs, half outside. So we're seeing prescriptions coming from both segments.

What we're also seeing is prescribers are really choosing to use WINREVAIR for those patients that really need this product right now. So they're prescribing in that area, and they've indicated their intent to prescribe in line with the STELLAR criteria. And in the STELLAR study, about 60% of the patients had triple background therapy. Around 35% were on dual therapy, around 5% on monotherapy. The indication is we should expect something similar.

In terms of access, we're pleased with how that's progressing. We're seeing patients receiving the product on Medicare, on Medicaid and commercially. And we're hearing of policies being written. So it's early days. We had high, high expectations for the impact of WINREVAIR, and we are, at the moment, seeing performance in line with those expectations.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

Perfect. Yes, that's helpful. And just a follow-up. When you guys initially did the Acceleron deal, I think WINREVAIR or sotatercept peak forecast were a few billion, and over time, the data looked better than expected. And now the label looks better than expected. If you surprised over to the upside over time, what do you think it could be? Is it duration of therapy? Is it deeper penetration in earlier-stage patients? Like what would be kind of the -- a more meaningful factor?

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

So I think our opportunity for WINREVAIR is to really help the patients that have pulmonary arterial hypertension. And initial upside with the STELLAR study is the opportunity to seek launch in markets across the world sooner than we had expected as we had thought that we would have needed the morbidity mortality data from ZENITH to launch in markets outside of the United States.

So the opportunity to positively impact those patients is sooner than expected. The opportunity to see sotatercept be as big as it can possibly be will come from the depth of prescribing and the range of prescribing across functional class as well as us continuing our efforts to research WINREVAIR not only in pulmonary arterial hypertension but also in left heart disease. So we're confident in the opportunities in front.

I won't give product-specific guidance here, but to try and give some indication, at the start of this year, we provided updated thoughts around the opportunity our company has in cardiometabolic disease. And that includes products such as WINREVAIR. It included our oral PCSK9 and also included our product MK-6024 in MASH. And given the confidence in our pipeline and the confidence in WINREVAIR, we increased our thoughts around the opportunity to $15 billion on a non-risk-adjusted basis by the early to mid-2030s, and we have that confidence today.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

Okay. That's helpful. Let's talk a little bit about the KEYTRUDA LOE, and it was a question for many, many years as well as concentration risk. And I think that sort of has diminished over time. But the -- I know you guys have said it's a hill, not a cliff.
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO
We have.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD
But I wanted to get maybe a little bit more meat on the bone on that. Is it that you expect less monotherapy KEYTRUDA, which is sort of substitutable? Is it -- it’s probably all of the above, but is it combinations within KEYTRUDA? Is it that you don’t expect there to be substitution broadly? Is it subcu? Like what’s the sort of fundamentals behind that comment?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO
So our company has got strong growth, and we aspire to grow through the KEYTRUDA LOE. And the way that our company will grow is through innovation. Now as we sit here today, we’ve made significant progress in our pipeline, and the progress in our pipeline is in the areas of oncology. Excluding KEYTRUDA, excluding the immuno-oncology co-formulations we’re working on, we have a portfolio of medicines that could really make a difference to cancer care, including the individualized neoantigen therapy, including a group of precision molecular targeted agents and our suite of ADCs.

We’ve also got our cardiometabolic franchise that I’ve just alluded to. And we have our immunology business, including our TL1A product. And we’ve got other opportunities in infectious diseases, in vaccines, in neuroscience and animal health. So as we talk about the prospects of growth into the future. At a minimum, we seek to minimize the overall decline in company revenues and quickly return to growth. And with this portfolio that we’ve developed thus far, we’re confident that we have a hill, not a cliff. We do have more to do, and we will continue to execute on our pipeline and execute on business development to enable further patient impact and growth into the future.

Unidentified Analyst
Then maybe just on kind of the TIGIT news over the past few days, how is Merck thinking about kind of that sort of approach in terms of the commitment with the TIGIT combo? Any updates on that?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO
Yes. So our company has a program with TIGIT and pembrolizumab covering different cancers. And earlier this week, we did announce that our co-formulation of TIGIT in early-stage melanoma is not successful. We also have program covering non-small cell lung cancer and small cell lung cancer. And those studies are still underway. So today, while we’re disappointed with what we’ve seen in melanoma, we still are progressing the programs in small cells and non-small cell lung cancer and are hopeful on what the outcomes may be, but we’ll need to see those studies play out.

Unidentified Analyst
And maybe kind of thinking about some of the different ways of -- if we just stick to, let’s say, the lung cancer space, kind of different ways of tackling that. I think there are [similar combination with] confirmation with or without ADC count. How is Merck thinking about that in terms of how that market will evolve over time?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO
We have a strong position today in lung cancer and in many other cancers with KEYTRUDA. And using that position of strength and understanding of the different cancers, we’re developing a whole suite of oncology products with the hope of furthering the impact that we will have for patients
and advancing standard of care. So specific in lung cancer, we’re looking forward to the opportunity of trying to improve upon standard of care in non-small cell lung cancer with a range of different possibilities, including TIGIT, including the INT, including ADCs.

Similarly in small cell lung cancer where we don’t have presence today, we’re looking forward to hopefully providing impact to patients, again, maybe with TIGIT, but maybe with some of these other agents that we’re looking at. So we have a really broad portfolio, a portfolio that we’re really trying to find the right mix of products that will really move forward patient care across all of the different cancer types.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

Well we're sticking with the oncology, the ASCO meeting is coming up. Care to highlight a few product or presentations that we need to talk through? I know you guys are hosting an event. You always do.

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

Yes, we are. So we’re proud of the progress we’ve made thus far in oncology and are very focused at furthering impact for patients. At ASCO this year, we’ll be providing some updates on the efficacy data and some patient-reported outcomes data, the KEYTRUDA, including in non-small cell lung cancer, bladder cancer, gastric cancer, biliary tract cancer and others. So that will be one theme. Another will be sharing information from the 3-year data with Moderna on the INT in melanoma.

We're also going to be providing some data on TIGIT in endometrial cancer in a Phase II study, and we will be providing some information in our partnership with Kelun on the TROP2 asset in non-small cell lung cancer, a Phase II study they have run as well as in triple negative breast cancer in a Phase III study. And as you note, we’ll be hosting an investor event, and we're looking forward to sharing with you our continued strategy in oncology and the breadth of the pipeline that we have.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

And speaking of that, I think it stems back to an event a few years ago where you talked about all the tumor types for which KEYTRUDA is indicated and then moving obviously towards premetastatic adjuvant. That was kind of the conversation when you guys said, look, we’ve had hyper growth, a step-up in growth in the past couple of years. And now that’s moderating, but it doesn’t appear really to be moderating. So is it that the penetration rates in the market is much bigger premetastatic? Or is it the OUS opportunity is sort of catching up? What’s been the bigger driver of kind of KEYTRUDA upside over the past, say, I don’t know, couple of quarters?

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

Yes. So we’re proud of the impact that we’re having for cancer patients. The growth that we’ve seen in recent quarters has really been driven by the penetration we’re having in earlier-stage cancers. And that includes triple-negative breast cancer. It also includes the early-stage lung cancer setting, where we’re launching here currently in the United States. And we’ve seen really strong penetration in both settings. So in the early-stage triple-negative breast cancer setting, we’ve seen great utilization of KEYTRUDA prior to surgery. And we’ve seen a strong continuation for patients after surgery, which has provided growth for our business and important impact for those patients.

In non-small cell lung cancer, what we’ve seen thus far with the KEYNOTE-671 launch is we’ve moved the level of treatment on IOs from 35%, which is where it was prior to our entry into the early-stage lung cancer setting, to now 65%. So that’s really enabled the strong performance that we’ve seen in KEYTRUDA here in the United States. And the story is somewhat similar outside the United States where we’re seeing strong impact for patients and the strong performance in the product.

Now as a CFO and as a business person, we love to see growth of 20-plus percent. I do think we’ll see some level of moderation of that as we do reach the peak saturation for those patients, but we’re excited at the opportunities for KEYTRUDA moving forward as we launch indications outside
of the U.S., but also as we get, hopefully, the endometrial cancer indication here in the U.S. with the PDUFA in June. We’re very excited about bladder cancer with A39 currently and a portfolio of indications hopefully to come. We look forward to impacting patients and driving KEYTRUDA growth into the future.

Geoffrey Christopher Meacham  -  BofA Securities, Research Division - MD

Great. That’s helpful. When you think about the grinding out oncology, you guys are obviously a leader in IO and you’ve added assets and ADCs. What other tools and technologies do you think are still underutilized and you could fully leverage? I mean thinking more in particular of gene and cell therapy. I know this isn’t -- has been a leading area for Merck, but clearly, there’s a lot going on in that direction in the field of hem/onc.

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

So we are focused on leveraging our position with KEYTRUDA, building out precision molecular targeted product and ADCs, which we see as the next generation of chemotherapy. And given how well KEYTRUDA and chemotherapy has worked in certain tumor types, we see that as a great evolution for patients and the company. So that’s where our focus is and remains. That said, we continue to watch the field and how the field evolves, and we’ll continue to evolve our pipeline with the goal of providing best impact.

Unidentified Analyst

Okay. Maybe if we switch gears to GARDASIL just a little bit. Has -- GARDASIL has performed very, very well -- quite well, say, exceed expectation, especially on the ex U.S. business. Just maybe just kind of walk us through how you think that trend will continue to evolve kind of this year or maybe even longer term. And obviously, there are -- I think China has its own -- trying to make its own 9-valent HPV vaccine. Kind of how Merck is thinking about that potential kind of competition?

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

So we feel very confidently about our GARDASIL business and its outlook going forward. Every day, 1,000 people in this will die from cervical cancer. Today, we’ve just protected a fraction of the global population. So we have an opportunity, and I would argue in an imperative to help protect more lives all around the world. And the opportunity set is to increase vaccination rates for adolescents. Even in the United States, the vaccination coverage rate is 74% for males, 78% for females. And the WHO would suggest a vaccination coverage rate of over 90% is necessary to eliminate cervical cancer.

We secondly have an opportunity to improve on gender-neutral vaccinations and improve the vaccination rates for males all around the world. And that includes getting regulatory approval for the male vaccines in certain countries, including in China.

The third opportunity we have is to ensure people in the age cohort 27 through 45 get vaccinated. GARDASIL is now 14, 15 years old. So people weren't necessarily in that adolescent cohort when they were being vaccinated. Now there’s an opportunity to vaccinate those people, especially given 50% of infections happen while you’re in that age group.

And finally, we have the opportunity to supply further GARDASIL to low- and middle-income markets to help coverage and protection there. So we’re confident in our opportunities for growth. And that growth is global. In the United States, as I’ve mentioned, it’s the adolescent cohort and the mid-adult segment. Outside of the United States, we’re really looking forward to improving on rates, improving male vaccinations and creating what we described for some countries as a private market for the mid-adult segment because in certain countries, if you’re in the age group of 27 to 45 and it’s a government paid health system, there isn’t a way to get GARDASIL. So we’re trying to create a private market where I would pay out of my pocket to get the vaccine.
As it pertains to China, China is a large market. And today, we are approved in girls and are addressing people who have the affordability to pay for the vaccine out of their pocket. That’s a group of around 200 million people. Today, somewhere between 30% and 40% of that group have received an HPV vaccine. The opportunity to provide further protection is still huge. We’ve been competing against a local bivalent vaccine. We’re aware of competition looking at a 9-valent, and we’re confident in our ability to compete at the same time moving into the male segment subject to regulatory approval. And we sought our filing there in mid-2023 (corrected by company after the call). So we’re confident in our business globally, and we remain confident in the opportunity to protect lives in China.

Unidentified Analyst

Great. But maybe on kind of V116, right, kind of we're expecting approval relatively soon. And then obviously, the ACIP meeting in June will be very important. How is Merck thinking about the potential recommendation and the opportunity in that space?

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

Yes. So we’ve taken a very targeted approach with V116, our adult pneumococcal vaccine, to provide the best coverage and protection for adults for invasive pneumococcal disease. And so what we have is a vaccine that protects against 83% of the prevailing disease at that age group. We’ve got clinical studies that show the effectiveness of the vaccine in age group 50 through 64, in age group 65 and above who have not had a vaccine previously and age group 65 and above who have previously been vaccinated. So we’re looking forward to the ACIP discussing what the appropriate recommendation is that they will give. And as a company, we have enough capacity to support whatever the outcome is of the ACIP meeting.

Geoffrey Christopher Meacham

Sticking with infectious disease. So RSV lots of excitement there. So talk a little bit about Merck’s approach with the antibody versus the internal vaccine and the opportunity that you see looking forward and with respect to competition as well.

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

So RSV is a very important area. Indeed, all our babies by the age of 2 have the potential of contracting RSV, and it’s important that they’re vaccinated. We have a monoclonal antibody, clesrovimab, that will have data reading out later this year in August. And what we have in this antibody is, number one, the opportunity to have a single fixed dose that can be given to the babies, which is different to others, which are weight-based.

So we have a simplicity around the dosing schedule. What we also have is a treatment -- prevention treatment that will provide protection for the whole of the RSV season, which is longer than what others have in the market today. We also have the ability to provide that to babies ahead of the season. And we do think it has a high barrier to resistance. Now this is a big market. It’s a market that needs support, and we’re looking forward to seeing our data and hopefully providing an option to the market in the near future.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

Perfect. Well, let’s go back to what you said in the beginning with respect to the LOE and the offsets and so the BD climate. So I wanted to maybe ask about capital allocation. And I know it's -- you guys have or among the few pharma's that still have capacity to do deals. There's not a need to delever at this point. How do you work through the process with us? And sort of what -- how -- is the urgency as acute as it was previously? And then is the hurdle rate different to look outside of the Merck core therapeutic areas? Clearly, there’s a focus outside of oncology still.
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Yes, there is. Our capital allocation priorities as a company have remained unchanged. First and foremost, it’s to invest in our business. We’ve got a rich and broad pipeline, and we are committed to investing in that pipeline to hopefully enable patient benefit and drive growth for the future. We also seek to augment that pipeline with scientifically focused, hopefully, financially disciplined business development. And so we’re looking at that pipeline in all different therapeutic areas.

We’re looking to augment in areas that we have strength to perhaps accelerate our efforts, but we also look to augment in areas maybe where we don’t have such strength or we’ve seen the science evolve externally so that we can play a role in advancing the science and having impact across the world. So we are very active in BD. We’ve done deals in the past that cover the range of therapeutic areas, oncology, outside of oncology, but also cover a range of deal constructs from collaborations through to outright acquisitions.

And I think you could look at what we’ve done in our past history as a good indicator of what we’re likely to do in our future. But we remain focused on business development, and we have humility that great science happens within Merck but also great science happens outside of Merck. And we stay abreast of that science, and we’ll seek to move on any targets where we think we could add value for patients, for our company and for our shareholders.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

It does seem like a lot of your peers are moving towards — I wouldn’t call it orphan but more narrow indications that are sort of one click away, for example, more rare I&I indications. And Prometheus, you could say, is an element of that. Is that how Merck is thinking about it as well? There’s not an intended strategy in rare disease per se, but it could be a similar capability that you have currently, right?

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

Yes. So there isn’t an intended strategy in rare disease. Our strategy is really following the best science. And if that science is in an area of unmet medical need and in our hands, we have the opportunity to really develop the program and enable impact for the world, for society, that’s where our focus is.

Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

I have to ask, and I wouldn’t — you know what I’m going to say, but given JANUVIA, JANUMET, you have a history in metabolic disease and existing -- I don’t know how much organic research there is still in that category. But if there is a company that could scale in a large indication, obesity, perhaps, is that -- how do you view that opportunity, especially as you look at other companies sort of scrambling to add an asset?

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

We today have a GLP, glucagon dual agonist. And we are researching this in MASH. And the data that we have is quite compelling at this stage. There was more than 70% liver fat loss for this product, which is superior to what we’ve seen with other compounds. And there was 10% to 12% weight loss, and that was after, I think, 24 weeks. So this is a program we’re advancing. And within our company, we have great competency in this area.

As we look at the future, our teams are focused in the area of cardiometabolic. We have programs internally beyond MK-6024, and we do look externally at the field and the opportunity to see what we can do to bring advancements to patient care. As we think about obesity specifically, we do think there’s the possibility for second and third waves of innovation, maybe with oral agents, agents that have more tolerability, maybe combination products and maybe products that will have weight loss that is more fat loss, not muscle loss. And it’s an area we’re focused on. So as a company, we look to build our strengths, and we will look to invest internally while we’ll also evaluate the external landscape.
Geoffrey Christopher Meacham - BofA Securities, Research Division - MD

Perfect. Okay. Thank you very much.

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

Thank you. Very good. Thank you all. Thank you all here.