

Merck & Co., Inc Q3 2023 Earnings Prepared Remarks

October 26, 2023



**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.

We continue to bring forward innovation that can save and improve the lives of patients and animals around the world. We're advancing our broad pipeline and executing in support of our key growth drivers, enabling strong progress for our business and providing tangible benefits to patients. To that end, I want to acknowledge the efforts of our talented global team. Their passion and commitment to our science-led strategy are fundamental to our continued success.

[SLIDE 5: Delivered on our key strategic priorities in Q3 2023]

Scientific innovation is truly the foundation of our strategy, and it drives everything we do. We're pushing the boundaries of science through the significant investments we are making across our deep pipeline, augmented by strategic business development. I'm pleased by the continued progress with these programs and our growing diversity across new therapeutic areas and modalities.

Along these lines, we're particularly excited by our recently announced clinical and commercial collaboration with Daiichi Sankyo for three potentially first-in-class antibody drug conjugates. The scientists at Daiichi Sankyo are proven innovators in this space, having developed proprietary ADC technology that has resulted in an approved product which is being rapidly adopted for patients with certain cancers. We're privileged to begin working alongside them to advance this important science and achieve both companies' objectives of addressing the significant unmet patient need in oncology.

Based on our strong conviction in these programs and the profound benefit they may bring to patients, we believe each has multi-billion dollar commercial revenue potential for Merck on a non-risk adjusted basis approaching the mid-2030s.

We're also applying our clinical expertise to accelerate the development of other potentially transformative treatments that we've added through strategic business development, such as sotatercept for pulmonary arterial hypertension and MK-7240, our TL1A inhibitor for ulcerative colitis and Crohn's disease. This is complemented by our strong commercial execution capabilities, which we expect to amplify the impact of these life-changing medicines and enable the creation of sustainable value for patients and shareholders over the long-term.

[SLIDE 6: Strong Q3 sales performance and earnings growth]

Turning to this quarter's performance.

We delivered robust growth driven by demand for our innovative portfolio. We are confident that we will close out 2023 with continued strong performance, which is reflected in the updated full-year outlook that Caroline will speak to in a few minutes.

[SLIDE 7: Advancing and enhancing our deep pipeline]

Moving to our research organization, as I mentioned, we're making remarkable progress across multiple therapeutic areas in our promising late-phase pipeline.

In oncology, Dean will speak to the significant success we're having in broadly leveraging the foundational position that we've achieved with KEYTRUDA. This includes the continued advancements we're making in the treatment of earlier-stage cancers. We're very excited by the recent FDA approval of a KEYTRUDA regimen for the neoadjuvant and adjuvant treatment of certain patients with resectable non-small cell lung cancer based on the KEYNOTE-671 trial results, which notably demonstrated an improvement in overall survival compared to a placebo and chemotherapy regimen.

In addition, we presented numerous important datasets at last week's European Society of Medical Oncology meeting, across a wide range of molecules, tumor types and indications.

Our progress across a broad set of programs reinforces our confidence in the sustainability of our oncology leadership well into the next decade.

We're also making exciting progress in our cardiometabolic pipeline. Most significantly, the FDA accepted for priority review our filing for sotatercept based on the unprecedented results of the STELLAR trial, and we look forward to the potential approval and launch in early 2024. We remain confident that sotatercept has the potential to change the treatment paradigm for patients suffering with pulmonary arterial hypertension.

We also initiated Phase 3 clinical trials for our oral PCSK9 candidate, MK-0616. We believe MK-0616 has the potential to provide significant benefit to patients with elevated cholesterol and impact cardiovascular disease on a global scale.

We're very pleased with our progress and what we achieved this quarter as we continue to focus on advancing and expanding Merck's pipeline, and I want to thank Dean and his team for their unwavering commitment to addressing unmet patient needs.

[SLIDE 8: Continuing to deliver on our purpose for patients]

In summary, we continue to move with urgency to deliver on our purpose, pursuing transformative science to save and improve lives around the world. We're executing scientifically, commercially and operationally on the significant opportunities now in front of us, while also making the disciplined investments needed to sustain strong growth well into the future. With the efforts of our global team, we have increased confidence that we will deliver value to patients, shareholders and to all of our stakeholders.

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

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

[SLIDE 9: Business/Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 10: Strong underlying Q3 worldwide sales growth]

As Rob highlighted, we achieved very strong growth this quarter driven by robust underlying demand across our innovative portfolio, and we remain confident in our ability to continue to deliver strong results in the near-term. We are also making disciplined investments to leverage leading-edge science to save and improve lives around the world well into the future – positioning us to deliver long-term value for patients and shareholders.

Now, turning to our third quarter results. Total company revenues were \$16.0 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered strong growth of 8%.

The remainder of my revenue comments will be on an ex-exchange basis.

Our Human Health business sustained its strong momentum. Excluding LAGEVRIO, growth was 10%, driven by Oncology and Vaccines.

Sales in our Animal Health business increased 2%.

[SLIDE 11: Oncology: KEYTRUDA continues to drive exceptional growth]

Turning to the performance of our key brands.

In Oncology, sales of KEYTRUDA grew 17% to \$6.3 billion driven by increased uptake from earlier stage cancers and continued strong global demand for metastatic indications.

In the U.S., KEYTRUDA growth was driven by increased utilization in both metastatic indications and earlier-stage cancers such as triple-negative breast cancer.

Uptake in earlier stages of non-small cell lung cancer remains strong and KEYTRUDA has now achieved brand leadership in this setting, reflecting the significant impact it is having as adjuvant treatment for patients with stage IB to IIIA disease. Our recently approved KEYNOTE-671 indication provides an important additional treatment option to patients and physicians by including usage in the neoadjuvant and adjuvant setting. We remain exceptionally well positioned to serve patients with non-small cell lung cancer and extend our leadership to the earlier stage setting.

In bladder cancer, we are excited to potentially expand usage of KEYTRUDA to cisplatin-eligible patients based on the compelling results from the KEYNOTE-A39 study. If approved, this study would more than double the eligible patient population for KEYTRUDA in first-line bladder cancer.

Outside the U.S., KEYTRUDA growth was driven by uptake in earlier stage cancers, including high-risk, early-stage triple negative breast cancer and renal cell carcinoma as well as increased demand in metastatic renal cell carcinoma and certain types of head and neck cancer.

[SLIDE 12: Oncology: Solid performance across broad portfolio]

Lynparza remains the market leading PARP inhibitor, with alliance revenue growing 6% this quarter.

Lenvima alliance revenue had growth of 30% driven by shipment timing in China, which we expect will negatively impact growth in the fourth quarter. Growth was also driven by increased demand for the treatment of certain patients with advanced renal cell carcinoma and endometrial cancer in the U.S.

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

Our vaccines portfolio delivered strong growth, led by GARDASIL, which increased 16% to \$2.6 billion, driven by underlying global demand, particularly in China. In the U.S., GARDASIL sales decreased due to CDC purchasing patterns.

Vaccine sales also benefited from continued uptake in the pediatric indication of VAXNEUVANCE in the U.S. and its launch in key European markets.

[SLIDE 14: Hospital: Contributions from key products]

In our Hospital Acute Care portfolio, BRIDION sales were flat as increased market share among neuromuscular blockade reversal agents in the U.S. was offset by the impact of generic entry in Europe.

[SLIDE 15: Animal Health: Growth driven by livestock]

Sales in our Animal Health business grew 2%. Livestock sales grew 7% reflecting price actions as well as higher demand for ruminant products. Companion animal sales declined due to a reduction in vet visits in the U.S., partially offset by pricing actions.

[SLIDE 16: Q3 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 77.0%, consistent with last year as the impact from unfavorable foreign exchange was offset by product mix.

Operating expenses decreased 4% to \$5.8 billion. There were no significant business development expenses in the quarter, compared with \$690 million of charges a year ago. Excluding these charges, operating expenses grew 9%. This growth reflects increased investments in support of our robust early- and late-phase pipeline, with research and development expenses increasing 17%.

Other expense was \$133 million.

Our tax rate was 15.0%.

Taken together, earnings per share were \$2.13.

[SLIDE 17: Merck updated full-year 2023 guidance]

Before I cover the outlook for the balance of the year, I wanted to briefly touch upon the recently announced strategic collaboration with Daiichi Sankyo. This transaction follows a similar, de-risked and disciplined financial structure as we have employed in prior successful collaborations, and we are very excited about the opportunity to create meaningful value for patients and shareholders.

Now turning to our 2023 non-GAAP guidance, which includes the strategic collaboration with Daiichi.

The continuing operational strength of our business has enabled us to raise and narrow our full year revenue guidance. We now expect revenue to be between \$59.7 and \$60.2 billion, an increase of approximately \$900 million at the midpoint. This range reflects strong, double-digit underlying year over year revenue growth of 11% to 12%, excluding LAGEVRIO and an approximate 2 percentage point negative impact from foreign exchange using mid-October rates.

Our gross margin assumption is unchanged at approximately 77%.

We now estimate operating expenses to be between \$39.8 and \$40.4 billion. This range reflects \$17.1 billion in acquisition and upfront collaboration research and development expenses, including \$5.5 billion for the collaboration with Daiichi as well as those associated with Prometheus, Imago and Kelun. Our guidance does not assume additional significant potential business development transactions.

We now assume Other Expense of approximately \$200 million, which reflects updated foreign exchange expectations given recent dollar strengthening and higher net interest expense related to Daiichi.

Our full year tax rate is expected to be between 39.0% and 40.0%, which includes an approximate 24.5 percentage point impact related to our business development activity. Our underlying tax rate is approximately 14.5% to 15.5%.

We assume approximately 2.55 billion shares outstanding.

Taken together, we expect EPS of \$1.33 to \$1.38. This range includes a negative impact from foreign exchange of approximately 6 percentage points versus 2022, using mid-October rates.

Recall our prior guidance range was \$2.95 to \$3.05. Including the one-time charge of \$5.5 billion, or \$1.70 per share, and an estimated 4 cents to advance the assets and financing costs from the collaboration with Daiichi, our prior guidance range would have been \$1.21 to \$1.31, with a midpoint of \$1.26. Our current guidance midpoint of \$1.36 represents an increase resulting from strength in our business of approximately \$0.15, partially offset by an incremental headwind from foreign exchange of approximately 5 cents.

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

Now turning to capital allocation, where our priorities remain unchanged.

We will continue to prioritize investments in our business to drive near- and long-term growth. We are proud of the significant progress our team is making to advance and augment our pipeline, including our collaboration with Daiichi.

We will continue to invest in our pipeline, which contains many assets with tremendous potential to address significant unmet medical needs, positioning us for strong performance well into the future.

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

Business development continues to be a high priority. Our track record demonstrates our ability to identify compelling science and technologies that have the potential to advance standard of care, access such opportunities in a disciplined and capital-efficient manner, and, importantly, to rapidly progress the opportunities for the benefit of the patients we serve and our shareholders. 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 continue to execute a modest level of share repurchases.

To conclude, as we finish the year, we remain very confident in the outlook of our business in the near- and long-term, driven by the global demand for our innovative medicines and vaccines and our exceptional pipeline. We are in a position of financial and operational strength, and our continued 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 19: Research Update]

Thank you, Caroline. Good morning, everyone.

Today I will start with our oncology programs followed by vaccines, immunology and conclude with cardiometabolic disease.

[SLIDE 20: Continuing to advance our oncology strategy]

Over the last few years our oncology strategy has focused on leveraging the remarkable properties of KEYTRUDA to establish a diverse clinical pipeline of candidates with novel mechanisms and modalities. This is broadly based on three strategic pillars: immuno-oncology, precision oncology and tissue targeting:

- In immuno-oncology we continue to evaluate KEYTRUDA in the metastatic and increasingly in earlier stage disease settings while also investigating multiple novel immuno-oncology combinations and coformulations.
- With precision oncology we are selectively targeting pathways to inhibit cancer cell growth.
- And in tissue targeting we are developing agents such as antibody-drug conjugates designed to increase cancer cell sensitivity and killing.

[SLIDE 21: Broadening and advancing our ADC presence]

The latter is exemplified by our recently announced collaboration with Daiichi Sankyo. Daiichi Sankyo scientists have made pioneering contributions in advancing novel antibody drug conjugate technology with proven benefit to patients.

By combining our companies' respective strengths, we are well-positioned to accelerate three, clinical stage, potentially first-in-class candidates with the goal of transforming the treatment paradigm. These include:

- Patritumab deruxtecan, an investigational fully humanized anti-HER3 ADC, in Phase 3
- Ifinatamab deruxtecan, an investigational humanized anti-B7-H3 ADC, in Phase 2 and
- Raludotatug deruxtecan, an investigational humanized anti CDH6 targeted ADC, in Phase 1.

We provided details during our investor event earlier this week and are eager to begin working with the team.

The Daiichi Sankyo collaboration complements our important, ongoing alliance with Kelun Biotech, whose talented scientists have developed their own innovative ADC platform.

At ESMO, new Phase 2 data for MK-2870 or SKB-264, a TROP-2 targeting ADC, in patients with previously treated metastatic, hormone receptor positive, HER2 negative breast cancer, showed encouraging anti-tumor activity with an objective response rate of 36.8%. This builds on existing data for MK-2870 both in triple negative breast and non-small cell lung cancer. We are now poised to initiate larger studies starting with non-small cell lung cancer and expand into additional tumor types. We are also advancing clinical development of MK-1200, an ADC targeting Claudin 18.2.

Recognizing the proven benefit of KEYTRUDA in combination with chemotherapy in certain tumor types we are exploring the tissue-targeting concept by evaluating regimens combining ADCs and immunotherapy. At ESMO, in collaboration with Seagen and Astellas, potentially practice-changing survival data were presented from KEYNOTE-

A39/EV-302, evaluating KEYTRUDA plus enfortumab vedotin as first-line treatment for patients with locally advanced or metastatic urothelial carcinoma. This regimen represents the first approval of a combination of a checkpoint inhibitor and an ADC.

[\[SLIDE 22: Sharing data from our earlier stage oncology program\]](#)

Turning to immuno-oncology.

Evidence continues to emerge for the benefit of KEYTRUDA in the treatment of earlier-stage cancer. Positive survival data from KEYNOTE-671 evaluating KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant therapy, followed by adjuvant KEYTRUDA in patients with resectable stage II, IIIA or IIIB non-small cell lung cancer compared to pre-operative chemotherapy, were presented at ESMO, further reinforcing the benefit of routine lung cancer screening for certain populations to enable early intervention. Based on the KEYNOTE-671 results, last week the FDA approved this indication with a differentiated label that includes overall survival. KEYTRUDA has now been approved for six indications to treat patients with non-small cell lung cancer. KEYNOTE 671 represents the eighth approval for KEYTRUDA in earlier stage cancer.

Positive data from additional earlier stage studies in women's cancers were also presented at ESMO, for:

- KEYNOTE-756 in patients with estrogen receptor-positive, HER2 negative breast cancer;
- KEYNOTE-522 in high-risk early-stage triple negative breast cancer, and
- KEYNOTE-A18 for patients with high-risk locally advanced cervical cancer. The FDA recently granted priority review for KEYTRUDA based upon this study with a target action date of January 20th.

We also announced KEYTRUDA significantly improved disease-free-survival for the adjuvant treatment of patients with localized muscle-invasive and locally advanced urothelial carcinoma based on KEYNOTE-123.

And finally, in collaboration with Moderna, the Phase 3 trial for KEYTRUDA in combination with V940, an individualized neoantigen therapy, in earlier stage non-small cell lung cancer has now been posted and is poised to start soon.

[SLIDE 23: Leveraging precision medicine to improve outcomes for patients]

In precision oncology, our efforts continue to yield progress.

WELIREG, our HIF 2 alpha inhibitor, is approved for treatment of certain cancers in patients with von Hippel Lindau Disease, a rare cancer-prone genetic disorder. Studies evaluating WELIREG in broader populations of patients whose tumors display analogous genetic underpinnings are ongoing.

Data presented at ESMO from LITESPARK-005 evaluating WELIREG for adult patients with advanced renal cell carcinoma following immune checkpoint and anti-angiogenic therapies showed statistically significant and clinically meaningful improvement in progression-free survival versus the standard of care. These findings support our supplemental new drug application for WELIREG which was granted priority review by the FDA with a target action date of January 17th. Additional Phase 3 studies in combination with KEYTRUDA and / or lenvatinib in advanced and adjuvant renal cell carcinoma are proceeding.

First-time safety and preliminary efficacy data for MK-1084, our oral KRAS inhibitor both as monotherapy in patients with solid tumors and in combination with KEYTRUDA for metastatic non-small cell lung cancer whose tumors

harbored KRAS G12C mutations were presented at ESMO. Notably the combination arm showed a compelling objective response rate of 71%.

While the data are early, we are encouraged by the potential to combine MK-1084 with KEYTRUDA.

In the hematologic space, we will begin enrolling patients in our Phase 3 study evaluating MK-3543 or bomedemstat, as second line treatment for essential thrombocythemia, an area with tremendous patient need. Bomedemstat is derived from our acquisition of Imago.

[SLIDE 24: Bringing new cancer treatments to patients around the world]

Outside of the US, the European Union granted approval for:

- KEYTRUDA for adjuvant treatment of patients with non-small cell lung cancer who are at high risk of recurrence following complete resection and platinum-based chemotherapy based on KEYNOTE-091
- And for KEYTRUDA in combination with trastuzumab and chemotherapy as first line treatment for patients with certain gastric or gastroesophageal junction adenocarcinoma based on KEYNOTE-811.

In Japan, Lynparza, in combination with abiraterone and prednisone, was approved for BRCA-mutated metastatic castration-resistant prostate cancer, with distant metastasis based on the PROpel study.

[SLIDE 25: Significant advancements across our broader pipeline and portfolio]

Now to our broader pipeline.

Building on the ongoing launch of VAXNEUVANCE which Caroline mentioned, progress continues in our population-focused pneumococcal conjugate vaccine program.

V116, our investigational pneumococcal conjugate vaccine specifically designed for adults has demonstrated a robust immune response to all 21 serotypes in the STRIDE-3 and STRIDE-6 studies. Detailed findings from the STRIDE-3 study will be presented at the World Vaccine Congress West Coast in November. If approved, V116 would be the first pneumococcal conjugate vaccine specifically designed to address serotypes responsible for the majority of adult invasive pneumococcal disease in adults.

Our company has deep expertise, given our breadth and depth of knowledge both in immuno-oncology and vaccines. We are leveraging these capabilities in immunology where the first patient is ready to be enrolled in the Phase 3 trial for MK-7240 in ulcerative colitis.

Turning to cardiometabolic disease programs.

Last month at the European Respiratory Society International Congress, we presented data for sotatercept, currently under review by the FDA for the treatment of adults with pulmonary arterial hypertension. In an exploratory post-hoc analysis of right heart catheterization and echocardiography data from patients in the Phase 3 STELLAR study, patients with PAH treated with sotatercept for 24 weeks on top of background therapy showed a reduction in right heart size and improved right-ventricular function and hemodynamic status. In addition, we presented promising data from an analysis of the Phase 3 SOTERIA open-label extension study in PAH. The results support the potential long-term durability of the response to sotatercept and represent the longest safety and efficacy analysis for this compound to date.

Given the serious patient need in pulmonary arterial hypertension, our regulatory and clinical teams worked swiftly to submit the necessary regulatory filings for sotatercept. The FDA has accepted the Biologics License Application under priority review with a target action, date of March 26th. In addition, the submission to the Committee for Medicinal Products for Human Use in the European Union has been completed.

Also in cardiology, momentum continues in the clinical development program for MK-0616, our oral PCSK9 inhibitor. We have initiated the CORALreef Lipids study in a broad patient population, and CORALreef Outcomes, a randomized, double-blinded study, evaluating the efficacy of MK-0616 with respect to major atherosclerotic cardiovascular events as well as a separate CORALreef study in patients with heterozygous familial hypercholesterolemia.

Over the last three years, we have moved with rigor and urgency to advance the best science while carefully coordinating our efforts internally and externally. We have, and continue to, leverage the foundational properties of KEYTRUDA while adding promising candidates with novel mechanisms and modalities in oncology. At the same time, we have expanded in our focused areas of excellence to establish a diverse pipeline of promising candidates spanning multiple additional disease areas.

We understand there is still work to be done but the tangible advances we are making underscore our purpose of creating innovative medicines and vaccines that save and improve lives.

And now I turn the call back to Peter.