Okay. Welcome to the second day of the BofA Healthcare Conference. My name is Geoffrey Meacham. I’m the senior biopharma analyst. We’re thrilled today to have Merck with us and Caroline Litchfield, CFO, is with me on stage. Welcome, Caroline.

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

Thank you. Great to be here.

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

Good to see you. So maybe just talk about following the first quarter give us kind of how you see growth over the balance of the year, and then we’ll get into some questions on some of the products and BD, et cetera, et cetera.

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

So let me start with -- it’s great to be here. It’s amazing that 1 year has flown, and I thank all of you for your interest and support of our company and for being here today. As we start 2023, we’ve started really strong. There is momentum in our business. Now if I take a step back, we’re really proud of the progress that we’ve made as a company. We’re progressing with the portfolio facets that we have today, we’re progressing our pipeline and we’re augmenting that pipeline with meaningful scientifically driven and disciplined business development.

So that gives us a lot of confidence in how we’re performing and the future prospects for the company. Specific to the first quarter, we had revenue growth excluding LAGEVRIO and foreign exchange of 15% in the quarter. That enabled us to raise and narrow our guidance. We’re expecting between 8% and 10% growth for the full year this year, excluding LAGEVRIO and foreign exchange. And that growth will be as a result of the continued demand that we have for our innovative portfolio across oncology, across vaccines as well as Animal Health.

We’re progressing our pipeline. I’m sure we’ll talk about that with some exciting progress in oncology, in cardiovascular, and we’re obviously pleased to progress that pipeline with business development and immunology with the proposed acquisition of Prometheus. So we’re feeling good about where we are as a company, we feel good about the momentum in our business, there’s always still more to do, but we think we’ve got a great foundation to continue to drive growth for our company.

QUESTIONS AND ANSWERS

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

Perfect. And that’s a good background. So Caroline, when you think about the drivers of top line, so KEYTRUDA obviously is the big one. So talk about like over the cadence of this year and maybe looking into next, like what are some of the newer line extensions that we should expect that could inflect and is there a bias like U.S. versus O.U.S.?
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So focusing just on KEYTRUDA at this stage, and I guess we'll go through the others. So KEYTRUDA is a phenomenal product, first and foremost, the impact it’s having on patients all around the world. And we’ve been seeing exceptional revenue growth from the product. As we go forward this year, we expect continued strong growth from KEYTRUDA. And that growth will largely come from moving increasingly into the earliest stage cancer setting.

So what we're expecting is strong growth in triple-negative breast cancer, renal cell carcinoma, melanoma, and we're moving into early stage lung. So we'll see that come through in the United States, albeit we will lap some of the launches that we've had, specifically triple-negative breast. So we'll expect that growth to moderate over the course of the year. As we look at outside of the United States, we've got great opportunities with the continued introduction of new indications, especially moving into the earlier-stage indications.

We've just started that journey for triple-negative breast ex U.S. Now one thing we did point out in the first quarter sales and earnings call is as we do launch those new indications in Europe, we will see some pricing pressure. This is something we've had throughout KEYTRUDA’s journey. As you introduce new indications, you then speak with the reimbursement body to talk about the incremental patients that you’ll be able to serve and what that new price point will be.

So we'll expect some pricing pressure on KEYTRUDA, but extremely strong volume growth as we introduce those new indications and therefore remain very confident in our ability to drive strong growth for KEYTRUDA and great patient impact.

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

And when you take that growth and you invest back in the business, so combinations with KEYTRUDA have been a pretty standard strategy for you guys and you have PCV combos coming up and there's lots of I/O -- I/O combos going forward. So maybe talk about the — how you’re investing back in the business and how do you think about the sort of the cadence of the end of the decade sort of dynamic with respect to the impact from all these combinations with KEYTRUDA?

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

So focusing first on oncology because we’re investing in R&D in many different areas. In oncology, we’re investing in continuing with KEYTRUDA and moving to earlier stage cancer treatment. And we've stated in the past, we expect 50%, 5-0 percent, of the growth of KEYTRUDA in the period of ‘21 through ’25 to come from that earlier stage cancer setting. And it will grow thereafter. And we've also stated representing 25% of the global business in the year ’25.

So clearly, that’s part of our investment to drive earlier stage cancer treatment and, therefore, improved prognosis. We are also investing, as Geoff noted, on combinations with KEYTRUDA. And those combinations are IO-IO, where we have programs in TiGIT, in CTLA-4, in LAG-3. We’re also investing now in what we were calling a personalized cancer vaccine, we now term it as an individualized neoantigen therapy with Moderna, where we’re really excited at the prospect of this treatment alongside KEYTRUDA to improve outcomes for patients.

We also have a platform of ADCs that we are developing, given how great KEYTRUDA is with chemotherapy, ADC is being that next generation of chemotherapy, we see real possibility to link with the ADCs that we have, where we have TROP2, we have another that we haven't disclosed what its mechanism is, and we have seven preclinical candidates with our collaboration with Kelun.

So we have a lot going on, and we have many other assets in oncology with our ORION partnerships there, hoping to do something in prostate cancer and obviously, still LYNPARZA and LENVIMA. So as we look out over this decade, we are confident in our ability to drive growth in KEYTRUDA. We have a subcutaneous formulation that we hope will enable us to continue to benefit patients, especially in the earlier stage cancer setting, and we have many new novel agents that we're working on to try and continue the progress that we're making in cancer care.
Right. And so Caroline, while we're talking about KEYTRUDA and sort of the intermediate to long-term growth, help us with kind of the policy impact of that, right? So looking at the end of the decade with respect to the IRA and how Merck is thinking about managing that?

Yes. So starting with the philosophy of our company has always been to invest in innovation and bring that innovation to countries around the world and price our products responsibly based on the value that those products can bring. So that's the headline of the Merck here. We now have the backdrop, though, of the Inflation Reduction Act, which brought some good things with it to cap out-of-pocket costs for patients, but also areas of, quite frankly, significant concern, which is the price setting or what's term price negotiation for products.

In Europe, there's also potential changes with the regulatory framework there that was recently announced. Some of it's good as they look to simplify the regulations and enable, hopefully, swifter access to innovation. But at the same time, there's a shortening of the time line of regulatory data exclusivity, while there's some conditions that allow you to increase it. But what we're seeing around the world is pressure on the time line the pharmaceutical industry has to generate returns on the significant investments that we make.

So what that means for us is we are looking at each of our investments in research. And the hurdle rates got higher for what our expectations are so that we can generate returns for our company, for our shareholders. As it pertains specifically to KEYTRUDA, the time line around the IRA negotiation is pretty much in line with the time line of the LOE of KEYTRUDA.

And as we look at combinations, co-formulations, what the government has announced is to active agents will not be required to be negotiated. So we are working on trying to bring forward innovation, looking at active agents that can together do more for patients and we'll continue to progress in that way.

And is that part of the life cycle management here if you have, say, a subcu or a fixed-dose combination? Obviously, monotherapy KEYTRUDA at the end of the decade, maybe that is subject to biosimilar launches, but like your combinations so I think, give you a little bit more just help us through that.

Yes. Yes. So exactly that. So the subcutaneous formulation is a formulation that we're working on, looking at the activating of hyaluronidase with pembrolizumab to try and bring benefit to patients and having them not to go into an infusion center and spend many hours visiting the hospital to get the treatment. As we increasingly move into earlier stage cancer treatment, the patient profile changes. It's often a younger patient, a patient who's working each day and caring for what's important in their lives.

And so we see a real opportunity to help the patient to help the health care system in having a different route of administration for that patient. And what we've stated at this stage is we think that approximately 50% of the patients on KEYTRUDA are likely to be in the earlier stage cancer setting or potentially on monotherapy or in combination with an oral agent. That means this could be a really beneficial profile of KEYTRUDA for those patients to be taking.

So we're working on that to bring that benefit. Similarly, the other co-formulations would be new products. in their own right with the different active ingredients that are coming forward.
Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

That's helpful. Yes, so let's go back to where we started on the first quarter. So GARDASIL is an asset that a lot of investors have been concerned about concentration risk. But if you look at what's today in Merck's portfolio that's growing, that's not KEYTRUDA, it's a major asset, right? So we're talking about 35% growth in the first quarter. Help us with kind of how we think about this over the cadence of this year? And then with respect to supply looking next year and beyond, like how do you envision that?

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

So GARDASIL is an amazing vaccine. It's helping prevent HPV-related cancers in both females and males. And quite frankly, we're still only at the start of the journey, 14 years in to this vaccine being available because we've only helped protect the lives of around 10% of the world's eligible population. Now there's work to do to create the demand side of an equation meaning people making sure they're going and getting their adolescent vaccinated.

People are in the age cohort 27 to 45 where 50% of HPV issues occur going and getting vaccinated, having governments approve vaccinations for boys and men as well as for girls. So there's work to do to activate the full cohort, which we are focused on as a team. At the same time, we're building supply. Over the last few years, we've been effective at driving productivity within the current supply chain of our company and adding to that supply chain at the drug product levels of the formulation and filling level of GARDASIL.

We are also bringing onboard two bulk manufacturing facilities. And those facilities will come online progressively during ’23, ’24 and ’25. And so by ’26, we'll be unconstrained. So I'd expect us to have a gradual ramp-up in the level of supply that we will have to the marketplace to support the protection of lives around the world.

Now as we think about the growth, we had an amazing 2022 with the growth of GARDASIL. I think we posted 27% growth, excluding the impact of foreign exchange. And we've guided that we think the growth in 2023 will be an acceleration on that growth we achieved a higher than 27%. As Geoff noted, we achieved 35% in the first quarter, 43% excluding the impact of foreign exchange, and that did include some shipment timing benefit as we did pull forward some shipments into the China market specifically to enable us to have enough vaccines on the ground as the China regulatory authorities have widened the age cohort for GARDASIL 9 from 16 to 26 now to 9 to 45 years old.

So we've seen some benefit of that. As we look for the full year, we expect the first half growth of GARDASIL to be stronger than the second half, full year to be extremely strong and acceleration versus 2022.

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

And Caroline, put this in the context of the overall top line at Merck. So when you look at non-KEYTRUDA sort of franchises, so vaccines, including GARDASIL, are really important. But how strategically do you think about it from an investment perspective from BD, internal versus external?

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

So we're in a position in our company where we actually have a rich pipeline to invest in. And that rich pipeline is in oncology. It's in vaccines, including PCV, pneumococcal vaccine, dengue, RSV. We're investing in cardiovascular quite significantly and with some impact, and we will be investing in immunology. So in terms of the investment posture of our company, we are investing in R&D. We're investing in that R&D both internally and augmenting that with the best science that we can find externally that is driving for solutions for unmet medical need, and we will continue that R&D investment with the focus of driving growth in the next decade.

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

So there's not an intention, though, per se, outside of oncology, but it just happens to be that you -- there are opportunities in that...
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

There are, yes. And there’s plenty of opportunities. So with Acceleron, that was a significant opportunity for us outside of our company to look in an area of significant unmet medical need, an area of great advancement in science and potential impact for patients and therefore, we acted. Internally, we’re investing in our oral PCSK9 program, which has significant opportunity to help the many patients around this world who are on statins who don’t get to goal. So we have a lot of investments going in many different areas.

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

And so the proposed Prometheus deal, let’s talk about that. So in the context of what Merck could have done, like this is, obviously, investors like the deal. But if you think about like the appetite for additional, how much of a priority is BD on top of what you guys have done with Prometheus and then, obviously, historically with Acceleron?

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

So let me start with our company’s core is innovation. A lot of great innovation happens within Merck. But a lot of great innovation happens outside of Merck. So therefore, we remain focused on business development is the priority of our company to go and find compelling science in areas of unmet medical need where we can align that with valuation of the company and bring that to Merck And while in Merck, the expertise that we have to hopefully accelerate, broaden programs and bring access to patients and value to patients and shareholders.

So we have, and Rob has stated this actually in our quarterly earnings call, we have a portfolio of BD that we continue to evaluate some that were on it have now got a checkmark or almost got the checkmark, but we will continue to progress with business development because it’s important ensuring a healthy innovation engine for our company and for long-term growth.

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

And if you look at the ADC deals that you guys did at the end of the year and Acceleron, so give us some context for is therapeutic area the main focus? Is it adding newer technologies that don’t exist or not heavily represented at Merck today, just the balance of those 2 priorities?

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

It’s kind of all of the above is the reality. We’re following the science, which means we’re not bounded by therapeutic area. We’re mindful, though, of the therapeutic areas to ensure that we’re building on the expertise we have and we’re building breadth. And we’re not just looking at products. We do also look at platforms and technology. So I would say our answer here is really following the science where we see unmet medical need and then we will move as you’ve seen us do so.

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

And if you think about the impact of these investments, so from a margin perspective, Merck has the potential to really accelerate as you anniversary some of these tumor types with KEYTRUDA. There’s not a lot of incremental investment. How do you think about like the balance of adding new assets in the form of BD or just M&A? And then just showing that with respect to P&L growth.

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

So our focus is on investing for the future, investing in R&D. We’re disciplined in our investments, but we are focused on investing in the pipeline we’ve got today, and it is a rich pipeline. We’re focused on making sure that we maximize the opportunities from these business development
transactions we've done to ensure we're investing the appropriate amount in R&D to see those assets hopefully come to their full potential. So that's priority number one.

That said, we are, as a company in quite a privileged position in that we expect margin expansion in our company. And the reason we expect that margin expansion is as a result of the top line and the mix of that top line. We have the roll-off of some royalties, specifically on GARDASIL and KEYTRUDA. And we will have disciplined expense management, looking for productivity in our manufacturing processes, in SG&A.

So we still do point to, and I should use the word underlying operating margin because it's what IP R&D may happen. Underlying operating margin in the year 2025 was greater than 43%.

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

Are there drivers beyond that, though, when you think about the lower royalty burden and coming off the Organon deal, I mean, the Merck has a smaller footprint and could benefit from efficiencies going forward. But is the goal here to reinvest some of that? Or to -- or could just show the 43% and sort of that's kind of it is what it is type of approach?

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

So I'm not wedded to the 43%. What I am wedded to is investing in a disciplined way in our business to drive growth over the longer term. With Organon, we delivered efficiencies across our business. We actually did it more than we stated publicly, and we invested in the business and in the pipeline that I think you're starting to see come to fruition.

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

Okay. And then one of the benefits of more recent deals from Acceleron. So sotatercept has had a fantastic profile so far. Give us some context for what we could see coming up at for the potential launch at the end of the year and how you're thinking about that franchise in the context of Merck's therapeutic focus?

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

Yes. So we as a team were delighted to go to ACC and show the phenomenal data that we have on sotatercept with the STELLAR study as well as show our Phase II data on the oral PCSK9. So Merck is back in cardiovascular, and we are really excited about the prospects we have on those two assets as well as many other assets that we have in our portfolio.

Specific to sotatercept, we are working with urgency to ensure that we get this product to as many patients that can benefit from it. So we're working with the FDA to complete our filing for the registration of sotatercept that will be during the third quarter, and we're expecting launch early 2024. Now because of the profound data that we had with the STELLAR study, not only the 6-minute walking distance, but we hit 8 out of 9 secondary endpoints, and that included time to clinical worsening.

This is really important because this is accelerating our time line to launch in markets outside of the United States, specifically Europe. So we're currently expecting to be filing during the second part of this year, launching the second part of 2024 in Europe. So what we're doing is making sure that we have our supply chain working effectively. So we'll support the demand that we expect to see.

We are building a world-class operating model to support this rare disease area so that we can provide the right kind of support to the health care professionals, to patients and to stakeholders. And so we're excited to be launching the product and are expecting a pretty strong take up, given the outstanding impact that sotatercept has for the PAH patients.
Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

So in the case of sotatercept, it’s cardiovascular, but it’s still relatively a niche or more of an orphan indication, right? So is this sort of a newer dimension of Merck to look into more orphan indications? Or is it just we found the asset, we found a great risk-benefit profile and you look at them sort of in a different sort of separately?

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

I think we look at the products and the impact that they can have for different patient groups and where that’s significant, we’ll move, which means we’re in a rare disease type areas, such as PAH, we’ll augment that further. We’ve got an inhaled sGC as well. So there’ll be more activity in that space. But at the same time, you see us operating in cholesterol lowering with our work for the oral PCSK9. So we will continue to follow the science, but we’re as focused on that science in the rare disease population of PAH as you described, as we are in broader population.

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

That’s helpful. And so if you think about other categories within Merck in the mid-stage pipeline, like what is the most -- what would you call out as something that like investors you may not have thought about or could be a pretty high impact like in the intermediate to longer term?

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

Sure. Yes, so I could talk for a long time because there's a lot of great things in our company. Maybe let me start with -- we've made a ton of progress over the last few years, and I expect our company will continue to make great progress. As we look at our pipeline today, if I start in vaccines, we are really excited about our population specific pneumococcal vaccine. We have VAXNEUVANCE targeting pediatrics, which has great data, especially in the first year of life, which is so important as the majority of pneumococcal disease will happen in that first year of life of babies.

And we have V116 coming Phase III data later this year for the adult segment. And the data that we've got thus far suggests this vaccine will help provide coverage for 85% of IPD. So we think this is significant. In vaccines, we've also got dengue coming, good data at the end of last year, and we've got We are really excited about the cardiovascular area, as we've touched on.

So sotatercept is going to be a hugely impactful product for patients and a multibillion-dollar opportunity for our company. The oral PCSK9 has got fabulous data that we shared at Phase II. We're working quickly to move to Phase III as well as doing simultaneous cardiovascular outcomes trial. We think this could be a huge product globally. We’re looking at trying to ensure a cost of goods that enables us to have access for this product all over the world. And we've got others in cardiovascular.

In oncology, we're excited about the areas we've touched on already, Geoff, in our opportunities to progress with KEYTRUDA, with combinations with co-formulations, with ADCs, with the individualized neoantigen therapy and others. And of course, we're really excited about the prospects of PRA023, the asset that we have from the acquisition of Prometheus, which could be a game changer for a population in need of new innovations in both ulcerative colitis and Crohn's disease. So those are just a few to keep your eyes on we’re really excited about.

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

And when you look at some of the -- across the biopharma space, I mean, neuroscience and metabolic, in particular, obesity or some of the higher profile, higher growth indications, is there an intention sort of a focus on future BD to capture some of that? Or do you just -- I know the answer is probably follow the science, but I just wanted to ask in that sort of perspective.
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So we're consistent, if nothing else. We do have assets in our own pipeline in both of those spaces earlier on, but assets we're pretty excited about in neuroscience as well as cardiometabolic. But we will also continue to scan the outside world to see what could make sense to augment our pipeline further.

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

And Prometheus, the framework of that, when you think about pipeline and a product like multiple indications and the like, I'm assuming that is for Merck today probably more of a priority than just a straight platform with the newer technology that you add to the mix.

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

Correct.

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

Okay. Perfect. Well with that, we're out of time. So thank you, everyone. Thank you, Caroline.

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

Thank you very much. Thank you all.