# Merck & Co., Inc, Rahway, NJ USA
# First-Quarter 2025 Sales and Earnings
# Prepared Remarks

April 24, 2025

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

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**Mr. Rob Davis - Merck & Co., Inc., Rahway, NJ, USA, Chairman and Chief Executive Officer**

[SLIDE 4 - Strategy & Business Update]

Thank you, Peter.

Good morning and thank you for joining today's call.

Our company made strong progress to start the year, with increasing contributions from our newer commercialized medicines and vaccines and continued advancement of our pipeline. We're working with focus and urgency to both realize the full potential of our near-term opportunities and to rapidly progress the next wave of innovation that will positively impact the lives of the patients we serve, and drive future value creation for all of our stakeholders.

In what is a dynamic global environment, we continue to work with regulators and policymakers around the world to tackle some of the biggest health challenges, and ensure patient and customer access to our life-saving and life-improving medicines and vaccines.

Over the last few years, we've been evolving our supply-chain strategy in an effort to better balance our manufacturing footprint, which aligns well with the new administration's efforts to regrow the U.S. manufacturing base. This can be seen by our efforts beginning with the passing of the Tax Cut and Jobs Act, and accelerated since the pandemic. Of note, since 2018, we've invested $12 billion in U.S. manufacturing, and we've committed to an additional $9 billion-plus for projects through 2028. Our investments are leading to more of our products for U.S. patients being manufactured in the U.S., as well as more opportunities for export.

[SLIDE 5 - Q1 2025 total company performance and pipeline progress]

Turning to our first quarter results, our performance was in-line with our expectations, with revenue of $15.5 billion reflecting strength in Oncology, Animal Health and increasingly meaningful contributions from the continued strong launches of WINREVAIR and CAPVAXIVE. As we look forward, we remain confident in our outlook for improved growth in the second half of the year. Considering the current environment, we are maintaining our full-year revenue and EPS guidance excluding business development charges, which Caroline will speak to in more detail. The benefit from improved foreign exchange is offset in part by approximately $200 million of expected cost from tariffs implemented to date primarily between the U.S. and China, and to a lesser degree Canada and Mexico. With respect to potential additional tariffs by the U.S. specifically on pharmaceuticals, our global supply chain and current inventory levels put us in a good position to navigate potential near-term impacts. And our ongoing efforts to locate more manufacturing in the U.S. for U.S. supply, including for the majority of our upcoming new products, will help us manage over the medium and long-term.

As I look at how we've started 2025, I'm proud of the continued advancement of our research efforts. Recently, we presented important Phase 3 data for WINREVAIR in additional patient populations, supporting the strong potential for this product to improve the lives of more people living with pulmonary arterial hypertension. In addition, our HIV pipeline is now coming into sharper focus, with data presentations from two Phase 3 trials of islatravir-based regimens. And new clinical trial starts and regulatory submissions in oncology reinforce our belief that we are well-positioned for long-term leadership, with the promise of helping even more patients with cancer.

[SLIDE 6 - Delivering the next wave of innovation]

The success of biopharmaceutical innovation on the scale we're driving is not measured in quarters, but rather in years. And we're seeing compelling progress on this front.

Since 2021, we've nearly tripled our late-phase pipeline through both the advancement of internally-discovered compounds as well as the completion of numerous important business development transactions across multiple therapeutic areas of great unmet need including oncology, cardiometabolic, ophthalmology and immunology. Together, our efforts have resulted in an expanded late-phase pipeline comprising programs having potential commercial opportunity of over $50 billion by the mid-2030s.

WINREVAIR and CAPVAXIVE represent the initial launches from this robust pipeline of 20 promising potential new growth drivers we expect to come to market over the next few years, almost all of which have blockbuster potential. Looking ahead, we have a rich slate of data readouts, presentations, filings and additional approvals. Our pipeline includes some of the world's most scientifically advanced modalities, and Dean and our research colleagues are advancing several molecules that have foundational, multi-indication potential in areas of significant unmet need.

We've also deepened and extended our commitment to early research and development, and over the next few years expect many of these programs to advance to Phase 2 and to become visible to you.

Thanks to the incredible efforts of our dedicated team and the strong progress we are achieving, we believe that we're well positioned to successfully navigate through the KEYTRUDA LOE period.

And our work is not finished. Science and value-driven business development remains a top priority, and we continue to assess opportunities with urgency and an eye toward driving near-and long-term growth and value creation.

[SLIDE 7 - Confident in strategic direction]

In summary, our results reflect the continued demand for breakthrough therapies and novel solutions that can address global health challenges. We're leveraging our scientific leadership to deliver the next wave of innovation that can save and improve lives around the world. Our commercial performance today continues to enable the advancement of our pipeline, and in turn, create long-term value for patients, customers and shareholders.

We remain confident in our strategic direction, our commitment to research and development as the source for sustainable value-creation, and our enduring promise to positively impact patients.

With that, I'll turn the call over to Caroline.

**Ms. Caroline Litchfield – Merck & Co., Inc., Rahway, NJ, USA, Chief Financial Officer**

[SLIDE 8 - Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 9 - Q1 worldwide performance driven by demand for our innovative portfolio]

As Rob noted, first quarter performance was in-line with our expectations. The fundamentals of our business remain healthy, fueled by robust global demand for our innovative portfolio. We are confident in our ability to deliver on the

promise of today, while we make strategic investments to enable the innovations of tomorrow, leveraging leading-edge science to save and improve lives around the world.

Now, turning to our first quarter results.

Total company revenues were $15.5 billion, a decrease of 2%, or an increase of 1% excluding the impact of foreign exchange.

As expected, results were impacted by a decline in sales of GARDASIL in China of approximately $1.1 billion, reducing growth excluding foreign exchange by 7 percentage points. Excluding these sales and the impact from foreign exchange, global growth was 8%, primarily driven by new products, WINREVAIR and CAPVAXIVE, as well as strength in oncology and Animal Health.

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

[SLIDE 10 - Oncology: KEYTRUDA continues to benefit patients and drive growth]

In Oncology, sales of KEYTRUDA grew 6% to $7.2 billion. Global growth was driven by increased uptake from earlier-stage cancers and robust demand from metastatic indications. In the earlier-stage setting, growth was driven by increased utilization in resectable triple negative breast cancer, renal cell carcinoma and non-small cell lung cancer. In metastatic disease, we saw increased use of KEYTRUDA in combination with Padcev in first-line, locally advanced urothelial cancer, as well as KEYTRUDA in combination with chemotherapy in first-line endometrial cancer. In the

U.S., as previously communicated, growth was negatively impacted by approximately $250 million due to the timing of wholesaler purchases.

[SLIDE 11 - Oncology: Important contributions across broad portfolio]

Our broader oncology portfolio achieved strong growth driven by WELIREG with sales increasing 63% to $137 million due to increased use in certain patients with previously treated advanced renal cell carcinoma in the U.S. WELIREG is now the market leader in the treatment of patients with advanced renal cell carcinoma following prior therapies.

[SLIDE 12 - Vaccines: Broad vaccines portfolio driving global impact]

In Vaccines, GARDASIL sales were $1.3 billion, a decrease of 40%, driven by China where we see elevated channel inventories and continued soft demand. In the rest of the world, growth was 16%. In the U.S., sales benefitted from price and demand. Outside the U.S. and China, growth was driven by higher overall demand including from the catch-up cohort in Japan.

In pneumococcal, CAPVAXIVE sales were $107 million, driven primarily by demand from the retail pharmacy segment. We have made great progress in the early stages of this launch and are well positioned to help protect adults from invasive pneumococcal disease.

VAXNEUVANCE sales increased 7%, as growth from launches in international markets was partially offset by competitive pressures in the U.S.

[SLIDE 13 – Cardiovascular: Successful ongoing launch of WINREVAIR]

In Cardiovascular, the strong momentum of the ongoing launch of WINREVAIR continues with global sales of $280 million.

The launch continues to perform in-line with our high expectations, and we remain excited about the significant benefit WINREVAIR is providing for patients.

In the U.S., more than 1,400 new patients received a prescription during the quarter. We are continuing to see a steady increase in the percentage of new prescriptions for patients whose background PAH therapies do not include a prostacyclin.

Outside the U.S., we continue to progress with launches and reimbursement.

Overall, we are very pleased with the uptake of WINREVAIR and look forward to positively impacting the lives of more patients with pulmonary arterial hypertension. The strength of the additional data from the clinical development program, which Dean will speak to in a moment, provides further confidence to physicians and patients and supports our belief in WINREVAIR's significant potential.

[SLIDE 14 – Animal Health: Robust growth driven by demand for livestock products]

Our Animal Health business delivered another quarter of robust growth, with sales increasing 10%. Livestock growth reflects higher demand across all species as well as the benefit from timing of sales in ruminants and sales from the aqua portfolio acquired from Elanco. Companion animal sales growth reflects price.

[SLIDE 15 – Q1 2025 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 82.2%, an increase of 1.0 percentage point driven by favorable product mix.

Operating expenses decreased to $6.1 billion. There were no significant business development expenses in the quarter, compared with a $656 million charge a year ago. Excluding this charge, operating expenses grew 6%, reflecting disciplined investments in support of our robust early- and late-phase pipeline and key growth drivers.

Other expense was $75 million.

Our tax rate of 14.2% benefited from certain discrete items.

Taken together, earnings per share were $2.22.

[SLIDE 16 – Updated 2025 financial outlook]

Now turning to our 2025 non-GAAP guidance.

As Rob noted, we are maintaining our full year revenue guidance of between $64.1 and $65.6 billion. This range represents growth of 1 to 3%, excluding a negative impact from foreign exchange of approximately 1% using mid-April rates.

Our gross margin assumption is now approximately 82.0%. This includes approximately $200 million in costs related to the tariffs implemented to date.

Operating expenses are now assumed to be between $25.6 and $26.6 billion. This range now includes a $200 million payment related to the license agreement with Hengrui Pharma, which is expected to close in the second quarter. It also includes the $300 million tech transfer payment related to LaNova, which remains in our guidance, but has not yet occurred. As a reminder, our guidance does not assume additional significant potential business development transactions.

Other Expense is expected to be between $300 and $400 million.

We assume a full year tax rate between 15.5% and 16.5%.

We assume approximately 2.51 billion shares outstanding.

Taken together, we expect EPS of $8.82 to $8.97. This range includes a negative impact from foreign exchange of more than 20 cents, using mid-April rates.

Recall our prior guidance range was $8.88 to $9.03. If not for the one-time charge of $200 million related to Hengrui, or $0.06 per share, our guidance range is unchanged.

[SLIDE 17 – Key modeling considerations]

As you consider your models, there are a few items to keep in mind.

Following the successful HPV catch-up vaccination program in Japan, we expect uptake to moderate as future sales will predominantly reflect the primary age cohort. As a result, global GARDASIL growth excluding China, while still strong, is anticipated to slow going forward.

For KEYTRUDA, the timing of wholesaler purchasing in the U.S. negatively impacted sales by approximately $250 million in the first quarter and is expected to positively impact sales by roughly the same amount in the third quarter.

As a reminder, we lowered the list prices for the JANUVIA family of products in the U.S. at the beginning of 2025. The lower list prices reduce the rebate amount our company pays to Medicaid and as a result, we expect higher net sales for these products in 2025. First quarter sales of the JANUVIA family of products in the U.S. also benefitted by more than $100 million from favorable one-time true ups.

[SLIDE 18 – Remain committed to balanced capital allocation strategy]

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

We will continue to prioritize investments in our business to drive near- and long-term growth and returns for our shareholders.

Our company is rapidly moving toward a future with a more diversified portfolio of growth drivers. As we continue to assess our business, we are likely to take actions that will seek to maximize the potential of these opportunities by investing with discipline, while transforming our business to drive continuous productivity across the company. We intend to communicate more about these efforts later this year.

We remain committed to our dividend, with the goal of increasing it over time.

Business development remains an important priority. We continue to actively evaluate opportunities to execute additional science-driven, value-creating transactions.

We increased our share repurchases in the quarter to approximately $1.2 billion, similar to the full year amount in 2024. We expect the pace of repurchase to continue at this level given our strong balance sheet. Our top priority, however, remains to invest fully behind our growth drivers and pipeline, as well as business development.

To conclude, we are confident in the outlook for our business driven by our strong portfolio and exceptional pipeline. With investment in innovation and our ongoing focus on execution, we are well positioned 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 Y. Li - Merck & Co., Inc., Rahway, NJ, USA, President, Research Laboratories**

[SLIDE 19 - Research Update]

Thank you, Caroline. Good morning.

Progress continued in the first quarter, with a steady cadence of positive clinical and regulatory milestones. Today, I will provide updates from programs in cardiometabolic disease, HIV, vaccines and will close with oncology.

[SLIDE 20 - Broadening our impact in cardiometabolic research]

Starting with cardiometabolic disease.

Since its first approval just over a year ago, WINREVAIR, the first and only activin signaling inhibitor for the treatment of pulmonary arterial hypertension, has continued to generate clear evidence of benefit for a broad spectrum of patients with PAH. Last month, detailed results from the Phase 3 ZENITH trial evaluating high-risk patients with PAH, were presented at the American College of Cardiology's ACC.25 conference. The findings showed an important 76% risk reduction in the composite of all-cause death, lung transplantation and PAH hospitalization with the Kaplan Meier curve illustrating an early and sustained separation, as early as four to five weeks after initiation of WINREVAIR. Results were published simultaneously in the New England Journal of Medicine.

ZENITH is the first positive trial in PAH with a primary endpoint comprised entirely of major outcome measures and the first to be stopped early for overwhelming efficacy. The significant reduction in risk of major morbidity and

mortality events reinforces WINREVAIR's efficacy. The safety profile in ZENITH was generally consistent with that observed in previous studies.

As a reminder, prompted by the early stoppage of the ZENITH study and a review of the totality of data from the WINREVAIR clinical program to date, the External Steering Committee determined that the Phase 3 HYPERION study had lost clinical equipoise and should also be stopped early. All participants have now been given the option to receive WINREVAIR. We anticipate sharing data from the HYPERION study later this year.

The clinical benefit and statistically significant improvement observed across a range of patients receiving WINREVAIR in the STELLAR and ZENITH studies, provide strong evidence for its potential to be practice changing and to alter the trajectory for patients with this devastating disease.

The clinical program also includes the ongoing long-term extension study, SOTERIA, as well as the Phase 2 LIGHTRAY study, which is being conducted to support the development of an autoinjector option for patients. In addition, the Phase 2 CADENCE study exploring the potential in pulmonary hypertension due to left heart disease, a specific segment within WHO Group 2, has completed recruitment and is on track for completion later this year.

We continue to bolster our portfolio of candidates targeting cardiometabolic disease. In March, we announced an exclusive license agreement with Hengrui Pharma, for HRS-5346, an investigational oral small molecule Lipoprotein(a), or Lp(a) formation inhibitor. Elevated levels of Lp(a) in the blood are an inherited atherosclerotic cardiovascular disease risk factor for which there are currently no approved treatment options.

Hengrui recently initiated a Phase 2 clinical trial for HRS-5346 in China. We are planning a robust global clinical development program that expands and complements our broader cardiometabolic pipeline.

[SLIDE 21 – Progress across vaccines and infectious disease programs]

Next to vaccines.

We continue to secure regulatory approvals globally for CAPVAXIVE. More recently, the European Commission granted approval for active immunization for the prevention of invasive disease and pneumonia caused by streptococcus pneumoniae in adults. This is based on safety and immunogenicity data from multiple pivotal studies in the program and is the fourth approval for CAPVAXIVE, building on prior approvals in the U.S., Canada and Australia.

GARDASIL 9 was recently approved by the National Medical Products Administration of China to help prevent certain HPV-related cancers and diseases in males 16 to 26 years old, making it the first 9-valent HPV vaccine approved for certain males and females in China.

Turning to HIV.

Detailed results from two pivotal Phase 3 trials evaluating adults with virologically suppressed HIV-1 who switched to the investigational, once-daily, oral fixed dose combination of doravirine and islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor were presented at the Conference on Retroviruses and Opportunistic Infections in March. In both trials, at Week 48, doravirine and islatravir met the primary efficacy success criteria for non-inferiority to comparator antiretroviral therapies and primary safety objectives.

The combination of doravirine and islatravir is the first complete two-drug regimen without an integrase strand transfer inhibitor to demonstrate comparable efficacy and safety to the three-drug InSTI-based regimen, Biktarvy, in a Phase 3 trial. We plan to submit applications for marketing authorization to regulatory agencies by mid-year.

These data and additional programs evaluating longer-acting regimens for treatment and pre-exposure prophylaxis underscore our ongoing commitment to find new options that address the evolving needs of people at risk of and living with HIV.

[SLIDE 22 – Continuing to advance our broad oncology program]

Moving to oncology.

Last month, at the European Lung Cancer Congress, we announced detailed findings from a pivotal Phase 3 trial, evaluating a six-week dosing regimen of the investigational subcutaneous fixed dose combination of pembrolizumab and berahyaluronidase alfa, with chemotherapy, versus intravenous KEYTRUDA with chemotherapy. The study met its dual primary endpoints, demonstrating non-inferior pharmacokinetics for subcutaneous pembrolizumab versus intravenous KEYTRUDA. Consistent results were also reported for efficacy and safety endpoints across treatment arms. The median time for administration of subcutaneous pembrolizumab given every six weeks was approximately two minutes, a meaningful reduction compared to the time needed to administer KEYTRUDA as an IV infusion.

Of note, at the American Association for Cancer Research meeting next week, data from another study evaluating a three-week dosing regimen will be presented.

The FDA has set a PDUFA date of September 23rd and the European Medicines Agency is reviewing the application. We are seeking approval for both a six-week and a three-week dosing option.

If approved, subcutaneous pembrolizumab would provide an important option for healthcare systems and patients, most notably for those in earlier stage settings where KEYTRUDA continues to have an unparalleled breadth of approvals and a significant impact for patients.

The FDA granted priority review for KEYTRUDA as part of a perioperative treatment regimen for patients newly diagnosed with stage III or IVA, resectable, locally advanced head and neck squamous cell carcinoma based on the KEYNOTE-689 study. The PDUFA date is June 23rd. As a reminder, this is the first trial in twenty years for patients with resected, locally advanced head and neck squamous cell carcinoma and the first Phase 3 trial to show a statistically significant event-free survival benefit of neoadjuvant plus adjuvant therapy for newly diagnosed patients in this setting. Earlier intervention has the potential to improve outcomes and reduce the burden of disease in this patient population.

Results will be submitted to regulatory agencies and, if approved, this would mark the tenth indication of a KEYTRUDA based regimen for the treatment of an earlier stage cancer. Detailed findings will be presented at the American Association for Cancer Research meeting next week, where it may be important to scrutinize the Kaplan Meier plot for the divergence of the curves as a sign of event free survival benefit.

Based on the LITESPARK-004 and LITESPARK-005 trials, we received the first conditional European Commission approval for WELIREG for the treatment of adults with:

- von Hippel-Lindau disease who require therapy for associated, localized renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, and
- advanced clear cell RCC that progressed following two or more lines of therapy that included a PD-1 or a PD-L1 inhibitor and at least two vascular endothelial growth factor targeted therapies.

[SLIDE 23 – Key upcoming dates and milestones]

Please mark your calendars for the evening of Monday, June 2nd for an investor event at the 2025 ASCO Annual Meeting in Chicago, where we will provide an update on pipeline progress and the latest on our oncology strategy.

Finally, we have a number of near-term milestones to look out for this year, including:

- In oncology, upcoming PDUFA dates for:

  - KEYNOTE-689 in earlier stage head and neck squamous cell carcinoma in June
  - subcutaneous pembrolizumab in September.
- In RSV, the upcoming PDUFA for clesrovimab in June.
- In the cardiometabolic space:
  - Anticipated results from three Phase 3 registration enabling studies evaluating our oral PCSK9 inhibitor candidate enlicitide for the treatment of hypercholesterolemia, and
  - the scheduled Fall primary completion date of the Phase 2 CADENCE study, evaluating WINREVAIR in pulmonary hypertension due to left heart disease
  - as well as the final readout from the Phase 3 HYPERION study.
- Lastly, in HIV:
  - filing for our doravirine and islatravir regimen, and
  - results from the Phase 2a trial for MK-8527, a novel NRTTI candidate, as a potentially important once-monthly oral option for pre-exposure prophylaxis.

In closing, we continue to advance our pipeline and execute on our strategy with speed and rigor. I look forward to providing further updates on our progress.

And now I turn the call back to Peter.