Merck & Co., Inc Q4 2023 Earnings Prepared Remarks

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

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Mr. Rob Davis – Merck & Co., Inc., Chairman and Chief Executive Officer

[SLIDE 4 - Strategy and Business Update]

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

[SLIDE 5 - Committed to saving and improving lives around the world]

2023 was another very strong year for Merck. I am extremely pleased by the progress we've made to develop and deliver transformative therapies and vaccines that will help save and improve lives around the world. We reached more than 500 million people with our medicines last year alone, over half of which were through donations. We also made substantial investments in research and development in our ongoing effort to discover and bring forward to patients the next generation of impactful innovations - over $30 billion in total including the cost of certain acquisitions and collaborations. As we move forward, I'm confident that our strong momentum will continue, underpinned by the unwavering dedication of our talented global team.

[SLIDE 6 - Delivered on our key strategic priorities in 2023]

We're realizing the benefits of our sustained focus on key strategic priorities. The excellence of our commercial and operational execution enables us to deliver tangible value in the short term, while we invest in new innovations and strengthen our pipeline for the long-term. In 2023, we advanced important clinical programs and augmented our pipeline with promising business development, such as the acquisition of Prometheus and our collaboration with Daiichi Sankyo. Guided by our science-led strategy, I'm confident that the focused and disciplined business decisions we make and the actions we take will lead to sustainable benefits for the patients we serve … and long-term growth and value for our shareholders.

[SLIDE 7 - Strong 2023 underlying performance and 2024 initial guidance]

Turning to our results and initial outlook for 2024.

We delivered excellent underlying growth in 2023, reflecting robust demand for our innovative portfolio. I'm pleased to share that we expect continued strong growth in 2024 driven by demand for our key products, which Caroline will speak to momentarily.

[SLIDE 8 - Maximizing potential impact for patients with our expansive pipeline]

Turning to the progress we're making in research, we're currently pursuing programs across a more diverse set of therapeutic areas with high unmet need, and across more modalities, than at any time in recent memory. This year, we'll remain keenly focused on advancing our broad and diverse pipeline, which includes two launches that will address critical health needs and have blockbuster commercial opportunity.

In cardiometabolic, we're very excited by the anticipated FDA action on our application for sotatercept in the U.S., which we believe has the potential to transform the treatment journey for many patients suffering from pulmonary arterial hypertension. Our commercial and manufacturing teams are fully prepared for the strong uptake we expect. Sotatercept is an important component of our growing cardiometabolic pipeline, which we believe has significant long-term potential.

In vaccines, the FDA accepted for priority review our filing for V116. If approved, V116 would be the first vaccine specifically designed to address the majority of invasive pneumococcal disease in adults ages 65 and older. Based on its compelling profile, V116 has the potential to become an important new preventative option for adults and we believe it can achieve majority market share in this setting. We look forward to a potential approval in June.

And in oncology, we continue to expand into additional tumor types and earlier stages of certain cancers, as well as progress our increasingly broad pipeline of novel candidates. We have achieved substantial diversification with a dramatically expanded set of late-stage programs, which Dean will speak to. I'm confident that Merck is well positioned to provide important innovation to patients and sustain its leadership in oncology well into the future.

I know Dean and his team are energized by our progress and are prepared to build on the success we've had in 2023 to further advance Merck's pipeline and bring transformative innovation to patients this year and beyond.

[SLIDE 9 - Expanding robust pipeline with opportunity for patient impact and value creation well into the next decade]

In summary, our science led strategy, which keeps the patient at the center of everything we do, is delivering important advancements and helping us build a sustainable growth engine for our company. We've made considerable progress over the past year in advancing and expanding our pipeline, which has resulted in substantially increased long-term commercial opportunities. We've taken meaningful steps to diversify and position ourselves for sustained leadership in Oncology, while also building one of our deepest and broadest pipelines across discovery and development in our recent history outside of Oncology, and notably in Cardiometabolic and Immunology.

Further, we also expect to benefit from promising late-stage programs across our Vaccines, Neurosciences, HIV and Animal Health pipelines, a robust set of early-phase programs, and the potential to add exciting innovation through

future science-led business development. As a result, we are increasingly confident that we're well positioned to drive patient impact and value creation this year and well into the next decade.

I would again like to thank our global teams for their commitment to strong research, commercial and operational execution. With a concerted focus on achieving continued excellence, I'm very confident in our ability to deliver short- and long-term stakeholder value. I look forward to providing future updates on our progress and impact.

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

Ms. Caroline Litchfield – Merck & Co., Inc., Chief Financial Officer

[SLIDE 10 - Business/Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 11 - Strong underlying Q4 and 2023 worldwide sales growth]

2023 was another impactful year for our company. We delivered strong revenue growth of 12%, excluding LAGEVRIO and foreign exchange. Growth was driven by robust performance across Oncology, Vaccines and Animal Health. We remain confident in our ability to continue to deliver strong results in the near-term, while making disciplined investments in innovative science which will drive long-term value for patients and shareholders.

Now, turning to our fourth quarter results.

Total company revenues were $14.6 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered strong growth of 13%.

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

Our Human Health business sustained its momentum. Excluding LAGEVRIO, growth was 14%, driven by Oncology and Vaccines.

Sales in our Animal Health business increased 4% driven by companion animal products.

[SLIDE 12 - Oncology: KEYTRUDA continues to benefit patients globally]

Turning to the performance of our key brands.

In Oncology, sales of KEYTRUDA grew 22% to $6.6 billion. Global growth was driven by increased uptake in earlier stage cancers, including triple negative breast cancer and renal cell carcinoma, with particularly strong growth in international markets due to the more recent launches of these important indications. Growth was also driven by the strong global need of patients with metastatic disease.

We continue to be encouraged by the positive impact our recent approvals are having on certain patients with earlier stage non-small cell lung cancer. In the U.S., we have made considerable progress in helping to improve drug treatment rates and have further increased our leadership position in the adjuvant setting.

We also received positive feedback from healthcare providers following the recent launch of KEYNOTE-A39 in advanced urothelial cancer. With this approval, KEYTRUDA in combination with Padcev is now indicated for first-line advanced urothelial cancer patients regardless of cisplatin eligibility. Based on the outstanding clinical data, we believe this regimen has the potential to transform the standard-of-care for these patients.

[SLIDE 13 - Oncology: Strong performance across broad portfolio]

Alliance revenue from Lynparza and Lenvima grew 8% and 5%, respectively.

WELIREG sales grew 78% to $72 million driven by increased uptake in VHL-associated tumors. We are excited by the opportunity to provide a new treatment option for certain patients with previously treated advanced renal cell carcinoma, following the recent approval based on the LITESPARK-005 study.

[SLIDE 14 - Vaccines: Robust growth driven by GARDASIL]

Our vaccines portfolio delivered excellent growth, led by GARDASIL, which increased 27% to $1.9 billion, driven by global demand, particularly in China. In the U.S., GARDASIL sales benefited from CDC purchasing patterns.

VAXNEUVANCE sales grew to $176 million driven by ongoing launches in Europe and continued uptake of the pediatric indication in the U.S. As a reminder, fourth quarter 2022 sales in the U.S. benefited from inventory stocking in preparation for the pediatric launch.

[SLIDE 15 - Hospital: Continued patient impact across portfolio]

In our Hospital Acute Care portfolio, BRIDION sales declined 3%. Increased market share among neuromuscular blockade reversal agents in the U.S. was more than offset by the impact of generic entrants in international markets, particularly in Europe.

[SLIDE 16 - Animal Health: Solid growth driven by companion animal]

Our Animal Health business delivered another solid quarter, with sales increasing 4%. Companion animal sales grew 12% driven by the BRAVECTO line of products due to strong underlying demand and timing of purchases. Livestock sales were flat reflecting favorable price actions, offset by the timing of ruminant product purchases.

[SLIDE 17 - Q4 2023 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 77.2%, an increase of 1.5 percentage points largely due to favorable product mix, including a benefit from lower sales of LAGEVRIO.

Operating expenses increased to $11.6 billion, including a $5.5 billion one-time charge related to our collaboration with Daiichi Sankyo. Excluding this charge, operating expenses grew 8%, reflecting disciplined investment in support of our expansive early- and late-phase pipeline and key growth drivers.

Other expense was $174 million.

Our tax rate was approximately 114%, which reflects the impact of the charge related to Daiichi Sankyo. Excluding this charge, the underlying tax rate was 13.1%.

Taken together, earnings per share were $0.03, which includes a $1.69 negative impact from the charge related to Daiichi Sankyo.

[SLIDE 18 - Initial 2024 financial outlook implies strong growth]

Now turning to our 2024 non-GAAP guidance.

We expect another year of strong growth driven by key marketed products, and will begin to benefit from the anticipated launches of impactful new products such as sotatercept and V116. We project revenue to be between $62.7 billion and $64.2 billion, representing growth of 4% to 7%. This growth includes a negative impact from foreign exchange of approximately 2% using mid-January rates. The headwind is primarily due to the devaluation of the Argentine peso, which we expect will largely be offset by inflation related price increases, consistent with market practice.

Our gross margin assumption is approximately 80.5%, which includes the benefit from reduced royalties paid on KEYTRUDA and GARDASIL.

Operating expenses are assumed to be between $25.1 billion and $26.1 billion, which includes an approximate $650 million one-time charge related to the announced acquisition of Harpoon Therapeutics. As a reminder, our guidance does not assume additional significant potential business development transactions.

Other Expense is expected to be approximately $200 million.

We assume a full year tax rate between 14.5% and 15.5%.

We assume approximately 2.54 billion shares outstanding.

Taken together, we expect EPS of $8.44 to $8.59. This range includes an approximate $0.26 per share charge related to the planned acquisition of Harpoon Therapeutics, which is not tax deductible, and a negative impact from foreign exchange of approximately $0.25, using mid-January rates, including the impact from Argentina.

[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 are excited by the significant progress our team has made to advance and augment our innovative pipeline in 2023. In 2024, we will increase this investment, including the initiation of more late-stage clinical trials across multiple novel candidates, each of which has significant potential to address important unmet medical needs.

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

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 going forward.

We will continue to execute a modest level of share repurchases.

To conclude, we enter 2024 with confidence in the outlook for our business in the near- and long-term. Global demand for our innovative medicines and vaccines remains strong, and we are excited about our expansive pipeline. We are in a

position of financial and operational strength as a direct result of our long-standing commitment to science in order to improve the lives of the patients we serve. Our continued investments in innovation and excellent execution will enable us to deliver value to patients, customers and shareholders 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

[SLIDE 20 - Research Update]

Thank you, Caroline.

Good morning. Today, I will provide notable R&D updates since our last earnings call and a brief summary of 2023 accomplishments.

Momentum in the pipeline remains strong. Progress is spanning both early and late phase programs across multiple therapeutic areas.

[SLIDE 21 - Diversifying our oncology program and executing on our strategy]

Starting with oncology, we are diversifying our portfolio and executing on our strategy which is broadly based on three strategic pillars: immuno-oncology, precision molecular targeting and tissue targeting.

[SLIDE 22 - Ongoing commitment to harnessing the power of immuno-oncology]

In immuno-oncology, we remain committed to the development of KEYTRUDA and further transforming cancer care to address the needs of certain patients. In the fourth quarter, we received approvals from both the FDA and the European Commission in two gastrointestinal indications: One in combination with chemotherapy, for the first-line

treatment of adults with locally advanced unresectable or metastatic HER2 negative gastric or gastroesophageal junction adenocarcinoma based on KEYNOTE-859 and another in combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer based on KEYNOTE-966.

As we continue to harness the potential of KEYTRUDA, we have an increased focus on earlier stages of disease where we believe timely effective intervention may significantly improve patient outcomes.

Last month we announced FDA approval for KEYTRUDA in combination with chemoradiotherapy for the treatment of FIGO Stage III through IVA cervical cancer based on the Phase 3 KEYNOTE-A18 trial. This is an important advancement and provides a new option that has potential to become the standard of care.

To date, with all the research conducted with checkpoint inhibitors, the only studies to have demonstrated statistically significant overall survival benefit in earlier-stage cancers are KEYTRUDA-based regimens: KEYNOTE-671, as part of a neoadjuvant followed by post-surgery adjuvant treatment regimen for certain patients with resectable non-small cell lung cancer, and KEYNOTE-564 as a post-surgery adjuvant treatment regimen for certain patients with renal cell carcinoma.

Since the approval of KEYNOTE-671, in October, it is notable that the American Cancer Society released guidance recommending that certain individuals with significant smoking history undergo an annual low-dose CT scan. The guidance also expands the age range for lung cancer screening. We look forward to the opportunity to help impact patients and support the identification of more patients at risk.

Additional data from KEYNOTE-564 demonstrating an overall survival benefit were presented at the ASCO GU conference last week.

Detailed findings from KEYNOTE-123 evaluating KEYTRUDA for the adjuvant treatment of patients with localized muscle invasive and locally-advanced, resectable urothelial carcinoma demonstrating a disease-free survival benefit versus observation, were also presented at ASCO GU.

Also, in the earlier-stage setting, along with our partner Moderna, we announced three-year recurrent free survival and distant metastasis-free survival data for our individualized neoantigen therapy, V940, in combination with KEYTRUDA, for the adjuvant treatment of stage III and IV melanoma following complete resection. We are encouraged by the durability of the responses observed and the potential for this regimen to impact patients earlier in their diagnosis. The Phase 3 trials in the adjuvant setting for certain patients with melanoma and non-small cell lung cancer are actively enrolling.

[SLIDE 23 - Important progress in precision and tissue targeting]

Progress continues in precision oncology. The FDA approval for WELIREG, our HIF 2 alpha inhibitor, for the treatment of adults with advanced RCC following a PD-1 or PD-L1 inhibitor and a VEGF-TKI marks the first drug approved in a new therapeutic class for eligible patients with advanced renal cell carcinoma in nearly a decade and builds on the 2021 approval for the treatment of adults with certain von Hippel-Lindau disease associated tumors. Additional Phase 3 studies for WELIREG in combination with KEYTRUDA and / or lenvatinib for the treatment of certain types of renal cell carcinoma in the advanced and adjuvant settings are ongoing.

And finally moving to the tissue targeting space. Together with, Astellas and Seagen, now Pfizer, we announced the FDA approval for KEYTRUDA in combination with Padcev, a Nectin-4-targeting ADC, for the first-line treatment of patients with locally advanced or metastatic urothelial cancer based on results from KEYNOTE-A39. These results demonstrated a superior overall survival benefit versus gemcitabine plus cisplatin or carboplatin and extend our

pioneering work in combining KEYTRUDA with chemotherapy, as well as reinforcing the value of an ADC to enable targeted delivery of chemotherapy to the tumor tissue.

Following the announcement of our collaboration with Daiichi Sankyo in October, we were pleased to receive priority review from the FDA for MK-1022, or patritumab deruxtecan, our investigational fully humanized anti-HER3 ADC, for patients with advanced EGFR-mutated non-small cell lung cancer previously treated with two or more systemic therapies. The agency has set a target action date of June 26th.

Through our agreements with Kelun and Daiichi Sankyo, as well as our own discovery programs, we have established a robust pipeline of tissue targeting ADCs. And the recently announced acquisition of Harpoon Therapeutics provides the opportunity to help complement and strengthen our approach by providing a portfolio of novel T-cell engagers, the most significant of which is HPN328, an investigational delta-like ligand 3 targeting T-cell engager being evaluated in small cell lung cancer and neuroendocrine tumors.

Our strong diverse portfolio of immuno-oncology, precision molecular and tissue targeting agents positions us well to have a profound impact on even more patients long into the future.

[SLIDE 24 - Notable progress across our vaccines and cardiometabolic programs]

Next to our vaccines pipeline. We are making notable advancements with our population-specific vaccine program for pneumococcal disease.

The FDA has accepted for priority review the new Biologics License Application for V116, our 21-valent pneumococcal conjugate vaccine specifically designed for adults, supported by results from multiple Phase 3 clinical studies evaluating V116 in both pneumococcal vaccine-naïve and vaccine-experienced adult patient populations.

Results from the STRIDE-3 trial were presented at the World Vaccine Congress West Coast in November and additional data from STRIDE-3 as well as STRIDE studies 4, 5, and 6 will be presented at the International Society of Pneumonia and Pneumococcal Disease congress in March.

If approved, as Rob noted, V116 would be the first pneumococcal conjugate vaccine specifically designed to address the serotypes responsible for approximately 83 percent of invasive pneumococcal disease in adults 65 years of age and older, according to CDC data from 2018-2021. Importantly, V116 includes eight unique serotypes which account for 30 percent of disease, according to the same CDC data. These serotypes are not covered by currently licensed pneumococcal vaccine options. The FDA has set a target action date of June 17th.

Turning to programs in the cardiometabolic disease pipeline. We are eager to bring sotatercept to patients as an important treatment option for pulmonary arterial hypertension. The FDA has set a target action date of March 26th.

Beyond data from the STELLAR trial, we have the Phase 3 ZENITH and HYPERION studies which are evaluating sotatercept in patients with more advanced disease, and those earlier on their disease journey. In addition, the Phase 2 CADENCE trial will evaluate WHO Group 2 pulmonary hypertension, focused on a type of left heart disease.

[SLIDE 25 - Significant progress across our broad pipeline in 2023]

As we close out 2023, it is important to highlight our significant progress and execution across therapeutic areas and modalities, as well as multiple business development transactions.

In the year, we had more than 25 regulatory approvals in major markets.

We also initiated over 20 Phase 3 studies across multiple new classes of assets, including in oncology with

- bomedemstat, our LSD1 inhibitor, in essential thrombocythemia,
- nemtabrutinib, our BTK inhibitor in first line chronic lymphocytic leukemia or small lymphocytic lymphoma,
- MK-2870, our TROP2 ADC in collaboration with Kelun in non-small cell lung cancer and endometrial carcinoma,
- MK-5684, our CYP11A1 inhibitor in collaboration with Orion in metastatic castration-resistant prostate cancer and
- V940 in collaboration with Moderna for the adjuvant treatment of certain types of melanoma and non-small cell lung cancer.

Also, in immunology with tulisokibart in ulcerative colitis. Finally, in cardiometabolic disease with multiple trials for MK-0616 in hypercholesterolemia.

As a result of the increasing depth and breadth of our pipeline, we are planning to initiate an even greater number of Phase 3 trials in 2024. Considerable credit goes to my colleagues across the organization for their hard-work and unwavering dedication.

We are executing on our science-led strategy, and I look forward to providing further updates on our progress throughout the year.

And now I will turn the call back to Peter.