

# Merck Q12021 Earnings



# Forward-looking statement of Merck & Co., Inc., Kenilworth, N.J., USA

This presentation of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2020 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

# Q1 performance highlights

Worldwide sales performance<sup>1</sup>

\$12.1B **♣** -1%

- Invested \$2.4B in research and development, making significant progress in advancing our pipeline and across our key growth pillars
- Returned \$1.6B to shareholders through dividends
- Executed value-enhancing business development, including announcement of Pandion Therapeutics<sup>4</sup> acquisition and collaboration with Gilead Sciences

Created shareholder value

Non-GAAP EPS performance<sup>1</sup>

\$1.40 **♣**-9%

- FDA approved 2 filings in oncology and cardiovascular, accepted 1 filing in chronic cough, and granted priority review for 2 assets in oncology and vaccines
- In the EU, received 2 approvals and 1 CHMP positive opinion for KEYTRUDA
- Received 2 approvals in oncology in China and Japan
- Presented data at SGO, ASCO GU, CROI and AACR
- Toplined results in oncology and HIV
- Advanced multiple assets into later stages of development in oncology, HIV and vaccines

Advanced the pipeline

<sup>1.</sup> Growth rates exclude impact of foreign exchange

<sup>2.</sup> The GAAP to non-GAAP reconciliation is available in the Supplemental Tables to Merck's Q1 2021 earnings release.

<sup>3.</sup> GAAP EPS =\$1.25

<sup>4.</sup> Transaction closed April 1, 2021

# Driving value for patients and shareholders by progressing our pipeline

#### Key regulatory milestones through April 29:

- In the U.S., the FDA approved KEYTRUDA in esophageal cancer (KN-590) and VERQUVO in chronic heart failure (VICTORIA); accepted filing for gefapixant in chronic cough (COUGH-1 and COUGH-2); and granted priority review for belzutifan in VHL-associated RCC and V114 in adults
- In the EU, received approval for expanded indications for KEYTRUDA in cHL (KN-204) and colorectal cancer (KN-177), and received a CHMP positive opinion for KEYTRUDA in urothelial carcinoma (KN-361)
- In China, received approval for KEYTRUDA Q6W dosing regimen for all approved indications
- In Japan, received approval for LENVIMA in thymic cancer

#### **Key data presentations through April 29:**

- Presented new data from KN-775/Study 309 in endometrial cancer at SGO, KN-581/Study 307 in RCC at ASCO GU, and from multiple oncology studies at AACR including KEYLYNK-007 studying KEYTRUDA+Lynparza in advanced solid tumors, KEYNOTE-555 studying subcutaneous administration of KEYTRUDA, KEYNOTE-629 studying KEYTRUDA in cSCC, and data for intratumoral KEYTRUDA+V937 (oncolytic virus) in advanced melanoma
- At CROI, presented data from broad HIV pipeline including a Phase 1 trial studying investigational
  islatravir subdermal implant for the prevention of HIV-1, which will be moving into Phase 2 as a once
  yearly implant
- Toplined results for Lynparza in early-stage breast cancer based on the pivotal OlympiA trial, for KEYTRUDA in RCC based on KN-564 and for Phase 2 once-monthly oral islatravir in PrEP
- Advanced novel mechanism coformulations with pembrolizumab into Phase 3: pembrolizumab+vibostolimab (TIGIT) in NSCLC and pembrolizumab+guavonlimab (CTLA-4) in RCC
- Advanced islatravir once-monthly oral into Phase 3 for the prevention of HIV, and MK-1654 (monoclonal antibody) into Phase 2/3 for RSV



## Oncology: continued strong growth

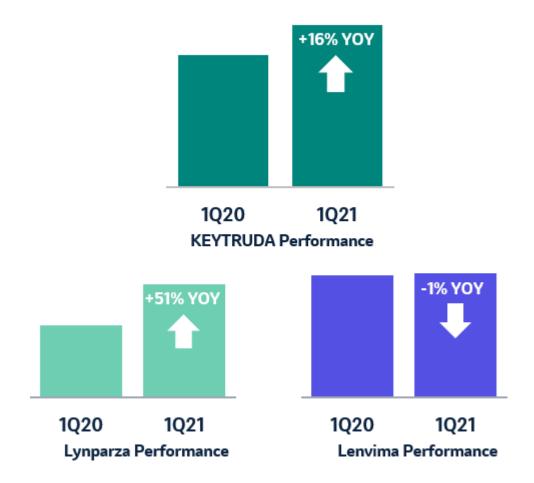








- KEYTRUDA sales of \$3.9B increased 16% yearover-year, driven by momentum in lung and strong performance across indications
  - In the U.S., sales of \$2.2B driven by growth across all key tumor types, including continued leadership in lung, as well as uptake in the Q6W dosing regimen
  - Ex-U.S., 18% growth was driven by global uptake in lung as well as RCC and H&N
- Lynparza sales increased 51%, with growth driven by continued uptake in approved indications
- Lenvima performance reflective of competition in HCC and an unfavorable impact to revenue for the recent NRDL listing in China





# Vaccines: COVID-19 dynamics more than offset underlying demand



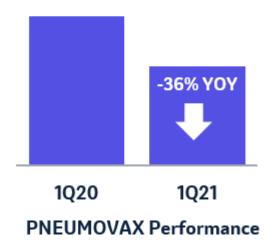






- GARDASIL sales of \$917M negatively impacted by timing of public sector purchases and timing of shipments in China
  - In the U.S., sales declined year-over-year primarily due to public sector buying patterns and impact from COVID-19 on access to healthcare providers
  - Ex-U.S., sales declined year-over-year, driven by lower shipments in China and negative impact from the pandemic, particularly in Europe
- PNEUMOVAX sales of \$171M reflect lower demand due to COVID-19, partially offset by higher volumes ex-U.S.





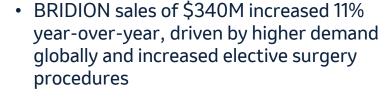


## Hospital: continued global recovery

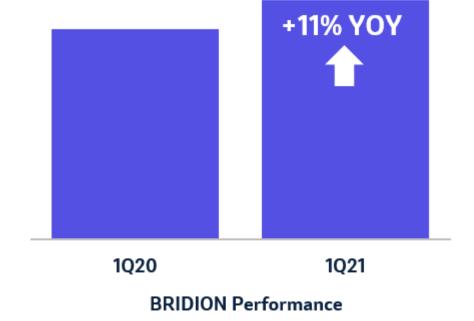








- Continued uptake in PREVYMIS, driven by ongoing launches
- Continued to build on long legacy in HIV through collaboration with Gilead







# Animal Health: strong growth across innovative portfolio

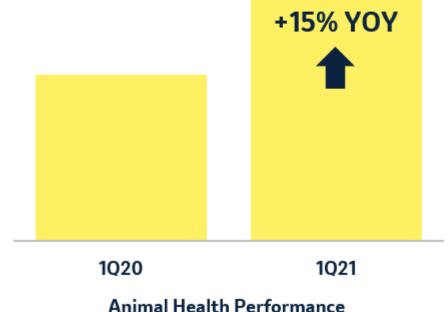








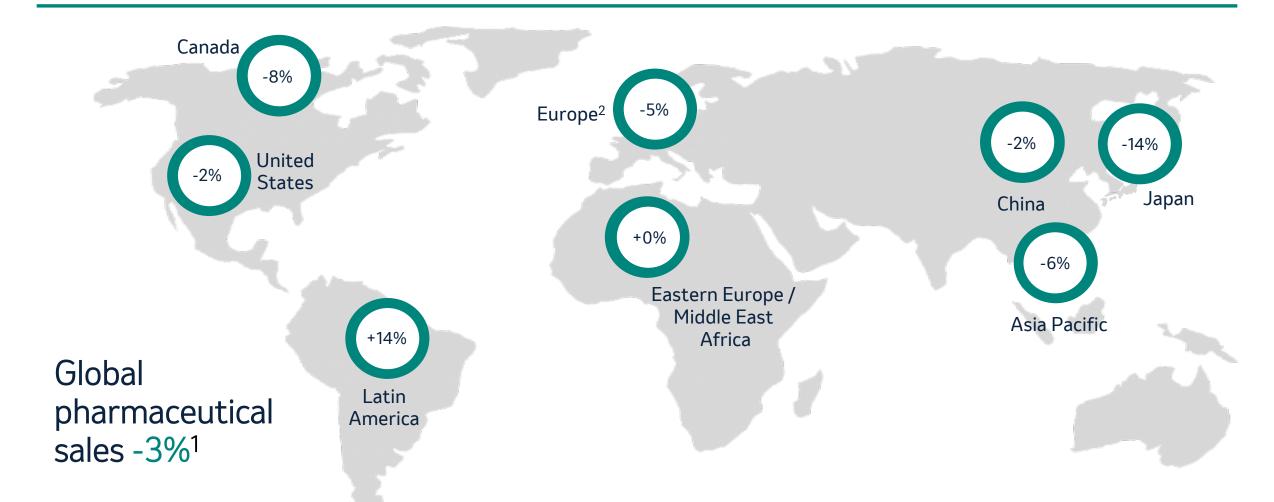
- Animal Health sales increased 15% to \$1.4B
  - Companion Animal sales increased 24%, driven by strength in parasiticides and vaccines
  - Livestock sales increased 9%, reflecting increased international demand in ruminant, poultry and swine, as well as global demand for Animal Intelligence products







## Global human health performance



<sup>1.</sup> All growth rates exclude the impact of foreign exchange.

 $<sup>2.\</sup> Europe primarily represents all \ European \ Union \ countries, \ the \ European \ Union \ accession \ markets \ and \ the \ United \ Kingdom.$ 

## Q1 2021 financial results summary: Growth offset by impact from COVID-19

#### \$ in billions, except EPS amounts

	Q1 2021	Q1 2020	Change	Change Ex-FX
Sales	\$12.1	\$12.1	+0%	-1%
GAAP Gross Margin	69.6%	72.5%	-3%	-3%
Non-GAAP Gross Margin <sup>2</sup>	75.7%	76.5%	-1%	-1%
GAAP net income <sup>1</sup>	\$3.2	\$3.2	-1%	-3%
Non-GAAP net income that excludes certain items <sup>1,2</sup>	\$3.6	\$3.9	-8%	-9%
GAAP EPS	\$1.25	\$1.26	-1%	-3%
Non-GAAP EPS that excludes certain items <sup>2</sup>	\$1.40	\$1.51	-7%	-9%

<sup>1.</sup> Net income attributable to Merck & Co., Inc.

<sup>2.</sup> Merck is providing certain non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results as it permits investors to understand how management assesses performance. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. As previously disclosed, beginning in 2021, Merck changed the treatment of certain items for purposes of its non-GAAP reporting. Prior periods have been recast to conform to the current presentation. For a description of the non-GAAP adjustments.

# Updated full-year 2021 guidance<sup>1</sup>

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$51.8B to \$53.8B +8% to +12% (+6% to +10% ex-FX)	\$51.8B to \$53.8B +8% to +12% (+6% to +10% ex-FX)	<ul> <li>Now assumes &lt;2% positive FX impact</li> <li>Now assumes ~3% negative impact due to COVID-19, particularly during the first half of 2021</li> </ul>
Non-GAAP Gross Margin Rate <sup>2</sup>	~77.0%	~76.0%	Slightly less than prior guidance as a result of the impact of COVID-19
Non-GAAP Operating Expenses <sup>3</sup>	Increase by high single to low double-digit rate	Increase by mid-to-high single-digit rate	Expense management helping to offset spend on COVID-19 research programs
Other (Income) / Expense	~\$400M of expense	~\$400M of expense	No change
Tax Rate <sup>4</sup>	~15.0-16.0%	~15.0-16.0%	No change
Shares Outstanding	~2.53B	~2.53B	No change
GAAP EPS <sup>5</sup>	\$5.52 to \$5.72	\$5.05 to \$5.25	
Non-GAAP EPS <sup>5,6</sup>	\$6.48 to \$6.68 +12% to +15% (+9% to +12% ex-FX)	\$6.48 to \$6.68 +12% to +15% (+9% to +12% ex-FX)	Now assumes < 3% positive FX impact

<sup>1.</sup> All estimates based on the assumption that the Organon business will be a part of Merck for all of 2021

<sup>2.</sup> GAAP Gross Margin Rate: Higher than 2020 by a low single-digit rate

<sup>3.</sup> GAAP Operating Expenses: Lower than 2020 by a mid-single-digit rate 4. GAAP Tax Rate: ~15.0% - 16.0%

<sup>5.</sup> The GAAP to non-GAAP reconciliation is available in Merck's Q1 2021 earnings release

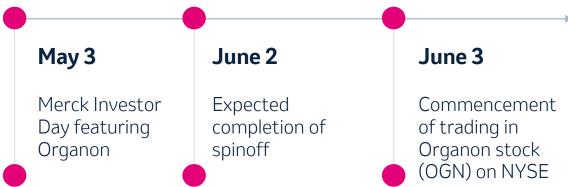
<sup>6.</sup> Growth rates reflective of recast of non-GAAP P&L presentation

# Accelerating towards the spinoff of Organon & Co.

#### • ORGANON Advancements



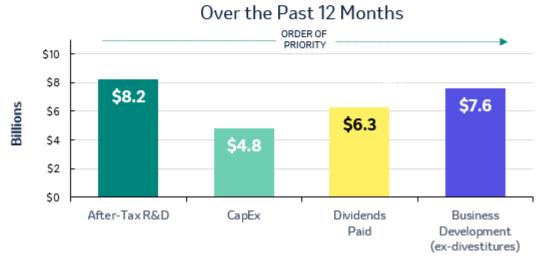
#### Upcoming milestones





#### Balanced approach to capital allocation: Investing in the business and creating value for shareholders





# Capital Investments 2020 to 2024



>\$20B

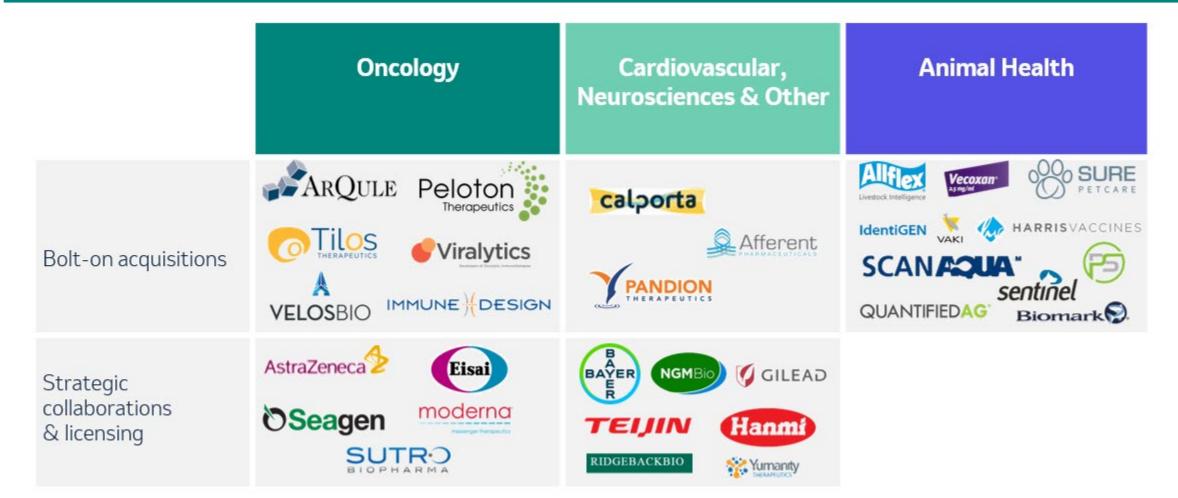
Over 5 years, including expanding manufacturing capacity for Oncology, Vaccines, and Animal Health. Includes > \$10B in the U.S.

# Balanced Capital Allocation to Invest in Growth While Returning Cash to Shareholders Over Past 12 Months

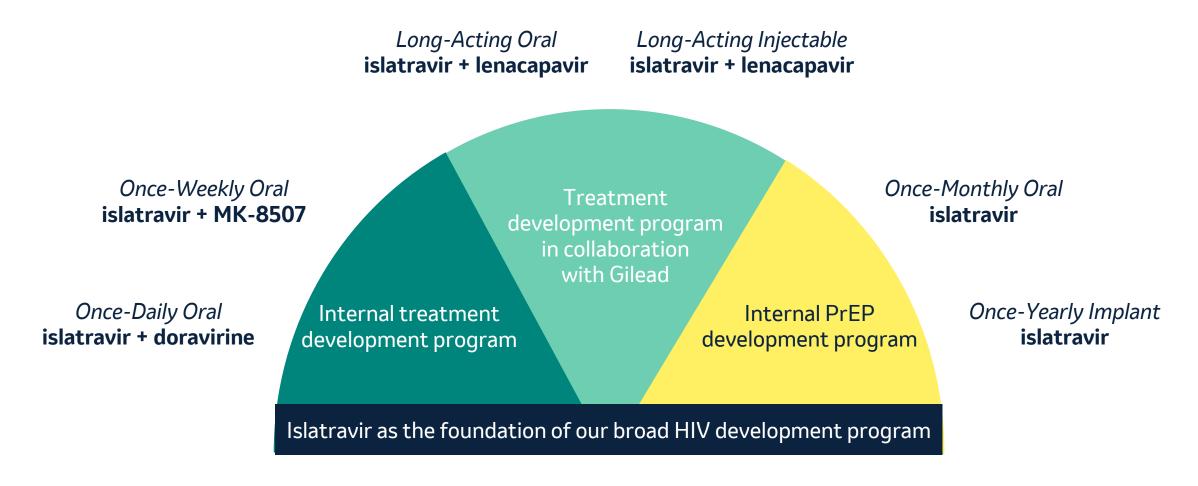
- \$9.5 billion invested in R&D (\$8.2 billion after-tax)
- \$7.6 billion spent on business development
  - Including acquisition of VelosBio and strategic oncology collaborations with Seagen
  - In addition, announced Pandion Therapeutics acquisition<sup>1</sup> and HIV collaboration with Gilead
- \$6.3 billion in dividends remain committed to the dividend, which increased 7% in 2021



### Merck has actively supplemented its pipeline and portfolio with strategic business development



# Expansion of HIV development program through collaboration with Gilead



### Creating long-term value for patients, employees and shareholders

#### **Next 5 Years**

Strong execution driving sustainable revenue growth, meaningful margin expansion and accelerated bottom-line growth



#### **5-10 Years**

Rich pipeline addressing areas of high unmet need to drive performance over the next 5 to 10 years



#### 10+ Years

Revitalized discovery efforts and increased expertise in biology to deliver ongoing scientific breakthroughs for decades to come

Anchored by our deep bench of talent and commitment to our mission



#### Continuing to make progress on our ESG commitments



Access to Health

#### Increasing access to health to advance Merck's efforts to serve more patients

- · History of making medicines and vaccines accessible and affordable through responsible pricing practices
- Implemented refreshed Access to Health Guiding Principles to ensure we continue to fulfill our commitment to access by focusing on the most critical issues
- Reaching more than 13 million women worldwide through Merck for Mothers, a \$500 million initiative
- Through our 30+ year old MECTIZAN® Donation Program, eliminated river blindness in 4 Latin American countries and in parts of 6 African countries so far, and eliminated lymphatic filariasis in 3 countries in Africa and the Middle East
- Thanks to the commitment of many collaborators across multiple sectors, ERVEBO, Merck's vaccine for the prevention of disease caused by Zaire ebolavirus in adults, is now registered in nine African countries at high risk of Ebola (with additional African country registrations pending review). These registrations followed WHO prequalification, conditional approval in the EU, and licensure in the United States.



**Employees** 

#### Fostering diverse and gender-balanced workforce essential to performance as a research-intensive company and to attracting most talented scientists

- Offering numerous programs to engage employees and promote positive work environment (including female mentorship by female Board members)
- · Partnering with Year Up, a nonprofit that enables low-income young adults of color to move from minimum wage to meaningful careers in just one year
- Increase in 2019 in women on our Board (33%), in executive roles (36%), and in management roles (43%)
- Recognized as a 2020 best place to work for LGBTQ equality by the Human Rights Campaign (HRC) Foundation
- Identified by the American Indian Science and Engineering Society (AISES) as a 50 Top STEM Workplaces for Indigenous STEM Professionals



Environmental Sustainability

#### Executing an environmental sustainability strategy to take advantage of opportunities to reduce environmental impact across operations and supply chain

- Featuring energy-conservation and water-use-reduction initiatives
- Reducing environmental impacts as evidenced by an EPA Green Chemistry Challenge Award four years running (seven awards overall)
- Purchasing electricity from renewable energy sources to reduce greenhouse gas emissions, including the launch of our first large wind virtual power purchase agreement
- Collaborating with suppliers and customers to address shared needs and interests in environmentally beneficial ways



Ethics and Transparency

#### Earning trust and confidence of stakeholders is critical for a company in the business of marketing and selling medicines and vaccines

- Demonstrated commitment to transparency through disclosures about our business and how we operate, including issuing a multi-year report about pricing practices
- · Work with broad range of stakeholders to help develop and advance innovative financing and solutions that address the needs of patients
- · Integrating the SDGs into our reporting to demonstrate our commitment to sustainable development

