

Merck & Co., Inc Q1 2023 Earnings Prepared Remarks

April 27, 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 began 2023 with significant advancements across key areas of our pipeline, and with continued strong performance of our key growth drivers. I remain very pleased with the consistency and excellence of our teams' execution and I'm confident that our strategy is leading to sustainable success. We remain grounded in our shared purpose to bring forward bold science that delivers solutions which address serious unmet medical needs and, importantly, save and improve lives around the world.

[SLIDE 5: Delivered on our key strategic priorities in 1Q 2023]

Our priorities remain consistent. By focusing on our science-led strategy, we intend to bring forward important innovation from our internal discovery pipeline and via strategic business development targeted at accessing the most compelling and complementary external science leveraging our best-in-class clinical development capabilities. We aim to sustain the momentum in our pipeline in 2023 and beyond, and we're confident that this will lead to strong commercial and financial performance, as well as value creation for patients and shareholders over the long-term.

[SLIDE 6: Merck continues to advance science-led strategy through acquisition of Prometheus Biosciences]

Speaking of accessing important external innovation, we're very pleased with our announced acquisition of Prometheus Biosciences. Prometheus brings us a potential best-in-class novel treatment that could transform the

standard of care for patients suffering from ulcerative colitis and Crohn's disease, potentially debilitating conditions, as well as a broader pipeline and a technology platform that enables a precision medicine approach. It accelerates our presence in immunology, increases the diversity of our pipeline, and brings us a potentially significant revenue growth driver through the next decade. This transaction is also another example of Merck acting decisively when science and value align.

[SLIDE 7: Very significant 1Q sales and underlying earnings growth]

Turning now to our first quarter results.

We delivered very significant underlying growth, excluding the expected year-over-year decline in LAGEVRIO sales. This reflects continued fundamental strength and momentum across our key growth drivers, particularly in Oncology and Vaccines. These results reinforce our confidence in the robust demand for our innovative portfolio, and in our outlook for the remainder of 2023, which Caroline will speak to in a moment.

[SLIDE 8: Advancing and augmenting deep pipeline in 1Q]

Moving to our research organization, we've made significant advancements in cardiovascular, we shared the remarkable work of our research colleagues at the American College of Cardiology conference in March. The strength of the data from the Phase 3 STELLAR trial studying sotatercept in pulmonary arterial hypertension reinforces our belief in this important new mechanism's potential to change the treatment paradigm for patients. In addition, impressive results from the Phase 2 trial studying our oral PCSK9 inhibitor suggest that this could be a globally accessible treatment option for patients in need of LDL-cholesterol reduction.

The successes we are achieving across our cardiovascular pipeline have created excitement across our company, and a belief that Merck will build on its strong legacy of bringing forth breakthrough therapies for the benefit of patients suffering from cardiovascular disease, and that these programs will contribute significantly to our long-term growth.

In oncology, we were pleased to share the positive topline results from KEYNOTE-671, which showed a significant improvement in event free survival in certain patients with earlier-stage non-small cell lung cancer, and we look forward to potential approval later this year. In addition, we are working with our partner Moderna to rapidly expand our efforts to study the combination of KEYTRUDA with an individualized neoantigen therapy, which we previously referred to as a personalized cancer vaccine therapy, in adjuvant melanoma and potential additional tumor types.

I'm very encouraged by the substantial progress we've made across our broad pipeline. We're now working on a greater number of late-stage programs across more therapeutic areas and modalities than at any time in recent years.

In summary, we've begun 2023 with scientific, commercial and operational momentum, and expect strong full-year growth across both our Human and Animal Health businesses. I'm proud of the progress we've made, but as always, recognize the need to move with speed and urgency to do even more.

I want to thank our global team for their steadfast dedication as we build a sustainable innovation engine that will deliver value for patients and shareholders well into the next decade.

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 Q1 sales growth across Human Health and Animal Health]

As Rob highlighted, we are off to a strong start to the year with robust underlying performance across our key growth pillars. These results further demonstrate that our focus on science and innovation as the core of our strategy is working. Our success is enabled by the excellent execution of our team of dedicated colleagues, who are delivering our important medicines and vaccines to people and animals across the globe. We remain very confident in our ability to continue to deliver in the short-term, while we make disciplined investments to maximize long-term value for patients and shareholders.

Now, turning to our first quarter results.

Total company revenues were \$14.5 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered very strong underlying growth of 15%.

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

Our Human Health business continued its strong momentum. Excluding LAGEVRIO, growth was 18%, driven by Oncology and Vaccines.

Our Animal Health business also delivered solid performance, with sales increasing 5%, driven by growth across both livestock and companion animal products.

[SLIDE 11: Oncology: KEYTRUDA drives strong growth]

Now, turning to the first quarter performance of our key brands.

In Oncology, KEYTRUDA grew 24% to \$5.8 billion driven by robust global demand for metastatic indications as well as increased utilization driven by approvals in early-stage cancers.

In the U.S., KEYTRUDA grew across all key tumor types and continues to benefit from uptake in earlier-stage cancers including triple negative breast cancer, as well as in certain types of renal cell carcinoma and melanoma.

We continue to anticipate gradual uptake from KEYNOTE-091 in earlier stage lung cancer as we are working with the medical community to increase adjuvant treatment rates for diagnosed patients receiving surgery. We, along with others, are also working to improve upon the low level of lung cancer screenings and follow-up through diagnosis, which we anticipate will increase over time. We are encouraged by the positive feedback we've received thus far. Furthermore, we are excited by the potential to bring an additional treatment option to patients following the positive results of the KEYNOTE-671 study. Together, these studies position us well to extend our leadership in non-small cell lung cancer.

We also look forward to providing a new treatment option to certain adult patients with bladder cancer following the recent approval of KEYNOTE-869.

Outside the U.S., KEYTRUDA continues to maintain its leadership in non-small cell lung cancer. Growth was driven by uptake in metastatic renal cell carcinoma and certain types of head and neck cancer, as well as in earlier-stage cancers, including certain types of high-risk, early-stage triple negative breast cancer, which continues to launch in additional markets.

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

Lynparza remains the market leading PARP inhibitor. Alliance revenue grew 8% primarily due to increased demand in key European markets in certain patients with ovarian cancer.

Lenvima alliance revenue grew 5% due to increased uptake in the treatment of certain patients with advanced renal cell carcinoma in key European markets.

[SLIDE 13: Vaccines: GARDASIL growth driven by strong international demand]

Our vaccines portfolio delivered excellent growth led by GARDASIL, which grew 43% to \$2.0 billion. Performance was driven by strong demand in major ex-U.S. markets, particularly China, as well as increased supply. Growth also benefitted from an acceleration of shipments to China from the second half to the first half of the year to ensure the availability of product to meet heightened demand following the approval of the expanded indication of GARDASIL 9 for girls and women 9 to 45 years of age. Vaccine sales also benefited from increasing demand for VAXNEUVANCE following the ongoing pediatric launch, particularly in the U.S.

[SLIDE 14: Hospital: Strong global demand across key products]

In our Hospital Acute Care portfolio, BRIDION sales grew 27%, driven by an increase in market share among neuromuscular blockade reversal agents.

[SLIDE 15: Animal Health: Solid growth driven by livestock]

Our Animal Health business delivered another good quarter, with sales increasing 5%, reflecting strong demand across our Livestock portfolio, particularly in ruminant and poultry products as well as strategic price actions.

[SLIDE 16: Q1 2023 continuing operations 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 76.9%, an increase of 6.1 percentage points due to favorable product mix, which reflects a benefit from the lower sales of LAGEVRIO.

Operating expenses increased to \$6.7 billion, reflecting \$1.4 billion of charges related to the acquisition of Imago and our license and collaboration agreement with Kelun. Excluding these charges, operating expenses grew 12% driven by increased investments to support our key growth drivers and pipeline.

Other income was \$70 million.

Our tax rate was 20.4%, reflecting the unfavorable impact from the Imago transaction, for which no tax benefit was recognized.

Taken together, we earned \$1.40 per share, which includes a \$0.52 impact from charges related to the acquisition of Imago and our agreement with Kelun.

[\[SLIDE 17: Merck updated full-year 2023 guidance\]](#)

Turning now to our 2023 non-GAAP guidance.

The continued operational strength of our business enables us to raise and narrow our full year revenue guidance. We now project revenue to be between \$57.7 and \$58.9 billion, including approximately \$1 billion from LAGEVRIO. We expect strong underlying revenue growth of 8% to 10%, offset by the decline in LAGEVRIO and an approximate 2 percentage point negative impact from foreign exchange using mid-April rates.

Our gross margin is still expected to be approximately 77%.

We have narrowed the estimated range of operating expenses to be between \$23.3 and \$24.1 billion. As a reminder, this range includes \$1.4 billion of upfront research and development expenses related to the acquisition of Imago and our agreement with Kelun. This guidance does not assume the proposed acquisition of Prometheus or any additional significant potential business development transactions.

Other Income is anticipated to be approximately \$250 million.

We continue to assume a full year tax rate between 17% and 18% and approximately 2.55 billion shares outstanding.

Taken together, we are increasing and narrowing our expected EPS range to \$6.88 to \$7.00. This range includes a negative impact from foreign exchange of approximately 4 percentage points, using mid-April rates.

It is important to note that this guidance does not include the impact of the proposed acquisition of Prometheus, which is expected to close in the third quarter of this year. We expect the transaction will result in a one-time charge that will increase research and development expense of approximately \$10.3 billion, or approximately \$4.00 per share. The impact of this charge will be reflected in both our GAAP and non-GAAP results.

In addition, ongoing investment to advance the pipeline assets as well as the cost of financing will negatively impact EPS by approximately \$0.25 in the first 12 months following close.

As Rob noted, we are very excited by Prometheus' compelling science and confident that this transaction has the potential to create meaningful value for patients and shareholders.

[SLIDE 18: Key modeling considerations]

Our guidance reflects our continued confidence in the underlying strength of our business driven by our key pillars in Oncology, Vaccines, and Animal Health.

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

In the U.S., KEYTRUDA has achieved exceptional growth over the past several quarters driven by recent launches, particularly in early-stage indications, such as triple negative breast cancer. While we continue to anticipate growth from these earlier stage indications, the year-over-year growth rate is expected to moderate as we anniversary their very strong initial uptake.

Outside the U.S., we continue to expect strong volume growth for KEYTRUDA; however, pricing is an increasing headwind, particularly as we launch new indications in key European markets, which will temper ex-U.S. growth.

Finally, we are confident in our ability to drive strong growth of GARDASIL, particularly in international markets. We are well positioned to protect many more people from HPV related cancers now and over the long-term and given the strong global demand for the vaccine, we see an acceleration of growth for GARDASIL in the full year 2023 relative to 2022, though not quite at the same level of growth achieved this quarter.

[SLIDE 19: Remain committed to balanced capital allocation strategy]

Now shifting to capital allocation, where we remain committed to our priorities following the announcement to acquire Prometheus.

We will continue to prioritize investments in our business and growing pipeline to realize the value of the many near- and long-term opportunities we see.

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

Business development remains a high priority, and we maintain the ability within our strong investment grade credit rating to pursue additional, science driven, value enhancing transactions going forward.

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

To conclude, we remain very confident in the outlook of our business driven by the global demand for our innovative medicines and vaccines. We are in a position of financial and operational strength, and our continued excellent execution will enable us to deliver value to patients 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.

[SLIDE 21: Driving value for patients and shareholders by progressing our pipeline]

Hello everyone.

Today, I will provide notable updates since the last earnings call, starting with our progress in cardiovascular disease, oncology, then infectious disease and subsequently immunology with our recently announced acquisition of Prometheus.

[SLIDE 22: Making tangible advancements in cardiovascular disease]

As Rob mentioned earlier, at the American College of Cardiology in conjunction with the World Congress of Cardiology meeting in New Orleans, results from the Phase 3 STELLAR trial, evaluating sotatercept for pulmonary arterial hypertension, as well as data from the Phase 2b trial for our oral PCSK9 inhibitor candidate, MK-0616, in development for the treatment of hypercholesterolemia, were presented.

In the STELLAR study, sotatercept, in combination with stable background therapy, met its primary endpoint with a substantial improvement in 6-minute walk distance at 24 weeks compared to placebo in combination with background

therapy. The trial also met 8 out of 9 secondary measures, including a compelling reduction in time to clinical worsening or death versus placebo. These findings were published simultaneously in *the New England Journal of Medicine*.

We are working diligently to submit filings from the STELLAR data to regulatory agencies and at this time, anticipate filing in the U.S. in the third quarter of this year followed by the EU.

We are advancing the broad sotatercept program, including the HYPERION, ZENITH, SOTERIA and Phase 2 CADENCE trials which are actively recruiting.

Also at the ACC meeting, detailed Phase 2b results for MK-0616 were presented showing a reduction of LDL-cholesterol levels from 41.2 up to 60.9 percent versus placebo. Up to 90 percent of patients receiving MK-0616, at the highest dose studied, were able to reach their LDL-C goal.

An oral PCSK9 inhibitor could provide the opportunity for broad, global access. We are initiating multiple Phase 3 studies including in secondary prevention; intermediate to high-risk primary prevention; and for patients with heterozygous familial hypercholesterolemia. In parallel, we will conduct a cardiovascular outcomes trial.

We are making progress towards our goal of developing medicines that improve and extend the lives of patients with cardiovascular diseases and look forward to providing updates in the future.

[SLIDE 23: Developing treatments for earlier stages of cancer remains a key area of focus and execution]

Turning to oncology.

As I have mentioned previously, a key area of focus and execution has been the development of treatments for earlier stages of cancer where there remains significant unmet need.

We announced FDA acceptance of our application for KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant, followed by adjuvant therapy in patients with resectable stage II, IIIA and IIIB non-small cell lung cancer, based on the findings to date from the KEYNOTE-671 study. The Agency has set a PDUFA action date of October 16th and detailed findings will be presented at ASCO in June.

Together, with the approval of KEYTRUDA in the adjuvant setting for certain patients with non-small cell lung cancer, based on KEYNOTE-091, the KEYNOTE-671 study builds on the wealth of data we have generated. Relevant additional ongoing studies include KEYNOTE-867 and KEYLYNK-012.

This comprehensive development program, underscores our commitment to an area where there is significant opportunity to improve patient outcomes. Importantly, it also reinforces the need for early detection through lung cancer screening.

At the American Association for Cancer Research annual meeting, in collaboration with Moderna, we announced detailed results from KEYNOTE-942, a Phase 2b study evaluating KEYTRUDA in combination with V940 also known as mRNA-4157, an individualized neoantigen therapy, for the adjuvant treatment of stage III and IV melanoma in patients with high risk of disease recurrence following complete resection.

These results are the first to demonstrate improvement of recurrence-free survival over adjuvant standard of care PD-1 blockade in resected high-risk melanoma, and provide the first randomized evidence that an individualized neoantigen therapy has potential benefit.

The FDA has granted this combination Breakthrough Therapy Designation and the European Medicines Agency has awarded PRIME designation for high-risk stage III and IV melanoma following complete resection.

Merck and Moderna plan to initiate a Phase 3 study in adjuvant melanoma this year, and rapidly expand to additional tumor types, including non-small cell lung cancer.

[SLIDE 24: Advancing our broader oncology portfolio]

Together with Astellas and Seagen, we announced the FDA's accelerated approval of KEYTRUDA in combination with enfortumab vedotin, an antibody drug conjugate, for the treatment of adults with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy. This accelerated approval followed priority review and is based on data from the KEYNOTE-869 trial.

This is an important advancement as this is the first U.S. approval of a regimen combining an anti-PD-1 therapy with an antibody-drug conjugate in these patients.

The approval adds to the success of our foundational work evaluating KEYTRUDA in combination with chemotherapy and provides promising evidence for combining immunotherapy with tissue targeted anticancer agents.

We are well positioned to build upon this work, with a portfolio of next generation antibody drug conjugates through our collaboration with Kelun Biotech. Planning is underway for an expansive global clinical development program and

we look forward to initiating Phase 3 trials for MK-2870, our TROP-2 targeting ADC, as both monotherapy and in combination with KEYTRUDA.

We also announced that the FDA has accepted our application for KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with HER2-negative locally advanced unresectable or metastatic gastric or gastro-esophageal junction adenocarcinoma. This filing is based on results from the Phase 3 KEYNOTE-859 trial, in which KEYTRUDA plus chemotherapy demonstrated a significant improvement in overall survival, reducing the risk of death by 22 percent compared to chemotherapy alone in these patients, regardless of PD-L1 expression. The agency has set a PDUFA action date of December 16th. This provides us the opportunity to expand upon our approval for patients with HER2 positive disease based on KEYNOTE-811.

We recently announced positive data from the Phase 3 NRG-GY018 trial investigating KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with stage III to IV or recurrent endometrial carcinoma.

This is an important advancement for women with endometrial cancer building on our approvals from KEYNOTE-146, 775 and 158. Earlier this year the American Cancer Society's 2023 annual report on cancer facts and trends, noted that survival for uterine malignancies had not improved over the past four decades due to a lack of treatment advances. We continue our work to provide better treatment options in women's cancers.

And finally the treatment of metastatic castration-resistant prostate cancer remains a significant and growing unmet need and therefore an area of ongoing commitment. We have gained important insights to date from our trials evaluating KEYTRUDA and Lynparza and are planning to initiate Phase 3 studies of MK-5684, a novel oral, non-steroidal inhibitor of CYP-11A1, from our collaboration with Orion, by the end of this year. Also, with AstraZeneca, we look forward to the discussion regarding the PROPEL study at the upcoming oncologic drugs advisory committee meeting.

We are proud of the progress we are making and look forward to hosting an investor event at ASCO in Chicago. Please mark your calendars for the evening of Monday, June 5th where we will provide an update on our oncology strategy and development program.

[SLIDE 25: Expanding our broader pipeline and portfolio]

Turning to the progress of our infectious disease program.

We are now actively enrolling multiple new Phase 3 studies for once-daily islatravir in combination with doravirine and, with Gilead, have resumed the Phase 2 study of an oral once-weekly combination treatment regimen of islatravir and Gilead's lenacapavir. We are committed to advancing the science to offer new treatment options for the treatment of HIV.

On LAGEVRIO, we continue to prioritize global access during surges of COVID-19 around the world, including in Japan, where the Ministry of Health Labor and Welfare recently granted full approval for the treatment of COVID-19. We are proceeding with the evaluation of LAGEVRIO for the treatment of other viral respiratory infections and will share more as studies read out.

Finally, to our recently announced acquisition of Prometheus.

Prometheus offers a strong scientific pedigree with a candidate that has shown exciting potential in both ulcerative colitis and Crohn's disease.

TNF-like 1A is, a novel target, which provides the potential opportunity to transform standard of care in a disease area where current therapies are often inadequate and high unmet need remains. Prometheus' anti-TL1A antibody, PRA023, is a potential first-in-class late-stage clinical candidate with a unique dual mechanism of action including anti-inflammatory and anti-fibrotic properties.

PRA023's Phase 2 results in both ulcerative colitis and Crohn's Disease demonstrated strong efficacy. Further, at an interim analysis, the data in the biomarker positive sub population suggested even greater efficacy with patients more likely to achieve clinical remission.

By combining Prometheus' deep understanding of inflammatory bowel disease and Merck's deep expertise in developing and implementing biomarkers, we hope to usher in a new era in Immunology where patients are matched with the right therapy based on a precision medicine approach.

Prometheus' biobank of IBD specimens has yielded deep molecular insights that formed the foundation for the discovery of PRA052 and we look forward to building on that knowledge to gain further insights which will enable the identification and prioritization of additional targets.

In closing, we continue to make progress towards our goal of creating innovative medicines that will improve the outcomes for patients.

And now I turn the call back to Peter.