Merck & Co., Inc Q3 2024 Earnings Prepared Remarks

October 31, 2024

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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 & Business Update]

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

[SLIDE 5 - Delivered on our key strategic priorities in Q3 2024]

At Merck, we're confronting some of the world's most challenging unmet medical needs with innovative science and differentiated solutions and we're delivering on our key strategic priorities. The strong progress we're making across our business increases the confidence I have in our ability to achieve long-term success and create sustainable value for both patients and shareholders.

- We're launching important new products that solve for unmet medical needs and which have significant commercial potential;

- We're advancing novel clinical programs across a pipeline of diversified therapeutic areas and modalities;

- And we're adding to our internal research and development efforts through value-creating business development transactions.

As a result, Merck is moving toward a future with a much more diversified portfolio. Our Phase 3 pipeline has nearly tripled over the past three-plus years to more than twenty unique assets. This will fuel a substantial set of new

medicine and vaccine launches over the next five years, in fact, approximately equal to what we launched over the past ten years, and we believe the majority have blockbuster-plus potential.

We have improved long-term visibility and are intensely focused on ensuring strong clinical execution across our diversified set of pipeline opportunities and future growth drivers.

As always, we remain science-driven and patient-focused as we work to bring these medicines and vaccines to those who need them most.

[SLIDE 6 - Strong Q3 underlying performance]

Turning to our third quarter results.

Commercial execution is a top priority, and we're highly focused on delivering in the near-term. The strength of our overall portfolio puts us on track to achieve strong full-year growth.

For the quarter, revenues increased 4%, or 7% on a constant currency basis. Our results benefitted from increased usage of KEYTRUDA globally, contributions from new launches, including WINREVAIR and CAPVAXIVE, and strong growth in our Animal Health business. I'm pleased with the launch performance of WINREVAIR, which is consistent with our high expectations, and remain confident in the long-term opportunity it represents for patients and for Merck.

As anticipated, results also reflect a decline in GARDASIL sales year-over-year. Notably, however, we achieved strong double-digit growth for GARDASIL in almost every major region outside of China.

In China, consistent with the expectations we discussed on our prior earnings call, we shipped less to our commercialization partner, Zhifei, and we expect fourth quarter shipments will be at a similar level to the third quarter. Overall channel inventories of GARDASIL have decreased, which is directionally encouraging, while inventory at Zhifei remains above historical levels.

We are highly focused on this market and are making progress with Zhifei to increase promotional resources and patient education efforts. We expect these efforts to translate to increased patient activation and demand, but as we've said, this will take time.

Taking a step back, we're proud of the role that GARDASIL is playing in helping prevent certain HPV-related cancers. There is a wide range of long-term growth opportunities around the world due to the tremendous remaining need to protect more individuals, with less than 10% of the global eligible population vaccinated and meaningful opportunities to improve vaccination completion rates, gender-neutral vaccination rates, mid-adult coverage and access in low- and middle-income markets. This includes in China, where there is an attractive long-term opportunity given the significant number of females yet to be immunized, and the potential approval for males next year. We're highly focused on using our scale and strong capabilities to drive education and awareness of the benefits of HPV vaccination and to reach and protect more patients globally. As such, we remain confident in our goal of achieving greater than $11 billion of sales by 2030.

[SLIDE 7 - Advancing and broadening our diverse pipeline]

Turning to our research efforts, we achieved important clinical and business development milestones this quarter.

Starting with our clinical advancements, in vaccines, we presented positive Phase 2b/3 results for clesrovimab, our investigational monoclonal antibody for the prevention of RSV in infants. Based on its differentiated profile and robust clinical data, we believe this opportunity is underappreciated. We're moving swiftly to make this important prevention option available in the U.S. during the 2025-26 RSV season.

In pneumococcal, ACIP voted to expand vaccination recommendations for CAPVAXIVE to include adults ages 50 to 64. We're pleased to bring CAPVAXIVE's effectiveness in protecting against invasive pneumococcal disease to this new cohort of patients, and this recommendation reinforces our confidence in its blockbuster commercial potential.

In oncology, It's been ten years since KEYTRUDA's first U.S. approval, and we remain highly focused on advancing standard of care and maintaining durable leadership in oncology. At ESMO, we presented overall survival and long-term follow up data for KEYTRUDA, and data also were shared from our innovative ADCs, underscoring our commitment to building a broad and diverse oncology pipeline.

In infectious diseases, we shared Phase 2 data from our collaboration with Gilead for the combination of once-weekly oral islatravir and lenacapavir for HIV treatment in treatment experienced adults. This data represents just a portion of our broad HIV development efforts to further advance the field.

In immunology, we shared positive Phase 2 maintenance data for our investigational TL1A candidate tulisokibart in ulcerative colitis and Crohn's disease that adds to positive prior clinical results.

Both our HIV and immunology programs address patient populations with significant remaining unmet need despite available therapies. Our investments in these therapeutic areas reflect our belief in the opportunity to deliver additional value to patients and fortify our sustainable innovation engine for the long-term.

Regarding business development, we continued to leverage our scientific expertise to identify promising therapeutic targets that can further broaden and fortify our pipeline. This quarter, we acquired a novel investigational bispecific T-cell engager from Curon with potential applications in both oncology and immunology, complementing our efforts in each of these areas of high unmet need and we closed the acquisitions of EyeBio and the Elanco aqua business.

In summary, we remain highly focused on strong commercial and operational execution to enable access to our medicines and vaccines. We're also continuing to make strategic investments in our pipeline that we're confident will lead to important innovations for patients and future growth drivers for our company.

I want to again recognize the commitment and efforts of our team across the world. Based on our continued progress, I'm more confident in our longer-term future today than I was a year ago, and I believe that Merck is even better positioned to deliver value to patients, shareholders and to all of our stakeholders long into the future.

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

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

[SLIDE 8 - Business/Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 9 - Strong Q3 worldwide sales growth]

As Rob highlighted, we delivered another strong quarter. The fundamentals of our business remain healthy, fueled by robust global demand for our innovative portfolio. This strong performance reinforces the conviction we have in our science-led strategy and in our outlook for continued growth. We remain confident in our ability to consistently deliver strong results in the short-term, while we make disciplined investments in leading-edge science, which positions us to generate lasting value for patients, customers, and shareholders.

Now, turning to our third quarter results. Total company revenues were $16.7 billion, an increase of 4%, or 7% excluding the impact of foreign exchange.

The following revenue comments will be on an ex-exchange basis. Our Human Health business sustained its momentum with sales increasing 8% primarily driven by Oncology. Our Animal Health business also delivered strong performance, with sales growth of 11%.

[SLIDE 10 - Oncology: KEYTRUDA continues to drive exceptional growth]

Turning to the performance of our key brands.

In Oncology, sales of KEYTRUDA grew 21% to $7.4 billion. Global growth was driven by increased uptake from earlier-stage cancers and continued robust global demand from metastatic indications.

In the U.S., KEYTRUDA grew across a broad range of tumor types. In the earlier-stage setting, the largest driver was increased use in resectable non-small cell lung cancer. KEYTRUDA's market leadership continues to grow as part of a treatment regimen in the perioperative setting, building on its existing leadership position as adjuvant therapy. In metastatic disease, we saw increased uptake in first-line advanced urothelial cancer based on KEYNOTE-A39. KEYTRUDA plus Padcev continues its leadership in new patient starts, outpacing platinum chemotherapy-based regimens.

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

[SLIDE 11 - Oncology: Updates across broad portfolio]

Lynparza alliance revenue grew 13% driven by increased global demand.

Lenvima alliance revenue declined 4% due to the timing of shipments last year.

WELIREG sales more than doubled to $139 million driven by increased uptake in certain patients with previously treated advanced renal cell carcinoma in the U.S.

[SLIDE 12 - Vaccines: Broad vaccines portfolio having significant patient impact]

In Vaccines, GARDASIL sales were $2.3 billion, a decrease of 10%, driven by a decline in China. In the U.S., sales benefitted from CDC purchasing patterns, as well as price and demand. Outside the U.S., sales increased by double digits in almost every region driven by robust demand.

In pneumococcal, VAXNEUVANCE sales increased 13% to $239 million, driven by ongoing launches in international markets. We are also excited by the recent launch of CAPVAXIVE, which is off to an encouraging start.

[SLIDE 13 - Cardiovascular: Continued successful launch of WINREVAIR]

In Cardiovascular, the launch of WINREVAIR continues to gain momentum, with global sales of $149 million.

In the U.S., we have seen steady progress in adding new patients. During the quarter, approximately 1,700 new patients received a prescription, bringing the total number of new patient prescriptions to more than 3,700 since launch. Based on our experience to date, approximately 80% of those patients will receive commercial product. Given this, and the approximate one-month timeframe to complete the steps to commence therapy, more than 2,600 new commercial patients have started treatment since launch.

We are seeing physicians prescribe WINREVAIR to more of their patients and new physicians prescribe the product. Through the end of September, nearly 800 physicians have written at least one prescription, with most prescribers coming from either large academic centers or larger private practices. Physicians are continuing to prioritize the sickest patients, who have already been receiving multiple PAH therapies.

We are also making important progress in enabling access. We have achieved coverage for approximately 60% of lives, nearly doubling the amount from last quarter. Many payors have established coverage policies consistent with the label or STELLAR study criteria.

Outside the U.S., initial feedback from scientific leaders has been positive following the recent EU approval. We are pleased that the first patients in Germany have received a prescription for WINREVAIR. We look forward to securing reimbursement in other European countries, which typically takes twelve months, as well as launching in other international markets.

In summary, we are excited with the continued progress of the launch and look forward to positively impacting more patients with pulmonary arterial hypertension.

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

Our Animal Health business delivered strong growth, with sales increasing 11%. Companion animal sales grew 17%, driven by uptake from new product launches, including the long-acting BRAVECTO injectable in certain international markets, as well as price. Livestock sales grew 7%, reflecting higher demand for poultry and swine products, the inclusion of sales from the recently acquired aqua portfolio from Elanco, which closed in mid-July, and price.

[SLIDE 15 - Q3 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 80.5%, an increase of 3.5 percentage points driven by reduced royalty rates for KEYTRUDA and GARDASIL as well as favorable product mix.

Operating expenses increased to $8.5 billion, including $2.2 billion of charges related to the acquisition of EyeBio and a promising candidate from Curon. Excluding these charges, operating expenses grew 9%, reflecting strategic investments in support of our innovative early- and late-phase pipeline and key growth drivers.

Other income was $193 million, which includes a payment of $170 million from Daiichi Sankyo related to the collaboration for our T-cell engager.

Our tax rate of 21.9% includes an unfavorable impact from the EyeBio and Curon transactions.

Taken together, earnings per share were $1.57.

[SLIDE 16 - Updated 2024 financial outlook]

Now turning to our 2024 non-GAAP guidance.

The continued operational strength of our business has enabled us to narrow our full year revenue guidance. We now expect revenue to be between $63.6 and $64.1 billion. This guidance range represents strong year over year growth of 6% to 7%, including an approximate 3 percentage point negative impact from foreign exchange using mid-October rates.

Our gross margin assumption remains approximately 81%.

We expect operating expenses to be between $27.8 and $28.3 billion, which now includes the $750 million one-time charge related to the asset acquisition from Curon. As a reminder, our guidance does not assume additional significant potential business development transactions.

Other Expense is now expected to be approximately $100 million, including the benefit of the $170 million payment from Daiichi.

Our full year tax rate is expected to be between 16.0% and 17.0%, which includes an unfavorable impact related to the Curon transaction.

We assume approximately 2.54 billion shares outstanding.

Taken together, we expect EPS of $7.72 to $7.77. This range includes a negative impact from foreign exchange of approximately 30 cents, using mid-October rates.

Recall our prior guidance range was $7.94 to $8.04. Including the one-time charge of $750 million, or $0.29 per share, related to the asset acquisition from Curon and the $170 million, or $0.05 per share, benefit from the payment from Daiichi, our prior guidance range would have been $7.70 to $7.80, with a midpoint of $7.75. Therefore, our current guidance midpoint is unchanged.

[SLIDE 17 - Remain committed to balanced capital allocation strategy]

Now turning to capital allocation, where our strategy remains the same.

We will prioritize investments in our business to drive near- and long-term growth. We will continue to invest in our key growth drivers and expansive pipeline of novel candidates, each of which has significant potential to address important unmet medical needs.

We remain committed to our dividend, with the goal of continuing to increase it over time. Adding compelling science through business development remains a priority and we are well positioned to pursue additional value-enhancing transactions. We will continue to execute a modest level of share repurchase.

To conclude, as we finish the year, we are confident in the momentum of our business, underpinned by robust global demand for our innovative medicines and vaccines. Our unwavering dedication to leverage compelling science to save and improve the lives of the patients we serve has put us in a position of financial and operational strength. Our commitment to bring forward important innovation 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 18 - Research Update]

Thank you, Caroline.

We have continued to execute on our strategy of diversifying in oncology and expanding into new therapeutic areas, while also investing in novel modalities and technologies. The third quarter was marked by several important clinical and regulatory milestones.

I will first cover infectious diseases, then oncology and conclude with updates on the broader portfolio.

[SLIDE 19 - Important updates across our vaccines, immunization and infectious disease programs]

As Rob noted, last week ACIP voted to update the adult age-based pneumococcal vaccination guidelines and recommend the use of CAPVAXIVE, our 21 valent pneumococcal conjugate vaccine, for individuals 50 years and older. CAPVAXIVE is specifically designed to cover serotypes responsible for the majority of invasive pneumococcal disease and includes serotypes responsible for approximately 84% of cases of IPD in adults 50 and older, based on national-level CDC data from 2018 to 2022.

Building on our company's proud legacy in infectious diseases, detailed findings from a pivotal Phase 2b/3 clinical trial evaluating clesrovimab, our investigational respiratory syncytial virus preventative monoclonal antibody for the protection of infants entering their first RSV season, were presented at IDWeek. Clesrovimab, administered as a single-dose immunization to healthy pre-term and full-term infants, regardless of weight, met all trial endpoints, with consistent results through both five-month and six-month time points. The incidence of adverse events and serious AEs were comparable between treatment and placebo groups, with no treatment or RSV-related deaths. As shown in the summary tables in the data press release, clesrovimab immunization is being studied across mild, moderate, and severe RSV disease endpoints. Importantly, clesrovimab significantly reduced the incidence of RSV, the primary

endpoint, and hospitalizations associated with RSV infection through five months by more than 84%, the secondary endpoint. It was also observed that clesrovimab reduced RSV lower respiratory infections by more than 90%, through five months, the tertiary endpoint.

Positive results were also presented from an interim analysis in a separate Phase 3 study, evaluating the safety and efficacy of clesrovimab versus palivizumab in infants and children at increased risk for severe RSV disease.

If approved, clesrovimab would be the first and only immunization designed to provide infants with direct, rapid and durable protection for the full six-month RSV season with the convenience of one dose, regardless of weight or month of birth.

Also, at IDWeek, positive data were presented from the Phase 2 study of the combination of islatravir and lenacapavir, Gilead's HIV-1 capsid inhibitor, as a once-weekly oral treatment option for people living with HIV. The 48-Week results build on the positive 24-Week data previously presented. These findings reinforce the strength of our HIV pipeline as we evaluate multiple, promising candidates in preventative and treatment settings.

[SLIDE 20 - Extensive ongoing, Phase 3 clinical development program for KEYTRUDA-based regimens in earlier stages of cancer]

Next to oncology. KEYTRUDA continues to raise the bar in treating earlier stages of disease.

In the earlier stage setting, KEYTRUDA is the only PD-1 or PD-L1 to date to receive FDA approvals for nine indications and is the only one to demonstrate a significant overall survival benefit in four earlier stage settings: non-small cell lung cancer, renal cell carcinoma, cervical cancer and triple negative breast cancer. And as Caroline spoke to, we continue to see strong patient impact.

KEYTRUDA based regimens have demonstrated positive results across thirteen pivotal trials in eight tumor types. We look forward to building on the data in the earlier stage setting.

We recently announced positive topline results for the KEYNOTE-689 trial, evaluating KEYTRUDA as a perioperative treatment for patients newly diagnosed with stage III or IVA, resected, locally advanced head and neck squamous cell carcinoma. The trial met its primary endpoint of event-free survival and demonstrated an improvement in major pathological response, a key secondary endpoint. This is the first positive trial to show a statistically significant benefit of neoadjuvant plus adjuvant anti-PD-1 treatment for newly diagnosed patients with resected locally advanced head and neck squamous cell carcinoma in twenty years.

Results will be submitted to regulatory authorities and, if approved, would mark the tenth indication of a KEYTRUDA based regimen for the treatment of earlier stage cancer.

[SLIDE 21 - Broadening the impact of KEYTRUDA]

On the regulatory front, we received FDA approval for KEYTRUDA in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma based on results from the KEYNOTE-483 study. This brings the number of distinct FDA approved indications for KEYTRUDA to forty-one.

The European Commission approved three KEYTRUDA based regimens which include:

- in combination with Pfizer's Padcev, a nectin 4-targeting antibody drug conjugate, for the first-line treatment of adult patients with unresesectable or metastatic urothelial carcinoma based on the KEYNOTE-A39 study,
- in combination with carboplatin and paclitaxel, for the first-line treatment of primary advanced or recurrent endometrial carcinoma and
- in combination with chemoradiotherapy, for the treatment of FIGO 2014 Stage III-IVA locally advanced cervical cancer in adults who have not received prior definitive therapy based on KEYNOTE-868.

KEYTRUDA was also approved by the Japanese Ministry of Health for three indications:

- in combination with Pfizer's Padcev, a nectin 4-targeting antibody drug conjugate, for the first-line treatment of adult patients with radically unresesectable urothelial carcinoma based on the KEYNOTE-A39 study,

- for patients with radically unresectable urothelial carcinoma who are not eligible for any platinum-containing chemotherapy based on KEYNOTE-052, as well as
- in combination with chemotherapy as neoadjuvant treatment, then continued as monotherapy as an adjuvant therapy, for patients with non-small cell lung cancer based on findings from KEYNOTE-671.

At the European Society for Medical Oncology Congress, three presentations for KEYTRUDA were showcased during Presidential Symposium sessions. These include:

- overall survival data from the KEYNOTE-522 trial in high-risk early-stage triple-negative breast cancer;
- overall survival data from the KEYNOTE-A18 trial in patients with newly diagnosed, high-risk, locally advanced cervical cancer, and
- 10-year follow-up overall survival data from the KEYNOTE-006 trial showing the long-term benefit over ipilimumab in patients with advanced melanoma.

And finally in oncology, we continue to advance our increasingly diverse pipeline including our efforts to evaluate the potential of new combination regimens to improve patient outcomes.

[SLIDE 22 - Continuing to advance our broader oncology program with BD]

Earlier this month, we announced a clinical development collaboration with Exelixis for their investigational tyrosine kinase inhibitor, zanzalintinib which will be evaluated in combination with:

- KEYTRUDA, for the treatment of patients with head and neck squamous cell carcinoma, and with
- WELIREG, for the treatment of patients with renal cell carcinoma.

In collaboration with Daiichi Sankyo, we initiated IDeate-Lung02, a Phase 3 trial, evaluating ifinatamab deruxtecan, a B7-H3 directed antibody drug conjugate, for the treatment of patients with relapsed small cell lung cancer. We also expanded our agreement to evaluate the combination of I-DXd with MK-6070, an investigational delta-like ligand 3 targeting T-cell engager. Evidence from clinical studies for each candidate provides strong rationale for evaluating this combination regimen.

[SLIDE 23 - Executing on our broader pipeline]

Next to our broader portfolio. As Caroline mentioned, we were pleased to receive approval from the European Commission for WINREVAIR, expanding the reach of this treatment option, which we believe has the potential to transform the treatment journey for patients suffering from pulmonary arterial hypertension.

In immunology, 50-week efficacy and safety data for tulisokibart, our investigational humanized monoclonal antibody directed to tumor necrosis factor-like cytokine 1A, from the Phase 2 ARTEMIS-UC and APOLLO-CD studies in ulcerative colitis and Crohn's disease were presented at the United European Gastroenterology Week Congress. The results reinforce the potential of tulisokibart to help patients achieve long-term clinical remission. The Phase 3 trials continue to actively enroll patients.

Finally, in ophthalmology, soon after completing our acquisition of EyeBio, we initiated the Phase 2b/3 BRUNELLO trial for MK-3000, an investigational tetravalent, tri-specific antibody that acts as an agonist of the Wingless-related integration site signaling pathway, being evaluated for the treatment of diabetic macular edema.

We are executing on our ONE PIPELINE approach, augmenting and complementing our internal programs through business development.

Recently, we completed the acquisition of CN201 a novel CD3xCD19 T-cell engager now known as MK-1045, from Curon Biopharmaceutical. MK-1045 has shown to significantly deplete B cell levels with potential applications in B-cell malignancies and autoimmune diseases. As with our previous acquisitions, we plan to seamlessly advance clinical development with rigor and speed.

In closing, during the quarter we saw a regular cadence of late-phase pipeline advancements including regulatory milestones and data readouts. We continue to make progress across therapeutic areas, and I look forward to providing further updates on our programs in 2025.