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OVERVIEW:

Company Summary

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CORPORATE PARTICIPANTS

Peter Dannenbaum *Merck & Co Inc - Vice President of Investor Relations*

Robert Davis *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

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

Dean Li *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

CONFERENCE CALL PARTICIPANTS

Akash Tewari *Jefferies LLC - Analyst*

Umer Raffat *Evercore Inc - Equity Analyst*

Terence Flynn *Morgan Stanley - Analyst*

Michael Yee *UBS AG - Analyst*

Geoffrey Meacham *Citibank Cameroon SA (Douala Branch) - Analyst*

Christopher Schott *JPMorgan Chase & Co - Analyst*

Courtney Breen *Sanford C Bernstein & Co LLC - Equity Analyst*

Jason Gerberry *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Mohit Bansal *Wells Fargo Securities LLC - Analyst*

Evan Seigerman *Bank of Montreal - Analyst*

Asad Haider *Goldman Sachs Group Inc - Analyst*

Luisa Hector *Joh Berenberg Gossler & Co KG - Analyst*

PRESENTATION

Operator

Thank you for standing by. Welcome to Merck & Company, Inc., Rahway, New Jersey, USA second quarter sales and earnings conference call. (Operator Instructions) This call is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the call over to Mr. Peter Dannenbaum, Senior Vice President, Investor Relations. Sir, you may begin.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Thank you, Shirley, and good morning, everyone. Welcome to the second quarter 2026 conference call for Merck & Company, Incorporated, Rahway, New Jersey, USA. Speaking on today's call will be Rob Davis, Chairman and Chief Executive Officer; Caroline Litchfield, Chief Financial Officer; and Dr. Dean Li, President of Research Labs.

Before we get started, I'd like to point out that we have items in our GAAP results such as acquisition-related charges, restructuring costs, and certain other items that we have excluded from our non-GAAP results. There is a reconciliation in our press release. I will also remind you that some of the statements that we make today may be considered forward-looking statements within the meaning of the safe harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of our company's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Our SEC filings, including Item 1A in the 2025 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those

projected in any of our forward-looking statements made this morning. Merck & Company, Inc., Rahway, New Jersey, USA, undertakes no obligation to publicly update any forward-looking statements.

During today's call, a slide presentation will accompany our speakers' prepared remarks. These slides, along with the earnings release, today's prepared remarks, and our SEC filings are all posted to the Investor Relations section of our company's website. With that, I'd like to turn the call over to Rob.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thank you, Peter. Good morning, and thank you for joining today's call. I remain very pleased with the substantial progress we're making across our business driven by strong execution, growing contributions from new product launches, and the continued advancement of the next wave of innovation from our pipeline.

Earlier this year, we provided insight into greater than $70 billion of commercial opportunity we have from over 20 new products that we expect will transform our portfolio. And in many cases, the practice of medicine, as well as fuel growth well into the next decade. We also outlined a series of clinical milestones that represent key events to substantially de-risk this opportunity. Since then, we've made meaningful advancements against that objective, including several important proof points that have occurred earlier than expected.

This progress further bolsters my high confidence in the future of our company and our ability to create long-term value for patients and shareholders.

Turning to our second quarter results, we delivered revenue of $16.6 billion, reflecting continued strength across oncology and animal health, as well as increasing contributions from our recent launches. Importantly, while we're delivering for patients today, we're also making substantial investments in the next generation of innovative medicines and vaccines.

We remain confident in our outlook for the remainder of the year, which Caroline will discuss in more detail in a moment. We also achieved several important clinical and regulatory milestones. In cardiometabolic, the FDA approved LIPFENDRA, the first and only oral PCSK9 inhibitor to help reduce LDL cholesterol in adults with hypercholesterolemia, along with diet and exercise.

We're pleased to have worked with the FDA through the Commissioner's National Priority Voucher process to bring this important new treatment option to patients on an accelerated basis. We look forward to providing broad access for patients to help address elevated LDL-C, a major modifiable risk factor for cardiovascular disease. In oncology, we received several approvals that underscore the ongoing impact of KEYTRUDA and the enduring strength of our oncology portfolio.

At ASCO, we presented encouraging data that further demonstrate the durability of KEYTRUDA, and at our investor event, we highlighted advances for a number of promising candidates across our pipeline. This included the first positive top-line results from our expansive Phase 3 global clinical development program for SAC-TMT, our TROP2-directed antibody-drug conjugate in certain patients with advanced or recurrent endometrial cancer.

In immunology, we announced positive Phase 3 top-line induction results for tulisokibart for certain patients with ulcerative colitis and are starting to see the first of numerous additional trial readouts, reinforcing our confidence in the potential of this program.

And at the AIDS 2026 Congress last week, we shared compelling data from our broad HIV pipeline, including islatravir in combination with lenacapavir, which has the potential to be the first oral once-weekly HIV treatment for virologically suppressed adults. We are excited to be returning to the HIV field with an array of important therapies, including the recent launch of IDVYNSO.

Ahead of the meeting, we also announced initial access plans for MK-8527, our investigational. Oral HIV-1 PrEP candidate now in Phase 3 studies, underscoring our commitment to help enable broad and sustainable access to this candidate upon its potential approval. We also

continue to augment our portfolio through disciplined business development. During the quarter, we completed the acquisition of Terns Pharmaceuticals, adding MK-4208, a novel potentially best-in-class therapy for certain patients with chronic myeloid leukemia.

This transaction strengthens our hematology pipeline, adds another promising late stage growth opportunity, and reflects our continued focus on pursuing science-driven business development that can benefit patients and enhance long-term shareholder value.

This quarter marks my fifth year as CEO, and as I reflect on the commitments our leadership team made in 2021, our strategy was clear. Maximize the transformative potential of KEYTRUDA, eexpand, deepen, and extend our leadership in oncology, bring forward new growth drivers across additional therapeutic areas, and advance Merck's mission of using the power of leading-edge science to save and improve lives around the world.

Today, I'm proud that we are successfully executing on that strategy. Each year, we're making important progress in building a stronger foundation for our future. We're broadening and diversifying our pipeline, advancing multiple potential blockbuster opportunities, and achieving clinical, regulatory, and commercial milestones that will benefit patients and enhance our long-term growth trajectory.

I believe Merck is substantially stronger, more diversified, and better positioned for sustainable growth than it was just five years ago, while more work remains. I'm increasingly confident in Merck's future, particularly with the rapid pace of clinical and regulatory events now occurring.

This confidence is grounded in the strength of our science, our disciplined approach to capital allocation, including business development, and the dedication of our colleagues around the world who work every day to deliver for patients.

I want to extend a special word of thanks to our global team for this substantial progress. And for their commitment and execution on behalf of patients, shareholders, and all of our stakeholders. And now I'll turn the call over to Caroline.

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

Thank you, Rob. Good morning. We delivered growth in the quarter, led by continued strength in oncology and animal health, along with increasing contributions from our diverse and compelling new products across an array of therapeutic areas.

Our strong commercial and operational execution continuous to drive near-term performance while we invest in our outstanding pipeline to create long-term value for patients, customers, and shareholders.

Now turning to our second quarter results. Total company revenues were $16.6 billion, an increase of 5%, or 4% excluding the impact of foreign exchange. The following revenue comments will be on an ex-exchange basis.

In oncology, sales of the KEYTRUDA family of products, which includes KEYTRUDA and KEYTRUDA QLEX, increased 4% to $8.4 billion, with global growth driven by strong uptake in earlier-stage cancers and continued robust demand from metastatic indications.

Strong utilization in tumors that primarily affect women, including breast and cervical cancers, and increased use of KEYTRUDA in combination with Padcev in locally advanced or metastatic urothelial cancer, were key contributors to growth. Sales of KEYTRUDA QLEX were $463 million. We have seen physician and patient adoption increase since the permanent J-code was established in April.

As expected, early use has been predominantly in patients who are either on monotherapy or in combination with an oral agent. We remain confident in the trajectory of KEYTRUDA QLEX adoption.

Our broader oncology portfolio delivered another quarter of strong growth. WELIREG sales increased 67% to $271 million, driven by continued uptake from international launches and increased use in certain US patients with previously treated advanced renal cell carcinoma. We are

excited that certain patients with earlier stage renal cell carcinoma may benefit from adjuvant treatment with WELIREG following the recent FDA approval of LITESPARK-022.

In vaccines and infectious diseases, GARDASIL sales were $1.2 billion, an increase of 3%. Sales in international markets grew 6%, while the US was roughly flat, as lower demand and timing of CDC purchases was largely offset by price.

In pneumococcal, CAPVAXIVE sales were $184 million, an increase of 40%. Growth was primarily driven by uptake from ongoing launches in certain international markets, as well as higher demand in the US.

In HIV, we are pleased to have launched IDVYNSO, our once daily oral two-drug single tablet regimen of doravirine and islatravir for certain virologically suppressed adults. We have seen encouraging early progress on access and reimbursement and look forward to broadening access over time.

In cardiometabolic and respiratory, WINREVAIR sales were $588 million, an increase of 75%, reflecting continued strong demand from adults with pulmonary arterial hypertension. In the US, we saw further progress with more than 1800 new patients having received a prescription and an increase in the proportion of patients whose background therapies do not include a prostacyclin.

Outside the US, we continue to progress with ongoing launches. OHTUVAYRE sales were $204 million, reflecting continued prescription demand from patients with COPD, as well as the benefit from the timing of specialty pharmacy purchases.

Our animal health business delivered another quarter of solid growth with sales increasing 5%. Livestock sales grew 6%, driven by higher demand for ruminants and poultry products. Companion animal sales increased 5% due to new product launches. I will now walk you through the remainder of the P&L, and my comments will be on a non-GAAP basis.

Gross margin was 81.1%, a decrease of 1.1 percentage points, primarily due to higher inventory reserves. Operating expenses increased to $12.6 billion. There was a $5.7 billion charge for the acquisition of Terns Pharmaceuticals in the quarter, compared with a $200 million business development charge a year ago.

Excluding these charges, operating expenses grew 7%, reflecting increased investments in support of our launches, as well as our robust early and late Phase pipeline. Partially offset by benefits from our multi-year optimization effort and recognition of a portion of the external funding for sac-TMT development.

Other expense increased to $290 million, primarily reflecting financing costs related to recent business development transactions. Our tax provision was $882 million. As a result of the non-tax deductible one-time charge for Terns, our tax rate was 160.3%. Taken together, we reported a loss of $0.13 per share, which includes a one-time charge of $2.31 per share from the acquisition of Terns.

Now turning to our 2026 non-GAAP guidance. We have raised and narrowed our full year revenue guidance range to be between $66.3 billion and $67.3 billion, representing growth of 2% to 4%, including a positive impact from foreign exchange of approximately 1 percentage point using mid-July rates.

Gross margin is now assumed to be approximately 81%, reflecting higher inventory reserves. Operating expenses are expected to be between $42 billion and $42.7 billion. This range includes $5.8 billion for the upfront charge for Terns and investment to advance MK-4208.

This guidance does not assume additional significant potential business development transactions. Other expense, which now includes the financing costs for Terns, is expected to be approximately $1.4 billion. We now expect a full year tax rate between 35% and 36%, which reflects the non-tax deductible one-time charge for Terns.

We assume approximately 2.48 billion shares outstanding. Taken together, we expect EPS of $2.66 to $2.76, with a midpoint of $2.71, including a positive impact from foreign exchange of approximately $0.15 using mid-July rates. This range also includes an upfront charge

of $2.31 per share related to the acquisition of Terns, as well as approximately $0.12 per share of ongoing costs to advance MK-4208 and finance the transaction.

As you consider your models, there are a few items to keep in mind for the second half of the year. First, for OHTUVAYRE. We remain excited about OHTUVAYRE's strong clinical profile and look forward to achieving its multi-billion dollar commercial potential in the coming years. Third quarter sales will be impacted by the unwind of specialty pharmacy purchases in the second quarter.

We continue to invest behind our sales force and promotion to reach more physicians and patients in the US. We are also working with our specialty pharmacies to improve patient experience. We expect these actions to lead to accelerated growth in 2027.

Next, we anticipate that total US KEYTRUDA year-over-year growth will moderate as we increasingly reach peak penetration across several key indications. Additionally, as a reminder, we benefited by approximately $250 million due to the timing of wholesaler purchases in the third quarter of 2025, which will not repeat this year.

For BRIDION, US sales are anticipated to decline at a slower pace than previously expected due to lower-than-anticipated generic competition.

Finally, other revenue in the second half of 2026 is expected to be significantly higher than the second half of 2025. This increase is primarily due to our revenue hedging program, as well as an expected milestone receipt in the fourth quarter related to an out-license agreement.

Now turning to capital allocation, where our strategy remains unchanged. We will continue to prioritize investments that support near and long-term growth, including our new product launches and robust pipeline. We remain committed to the dividend, with the goal of increasing it over time.

Business development remains a high priority and we maintain the ability within a strong investment grade credit rating to pursue additional science driven value creating transactions. We are on pace for approximately $3 billion in share repurchases this year as previously communicated.

To conclude, as we enter the second half of the year, we remain confident in the outlook of our business supported by global. Demand for our innovative medicines and vaccines, including our many new product launches. The transformation of our portfolio is underway, and we are well positioned to deliver value for patients, customers, and shareholders now and into the future.

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

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Thank you, Caroline. Good morning, everyone. The second quarter was marked by several important regulatory and clinical milestones. Today, I will provide updates in cardiometabolic disease, HIV, infectious disease, immunology, and oncology.

I will conclude with key upcoming milestones as we look toward the second half of 2026. First in cardiometabolic disease. As Rob mentioned, we recently received FDA approval for LIPFENDRA, the first approved oral PCSK9 inhibitor.

In the CORALreef Lipids trial, LIPFENDRA was shown to be highly effective in lowering LDL cholesterol with up to a 60% reduction when added to [a statin]. Earlier this year, updated US guidelines on the management of dyslipidemia from the American College of Cardiology and American Heart Association recognized that atherosclerotic cardiovascular disease remains the leading cause of morbidity and mortality and underscored the need for earlier intervention to help reduce lifelong risk from prolonged elevated lipoprotein exposure.

Guidelines also reestablished and lowered LDL cholesterol treatment goals, including to under 55 milligrams per deciliter for individuals with ASCVD who are at very high risk of ASCVD events.

The approval of LIPFENDRA is a major milestone in our effort to make PCSK9 inhibition accessible in a convenient daily oral option. As an oral macrocyclic peptide, LIPFENDRA has the potential to extend the reach of this therapeutic approach globally.

Additional regulatory reviews are underway in the European Union and China. We are also advancing combination approaches designed to further reduce LDL cholesterol and target additional ASCVD risk factors. Studies are ongoing to support the development of two potential fixed-dose combinations anchored by LIPFENDRA, one with rosuvastatin and another with MK-7262, our oral Lp(a) inhibitor.

Turning to HIV, yesterday we hosted an investor event focused on our HIV program, including new data presented at AIDS 2026. IDVYNSO provides the foundation of what we believe will be a series of novel entries into the field. Our late stage pipeline aims to address unmet needs for those living with or at risk of HIV through innovative oral options including two once-weekly treatment regimens and a monthly oral option for pre-exposure prophylaxis.

In collaboration with Gilead, we announced full results of the Phase 3 ISLEND-1 and 2 trials evaluating the investigational oral once-weekly regimen of islatravir and Gilead's lenacapavir. Both studies demonstrated maintenance of virologic suppression in adults living with HIV who switched therapy from a daily standard of care. These results support the potential for ISLEND to become the first approved oral. Once weekly treatment regimen for adults with virologically suppressed HIV.

Results were also presented from a Phase 2B study evaluating the investigational oral once weekly combination of islatravir and [ulonivirine], an internally developed investigational non-nucleoside reverse transcriptase inhibitor in adults with virologically suppressed HIV.

Based on these results, we plan to advance ISO/ULO into Phase 3 studies for people living with HIV who are previously untreated and those with prior treatment experience. We also continue to evaluate our monthly oral HIV PrEP option, alimatravir in 2 Phase 3 studies anticipated to read out next year. Next, in infectious disease. We are progressing our Phase 3 study of MK-1406, an investigational long-acting strain agnostic antiviral designed to prevent influenza.

Enrollment was completed in the Southern Hemisphere. Plans are now in place to continue the study through a second northern hemisphere flu season to strengthen our global regulatory submissions. We remain on track for potential approval in 2029. Moving to immunology to tulisokibart became the first anti-TL1a monoclonal antibody to demonstrate positive results in a Phase 3 trial.

In June, we reported on the induction only study of the ATLAS-UC trial in patients with moderately to severely active ulcerative colitis, tulisokibart met the primary endpoint of clinical remission as well as key secondary endpoint with no new safety concerns identified. We look forward to the upcoming readout of the larger induction and maintenance study, which together with the induction only study would form the basis of a regulatory filing and will be presented at an upcoming scientific congress.

These findings reinforce the potential of targeting TL1A to help address immunofibrosis, a key driver of disease progression across multiple immune-mediated inflammatory conditions. We have advanced a broad Phase 2 development program to further explore this hypothesis and now have results from two of these studies.

In SSc-ILD, the study did not meet its primary end point. In Hidradenitis Suppurativa, we are pleased to share that the study met its primary and key secondary endpoints. Results will be shared in due course. Finally, in oncology, KEYTRUDA continues to generate compelling clinical data and regulatory approvals, including in earlier stages of disease.

Recently, building on the approval of KEYNOTE-905, the FDA approved an expanded indication for KEYTRUDA and KEYTRUDA QLEX, each with Padcev treatment before and after surgery for adults with muscle invasive bladder cancer based on the data from KEYNOTE-B15, this regimen is now improved regardless of cisplatin eligibility and is the first and only perioperative immunotherapy plus ADC regimen to extend survival for these patients.

We are also pleased that the FDA recently approved KEYTRUDA and KEYTRUDA QLEX in combination with WELIREG for the adjuvant treatment of certain patients with clear cell renal cell carcinoma based on the LITESPARK-022 study. This marks WELIREG's first approval in earlier-stage disease and brings the total number of earlier-stage indications for KEYTRUDA-based regimens to 13.

In June, at our ASCO investor event we shared updates across our broad and diverse oncology portfolio. We also highlighted a series of pivotal readouts expected over the next several years. We are now beginning to see the first of those milestones materialize with the announcement of positive Phase 3 results from our global profuse development program evaluating sac-TMT.

In TroFuse-005, sac-TMT demonstrated statistically significant and clinically meaningful improvement in both overall survival and progression-free survival versus chemotherapy in certain patients with advanced or recurrent endometrial cancer. We plan to apply the National Priority Review Voucher for sac-TMT towards our filing in endometrial cancer.

These results represent the first readout from our global TroFuse program which includes 17 Phase 3 studies. The TroFuse program was intentionally designed to pursue both first-mover opportunities where sac-TMT can establish early leadership and indications in breast and non-small cell lung cancer where we can apply novel development approaches. This global effort continues to be informed by promising results generated by our partner, Kelun from their program evaluating sac-TMT in China.

Positive results from the OptiTROP-Lung05 and more recently, OptiTROP-Lung06 further strengthens our confidence in the potential of this differentiated TROP2-directed ADC. In closing, we anticipate a busy second half of the year. with multiple events and milestones, including in cardiometabolic and respiratory, the September 21 PDUFA date for WINREVAIR for the label update based on the Phase 3 HYPERION study, in immunology for tulisocobart, the second readout from the ATLAS-UC trial and the presentation of data from the Phase 2 HS study.

In ophthalmology, data from the Phase 3 BRUNELLO study of remigromig also known as MK-3000, our novel wind agonist being evaluated in patients with diabetic macular edema.

And finally, in oncology, potential approvals for WELIREG plus LENVIMA in advanced renal cell carcinoma and for IDXD in extensive stage small cell lung cancer and data presentations from across our broad oncology portfolio, including detailed results of the Phase 3 TroFuse-005 study. Please mark your calendars for the evening of Monday, October 26, and where we will host an investor event at the European Society for Medical Oncology in Madrid.

I look forward to providing further updates on our progress. And now I will turn the call back to Peter.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Thank you, Dean. Shirley, we're now ready to begin Q&A. And we kindly request that analysts limit themselves to one question today so we can get to as many questioners in the time that we have. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Akash Tewari with Jefferies.

Akash Tewari - *Jefferies LLC - Analyst*

Dean, you any stated a biomarker strategy would be the right approach for first-line -- but with sac-TMT, we've seen a signal regardless of PD-L1 expression with the OptiTROP-Lung05 and OptiTROP-Lung06 data, what are the chances we could see a broad sac-TMT pembro trial that goes head-to-head against KEYNOTE-189 and is it fair to say we could see SAC TMT combos with both pembro and a PD-1 VEGF for first-line lung?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

My simple answer is yes on all accounts, but I'll just step back a little bit, which is for a -- sac-TMT we've stated, we think it's a cornerstone ADC. I mean it's a TROP-2 ADC, but it has a novel linker and payload. And as described in the prepared remarks, we've sort of split the Phase 3 into 1st mover where we go into indications where we thought we could be first. And actually, what we're hoping is that the shops 005 and endometrial sort of gives validation to that strategy.

And as we've noted, we've talked to the administration's FDA, and this will be the 1 that goes for national priority vouchers. In breast and lung, we've said that we need to be differentiated given other TROP-2 ADCs. But as you point out, the OptiTROP-Lung06 gives us a lot of confidence in the target and to target it across the full spectrum of PD-L1 -- so yes, we are going to rethink KEYNOTE-189, which is KEYTRUDA plus chemo, and now we have a TMT as an ADC as a next-gen chemo.

I do think that we're going to be very thoughtful as to the IO agent and when we should use KEYTRUDA and when we should use other agents such as MK-2010, and -- and as you might imagine, we're advancing MK-2010. With that in mind, we are moving quite fast in relationship to initiating trials some that are signal finding some that are dose and scheduling to optimize with novel agents, and we're advancing trials that can go from a Phase 2 to Phase 3 seamlessly.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Thank you, Akash.

Next question, please.

Operator

Umar Raffat, Evercore.

Umer Raffat - *Evercore Inc - Equity Analyst*

Hi, guys. Thanks for taking my question. Dean, congrats on the HS trial update for the TL1A. I'm just trying to think out loud. To what extent as we go into these new indications is the activity we're seeing for these TL1As beyond what we would have expected from a TNF? I'm sure you can appreciate where I'm coming from on this. Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes, thank you very much. So just to step back a little bit, I think the question is posed and the fact that TL1A is a member of the TNF superfamily. The TNFs have been really important drugs. They have been advanced. There is often problems with combining them because of their safety signal.

In relationship to what we've seen so far, clearly when you think of immunology, you think of three buckets. You think of GI, you think of derm, and you think of rheumatology. In GI, clearly we're very eager to move forward in ulcerative colitis and Crohn's disease, and we're really eager to see the other half of the UC study. In the derm sort of space, we have it in HS, and I think that's important, as well as we have psoriatic arthritis.

I think the positive readout for HS gives us more confidence in the derm sort of possibilities for this drug, and so that's where we're looking at. I still think that within the rheum space, which is, let's say, RA, to some degree of arthritis, we'll have to sort of play that out as the data comes out. But I can just tell you, for example, for rheumatoid arthritis, we have very clear biomarker data suggesting we should go after TL1A. And clearly in something like rheumatoid arthritis, there are animal models in preclinical where you can guesstimate what your activity is. And we have that data that gives us the strength to move forward in rheumatoid arthritis.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great. Thanks, Umer.

Next question, please.

Operator

Terrence Flynn, Morgan Stanley.

Terence Flynn - *Morgan Stanley - Analyst*

Great. Thanks for taking the question. Two-part for me.

I was just wondering, Dean, if you could help us think about, ahead of Astra's AVANZAR data, what you'd be most interested to see in that data set and implications for your sac-TMT development strategy. And then anything you can say, I know it's a Kelun-Biotech study, but OptiTROP-Lung06, just in terms of control arm performance in that trial. Any comments? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. So let me take the last question first. We have a great partner in Kelun. We see very detailed data and we are very comfortable with the data that they've shown us and it gives us great confidence in moving forward. I would just highlight that some of the data that we saw is why we, for example, moved quickly to endometrial.

So we have a lot of confidence in how they run their clinical trials and their data. I forgot the first half again.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Avanza.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Avanza. I think the critical thing is, I think the AVANZAR-- I think we're waiting to see what the readout looks like. We're looking to see what it looks like in Alchimers comers, what we look like in relationship to biomarker selected. And that will give us some views as to how do we advance ours, the need for a biomarker. You can always have a biomarker, but that doesn't mean that you always need it.

And then the other sort of thing is how we think about advancing it in relationship to combination with an excellent PD-1 like KEYTRUDA or whether or not we should move it forward with an excellent PD-1 VEGF.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great. Thanks, Terrence.

Next question, please.

Operator

Michael Yee, UBS.

Michael Yee - *UBS AG - Analyst*

Great, thank you. Great. On TL1A, 2-part question. You had 1 positive Phase 3 in UC but not a whole lot was said. So how do you think we should think about the profile in ulcerative colitis appreciate in the second studies coming and then it's supposed to be all about fibrosis, but then the SSC study wasn't positive today. So how does that change your thinking around Crohn's and that fibrosis opportunity. Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. So thank you very much for that question. In terms of the tulisokibart Study 2, I mean we're very eager to see Study 1 because together, that will be the package that we sent to the FDA. And we are looking forward to that readout as we advanced it.

Again, in Crohn's disease, there's a clear signal, not just from us but from others. And it's what do we see in Phase 3. So I think we're very interested in moving those forward. You can look at some of the derm in the room indications that I spoke about. They will also have fibrosis component.

In relationship to SSC ILD. I would just step back. I don't know any anti-cytokine that has worked. So this was a bold move to move that forward. It's a challenging and refractory disease.

We see no safety concerns. But I will tell you that when we publish that data as you might imagine, we will.

I look very carefully at the placebo arm. If I see no progression in the placebo arm, it is an SSc-ILD, but if I have no progression in the placebo arm, the chances that I will be able to show benefit in a treatment arm becomes much more difficult. So I would not throw out the immuno fibrosis based on the SSc-ILD study not reading out positive in the specific patient population we recruited.

Operator

Geoff Meacham, Citi.

Geoffrey Meacham - *Citibank Cameroon SA (Douala Branch) - Analyst*

Dean, on the LIPFENDRA launch, I wanted to ask how you guys view the pace of maybe initial access. I wasn't sure what the right reimbursement expectation or if you thought the outcomes trial maybe would be more needed as a commercial tipping point.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

So why don't I turn the commercial to Rob, if that's okay? And then I can answer the remaining questions from a scientific standpoint.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. Great. Thanks for the question, Jeff. If you look at it overall, I would just say we're very pleased with what we're seeing so far. Obviously, you saw the label.

We have a very clean label, one we feel very good about. And with the fact that we have up to 60% LDL lowering, I think this is going to be a meaningful treatment. We're seeing very high interest from physicians and patients based on the approval announcement and ordering has begun last week, and we expect to be able to have it to pharmacies here shortly.

As we look at it from an access perspective, overall, we're, I think, in pretty good shape. You remember, we really tried to set this up for broad access in the way we priced it and the way we're going. That said, we do believe it's going to take time to get that access established. So we are expecting to see the pace not be as fast out of the gate. But with long term, continue to expect to see this to be definitely a blockbuster opportunity as we move forward.

I'll let Dean speak specifically to the broader question from a science perspective.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. So one of the thing I do want to highlight is there's often a lot of discussion of this FDA or this administration FDA, I can tell you, in our conversations with this administration's FDA, they wanted to use LIPFENDRA as a cornerstone way to demonstrate what they're trying to do with their priority sort of review. Most of the programs in that priority review only touch one of the sort of the pillars of what they're trying to do. But they were very clear to us they want us to touch all of these pillars. And those pillars is to target public health crisis, an innovative breakthrough, a large unmet need, especially in chronic disease, which is a pillar of this HHS.

They were very clear they want onshoring and supply chain and resilience in the US, and they were very interested in accessibility in relationship to increasing accessibility. So those five sort of pillars, that's what the FDA and us are racing to do as we launch this important product.

Great.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Thanks, Geoff.

Next question, please.

Operator

Chris Schott, JP Morgan.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Great. Thanks so much for the question. I guess with the pipeline derisking we've seen over the past year, can get any directional views or updated color on what you're envisioning Merck's earnings profile could look like as we move through the KEYTRUDA LOE? I know the focus of the company is more on the return to growth as we look out into the early 2030s. But just would be any thoughts on that transition period of earnings could look like over that, let's say, 2028 through early 2030s period. Thanks so much.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes, Chris, thanks for the question. As we've said in the past, we feel very good about the progress we're making with the over 20 products we have coming, $70 billion of commercial opportunity, and we've already started to see meaningful clinical derisking happening at a pace faster than we expected as well as good solid launches from the products that have launched.

So as we sit here today, we feel very good, as I've said in the past, -- we see that as the LOE period is more of a hill than a cliff. Nothing has changed in our view. I do think you're going to see a shallow dip with a fast return back to growth.

And candidly, if we look at it on a non-risk-adjusted basis, we still aspire to grow through it. There still is the potential more to do to achieve it, but we're working to get there. So as I sit here today, I feel very good about where we are and the progress we're making. Always more to do, but I feel good about the hand we have right now.

Operator

Great.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Thanks, Chris.

Next question, please.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Sanford C Bernstein & Co LLC - Equity Analyst*

Martine, thanks so much for the question today. Just one on LIPFENDRA, following up on the comments regarding kind of fixed-dose combinations. You highlighted rosuvastatin in your own Lp(a). Particularly with rosuvastatin, I would love to hear a little bit about how you're thinking about which dose you might consider. Is this just for those patients that need further escalation once they've made it to the 40 mg, recognizing there are some more adverse events there?

And then secondarily, are you looking at kind of continuing other combinations. We've heard GLP-1 combinations with the PCSK9s from peers and wanted to understand if you're still advancing or considering this opportunity. Finally, we haven't seen it yet pop up on TrumpRx. Just wondering kind of when we can expect that access channel to begin to become available? Thank you so much.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Why don't I let the TrumpRx go to Rob and then I'll take the rest of them?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes, we're excited about the opportunity. And as you know, in our MFN agreement, we did commit to putting Lifendra on Trump Rx. Those plans are underway. We're working on obviously getting the initial launch moving -- and as soon as we get that going, we'll get it on TrumpRx. So more to come on timing there.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. In relationship to your combination question, thank you very much. I mean right now, we have an oral PCSK9 that was designed based on the learnings of the antibodies, and we have been able to achieve up to 60% reduction in LDL cholesterol. We are hoping that with rosuvastatin, we would provide to be all the doses. But that combination, we think that we could get up to 80%.

I mean, if we could get up to 80% in a combination, that's a good day for medicine. So those are the sort of way that we think about the rosuvstatin for the LP liter way, we'll have to see what the LP(a) actually does in relationship to the reduction -- but we are hoping that in a patient who has high LPA that our combination will be able to give unprecedented CVOT outcomes in relationship to that.

In relationship to GLP, we have focused and said that we're focused on oral combinations. And there is clearly the ability to combine GLP and PCSK9. One of the things that we are very thoughtful about is that for the GLPs, you kind of do the step-up sort of dosing -- there's a lot of nausea and vomiting. So we can combine GLP plus PCSK9, but so far, we have not announced that, that's a combination that we're actively doing in the clinical trials website at this point.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great. Thanks, Courtney.

Next question, please.

Operator

Jason Gerberry, Bank of America.

Jason Gerberry - *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Just another LIPFENDRA question. How do you guys think about the opportunity for injectable PCSK9 switch versus is the bulk of the opportunity more in PCSK9 naive patients. And one thing that we've noticed with injectable PCSK9 relative to statins is pretty low use in the primary care setting. So how do you see kind of the availability of now an oral when you say democratize access to sort of adoption dynamics in the primary care setting?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. Thanks for the question. As we've said many times, we are not focusing this market on how do we take share from the injectable PCSK9s. If you look today, injectables only reach about 5% or less of the total market. We're sitting today here in the United States with 30 million people receiving lipid-lowering therapies, who are not at their recommended LDL levels and who -- even more who go untreated.

So the potential here is much bigger. What we are about is market expansion and helping people understand that cardiovascular disease continues to be the number one silent killer in the United States. We now have a drug that reduces LDL, which is one of the leading causes of atherosclerosis, leading to that cardiovascular death, by up to 60% on top of statins and everyone who is at risk should be on one of these medications.

So our goal is to expand, build the market, educate the market, and we're doing that with what we're doing with the guidelines. Obviously, this will all take time because there is inertia we're working against. But if we are successful, this frankly, should raise the water for all boats and not be one where we're taking share.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. And in relationship with the inertia, I think like, for example, the American Heart Association, the American College of Cardiology and other important associations realize the inertia. So they specifically changed the guidelines. And for right now, for example, for secondary ASCVD, they actually said the vast majority of that secondary ASCVD should be less than 55. There's another patient population in there that could be less than 70.

But the vast majority of people with secondary ASCVD should be less than 55, which is consistent with what Europe and other countries do. And in the prepared remarks, I did say that we are not just advancing this with an approval and a launch in the US, but we're under regulatory sort of discussions and review with the European Union as well as China.

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

And to add to the comments that Rob and Dean have made -- what we've seen thus far is extremely strong feedback from key scientific leaders, understanding the change in the guidelines, understanding what this product can do to help patients.

What we need to do is to translate that to the primary care setting. So that will take some time for us to do so. But our sales teams will be focused on ensuring the right education to the primary care setting as well as to patients on the importance of this medicine.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great. Thanks, Jason.

Next question, please.

Operator

Thank you.

Mohit Bansal, Wells Fargo.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Okay. Thank you very much for taking my question. I have a question regarding the flue drug program, CD388. Can you talk a little bit about what -- like what were the reasons why you decided to add 1 more seasonal northern hemisphere here. And I think the big question here is that was this decision based on any data you have seen? Or is it was just to satisfy with regulatory components rather than any confidence or lack of confidence in the data so far? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Thank you very much for that question. So just to highlight, this is a first-in-class once-per-season strain agnostic antiviral that we're doing for the prevention of flu, especially for those people who are at high risk. What we have said all along is that we plan to launch in 2029 and that, at the same time, I needed to do CMC work in relationship to getting it from three shots to two shots.

And so that's the rate-limiting step. I also said that between now and that time, I would do everything to have the most robust label and the robust packages that would allow us to have a broader footprint of sites to support a global registration and allow me to get the right value proposition in ex-US markets, especially something that we have to think in the day and age of MFN.

We've also added key secondary endpoint, which is all caused hospitalization, which I think will be critical in that pursuit. And finally, we're collecting data on subgroups and diverse circulating viral strains throughout the world as we do this. I was also very clear that I did not need and would not take an interim. I did not take or saw an interim. I am going to maximize what this molecule can do in the time frame that I need to such that I do nothing to imperil the launch timing of 2029, but that have the most robust label as well as robust real-world evidence that will be important for health authorities.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Maybe just to summarize all that, there's no change in our confidence nothing we've seen in data. This is all about strength of filing given the fact that we have the time because we do have to do the bridging study that Dean mentioned.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Thank you, Mohit.

Next question, please.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - *Bank of Montreal - Analyst*

Well, thank you so much for taking my question. Kind of a key theme from this call talked about the $70 billion a potential opportunity that you talked about over the next wave of products. What's the biggest risk to achieving this number? And conversely, which programs in the past six months have increased in your confidence? Thank you very much.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. Thanks for the question. I mean, obviously, I would say, if you look at where we have confidence from what we've seen, it's the fact that we're getting readouts faster than expected. When we talked about this back in January, we had highlighted sac-TMT as well as I-DXd as not having readouts until we got until 2027. We've now seen positive readouts from both.

The Tuli has read out faster than we expected. -- everything is moving. So as we sit here today, my confidence is higher than it was in January because we are seeing meaningful derisking. As you recall, at that time, we said there were 10 programs that represented 70% of the $70 billion. And the fact that so many of those are already having positive data.

So we are clinically derisking them, and we're seeing good launches of those that are underway including an accelerated launch of LIPENDRA by several months. It's hard to frankly point anything I'm worried about. I'm actually feeling quite bullish across the board. Got to knock on wood because things are going well. But credit to our scientific team and the strength of the clinical studies we put in place.

I feel very good about where we are.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great. Thanks, Evan.

Next question, please.

Operator

Asad Haider, Goldman Sachs.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Great. Thanks for taking the question. Maybe for Dean, on the PD-1 VEGF bispecific program, just any updates on how the pace of that development is progressing and how you're thinking about any potential read across from Summit HARMONi data coming up? And any update on where you are with potential combination trials with the PD-1 VEGF and your ADC assets?

And if I can just have a quick follow-up on TL1A, I know it's been discussed a lot already, but I just appreciate any context or color that you have on where you are with evaluating combination approaches, which is whether field and IBD seems to be moving towards, so how are you thinking about TL1A as a single agent in terms of its competitiveness versus these combo trials that J&J and AbbVie aggressively are pursuing? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. Thank you very much. In relationship to the PD-1 VEGF sort of story, the way that I think about it is there's a large body of data in relationship to where PD-1 is active, we ourselves have 44 and other people have others. So there's that. There's also a body of evidence of where VEGF is active as well. So you look at that overlap, and that's the place that you would go first.

The other sort of thing is that in some of those tumors, we have unique assets that can be combined and that we know are active. So we're going to focus our efforts on PD-1 VEGF in those three sort of Venn diagrams where we are uniquely able to move forward. We are very interested in following the Summit Akeso data. We think that that's important data for us to follow. But this is our sort of general strategy of PD-1 VEGF in relationship to PD-1, where VEGF is active and where we have unique assets that we know are active that could be combined.

In relationship to combination, you're exactly right. The whole immunology field is trying to think about how it can go to combinations. There has been lots of combinations in the past. TNF and IL-23, there are some evidence that, that would be important. So when we look at TL1A, we're looking to have one of the most effective, if not the most effective anti-cytokine, in whatever the indication we have -- but we think it's also very important to know that the safety profile is extremely clean, which then makes it possible to do combinations.

The combinations that you would do, for example, in IBD would be different than that of HS, which would be different than what you might do for rheumatoid arthritis. So for each one of those indications, we are looking at the profile of our TL1A and also asking what is the ideal combination for that indication.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great.

Thank you, Asad.

Next question, please.

Operator

Luisa Hector, Berenberg.

Luisa Hector - *Joh Berenberg Gossler & Co KG - Analyst*

Hello. Thanks for taking my question. It's another one on LIPFENDRA, please. Just the specific wording on the label, which talks about reduction, but then the cardiovascular outcomes trials have shown to be have shown that you get a reduction in LDL also leads to the reduction in events, specifically for monoclonal antibody PCSK9 inhibitors.

So just wanted to check whether that wording is a help or a hindrance as you speak to payers and as you go about your promotion? And then still on this CVOT topic. What is the timing of your LIPFENDRA CVOT? And can you comment on how you can ensure that GLP-1 use increasing for weight loss won't impact the result. Would you expect that to be balanced across arms if it does happen? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. So let me answer that question. I need to be a little bit careful to talk about what the intention of the FDA of putting note that they put in the label. I think it's going to be extremely helpful. We believe that LIPFENDRA should be added on top of statins.

So I think that's really important. We also know that the design principle, the design principles of LIPFENDRA, the agency understood was informed by the two antibodies out there.

So I think that it could be helpful from a commercial standpoint, but I think that was the way that we -- that the FDA and ours, the discussion was. I should emphasize that we do not have CLT right now, and we have an ongoing trial that will read out in 2029.

Peter Dannenbaum - *Merck & Co Inc - Vice President of Investor Relations*

Great. Thank you, Louisa. We're going to end the call there. I know there's a pure call about to start. So thank you all for your time and attention this morning.

We appreciate it. We look forward to catching up at your convenience.

Operator

Thank you. This does conclude today's conference. We thank you for your participation. At this time you may disconnect your lines.