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OVERVIEW:

Company Summary

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Mohit Bansal *Wells Fargo Securities LLC - Analyst*

PRESENTATION

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Awesome. I don't have a glass (laughter) I would do this. But yeah, thank you very much for joining us today for the lunch session. My name is Mohit Bansal. I'm Biotech and Pharma Analyst here at Wells Fargo.

And I'm very happy to have the Merck management team with us. We have Caroline Litchfield, the EVP and CFO of the company. We also have Eliav Barr, to talk about all the pipeline here, exciting pipeline. So Eliav is the Senior Vice President and Chief Medical Officer of all the pipeline here, managing all the pipeline development here at Merck. Thank you very much for joining us today.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Thank you.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Thank you.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

So Caroline, why don't we start with -- just give a high-level overview of what the progress Mark has been making and what you are -- how -- what is the investment case in the company right now, given the investor set up here?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So thank you all for being here and thank you for your interest in and support of Merck. Merck is at a time of transformation. We're moving forward with the diversified set of growth drivers for our future. Indeed, we're in the midst of launching 20 products all of which have the potential to advance patient care, almost all of which have blockbuster potential. We have stated that we have the potential for more than $50 billion of revenues by the mid-2030s from this expansive pipeline.

And as a team, we're focused on bringing forward these innovations and excelling in the marketplace. We're pleased with our recent launches of WINREVAIR of CAPVAXIVE. We're at the early stages of our ENFLONSIA launch. You've seen some data readouts. Just this week, we highlighted our Phase III data for enlicitide, our oral PCSK9.

We'll have readouts in ophthalmology in HIV in the coming months next year. So we're excited about our future and are confident in our ability at navigating the KEYTRUDA LOE is increasing. But we acknowledge we're not yet done. We continue to look to bring forward our pipeline to excel in our launches and augment our pipeline and portfolio with business development as we did with the planned announcement of the acquisition of Verona. So we're excited for our future, and we look forward to all of your questions.

QUESTIONS AND ANSWERS

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Awesome. Great. So why don't we start with a small product named KEYTRUDA you have? So the product has been growing. So again, people are concerned about the cliff and all that, but we'll come to that. But before that, we have seen tremendous growth and then in early lines of setting. So what are the next avenues of growth there? And can this sustain the growth in the next few years here as well?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So if I start, Eliav can add to what we have coming through, we're really proud of the impact that KEYTRUDA is having for the patients as they're being treated with cancer. And as you all know, we are offering treatment for a wide range of different cancers, 42 indications now approved in the United States across 18 different tumor types and tumor agnostic indications also.

So we've seen profound impact for patients and extremely strong growth and impact for our company, as we go forward, we do expect continued growth for KEYTRUDA the opportunities for growth will come from new indications. We are still launching the early-stage lung cancer indication in our ex-US market.

We have women's cancers such as endometrial cancer, cervical cancer, which are important opportunities for patient impact and growth. And we have bladder cancer indications some launching right now, some that we're hopeful for readouts next year. So we do see continued growth in KEYTRUDA, albeit it will slow as we continue to penetrate in some of those indications we've been in for some time.

Another opportunity for us with KEYTRUDA is also the new formulation, our subcutaneous version. And that will enable us to benefit many patients by having an administration that will just take a minute or two for the patient, it's going to be extremely helpful for patients, we believe who are taking KEYTRUDA in monotherapy or in combination with another oral agent or in the earliest stage cancer setting.

Today, about 25% of the revenue of KEYTRUDA is for patients being treated in the earlier stage second, and that's growing. And this will be an opportunity for those patients. So as we look at the subcutaneous opportunity. We're very excited about that and would expect adoption to be around 30% to 40% of the overall KEYTRUDA business in about an 18- to 24-month window, post-launch. So there seems the element we remain excited about as we continue to help patients with cancer.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

And can you talk a little bit about, I mean, what could make this adoption faster or slower? I mean -- and I mean, there is another PD-1 with subcu option out there. So what can you learn from that experience?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So I think what's unique for KEYTRUDA is the breadth of indications it has and its utilization in the earliest stage setting. And that will, we hope, enable more patients to benefit from a subcutaneous formulation in their treatment journey. What we've learned from others is the importance of pricing access and the J-code.

So as we look at entering the marketplace, we are pricing to enable broad access for the product. And we are also mindful though that within that first six-month window where we will not have a permanent J-code. We will expect that to be somewhat of a headwind to growth in those initial months. That said, and as I mentioned, we still expect to see us get to a 30% to 40% adoption and to get to that level in an 18- to 24-month window.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very, very helpful. I think the question is for you, again, if you think about now like -- last few years, you have been trying to build up pieces of the puzzle to actually fill that perceived holes when KEYTRUDA goes off patent, so you have TROP2, you have PD-1/VEGF, now early stage and you use a bunch of other assets. So if you look at that portfolio, I mean, if you have to like how would you -- which give you like the most kind of question, right?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Well, you have to be careful not to discriminating against all of your children, but -- we have -- but in reality, we've got 24 oncology assets in clinical trials right now. Among those, we can divide them into three categories. those to continue the immune stimulation against cancer and V940, our collaboration with Moderna on personalized individual neoantigen therapies, one.

The second category is to improve on chemotherapies and other tissue targeted approaches. And here, I would highlight our TROP2 sac-TMT as well as our collaboration with Daiichi Sankyo. And among those, both I-DXd and R-DXd, these are two compounds for in small cell, prostate ovarian cancer and others.

And so you can see they're relatively broad. With respect to the last category, the last category is specific targeting agents that address those drivers of tumor growth. MK-1084, our KRAS G12C mutant inhibitor is really an outstanding exemplary of that. Belzutifan is already marketed and is continuing to be in large-scale clinical trials.

We've had some positive results there. And then there'll be others like KRAS and other agents that are novel hormonal agents that I think will be very important in the treatment of different kinds of cancers. So we have a very large portfolio in oncology. I really feel confident that we'll be able to leverage pembrolizumab to create very important new medicines that will help outcomes and improve lives.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. So like let's start with TROP2 ADC here because you have a massive program going on. We have not seen a ton of data, but you obviously have seen the data. So can you talk a little bit about your confidence level in terms of what you are seeing with the data Kelun has been generating? And what gives you confidence to start this past program?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Absolutely. So the TROP2 ADC from -- that we have, sacituzumab, tirumotecan or SAC-TMT is a unique molecule that was developed in Kelun in China. And one of the things that very much helps us with this is that we have a lot of advanced notice from them in the clinical trials that they've seen there. But it's unique to the extent that it's very potent. It does not have interstitial lung disease issues.

And if the dose we've chosen is actually fairly well tolerated and can be used in the more maintenance settings. So if you compare the strategies that we've employed compared to some of the other TROP2 ADCs, they're quite different. We have seen a very exciting early signals that have led us to 14 clinical trials that are available, nine of which that are publicly available on ct.gov, nine of which are for new indications where others have not gone and five of which are where we have a differentiated approach.

We think that those -- that TMT will be a great workhorse agent for -- to combine with pembrolizumab or any other immune checkpoint inhibitor. And we're also -- going back to the beginning with Kelun, we've already seen they have some pretty amazing results in China. Of course, we have to replicate that in the global setting. But that provides us with a lot of confidence.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. So what's the confidence level that this TROP2 ADC or Kelun [TROP3 ADC] would be able to differentiate against especially Trodelvy, right? Because obviously, the other one has ILD issue, but to that will be set.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Sure. And Trodelvy has got pretty significant GI tox. But those drugs have been focused on specific lung and breast indications whereas and they've not done very well elsewhere. We have actually a program that's much broader in maintenance settings. And the first indications will be in things like GYN cancers.

Caroline mentioned the importance of pembrolizumab in the patient population. And we're -- we think that, that will be an important leverage point for us. I'd also point out that there's a lot of excitement at least for us, in maintenance settings where we've seen, for example, in lung cancer, maintenance chemotherapy, it has been difficult to take, and maintenance VEGF has been difficult to take.

But with TROP2 ADCs, we think we'll be able to achieve that. So it's a differentiated program. We think we're going to have we've hit the sweet spot in terms of the dose. And with that, I think it's going to be a very important addition.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. Thank you for that. Now let me just talk a little bit about the immune checkpoints, right? I mean, so before we get to VEGF PD-1, I mean, the question I want to ask is that, we have seen multiple iterations like there was IDO, there was LAG-3, there was TIGIT.

Like, again, early trial kind of proves that KEYTRUDA is a very good drug. So like if you're trying to compare against it, what is different with VEGF PD-1 versus the prior failures, which made you look into it?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Sure. So just to step back, VEGF inhibitors have been tested pretty extensively in the setting of various cancers. One of the things that's clear is that in some cancers, they have both PFS and OS benefit. So the most important is overall survival benefit, right? Progression-free survival is important, but nothing like overall survival.

So that mechanism of action has been important. One of the things that's notable about VEGF inhibitors in general is that they have really good progression-free survival and not so good overall survival. And so that's been sort of a cloud and a limitation to that field where there's only been a few indications where VEGF inhibitors have been incorporated.

We've done an extensive program looking at the combination of VEGF inhibition and PD-1 separately. In those cases, the benefits are really quite limited to renal cell cancer and endometrial cancer, which are really quite vascular tumors. Now come the PD-1 VEGF bispecifics, and there's all sorts of theories around why these drugs might have a specific and special benefit.

The results so far that we've seen with ivonescimab and to some extent, with BNT327 has been interesting with respect to progression-free survival. Akeso has noted that there is -- that they have hit in the final analysis and overall survival benefit in one of their studies in EGFR mutant non-small cell lung cancer. But that was only in the final analysis.

So the big question with all of these drugs will you be able to have an OS advantage. And the reason for that is that VEGF inhibition chronically administered is not well tolerated. And there's always been a question about the second agent that is after you progressed, whether you've created a change in the biology that leads to high resistance that's why everyone has been so focused both from an investor point of view and certainly

for us, where is the OS benefit? Is there OS benefit? Is that OS benefit convincing? Does it justify some of the talks that they've seen in what specific settings will that be good? So we'll have to see about that.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

And you have quite a lot of experience with your own Lenvima experience there. So how can you use those learnings into the development of this program?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

A lot. There's a lot of -- so one of the things that is so wonderful about our oncology group is that we have all of the data from hundreds of pembro trials now forming the basis of standard of care around the world. As well as the so-called LEAP program, which is the program that was with lenvatinib. From all of the data, we can model out what are the potential additional issues -- benefits that you have? And what might be the places where you start to see problems with VEGF inhibition.

And so we've looked at that carefully. And our development strategy for MK 2010, which is the -- our PD-1 VEGF will be very much focused on settings where we might -- where we think the sweet spot will be. Again, it still remains to be determined whether these ages are going to be just PFS agents but have issues with OS. And that uncertainty, even with that one result still remains.

And remember, in China, for a regulatory approval, you need progression-free survival. That's it. In the United States, OS is king, and FDA has insisted on it, especially in settings like frontline metastatic lung cancer. So that's going to be the challenge for the field.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

So this brings me to the next question because if you look at the front runners, Summit/BioNTech. They're all going after KEYTRUDA in its strongest indication that is lung cancer, right first-line lung cancer. Logically makes sense. But at the same time, you are going after KEYTRUDA in an indication where KEYTRUDA is very good.

So I mean when you think about -- I mean you will have an advantage of like slightly behind, but at the same time, you can learn from them. Is there a room -- is there a way to think about going after indications where KEYTRUDA works, but it could work better with the VEGF PD-1 or how -- you get my question here, right?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

I get the question. So the question is whether you can -- is there places where there's room to go with your PD-1 inhibition? And the answer is that's very -- that's one of the reasons why we are so excited that we have the ability to look across therapeutic indications with pembro, not only with lenvatinib, but also recall, we've done some clinical trials with a whole variety of other TKIs based on collaborations that we've done with ADCs, with all sorts for of things.

So we can take a good look at where that special advantage might be. The way I consider PD-1 VEGF, there won't be -- it's not going to be another KEYTRUDA. They're just not. They're going to be specific places with specific potential benefits and specific strata of patients.

That's that last bit is the important bit because all comers is going to be -- it's sort of a very high bar to win in a drug like pembrolizumab that is pretty extremely active. So you'll have to look at even in places where KEYTRUDA is somewhat less active where the hazard ratio is a little bit less -- it's still a pretty high bar because oftentimes, it's given with chemo.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. And then so now that you're generating data with your partner in China. So could we expect a TROP2 situation where you start to see the data and then you invest in this program?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

We are always -- we give all of our asset stage appropriate investment deserves no more and no less. So we're very, very data-driven. We've had a lot of -- we've had a pretty rapid development program in China.

And based on that, we'll come forward with some interesting trial designs. It's also helpful that our partner, Kelun there as well. So we can do a lot of work in that environment and prepare for Phase III should the data support it.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Is there -- like what is your internal understanding about? There are differences in molecules, but is it going to be a PD-1 like situation where ultimately, clinical profiles were different than the molecules as such?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Well, I do think in this particular instance, it's going to be important to look at the ratios. And I'm not -- and this isn't because of some magic, it's just too much VEGF inhibition. If you get bevacizumab VEGF inhibition, that's not so good.

They're just not tolerable it. The same is true with some of the other TKIs that are valuable, but only in a specific segment of patients. And so you have to get to that sweet spot. We've always been a believer in PD-1 inhibitors, that PD-L1, but that all will depend on the clinical profile.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Yes. This is what I've heard light. I mean, bevacizumab has a 21 days half-life in bispecific, at least the one which has reported is only four days. So that may be one of the reasons why safety is --

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Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

But the other piece is if you have to really thread that needle, you wonder. I mean, that's going to be an issue that we have to address. Again, I'm excited about this class, but it has to be in a very data-driven way and OS is king.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. And where are you with the cancer vaccine program at this point? I mean we had some interesting Phase II data. So how do you think about development there?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

So one of the things that's been exciting about this program is how enthusiastic investigators are. I've always believed that enrollment speed is a not bad indicator of excitement and interest in the mechanism of action and then subsequent commercial success. The area where we've chosen a different development strategy than other cancer vaccine simply because we're interested in early cancers.

We're interested in those cancers where patients have a potential curative opportunity where they still have a fairly intact immune system and where we can define the tumor mutations that are going to be most immunogenic. That said, we are spreading out. We have now looked at some cancers that are very immune responsive but don't have quite as many tumor mutations.

And we will be doing some evaluations in the first-line metastatic settings. But more than anything, I think that this -- the Phase III trials that we've put together in the Phase II programs are really focused on early-stage cancers. The readouts will occur in the next couple of years. And with melanoma being first, and we're really excited to see what those results are. In the meantime, Moderna is gearing up to prepare for the good news should it occur, and we'll be ready.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Awesome. So before we go into non-oncology side, so I have some questions for you. So obviously, you have to talk about MFN and tariffs there. So the macro has like how do you see all these macro headwinds at this point coming out from administration? And how can a company like Merck can prepare for something like MFN, tariffs and all those situations.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So from a tariff regard, you've heard Rob talk to the fact that our company is well positioned for what we currently know. We have worked very hard over many years to ensure that we have a diverse footprint for our supply chain. So we have manufacturing here in the United States and outside of the United States, and we've been investing here in the US.

So as we look at tariffs, and we look at the placement of our products for our current portfolio, we feel that the impact of tariffs are manageable for our business. And as we look at the many launches that we have coming, we're ensuring we have the footprint that enables manufacture here in the US -- the US, in Europe, for Europe, in Asia for Asia.

Now clearly, we need to see the final details whether we sit here today, we feel that we are well positioned. With regards to MFN, we and the industry is supportive of the agenda to try and lower our pocket costs here in the United States and ensure that countries around the world are paying their fair share for innovation.

Through recent letters we all received from the President has MFN focus in the Medicaid segment, that's a relatively small segment, less than 10% of the revenues for our company here in the US. It looks at MFN as you launch products, and we would make sure we're launching products, Cognizant of MFN. And there's some other elements to it.

So for us as a company, we remain focused on innovation, focused on our pipeline because if we have products that truly make a difference in the world, we price them commence to it with the benefit that we're offering in to society that will drive growth into the future. And we'll see what the details of MFN may or may not be as the next months and years unfold.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. So the question we get a lot is that, I mean, would the companies consider pricing their ex US trucks differently for the new year launches going forward, considering the MFN and all those issues?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Yes. So we always look to price our products around the world commence through with the value that we're bringing often in certain countries around the world, the processes that they have around the pricing is formulaic in nature.

What is helpful with the MFN news flow at the moment is governments understand that if they don't step up, they will be at risk of not having innovations come to those markets. So for our company, we will continue to stand firm in launching our products at a price point that we think is appropriate and commensurate with the value that we're bringing.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Really makes sense. Thank you for that. And then the other question is to -- like, I mean, an IRA and the question we get a lot. Now I think with IRA with the big, beautiful builds, you probably would have no extension for KEYTRUDA, but the question always is, would subcu be part of because the first guideline kind of suggested it won't be, but now it does look like it would be. But how are you thinking about subcu being part of or not part of?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So as we talked about earlier, we're really excited about the opportunity to launch a subcutaneous formulation of pembrolizumab. As we look at the IRA, the original IRA was in line with the FDA in that subcutaneous is a new product, two active moieties combined and therefore, would not be subject to IRA at the same time as to KEYTRUDA, the IV portion.

The CMS requested responses to a proposal that suggested maybe it would be subject to the at the same time as KEYTRUDA IV is. We obviously gave our responses, and we think that's just bad policy, bad practice. That said, should KEYTRUDA IV and the subcutaneous formulation of pembrolizumab be under the IRA price setting at the same time, it doesn't fundamentally change the economics for the subcutaneous formulation.

And the reason is we are pricing the product to ensure broad access. We'll do that at launch, but we'll also need to ensure we understand the market dynamics as biosimilars enter the market as there's IRA price setting on KEYTRUDA IV so that we do maintain access and maximize really the volume that we will have from KEYTRUDA subcutaneous formulation.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. One more question before we move back to the pipeline side. So like you mentioned like so -- like you announced the plans to reinvest the savings from $3 billion restructuring program here. So it is quite impressive, right?

I mean, like, so there's restructuring, but again, at the same time, Merck, at this stage has to invest in pipeline as well, right, and given the exciting opportunities out there. So how should we think about operating expenses growth, specifically R&D in the next few years here?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So as Mohit mentioned, our company announced last quarter a multiyear optimization program. and this multiyear optimization program will drive productivity across every element of our business, from our manufacturing supply chain, the way we conduct our business, sales and marketing, research -- and we're doing that to drive $3 billion of annual cost savings that we will fully reinvest in our future.

Our company has one of the strongest pipelines we maybe ever had. And we must fuel that pipeline. So we will be increasing R&D investments because of the breadth of the pipeline. We have eight Phase III clinical programs today. We've got these 20-plus products launching.

We've got an invisible pipeline, the early stage that will be turning visible. So we will, as Eliav mentioned, appropriately fund R&D grow R&D, we will appropriately fund SG&A as we're bringing these new products to the market, ensuring that we're funding our launches to compete effectively in excel in those launches so that we drive growth for our business into the future.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. Thank you for that. Maybe moving back to the non-oncology pipeline here. So WINREVAIR, I mean there is launch has been exciting. You have a new set of data and new indications coming with CADENCE. Can you help us set the stage here vis-a-vis the PAH, how big the opportunity could be because you will probably go after a subset there. So can you help us understand all that.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

So you're talking about the CADENCE?

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Yes.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Yes. Sorry. I didn't quite hear. So you're right, we have a Phase II program in type 2 pulmonary hypertension. Type 2 preliminary hypertension is a diverse set of diseases that are associated where pulmonary hypertension or high blood pressure in the pulmonary arteries is caused by different problems in the heart, in the left heart.

And so there are different kinds of diseases that cause that. We have a specific type of disease that roughly is in the size of pulmonary arterial hypertension, although not as well diagnosed. Where there's pressure both before -- in the precapillary and post-capillary. So it's called [Cpc-PH], very long name. But in short, people who've got high pressure both in the arterial system and in the venous system.

We have hopes that sotatercept will be -- or WINREVAIR, will be active there simply because the biology is not too dissimilar. And when we look at how the -- what the arteries look like, they also have the same kind of proliferation of the vessel wall, the thickness of the vessel wall that happens with PAH.

But it's a separate indication. Those data will be available later on this year and we'll be discussing them hopefully at the beginning of next year. And we'll see, based on those data, it'd be a very important new addition to the WINREVAIR indications.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. Another cardiovascular drug, I mean, PCSK9, oral PCSK9. Again, there have been ebbs and flows on this one, like obviously like you have had good data in Phase II. The question is now with the AstraZeneca having no food effect versus food effect. I mean how do you think about this triply evolving there? Because the drug should work, did work.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

So look, the most important thing that physicians are looking for is a drug that's really active. First of all, statins have been terrific, but guidelines are pushing people to have ever lower LDL-cholesterol levels. And it's really important because obviously, the benefit of LDL lowering has no basement.

There's no bottom where it is no longer important. So you need to have medicines that are available that can be given and really improve on what statins have. Enlicitide or MK-0616, our PCSK9 oral inhibitor will democratize access to this particular mechanism of action as opposed to the injectables. It will give the ability to take one pill once a day. No problem in terms of access barriers and so on.

And we think that's going to be a very important addition. And the data from Phase II showed 60%-ish percent reduction in LDL-cholesterol. That's essentially consistent with the injectables. What we've seen in our Phase III program is exciting results that are consistent with what we think we need to create a really important innovation for patients akin to the injectables.

We've -- in the Phase III studies, the proof of the pudding, including the largest one, this business around taking it after when you get up in the morning has not been an issue at all. Compliance was really terrific. We had no adverse experience. There's no difficulties where patients had a problem.

And when we talk to our scientific leaders and practitioners, this really isn't an issue. What they're interested in is what's the best reduction that you're going to get. And if you look at our Phase II data, a little over 60% reduction in LDL-cholesterol reductions in Lp(a) and time to market is very important. We have two years during which we'll be the sole or old PCSK9 inhibitor, we think. And at the same time, we'll also have the best profile, I think, overall.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. Maybe like finishing up the cardiometabolic. So where are you with your GLP-1 at this point?

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

So we've -- we're very excited about cardiovascular and metabolic space because there's still such a high unmet medical need. And as we look at enlicitide, we're looking at also next generations where we would combine it with different agents that might further improve prevention of atherosclerosis.

On the GLP-1 front, you've seen that there's been a lot of expectation setting around what kind of reductions are needed to excite investors. But from my point of view, I think and from our point of view, the fact that you can have an oral medicine really is a big deal. And so we have a MK4082 that will enter Phase I later on this year.

And we think that the differentiation will be and what combinations you're going to put in together. What combinations are going to be tolerable, how many different titration steps you're going to need? Because remember, it's not -- it's not easy for physicians to keep track of all of this, especially if they have to rush every patient through to meet their numbers. And so we'll have to see. But I think oral, in general, in my mind, oral is always better than injectable.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. Very helpful. Moving to the BD a little bit here, and I'll talk about GARDASIL as well. I wanted to know -- 35 minutes we did not talk about GARDASIL. So -- I mean, like we saw -- I think Verona is one deal which is more commercial than the development much been historically much has done more development deals than the commercial deal. So should we think of this as a change in direction a little bit? And I mean, how should we think about deals going forward, given your balance sheet?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Business development remains a key priority for our company. There's so much good science that happens outside of Merck. And our goal is to bring that science into Merck where the sites and value aligns that we can bring benefit to patients as we have with WINREVAIR as we hope to, with our TL1A asset as we will do, we hope, with the Verona asset.

As we look at business development, our starting point is around the science. And is this innovation that will address an unmet medical need. We are not bound by what phase of development it is, and we're not actually bound by value, by price.

What we're bound by is innovation that will make a difference that in our hands, we can drive growth, and we can drive value for the shareholders. So we will continue to progress on a whole suite of opportunities that span multiple phases of development and also will span multiple TAs as we look, first and foremost, to drive patient benefit, growth for our business as we look out to the end of this decade and beyond.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. So very active. Very helpful. So now moving to GARDASIL. So I think I mean, at this point, I mean, how do you think about -- I mean like is it fair to think that China is probably going to be where it is right now and then growth will come from outside of the China market at this point?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

GARDASIL in China is an immaterial revenue driver now for the company, less than 1% of revenues. And as we look to '26 and beyond, we're not counting on GARDASIL in China to drive our growth. We have resources on the ground with our partner to ensure that we are educating people of the continued benefit of HPV protection.

But we're not counting on it for our growth. Instead for GARDASIL, we expect growth will continue to come from further penetration of adolescent segment, especially the mail cohort in countries internationally. Growth will come from the mid adult segment. That's the age group 27 through 45%, 50% of infections happen at that age.

And so we are working on activating that group, although it takes time. And we will see growth from the low and middle income market. But most importantly, our company's growth is really going to be fueled by all of these new launches and new products that we've got coming through.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Got it. And then, I mean, there is a lot of headlines from the administration about the vaccines and then the necessity. And like, I mean -- so GARDASIL this is -- I mean, there could be potentially ASP chances of less number of doses.

So how do you think about that as a possibility? Also, I mean, similarly, like we are hearing something about RSV as well. So like, again, I don't know, like how do you think about this negative out there?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Maybe I'll let Eliav to comment on that.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Right. So first of all, let's take GARDASIL -- the single-dose GARDASIL story is unfolding. We don't know. We don't think that the ACIP is going to consider it in September, a future that we don't know. What we do know is that the food and drug administration has been very, very clear about the evidentiary standards that they need to enable single-dose vaccination.

And those standards are much higher than anything that's been generated to date. They're looking for tissue endpoints that is hard endpoints like precancerous lesions in both men and women and in both for short-term but also long-term durability and no loss of efficacy.

So when you think about all of that -- all of those requirements, it's going to be very difficult to be able to get an FDA-approved single dose. There are settings where ACIP may disagree with FDA and choose to make its own recommendations. We don't think that the evidentiary standard is there for this. There's no reason for this to be done.

Now more broadly, we can't control, and we don't know what ACIP will do. We're very confident that vaccines are a critical part of the health care infrastructure. They save lives that really made a difference over the past 50, 60 years. And some of our vaccines have been out there for quite some time.

Our RSV preventive clesrovimab or ENFLONSIA has been studied extensively. It went through a full FDA review. That was all very clear. went through the ACIP review process. A lot of the data are fully public, and we got all the relevant recommendations.

So how they ACIP will think things through in September? We don't know. But we're very confident that the efficacy and safety of ENFLONSIA, of GARDASIL of all of our vaccines. And frankly, the vaccines of all the manufacturers that are part of the immunization schedule. These vaccines are incredibly well tested.

They are incredibly valuable there's enormous post-marketing data. And I think that at the end of the day, professional societies and physicians who work with parents, will understand that. And we hope that, that will continue to reinforce vaccines.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Awesome. So my last question. My last question is always the same. Fast forward one year 2026 September. I hope you are here. I hope I'm here. So if I ask you the question one year down the line, that what would make you look back and say this was a great year for us.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

So for me, it starts with our pipeline. You will have seen the progress in our pipeline as we really are moving as I open today to a much more diverse set of growth drivers that will make a difference in the world. So seeing positive readouts on all of these assets that we have coming through and seeing excellence in our launches. That's what it looks like for me, with continued augmentation from business development.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Again, I look forward to the readouts of a lot of really exciting results. We haven't talked much about our HIV pipeline, but there's going to be some really important readouts there. Same move with some of our oncology products. And I look forward to, hopefully, one year from today where we see that there is stability in thinking around vaccination schedules and around how the enormous value that these vaccines have brought.

And I'm really excited also to -- we'll be excited to showcase our new oncology pipeline as well. So lots and lots of stuff going on. We're going to have a lot of readouts, and I'm really looking forward to a good year.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Great. On that high note, thank you very much.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Thank you, Mohit.

Eliav Barr - *Merck & Co Inc - Senior Vice President, Head of Global Clinical Development & Chief Medical Officer*

Thank you.