Forward-looking statement of Merck & Co., Inc., Rahway, N.J., USA

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Thanks Peter. Good morning and thank you for joining today’s call.

We’ve begun 2024 with continuing momentum in our business. We’re harnessing the power of innovation to advance our deep pipeline and are maximizing the impact of our broad commercial portfolio for the benefit of patients. We drove strong growth across key therapeutic areas, executed strategic business development, and are now launching a significant new product in the cardiometabolic space, while also preparing for the potential approval and launch of two additional important candidates in vaccines and oncology.

We have significant opportunities ahead of us across all areas of our business, and we’re highly focused on realizing them. I continue to be inspired by the dedication of our talented global team which is working tirelessly to bring differentiated medicines and vaccines to patients through seamless scientific, commercial and operational execution.

In March, we received FDA approval for WINREVAIR, a first-in-class treatment for adults with pulmonary arterial hypertension, a rare, progressive and ultimately life-threatening disease. This marks the achievement of a significant milestone for our company, it exemplifies the value of our strategic priorities and demonstrates how our enduring commitment to our purpose is resulting in tangible benefits for patients.
Just over two years since adding WINREVAIR to our pipeline, our attention now turns to the execution of a strong commercial launch, where we have already seen prescriptions being written. We see a tremendous opportunity to positively impact the lives of people living with PAH. And further, the importance of this therapy to patients provides us with increased confidence in our ability to deliver sustainable long-term value for our shareholders.

Strategic business development focused on the best external science remains an important priority for our company. We’ve demonstrated that we can leverage our deep discovery prowess to identify important acquisition targets and then add significant value through our powerful clinical research engine, our regulatory expertise and our commercial scale, which together can serve to accelerate development and enable broad global access to important medical discoveries for patients in need.

Turning to our first quarter results, we achieved strong growth, reflecting robust demand for our innovative portfolio. We’re pleased to reflect this momentum in our updated full year guidance, which Caroline will speak to in a moment.

Turning to our broader research efforts, we’re focused on advancing our expansive and diverse pipeline of leading-edge programs for the benefit of patients.

In vaccines, we continue to pioneer new approaches to optimize disease prevention. In HPV, we’re building on the foundation set by GARDASIL to further reduce the global burden of certain HPV-related cancers and disease by potentially providing broader protection with a new multi-valent HPV vaccine, and by generating data to clearly
demonstrate whether or not a single dose of GARDASIL 9 provides comparable long-term protection to the approved three-dose regimen in males and females ages 16 to 26.

In pneumococcal, we presented additional compelling data for V116, a vaccine that is specifically designed to help protect against the majority of invasive pneumococcal disease in adults ages 65 and older, and look forward to its potential approval in June.

Each of these programs are platforms where we can provide meaningful protection to broad populations on a global scale.

In HIV, in partnership with Gilead, we shared promising data from our revitalized program for a once weekly combination of islatravir and lenacapavir in the treatment setting. We’re actively progressing our comprehensive clinical program which is focused on both treatment and prevention strategies to meet the evolving needs of the HIV community.

And in oncology, we initiated several late-stage programs of novel candidates from our diverse pipeline as we work to expand our impact for patients and reinforce our leadership position over the long term.

Finally, across our deep pipeline we have significant clinical momentum in a range of therapeutic areas. Cutting-edge science is at the core of who we are, and I’m confident that Merck is well positioned to deliver the next wave of important innovations and value to patients, shareholders and to all of our stakeholders.
In summary, our science-led strategy is delivering compelling proof points that we are creating a sustainable innovation engine that, with continued clinical success, will lead to a more diversified portfolio of growth drivers over the next decade and beyond.

I again want to recognize the enormous efforts across our global organization. My confidence is strong and growing that we’re well positioned to build on this momentum and drive patient impact and value creation this year and well into the future.

With that, I’ll turn the call over to Caroline.
Thank you, Rob. Good morning.

As Rob noted, we have had a strong start to the year with robust growth across our business, which reinforces the confidence we have in our outlook. We are also making strategic investments to leverage leading-edge science to save and improve lives around the world – positioning us to continue to deliver long-term value for patients, customers and shareholders.

Now, turning to our first quarter results.

Total company revenues were $15.8 billion, an increase of 9%, or 12% excluding the impact of foreign exchange. The impact from exchange is primarily driven by the devaluation of the Argentine peso which was largely offset by inflation-related price increases, consistent with market practice.

The following revenue comments will be on an ex-exchange basis.

Our Human Health business continued its momentum with double-digit growth of 13%, driven by Oncology and Vaccines.
Sales in our Animal Health business increased 4% across both companion animal and livestock products.

[SLIDE 11 - Oncology: KEYTRUDA continues to drive excellent growth]

Turning to the performance of our key brands.

In Oncology, sales of KEYTRUDA grew 24% to $6.9 billion driven by increased uptake from earlier stage cancers and continued strong demand from metastatic indications.

In the U.S., KEYTRUDA grew across a broad range of tumors. In earlier-stage cancers, the increase was largely attributable to non-small cell lung cancer following the launches of KEYNOTE-671 and KEYNOTE-091. In the metastatic setting, we saw strong uptake from the recent launch of KEYNOTE-A39 in first-line advanced urothelial cancer.

Outside the U.S., KEYTRUDA growth was driven by continued uptake in earlier stage cancers, including high-risk, early-stage triple negative breast cancer and renal cell carcinoma as well as continued strong demand from patients with metastatic disease. Inflation-related price increases consistent with market practice in Argentina also contributed to growth.

[SLIDE 12 - Oncology: Strong performance across broad portfolio]

Alliance revenue from Lynparza and Lenvima grew 7% and 10%, respectively.
WELIREG sales more than doubled to $85 million driven by the additional indication following FDA approval of LITESPARK-005 for certain patients with previously treated advanced renal cell carcinoma as well as by increased uptake in certain VHL disease-associated tumors.

[SLIDE 13 - Vaccines: Robust growth driven by GARDASIL]

Our vaccines portfolio delivered strong growth, led by GARDASIL, which increased 17% to $2.2 billion, driven by global demand. Sales also benefitted from the timing of shipments in China and CDC purchasing patterns in the U.S.

VAXNEUVANCE sales grew to $219 million driven by continued uptake of the pediatric indication in the U.S. and ongoing launches in international markets, particularly in Europe. In the U.S., VAXNEUVANCE sales also benefited from CDC purchasing patterns.

[SLIDE 14 - Animal Health: Growth across livestock and companion animal]

Sales in our Animal Health business grew 4%. Livestock sales growth was driven by price actions as well as demand for swine and poultry products. Companion animal growth reflects price actions.

[SLIDE 15 - Q1 2024 non-GAAP financial results summary]

I will now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis.
Gross margin was 81.2%, an increase of 4.3 percentage points driven by reduced royalty rates for KEYTRUDA and GARDASIL, which went into effect at the beginning of this year, as well as favorable product mix.

Operating expenses decreased 4% to $6.4 billion. A charge of $656 million related to the acquisition of Harpoon Therapeutics this quarter was lower than the $1.4 billion of charges a year ago for certain business development transactions. Excluding these charges, operating expenses grew 8%. We remain committed to investing appropriately to realize the promise of our expansive early- and late-phase pipeline and support the promotion of our key growth drivers.

Other expense was $87 million.

Our tax rate was 16.1%, including the impact from the Harpoon transaction, for which no tax benefit was recorded.

Taken together, earnings per share were $2.07, which includes a $0.26 negative impact from the charge related to Harpoon.

Now turning to our 2024 non-GAAP guidance.

The operational strength of our business has enabled us to raise and narrow our full year revenue guidance. We now expect revenue to be between $63.1 and $64.3 billion, reflecting strong year over year revenue growth of 5 to 7%,
including the negative impact from foreign exchange. At the midpoint of this range, operational strength in our business of approximately $600 million is partially offset by an incremental headwind from foreign exchange of approximately $400 million using mid-April rates, resulting in a full year negative impact from foreign exchange of approximately 3%.

Our gross margin assumption is now expected to be approximately 81%.

Our estimated range of operating expenses is between $25.2 and $26.1 billion, which does not assume additional significant potential business development transactions.

Other Expense is expected to be approximately $250 million.

Our full year tax rate is unchanged between 14.5% and 15.5%.

We assume approximately 2.55 billion shares outstanding.

Taken together, we are increasing and narrowing our expected EPS range to $8.53 to $8.65. This is a 7 cent increase at the midpoint, despite an incremental headwind from foreign exchange of approximately 5 cents using mid-April rates, resulting in a full year negative impact from foreign exchange of more than 30 cents.

[SLIDE 17 - Key modeling considerations]
As you consider your models, there are a few items to keep in mind.

The increase in our sales guidance is driven by the strong performance across our current product portfolio led by KEYTRUDA, which continues to experience growth from additional indications and patient demand.

For GARDASIL, second quarter ex-U.S. growth will be adversely impacted by shipment timing to China. This year we expect more evenly distributed quarterly shipments to China. Recall in 2023, we accelerated shipments from the second half to the first half of the year, which primarily impacted the second quarter. Over the near- and long-term, we remain confident in our ability to protect many more people from HPV related cancers and drive growth of GARDASIL.

Sales of LAGEVRIO in the first quarter were driven by an extended wave of COVID-19 in Asia-Pacific markets. LAGEVRIO continues to be an important treatment option for certain patients with COVID-19, though we continue to anticipate full year sales to be lower than last year.

[SLIDE 18 - WINREVAIR: Excited to bring a novel treatment option to adult patients with PAH]

We are excited to provide a novel treatment option for adult patients with pulmonary arterial hypertension, following the recent FDA approval of WINREVAIR.

We are seeing high interest from patient groups and a range of relevant prescribers.
We are also making good progress in enabling access. Several payers have already established coverage policies
consistent with the label and STELLAR study criteria, while others are in the process of developing their policies.

As we go forward, we intend to provide an appropriate level of transparency to enable insight into the impact we are
having on patients, including prescription data and revenues.

In summary, we are confident in a successful launch of WINREVAIR, consistent with our prior expectations, and look
forward to providing updates on our progress.

[SLIDE 19 - Remain committed to balanced capital allocation strategy]

Now turning to capital allocation, where our strategy remains unchanged.

We will prioritize investments in our business to drive near- and long-term growth. We will continue to invest in our
innovative pipeline – including the initiation of many new late-stage clinical trials across multiple novel candidates,
each of which has the potential to meaningfully address important unmet medical needs.

We remain committed to our dividend, and plan to increase it over time.

Adding compelling science to our pipeline through business development remains a high priority. We maintain ample
capacity given our strong investment grade credit rating and cash flow to pursue additional, science-driven, value-
enhancing transactions.
We will continue to execute a modest level of share repurchases.

To conclude, we remain confident in the near- and long-term outlook of our business driven by the global demand for our innovative medicines and vaccines, as well as our exceptional pipeline. Our unwavering commitment to use the power of cutting-edge science to improve the lives of the patients we serve has put us in a position of financial and operational strength. Our excellent execution and continued investments in innovation will enable us to deliver value to patients, customers and shareholders now and well into the future.

With that, I’d now like to turn the call over to Dean.
Dr. Dean Li – Merck & Co., Inc., President, Merck Research Laboratories

Thank you, Caroline.

In the first quarter, we continued to make progress with a steady cadence of clinical and regulatory milestones across our pipeline. Today, I will provide updates from our cardiometabolic disease portfolio, HIV and vaccine programs and close with advances in our oncology pipeline.

As Rob and Caroline noted, late last month we received approval from the FDA for WINREVAIR, our first-in-class activin signaling inhibitor, for the treatment of adults living with pulmonary arterial hypertension to increase exercise capacity, improve WHO functional class, and reduce the risk of clinical worsening events. WINREVAIR is a novel therapeutic option that targets a new PAH treatment pathway and is indicated to treat a broad PAH population. This approval marks a significant step towards our goal of transforming the treatment journey for many patients with PAH.

WINREVAIR is currently being reviewed by the European Medicines Agency with a decision anticipated in the second half of this year.

The Phase 3 ZENITH and HYPERION studies evaluating patients with more advanced disease and those earlier on in their disease journey, respectively, are ongoing, as well as the Phase 2 CADENCE trial, evaluating WHO Group 2 pulmonary hypertension, a type of left heart disease.

Our commitment extends to a broad range of pulmonary hypertension.
Informed by results from the Phase 2 cohort of the Phase 2 / 3 INSIGNIA-PAH study evaluating MK-5475, our inhaled soluble guanylate cyclase stimulator, and the STELLAR trial results for WINREVAIR, we have made the decision to focus the development of MK-5475 on WHO Group 3.1 pulmonary hypertension associated with COPD and not further proceed in PAH. PH-COPD is an area of significant need, with no specific therapies currently approved.

[SLIDE 22 - Progress across our HIV clinical program]

Our HIV pipeline continues to advance. Last month, presentations at the Conference on Retroviruses and Opportunistic Infections reinforced progress in our strategy to develop less frequent dosing regimens for managing and treating HIV. We believe these programs have the potential to help address adherence, stigma and other challenges faced by some individuals taking daily antiretroviral pills.

In collaboration with Gilead, safety and efficacy findings were presented from a Phase 2 study evaluating a once-weekly oral combination of islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor, and lenacapavir, a first-in-class capsid inhibitor, for the treatment of adults living with HIV. At 24 weeks, the trial met its primary endpoint and, in a secondary endpoint, maintained a high rate of viral suppression. Additional longer-term data will be presented at a later date.

In addition, safety and tolerability data were presented for MK-8527, a novel oral NRTTI candidate, from two Phase 1 trials that evaluated ascending single dose and multiple doses in adults 18 to 55 years old not infected with HIV. MK-8527 is being investigated as a potential monthly option for HIV pre-exposure prophylaxis.

[SLIDE 23 - Important updates across our vaccines programs]

Vaccines remain an important element of our pipeline and we are making progress across several programs.

Findings from multiple Phase 3 trials of V116, our investigational 21-valent pneumococcal conjugate vaccine, were presented at the Meeting of the International Society of Pneumonia and Pneumococcal Diseases last month.
V116 was shown to be immunogenic for all 21 serotypes covered by the vaccine, including in pneumococcal vaccine-naïve and vaccine-experienced adults as well as those at increased risk for pneumococcal disease.

If approved, V116 would be the first vaccine specifically designed to address the majority of serotypes that cause invasive pneumococcal disease in adults ages 65 and older. The target action date is June 17th. The meeting of the CDC’s Advisory Committee on Immunization Practices is scheduled shortly thereafter.

Since the initial approval of GARDASIL, a steady flow of clinical and real-world evidence has been generated to support the favorable efficacy, effectiveness, safety and long-term durability of protection against certain human papillomavirus related cancers and diseases in both males and females. Despite the proven public health benefit of HPV vaccination, the latest global cancer statistics from the International Agency for Research on Cancer indicate there is more to do to help increase vaccination rates. The latest statistics from 2022 ranked cervical cancer as the fourth most common cancer globally in terms of incidence and mortality in women, and the leading cause of cancer death in 37 countries, predominantly in sub-Saharan Africa, South America and South-East Asia regions.

At the EUROGIN Congress last month, we disclosed plans to build on the development of GARDASIL with a new clinical program to identify a novel multi-valent HPV vaccine candidate with the potential to extend protection against a broader array of HPV types. This includes several types known to disproportionately impact African and Asian populations and individuals of African and Asian descent. First-in-human studies are scheduled to start in the fourth quarter of this year.

In addition, we announced plans to conduct two randomized, double-blind, multi-year clinical trials in females and males ages 16 to 26 years to examine the short and long-term efficacy and immunogenicity of a single-dose of GARDASIL 9 versus the currently approved three-dose regimen. The goal of these studies is to generate data that clearly demonstrates whether or not a single dose of GARDASIL 9 provides comparable long-term protection to the approved regimen, while also satisfying the high standards required by regulatory authorities. The clinical trials are anticipated to start enrolling in the fourth quarter.
In oncology, we continue to focus on our three-pillared strategy comprised of immuno-oncology, precision molecular targeting and tissue targeting agents.

In immuno-oncology, September 2024 will mark a decade since the first approval of KEYTRUDA in metastatic melanoma. KEYTRUDA has since amassed approvals for 39 indications and continues to reinforce its reputation as a foundational therapy for certain types of cancer.

Building on the recent FDA approval for KEYTRUDA in combination with chemoradiotherapy for the treatment of FIGO 2014 Stage III through IVA cervical cancer, we recently announced that the pivotal KEYNOTE-A18 trial met its primary endpoint of overall survival, potentially providing a new standard of care for these patients. Our commitment to providing better options to prevent and treat cervical cancer remains strong.

Also in women’s cancer, the Phase 3 KEYNOTE-868 trial, known as NRG-GY018, was granted priority review by the FDA for the first line treatment of patients with primary advanced or recurrent endometrial carcinoma. The agency has set a target action date of June 21st.

Outside of the U.S., the European Commission approved KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant therapy, followed by adjuvant KEYTRUDA in adult patients with non-small cell lung cancer at high risk of recurrence based on the Phase 3 KEYNOTE-671 study. This marks the first approval in Europe for an anti-PD-1 / PD-L1 therapy as part of a treatment regimen for the neoadjuvant followed by adjuvant treatment of resectable non-small cell lung cancer based on positive overall survival results.
Next, to precision targeting.

Building on the success of KEYTRUDA for certain patients with non-small cell lung cancer, earlier this month, we announced the initiation of the Phase 3 clinical trial for MK-1084, an investigational oral selective KRAS G12C inhibitor, in combination with KEYTRUDA for the first line treatment of certain patients with metastatic non-small cell lung cancer.

The decision to proceed to Phase 3 was based upon early, promising evidence from a Phase 1 study showing anti-tumor activity and a manageable safety profile. KRAS is one of the most prevalent oncogenes in human cancers and G12C is the most common KRAS mutation in patients with non-small cell lung cancer.

In the tissue targeting space, we are moving with speed and rigor to advance a broad pipeline of antibody drug conjugates with multiple planned and ongoing Phase 3 trials.

In just over six months we have made remarkable progress in our collaboration with Daiichi Sankyo. Recently, we announced that the first patient has been dosed in the Phase 2 / 3 REJOICE-Ovarian01 trial evaluating the efficacy and safety of raludotatug deruxtecan, an investigational CDH6 directed DXd ADC, in patients with platinum-resistant ovarian cancer.

We are poised to begin a Phase 3 study evaluating ifinatamab deruxtecan, a B7-H3 directed ADC, in small cell lung cancer, a notably difficult-to-treat tumor type. New treatment options are desperately needed for these patients where the prognosis remains poor.

We are pleased to have recently completed the acquisition of Harpoon Therapeutics which provides novel T-cell engagers, including MK-6070, an investigational delta-like ligand 3 targeting T-cell engager, also being evaluated in certain types of small cell lung cancer, as well as neuroendocrine tumors.
Finally, please mark your calendars for the evening of Monday, June 3rd where we will host an investor event at ASCO in Chicago, and provide an update on our diverse portfolio of immuno-oncology, precision molecular and tissue targeting agents.

Looking forward, June promises to be a busy month with three regulatory action dates including:

- V116 for prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults
- KEYTRUDA for primary advanced or recurrent endometrial carcinoma and
- patritumab deruxtecan for advanced EGFR-mutated non-small cell lung cancer

We continue to execute on our strategy, with a focus on operational excellence and look forward to providing further updates on our progress throughout the year.

And now I will turn the call back to Peter.