Merck & Co., Inc, Rahway, N.J. USA Fourth-Quarter 2025 Sales and 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., Rahway, N.J., USA, 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 - Transforming our portfolio with next wave of innovation]

Our company's purpose to save and improve lives guides everything we do. In 2025, we advanced key programs across all phases of development, furthering our mission to deliver transformative medicines and vaccines that will improve health outcomes for patients around the world. I'm very proud of the significant progress we are making. And as we look ahead, we'll remain intently focused on bringing forward breakthrough science and innovation which is the foundation for creating sustainable, long term value for both patients and shareholders.

The transformation of our portfolio is well underway, and momentum is building as we continue to execute on our strategy. In 2025, our business benefitted from successful new product launches, the advancement of important clinical programs, and the expansion of our respiratory and infectious disease portfolios through the acquisitions of Verona Pharma and Cidara Therapeutics. As a result of this progress, we now have line of sight to over $70 billion of potential commercial opportunity by the mid-2030s, $20 billion more than just a year ago and more than double consensus 2028 peak KEYTRUDA revenue of $35 billion. While we still have more to do, this meaningful progress further bolsters my already high confidence in our ability to deliver sustainable growth post the KEYTRUDA LOE period.

[SLIDE 6 - Delivering revenue growth while investing for the future]

Now, turning to our results and initial outlook for 2026.

Growth in 2025 reflects demand for our innovative portfolio, including for KEYTRUDA, which continues to benefit more patients with cancer globally increasing contributions from new launches in cardiometabolic and respiratory as well as vaccines and strong performance of Animal Health. We're well positioned to achieve commercial success across key products in 2026 while we make important investments behind our new product launches and expanded pipeline, which Caroline will speak to momentarily.

[SLIDE 7 - Remarkable progress across broad and deep pipeline]

Our research colleagues continue to achieve remarkable progress across our broad and deep pipeline.

Focusing on a few key events from the fourth quarter.

In cardiometabolic and respiratory, at AHA, we presented Phase 3 results for enlicitide that underscore the practice-changing potential of an oral PCSK9 inhibitor. Cardiovascular disease is the leading cause of death globally, and we look forward to bringing a potential new option to help address the CV epidemic.

For WINREVAIR, we announced Phase 2 topline findings from the CADENCE trial that are supportive of its continued development in a different type of pulmonary hypertension.

And building on recent momentum in HIV, we shared positive topline results for islatravir in combination with doravirine for treatment-naïve adults living with HIV.

Finally, we're pleased that both enlicitide and sac-TMT, our investigational TROP2-directed antibody drug conjugate, were granted Commissioner's National Priority Vouchers by the FDA, which may expedite review of these important investigational candidates after applications are filed.

[SLIDE 8 - Completed strategic acquisition of Cidara Therapeutics]

We recently completed the acquisition of Cidara, which complements our portfolio and builds on our long legacy in combatting infectious diseases. MK-1406, formerly CD388, is a potentially first-in-class long-acting antiviral candidate designed to help prevent influenza infection in individuals at higher risk of developing serious complications. There is a substantial unmet need for influenza prevention in a large at-risk population, and Phase 2 results were very promising. We believe MK-1406 has greater than $5 billion in revenue potential and can be a meaningful driver of growth later this decade and through the next. We're excited to welcome the Cidara team to our company, and look forward to advancing this novel preventative antiviral agent.

[SLIDE 9 - Transforming our portfolio with more than 20 new growth drivers, almost all with blockbuster potential]

Today, our business is anchored by an important set of commercial products that address critical unmet needs. We're also executing on the transformation of our portfolio with initial launches from over 20 potential new growth drivers that have the promise to advance the practice of medicine and change patient lives.

Ten of these programs could be substantially clinically derisked over the next two years, and represent the majority of our $70 billion of non-risk adjusted commercial opportunity by the mid-2030s. And our long-term outlook is further bolstered by the strong growth we expect in our Animal Health business by the many early-phase programs that will enter Phase 2 in the near-term and through additional potential science-led, disciplined and value-enhancing business development.

[SLIDE 10 - Data-rich period ahead with multiple Phase 3 readouts across novel mechanisms]

We're entering a particularly robust period of first-time, Phase 3 data readouts from novel candidates. In 2026, these include:

- Islatravir combined with lenacapavir, potentially the first once-weekly oral treatment regimen for people living with HIV;

- MK-3000, potentially the first new mechanism of action in two decades for patients with certain retinal diseases; and

- tulisokibart, where we expect to see Phase 3 results in ulcerative colitis as well as Phase 2 data in other autoimmune diseases.

There is an even richer array of expected readouts in 2027 including Phase 3 results for sac-TMT, which we believe is a differentiated TROP-2 ADC; for I-DXd, our B7H3 antibody drug conjugate being studied in small cell lung cancer and other tumor types; for MK-1406, as well as for a number of other important programs.

[SLIDE 11 - Delivering on our purpose for patients and creating long-term value]

In summary, we're successfully executing multiple product launches, making significant clinical advancements and augmenting our pipeline with strategic business development. We're also making the necessary investments that will sustain our success over the long-term. Our progress and momentum positions us to continue delivering on our purpose for patients and create durable value for shareholders.

I want to recognize and thank our global teams for their commitment. While there is more to do, the actions taken, the progress we've made, and our continued disciplined execution provide me with strong confidence that we're well positioned for our next chapter of success.

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

Ms. Caroline Litchfield - Merck & Co., Inc., Rahway, N.J., USA, Chief Financial Officer

[SLIDE 12 - Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 13 - Growth driven by strength in Oncology and Animal Health as well as new product launches]

As Rob noted, in 2025, we made meaningful progress in benefitting patients and customers around the world with our portfolio of innovative medicines and vaccines. Our business delivered growth driven by continued strength in Oncology and Animal Health as well as increasing contributions from new product launches. These results demonstrate the enduring strength of our business and give us confidence in our outlook as we enter a period with many new launches. Our commercial and operational execution enable us to invest in discovering, developing, and launching the next generation of innovations which will drive long-term value for patients, customers and shareholders. Now, turning to our fourth quarter results.

Total company revenues were $16.4 billion, an increase of 5%, or 4% excluding the impact of foreign exchange. The following revenue comments will be on an ex-exchange basis.

[SLIDE 14 - Oncology: KEYTRUDA continues to benefit patients and drive growth]

In Oncology, sales of the KEYTRUDA family of products, which includes KEYTRUDA and KEYTRUDA QLEX, increased 5% to $8.4 billion, with global growth driven by robust uptake in earlier-stage cancers and strong demand from metastatic indications.

Utilization in tumors that primarily affect women, including breast, cervical, and endometrial cancers, continues to be a key contributor to growth. In addition, we saw increased use of KEYTRUDA in combination with Padcev in locally advanced or metastatic urothelial cancer. In the U.S., growth was negatively impacted by approximately $200 million due to the timing of purchases.

We are pleased with the positive provider feedback following the recent launch of KEYTRUDA QLEX. As expected, sales in the quarter were $35 million. We look forward to having a greater impact on patients and health care systems following implementation of a permanent J-code in the U.S., which we continue to expect to occur in the beginning of April.

[SLIDE 15 - Oncology: Continued growth across broad portfolio]

Our broader oncology portfolio achieved another quarter of strong growth. Notably, WELIREG sales increased 37% to $220 million predominantly driven by increased use in certain patients with previously treated advanced renal cell carcinoma in the U.S. as well as continued uptake from ongoing launches in certain international markets. We look forward to potentially reaching more patients with renal cell carcinoma following positive data from the LITESPARK-011 and -022 studies.

[SLIDE 16 - Vaccines & Infectious Disease: Protecting lives globally]

In Vaccines, GARDASIL sales were $1.0 billion, a decrease of 35% driven by lower demand in China and Japan. Other international markets grew 8%, benefitting from the timing of purchases. In the U.S., sales grew 7% largely due to price.

In pneumococcal, the CAPVAXIVE launch continues to progress well, with sales of $279 million, driven by demand from both retail pharmacies and non-retail customers including uptake from increased seasonal immunization activity in the U.S.

In RSV, ENFLONSIA sales were $21 million. Initial uptake has been constrained by a lower than expected infant immunization rate coupled with high levels of total RSV monoclonal antibody inventory in the market.

[SLIDE 17 - Cardiometabolic & Respiratory: Continuing to drive impact for patients with successful ongoing launches]

In Cardiometabolic and Respiratory, WINREVAIR continues to have a positive impact for patients with pulmonary arterial hypertension. Global sales were $467 million, a reflection of the continued strong demand for this important treatment.

In the U.S., more than fifteen hundred new patients received a prescription and over twenty seven thousand total prescriptions were dispensed. We also saw an increase in the proportion of patients whose background therapies do not include a prostacyclin.

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

We are excited to build upon the successful U.S. launch of OHTUVAYRE, a maintenance treatment for adults with COPD with a novel mechanism of action. In the quarter, sales were $178 million, reflecting revenues following the acquisition of Verona on October 7th.

We delivered strong growth in new patient starts and total patients treated. We also saw physicians prescribe OHTUVAYRE to more of their patients and an increase in the total number of prescribing physicians. As a reminder, we expect seasonality in the early part of the year as Medicare deductibles are reset.

We are making investments to maximize the ongoing launch in the U.S. and look forward to benefitting more adult patients with COPD.

[SLIDE 18 - Animal Health: Strong growth driven by livestock portfolio]

Our Animal Health business delivered another quarter of strong growth, with sales increasing 6%. Livestock sales grew 9% driven by higher demand across all species. Companion animal sales were flat as growth from new product launches was offset by a reduction in vet visits.

[SLIDE 19 - Q4 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 79.7%, a decrease of 1.1 percentage points due to higher inventory reserves partially offset by favorable product mix.

Operating expenses decreased to $6.8 billion. A charge of $150 million related to an agreement with Dr. Falk Pharma to acquire sole global rights to MK-8690 was lower than the $700 million in business development charges a year ago. Excluding these charges, operating expenses were flat, reflecting an increase in investments in support of our innovative pipeline and key growth drivers, offset by the benefits of our multiyear optimization initiative.

Other expense was $226 million. Our tax rate was 15.4%.

Taken together, earnings per share were $2.04.

[SLIDE 20 - 2026 financial outlook]

Now turning to our 2026 non-GAAP guidance.

We expect revenue to be between $65.5 and $67.0 billion, representing growth of 1 to 3%, including a positive impact from foreign exchange of approximately 1 percentage point using mid-January rates.

Our gross margin assumption is approximately 82.0%.

Operating expenses are assumed to be between $35.9 and $36.9 billion, which includes a one-time charge of approximately $9.0 billion related to the acquisition of Cidara. As a reminder, our guidance does not assume additional significant potential business development transactions.

Other Expense of approximately $1.3 billion, includes financing costs for Cidara and Verona.

We assume a full year tax rate between 23.5% and 24.5%, which reflects the non-tax deductible one-time charge for Cidara.

We assume approximately 2.48 billion shares outstanding.

Taken together, we expect EPS of $5.00 to $5.15, with a midpoint of $5.08, including a positive impact from foreign exchange of approximately 10 cents, using mid-January rates. Excluding approximately $3.65 per share related to the upfront charge for the acquisition of Cidara, as well as 30 cents per share of ongoing costs to advance MK-1406 and finance the transaction, our midpoint would be $9.03.

[SLIDE 21 - Key modeling considerations]

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

We expect to deliver growth in 2026 driven by increasing contributions from our new launches as well as continued strength in oncology and Animal Health despite a headwind of approximately $2.5 billion from generic competition, IRA price setting and the restructured agreement for Koselugo. Generic competition primarily impacts the JANUVIA family of products, BRIDION and DIFICID. We also expect significantly lower sales of LAGEVRIO due to continued soft demand.

[SLIDE 22 - 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, including new product launches and our robust pipeline.

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

Business development remains a high priority. We are well positioned to pursue additional transactions when science and value align.

Our guidance assumes approximately $3 billion of share repurchases and we remain committed to not having excess cash build on the balance sheet.

To conclude, we enter 2026 with confidence in the outlook for our business, driven by global demand for our innovative medicines and vaccines, including the exciting progress of our many launches, and upcoming clinical milestones from our promising pipeline. We maintain our long-standing commitment to bringing forward medically significant innovations that 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 Y. Li – Merck & Co., Inc., Rahway, N.J., USA, President, Research Laboratories

[SLIDE 23 – Research Update]

Thank you, Caroline.

Good morning, everyone,

Progress continues across programs spanning multiple therapeutic areas. Today I will provide updates across cardiometabolic and respiratory, infectious disease and oncology programs, then conclude with a summary of highlights from 2025 and upcoming milestones for this year.

[SLIDE 24 - Clinical and regulatory advancements across cardiometabolic and respiratory pipeline]

Starting with advancements across our cardiometabolic and respiratory pipeline and programs.

Enlicitide, our investigational oral PCSK9 inhibitor has been designed to deliver antibody-like efficacy while offering a simple, once-daily oral treatment option with the potential to help address the CV epidemic.

Data from two Phase 3 studies evaluating enlicitide, for the treatment of adults with elevated LDL-cholesterol were presented at the American Heart Association Scientific Sessions in November.

In both the CORALreef Lipids study, which included a broad population of adults with or at risk for atherosclerotic cardiovascular disease on background lipid-lowering therapies or with statin intolerance, and the CORALreef HEFH study in adults with familial heterozygous hypercholesterolemia, enlicitide demonstrated statistically significant, sustained reductions in multiple atherogenic factors including LDL-C, ApoB, non HDL-C, and Lp(a).

The findings from the CORALreef HEFH were published in the Journal of the American Medical Association and from CORALreef Lipids have been accepted to the New England Journal of Medicine.

In addition, positive results of the third Phase 3 trial, CORALreef AddOn, evaluating enlicitide compared to other oral non-statin therapies in adults with hypercholesterolemia and treated with a statin, will be presented at the American College of Cardiology congress in March.

The Phase 3 CORALreef Outcomes study is ongoing and fully enrolled.

For WINREVAIR, we continue to make progress on our global regulatory strategy. Last month, the European Commission approved an expanded indication in adults with pulmonary arterial hypertension with WHO functional class II, III and IV based on the Phase 3 ZENITH study.

We are continuing to evaluate WINREVAIR in an additional indication associated with progressive vascular remodeling and resistance. The Phase 2 CADENCE study met its primary endpoint, achieving statistically significant and clinically

meaningful reduction of pulmonary vascular resistance compared to placebo in adults with combined post- and precapillary pulmonary hypertension due to heart failure with preserved ejection fraction. These findings support proof-of-concept which will inform a Phase 3 program in this population. Detailed results will also be presented at the American College of Cardiology congress in March.

[SLIDE 25 - Building on our strong legacy in combatting infectious disease]

Next to infectious disease.

Last month, we completed the acquisition of Cidara Therapeutics. The scale of the ongoing seasonal flu outbreak in the Northern Hemisphere reinforces the threat posed by influenza, the corresponding burden on health care systems, and importantly, the need for improved prevention strategies, specifically for those individuals at high risk of serious complications.

The Phase 3 ANCHOR study evaluating MK-1406, a potentially first-in-class, long-acting, preventative, strain-agnostic antiviral with a differentiated mechanism of action, completed enrollment in November in the Northern Hemisphere. In parallel, we will enroll participants in the Southern Hemisphere to ensure the collection of a robust dataset spanning a broad patient population, including adults who are immunocompromised, and to capture additional data on diverse circulating strains. Furthermore, it is also important for the study to encompass those who have been vaccinated against the flu and those who have not.

Turning to HIV.

In November, we announced positive topline results for our investigational once-daily, single-tablet, two-drug regimen of doravirine and islatravir, a next generation nucleoside analog leveraging translocation inhibition, from a Phase 3 study in previously untreated adults with HIV-1 infection. This is the first two-drug regimen without an HIV integrase strand transfer inhibitor to demonstrate non-inferior efficacy and safety versus the broadly used three-drug INSTI-based regimen, Biktarvy.

Based on its potent antiviral properties and barrier to resistance, it is our ambition that islatravir will serve as a novel anchor medicine across multiple two-drug treatment regimens, providing new daily and weekly options for people living with HIV.

Detailed results will be presented at an upcoming medical congress.

[SLIDE 26 - Progress across oncology development program]

Moving to oncology.

Data continue to demonstrate KEYTRUDA's impact in treating a wide spectrum of cancers.

In bladder cancer, there were two recent notable developments.

First, the FDA approved KEYTRUDA and KEYTRUDA QLEX, each in combination with Padcev, as neoadjuvant treatment and continued after cystectomy as adjuvant treatment for adults with muscle-invasive bladder cancer who

are ineligible for cisplatin containing chemotherapy based on the Phase 3 KEYNOTE-905 trial. This is the first PD-1 inhibitor plus antibody-drug conjugate regimen approved for this population.

Second, we announced positive topline results from the Phase 3 KEYNOTE-B15 study. The combination of KEYTRUDA plus Padcev, given as neoadjuvant and adjuvant treatment, demonstrated statistically significant and clinically meaningful improvements in event-free survival, overall survival, and pathologic complete response rates versus neoadjuvant chemotherapy and surgery. This is the first and only perioperative immunotherapy plus ADC regimen shown to extend survival for cisplatin-eligible patients with muscle invasive bladder cancer. Detailed results will be presented later this month at the ASCO Genitourinary Cancer Symposium.

Together, these regimens have the potential to offer patients with muscle invasive bladder cancer who are either eligible or ineligible for cisplatin chemotherapy, a KEYTRUDA-based option.

Three additional Phase 3 studies are ongoing evaluating KEYTRUDA across different stages of bladder cancer, including KEYNOTE-992, KEYNOTE-866, and KEYNOTE-676.

In collaboration with Moderna, we recently announced 5-year follow-up data for the Phase 2b KEYNOTE 942 study evaluating intismeran autogene, an individualized neoantigen therapy candidate, in combination with KEYTRUDA in patients with high-risk stage III or IV melanoma following complete resection. In the follow-up analysis, the study demonstrated a sustained improvement in recurrence-free survival with a 49% reduction in the risk of recurrence or death compared to KEYTRUDA alone building on the previously announced primary and 3-year analyses from the trial. The Phase 3 INTerpath-001 trial in adjuvant melanoma is ongoing and fully enrolled.

In November, the European Commission approved a subcutaneous injection of pembrolizumab and berahyaluronidase alfa, marketed in the EU as KEYTRUDA SC, for use in all 33 KEYTRUDA indications for adult patients. It is the first and only subcutaneous immune checkpoint inhibitor in Europe that can be administered in one minute every three weeks or in two minutes every six weeks.

The availability of more rapid subcutaneous pembrolizumab administration is being integrated into our clinical development programs—KANDLELIT-007, a Phase 3 study evaluating calderasib, an investigational oral, selective KRAS G12C inhibitor, in combination with KEYTRUDA QLEX for the first-line treatment of patients with KRAS G12C-mutant, advanced or metastatic, non-squamous non-small cell lung cancer.

Last month at the American Society of Hematology Annual Meeting, we highlighted progress across our hematology pipeline with positive data spanning multiple candidates, including:

- MK-1045, an investigational CD19xCD3 T-cell engager, in adults with relapsed or refractory B-cell acute lymphoblastic leukemia,

- nemtabrutinib, an investigational, non-covalent BTK inhibitor in patients with chronic lymphocytic leukemia or small lymphocytic lymphoma,

- and bomedemstat, an investigational LSD1 inhibitor, in patients with polycythemia vera who were resistant or intolerant to cytoreductive therapy.

In addition, there are two ongoing Phase 3 studies evaluating bomedemstat in essential thrombocythemia, an orphan disease.

[SLIDE 27 - Significant progress across broad pipeline in 2025]

2025 was marked by significant pipeline progress including positive data announced from 18 Phase 3 trials and the initiation of 21 Phase 3 trials spanning cardiometabolic and respiratory, immunology, infectious diseases, oncology and ophthalmology.

We also secured regulatory approvals across therapeutic areas, including:

- In oncology, KEYTRUDA QLEX and additional KEYTRUDA based regimens including in patients with cisplatin-ineligible MIBC and locally advanced head and neck squamous cell carcinoma;

- In infectious disease, ENFLONSIA, our long-acting monoclonal antibody for the prevention of respiratory syncytial virus lower respiratory tract disease in infants born during or entering their first RSV season;

- And in cardiovascular, the label update for WINREVAIR in PAH.

Finally, we continue to deliver on our “one pipeline strategy”, by leveraging our clinical expertise and robust business development capabilities. The acquisitions of Verona Pharma and Cidara Therapeutics further strengthen our pipeline and bring forward promising candidates with the potential to serve areas of significant unmet patient need.

[SLIDE 28 - Key upcoming dates and milestones]

Building on our momentum in 2025, we anticipate a series of milestones across multiple therapeutic areas in the coming months including:

- In oncology:
  - the February 20th PDUFA date for certain patients with platinum-resistant recurrent ovarian cancer based on the KEYNOTE B-96 trial
  - presentation of detailed findings at ASCO GU:
    - for WELIREG, our first-in-class oral HIF-2 alpha inhibitor, across adjuvant and certain types of advanced renal cell carcinoma based on the Phase 3 LITESPARK-011 and -022 trials and
    - for KEYNOTE B-15 in cisplatin-eligible patients with MIBC.
- In HIV:
  - the April 28th PDUFA date for doravirine and islatravir, a once-daily oral, two drug treatment regimen and
  - topline data from the Phase 3 ISLEND-1 and 2 trials evaluating islatravir and lenacapavir, as a once-weekly oral two drug treatment regimen, in collaboration with Gilead
- In cardiometabolic and respiratory, the presentation of detailed results at ACC in March:
  - For WINREVAIR
    - From the Phase 2 CADENCE study in a subset of pulmonary hypertension due to left heart disease
  - And for enlicitide:
    - from the Phase 3 CORALreef AddOn trial
- In immunology, data for tulisokibart, our TL1A inhibitor, based on the:
  - Phase 3 ATLAS-UC trial in ulcerative colitis and
  - Phase 2 ATHENA study in SSc-ILD and
- Finally in ophthalmology, data from the:
  - Phase 3 BRUNELLO study of MK-3000, our novel Wnt agonist, being evaluated in diabetic macular edema, and

- The Phase 2 RIOJA study of MK-8748, our potential first in class Tie2 agonist VEGF inhibitor being evaluated for the treatment of certain retinal diseases.

We continue to advance our diversified pipeline with a focus on executing with speed and rigor. I look forward to providing further updates through 2026.

And now I turn the call back to Peter.