

## Merck Q4 2021 Earnings

February 3, 2022



## Agenda



**Strategy and Business Update** 

**Rob Davis**President & Chief
Executive Officer



**Business/Financial Results and Outlook** 

Caroline Litchfield Chief Financial Officer



Research Update

**Dr. Dean Li**President, Merck
Research Laboratories



**Question & Answer Session** 

## 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 candidates that the candidates 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).





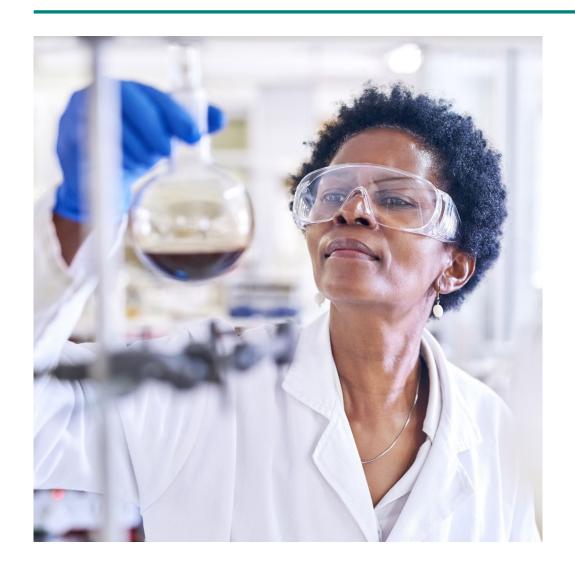
# Strategy & Business Update

#### **Rob Davis**

President & Chief Executive Officer



## Delivered on our key strategic priorities in 2021





Achieved strong commercial and financial performance



Advanced the pipeline to meet patient unmet need



Executed on strategic business development to enhance pipeline



Created long-term value for patients and shareholders

## Exceptional Q4 and 2021 sales and earnings growth<sup>1</sup>



**Q4 Worldwide Sales** 

\$13.5B

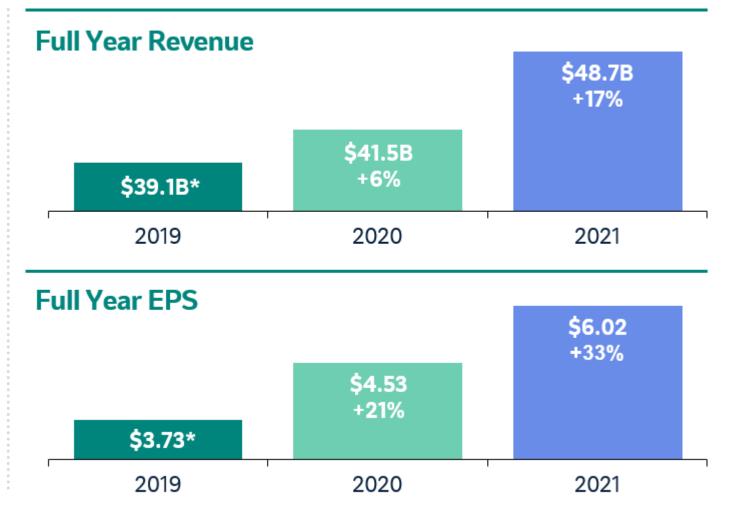
+24%



**Q4 Non-GAAP EPS** 

\$1.80

+84%



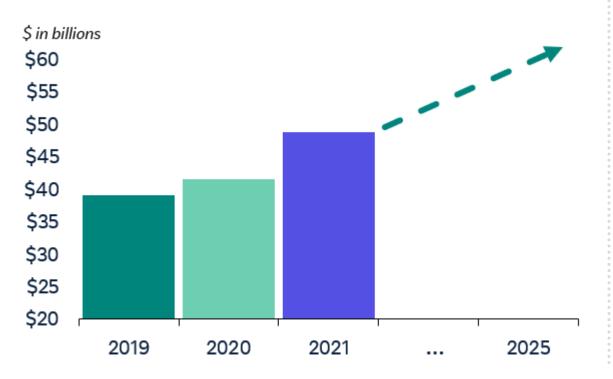
<sup>\*</sup> Growth rate not available as restated 2018 results are not provided.

<sup>1.</sup> Results from continuing operations attributable to Merck & Co., Inc.

## Expect continued strong growth in revenue and earnings

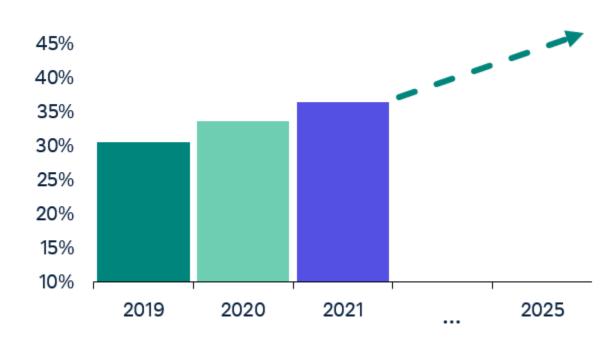
#### Revenue

Delivering visible de-risked revenue growth through 2025

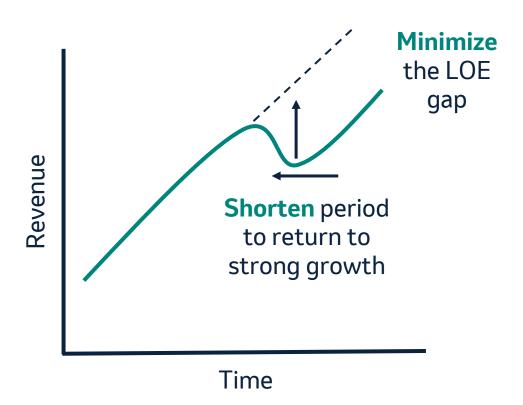


### Operating margins<sup>1</sup>

Commitment to drive leverage in the P&L with operating margins >43% by 2025



### Multiple levers to navigate the KEYTRUDA LOE



- Leverage leadership in oncology
- Enhance durable growth drivers
- Deploy cash flow from key assets to business development
- Advance pipeline across key therapeutic areas



### Business development remains an important strategic priority

- Accessing the best external science through value-enhancing business development
- Financial flexibility to pursue both early- and late-stage opportunities
- Unbounded by therapeutic area
- Appropriately aggressive in adding innovative assets to help drive long-term revenue growth

\$34.0B

on business development transactions over the past 4 years \$14.0B in 2021

\$10.6B in 2020

\$6.1B in 2019

\$3.3B in 2018

Includes bolt-on acquisitions, strategic collaborations & licensing, and milestone payments



## Made progress towards integrating ESG into our strategy

- Inaugural issuance of \$1 billion sustainability bond
- Agreement with UNICEF to help ensure broad global access for molnupiravir
- Hosting ESG Investor Event on February 23, 2022





## Business/Financial Results and Outlook

**Caroline Litchfield**Chief Financial Officer



## Merck achieved exceptional 2021 financial performance<sup>1</sup>

**WORLDWIDE SALES<sup>2</sup>** 

\$48.7B

+17% growth +16% ex-exchange



**NON-GAAP EPS<sup>3,4</sup>** 

\$6.02

+33% growth +32% ex-exchange



<sup>1.</sup> Results from continuing operations attributable to Merck & Co., Inc. 2. Worldwide Sales includes Other Revenue; 3. Merck is providing certain 2021 and 2020 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 and 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. 4. GAAP EPS of \$1.51.

### Strong Q4 sales growth across Human Health and Animal Health



### Merck

**WORLDWIDE SALES**<sup>1,2</sup>

\$13.5B

+ 24% growth +23% ex-exchange +14% ex-exchange, molnupiravir<sup>3</sup>



**Human Health** 

\$12.0B

+23% growth +23% ex-exchange +13% ex-exchange, molnupiravir<sup>3</sup>



**Animal Health** 

\$1.3B

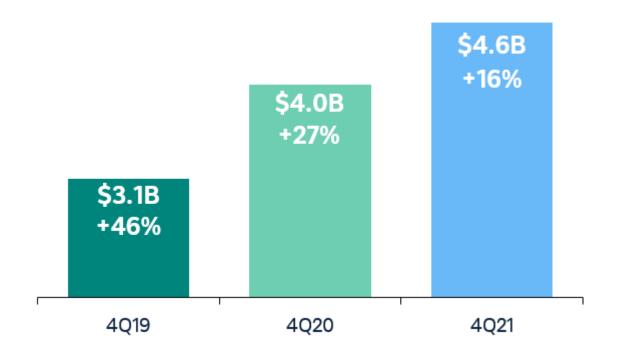
+8% growth +8% ex-exchange



## Oncology: KEYTRUDA drives continued momentum

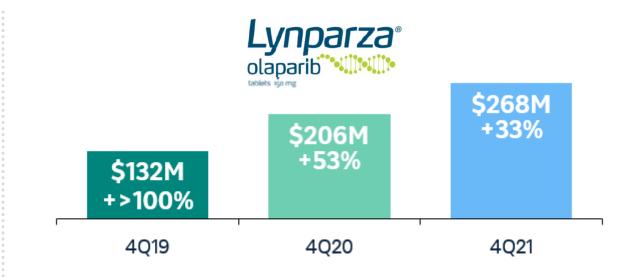
- KEYTRUDA sales of \$4.6B increased 16% year-over-year, driven by momentum across key tumor types and recent launches
  - In the U.S., sales of \$2.7B driven by growth across all key tumor types, including continued leadership in lung, as well as TNBC, RCC, HNSCC and MSI-H
  - Ex-U.S., 12% growth was driven by global uptake in lung as well as RCC and HNSCC
- KEYTRUDA will continue to expand into earlier lines of therapy
  - Recent approvals in adjuvant RCC and Stage IIB or IIC melanoma, top-line results in NSCLC
  - In the U.S., more than half of KEYTRUDA's annual growth will come from indications in earlier-stage treatment settings through 2025, and will represent roughly 30% of total U.S. KEYTRUDA





## Oncology: Strong growth across broad portfolio

- Lynparza sales increased 33%, with growth driven by advanced breast and continued uptake in other approved indications, including advanced prostate
- Lenvima sales grew 31% driven by RCC and endometrial in the U.S.
- WELIREG launching successfully in patients with certain VHL-associated tumors; potential to expand to broader RCC indications in the future



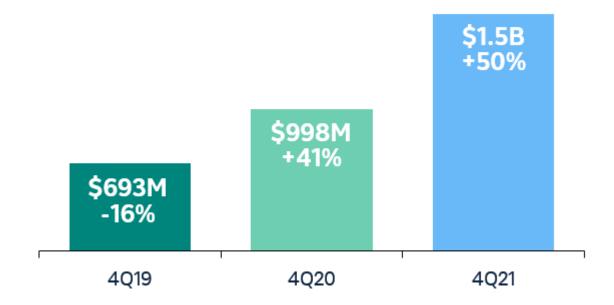


## Vaccines: GARDASIL benefitting from robust global demand and improved supply

- GARDASIL sales of \$1.5B increased 50% yearover-year driven by strong global demand and increased supply
  - Ex-U.S., growth was driven by robust demand, increased supply and reallocation of doses
  - U.S. impacted by CDC purchase timing, stockpile replenishment in Q4 2020 and COVID-19 vaccine prioritization





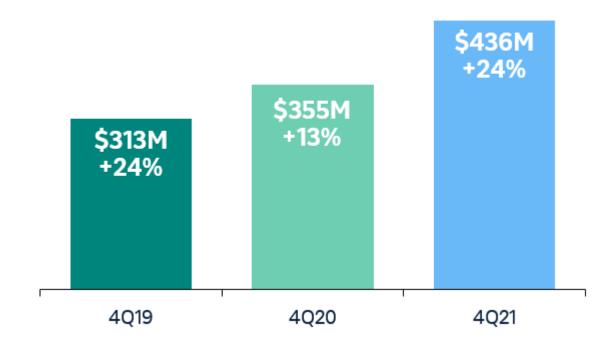




## Hospital: Strong performance by BRIDION and PREVYMIS

- BRIDION sales of \$436M increased 24% year-over-year driven by increased usage of neuromuscular blockade reversal agents and BRIDION's growing share within the class
- Continued uptake of PREVYMIS, driven by ongoing launches
- ZERBAXA supply reinitiated in Q4 following voluntary recall



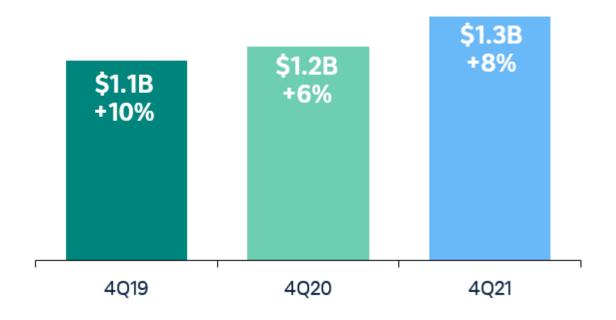




## Animal Health: durable growth across portfolio

- Animal Health sales increased 8% to \$1.3B, reflecting growth across geographies and species
  - Companion Animal sales increased 26%, driven by the BRAVECTO parasiticide line of products and vaccines
  - Livestock sales reflect higher demand globally for poultry and swine products
    - Sales were relatively flat compared with Q4 2020 due to an extra month of sales recorded in Q4 2020 related to the acquisition of Antelliq





## Q4 2021 continuing operations non-GAAP financial results summary: Delivered strong revenue and EPS growth

	Q4 2021	Q4 2020	Change	Change Ex-FX
Sales	\$13.5	\$10.9	+24%	+23%
Non-GAAP Gross Margin <sup>1</sup>	74.8%	75.0%	-0.2pts	-0.8pts
Operating Expenses	\$5.3	\$5.2	+2%	+3%
Tax Rate	4.3%	15.3%	-11.0pts	N/A
Non-GAAP EPS that excludes certain items <sup>1</sup>	\$1.80	\$0.98	+84%	+82%

<sup>1.</sup> Merck is providing certain 2021 and 2020 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 and 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.



## Merck full-year 2022 guidance

	Guidance	Key Assumptions		
Revenue	\$56.1B to \$57.6B +15% to +18% (+17% to +20% ex-FX)	<ul> <li>Assumes ~2% negative FX impact</li> <li>Includes an expected \$5-6 billion of molnupiravir revenue</li> </ul>		
Non-GAAP Gross Margin Rate <sup>1</sup>	~74.0%	Impacted by inclusion of molnupiravir profit share		
Non-GAAP Operating Expenses <sup>2</sup>	Increase by mid-to-high single-digit rate	<ul> <li>Includes a full year of R&amp;D expenses as a result of the Acceleron acquisition; investments in portfolio and pipeline</li> </ul>		
Other (Income) / Expense	~\$350M of expense			
Tax Rate <sup>3</sup>	~13.0-14.0%	Reflects impact of increased molnupiravir revenues and certain tax legislation changes for research and development expenses in 2022		
Shares Outstanding	~2.53B			
GAAP EPS <sup>4</sup>	\$5.76 to \$5.91			
Non-GAAP EPS <sup>4</sup>	\$7.12 to \$7.27 +18% to +21% (+19% to +22% ex-FX)	Assumes ~1% negative FX impact		

<sup>1.</sup> GAAP Gross Margin Rate: ~68%. 2. GAAP Operating Expenses: Lower than 2021 by a low to mid-single-digit rate. 3. GAAP Tax Rate: ~12.0% - 13.0%

<sup>4.</sup> The GAAP to non-GAAP reconciliation is available in Merck's Q4 2021 earnings release

## Molnupiravir can be an important treatment option to combat ongoing global pandemic

- Revenue guidance range of \$5B to \$6B in 2022, weighted to the first half of the year
- Obtained 10 regulatory authorizations/approvals, including EUA from the FDA in December
- Announced a number of supply and purchase agreements totaling ~10M courses of therapy; broad access strategy for low- and middle-income countries
- Within the next few days, will have shipped >4M
   courses of therapy to >25 countries, including ~3M
   courses to the U.S.
- Share global profits equally with partner Ridgeback Biotherapeutics



## Key modeling assumptions & outlook

### Oncology

 Strong growth across oncology portfolio

#### **GARDASIL**

- Very strong growth driven by robust demand and increased supply in 2022, albeit not at the same pace as in 2021
- Global HPV vaccination levels remain low in eligible patient cohort
- Sales to potentially double by 2030

#### **Pneumococcal**

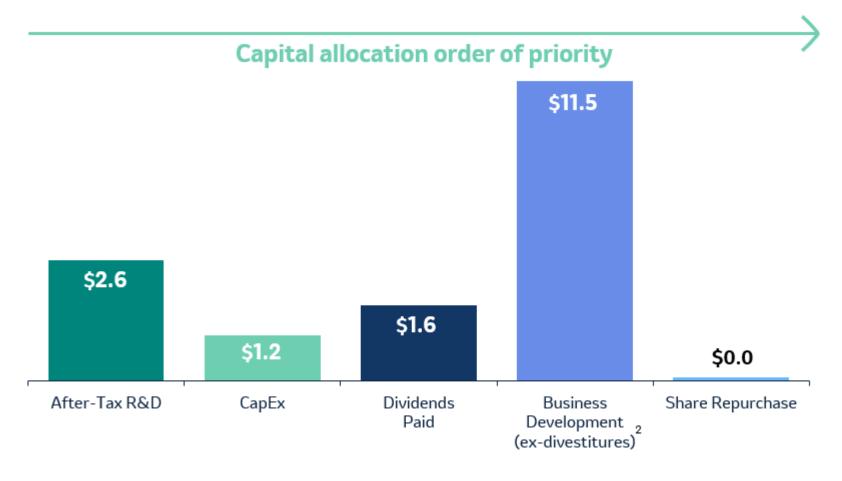
- Expect pneumococcal franchise to grow in 2022
- Uptake from recent launch of VAXNEUVANCE partially offset by PNEUMOVAX23 as the market shifts toward newer pneumococcal conjugate vaccines

#### **Animal Health**

- Above market growth in 2022
- Normalization of favorable companion animal trends

## Higher Q4 business development spend driven by Acceleron acquisition

\$ Billions<sup>1</sup>



Well positioned balance sheet with capacity to fund additional value-enhancing business development opportunities



## Research Update

**Dr. Dean Li**President, Merck Research Laboratories



## Driving value for patients and shareholders by progressing our pipeline in 2021

### **Key regulatory milestones**

#### In the U.S. received 11 FDA approvals<sup>1</sup>, 1 NME (WELIREG). FDA accepted filing for KN-158 and granted priority review for OlympiA

- In the EU, received 6 approvals<sup>2</sup> and Q6W dosing regimen for KEYTRUDA. Received CHMP positive opinion for KN-361 and KN-564<sup>2</sup>
- In Japan, received 5 approvals
- In China, received 3 approvals and Q6W dosing regimen for KEYTRUDA

#### **Vaccines**

Oncology

- In the U.S., received FDA approval for VAXNEUVANCE in the adult setting. FDA granted priority review for VAXNEUVANCE in the pediatric setting
- In the EU, received CHMP positive opinion for VAXNEUVANCE in the adult setting
- Infectious diseases, cardiometabolic & new products
- Received FDA Emergency Use Authorization for molnupiravir as well as authorization in other markets
- In Japan, received approval for LYFNUA (gefapixant<sup>3</sup>) and RECARBRIO
- Verquvo received approvals in the U.S., EU and Japan

#### **Data and pipeline milestones**

- Presented new data and announced topline results for assets across our broad portfolio, including KN-091 and PROpel
- Advanced novel mechanisms including coformulations with pembrolizumab into Phase 3:
  - vibostolimab+pembrolizumab (TIGIT)
  - quavonlimab+pembrolizumab (CTLA-4)
  - favezelimab+pembrolizumab (LAG3)

 Announced topline results from Phase 3 trials for VAXNEUVANCE (i.e.: PNEU-PED)



In US, EU, Japan and China in 2021, more than:

30 Approvals

20 NDAs and sBLAs filed

- Presented new data for MK-0616 (oral PCSK9)
- Advanced pipeline assets MK-2060 (Factor XI inhibitor), MK-5475 (inhaled SGC) and Verquvo
- Advanced molnupiravir in post-exposure prophylaxis for COVID-19
- Acquired new assets through business development, including MK-6194 (IL-2 mutein) and sotatercept (ligand trap)



## Molnupiravir represents an important treatment option against COVID-19 in high-risk, non-hospitalized patients

- Pandemic continues to impact communities and health care systems
- Accessible therapeutic options are needed for high-risk patients
- Six independent preclinical studies demonstrated molnupiravir showed activity against Omicron variant in vitro
- Molnupiravir is well-positioned to play a role due to its key attributes:
  - Oral treatment option
  - Reduction in hospitalizations or deaths in MOVe-OUT trial, including ~90% fewer deaths
  - Low propensity for drug-drug interactions
  - Activity against Omicron in vitro
  - High barrier to resistance



Early treatment with molnupiravir reduced the risk of hospitalization or death in at-risk, unvaccinated adults with Covid-19.

### Cell Research

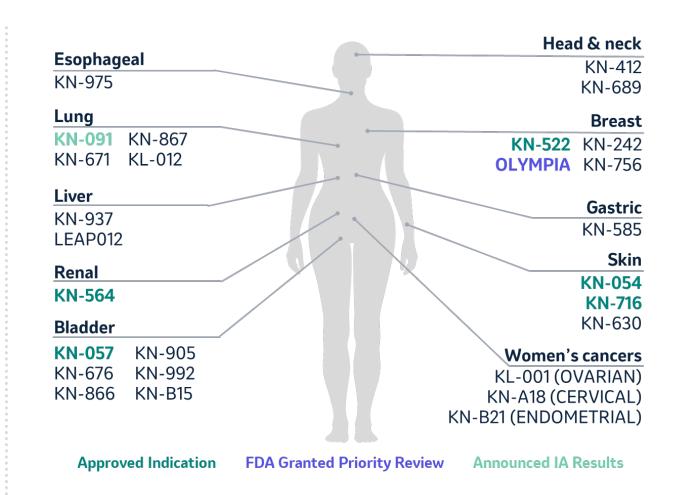
This study has demonstrated that molnupiravir ... potently inhibited the infection of SARS-CoV-2 Omicron variant.





## Continuing to make progress with the broadest early-stage IO clinical development program

- Recent approvals in RCC and melanoma
  - KEYTRUDA is the first and only immunotherapy treatment option in the adjuvant RCC setting
  - KEYTRUDA is first and only anti-PD1 therapy approved as adjuvant treatment in melanoma across stages IIB, IIC and III disease
- Announced findings in NSCLC
- Priority review in early-stage, high-risk breast cancer



### Pipeline updates and progress

### **Chronic Cough**

- Discuss next steps with the FDA for gefapixant
- Committed to addressing significant unmet need
- Received approval for LYFNUA (gefapixant) in Japan

#### **Pneumococcal Disease**

- VAXNEUVANCE approved for adults in U.S. and EU
- Under priority review by the FDA in the pediatric setting

#### HIV

- Continue to evaluate data in studies with islatravir<sup>1</sup>
- Confident in the potential of the NRTTI mechanism for prevention and treatment of HIV

#### **Cardiometabolic**

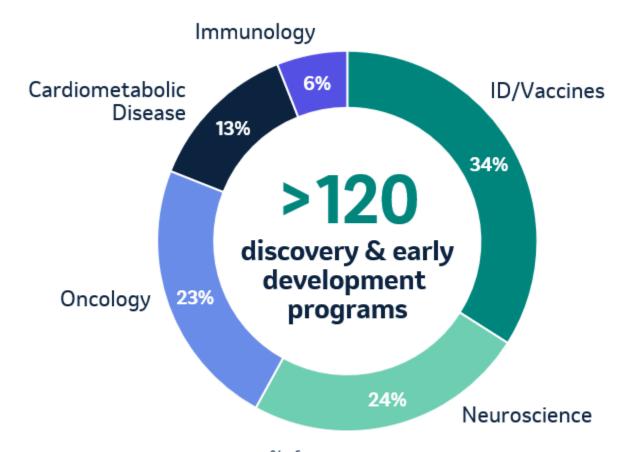
- Completed acquisition of Acceleron with ongoing integration
- Phase 3 program studying sotatercept for pulmonary arterial hypertension on track



### Extensive research efforts across multiple therapeutic areas and modalities

### **Executing on our strategy to:**

- Become the leading oncology company by 2025 and ensure that position is durable beyond
- Extend our impact across cardiometabolic, immunology, infectious diseases, neuroscience and vaccines
- Advance internal pipeline and augment with external assets



% of programs per area Programs under other research areas are included within above categories



## Q&A



**Rob Davis**President & Chief Executive Officer



**Caroline Litchfield**Chief Financial Officer



**Dr. Dean Li**President, Merck Research Laboratories



**Peter Dannenbaum** Vice President, Investor Relations



## Appendix

## Q4 2021 continuing operations GAAP financial results summary:

	Q4 2021	Q4 2020	Change	Change Ex-FX
Sales	\$13.5	\$10.9	+24%	+23%
Operating Expenses	\$5.9	\$8.4	-30%	-30%
Tax Rate	2.2%	-2.7%	+4.9%	N/A
GAAP EPS	\$1.51	(\$1.03)	+>100%	+>100%

## 2021 continuing operations GAAP financial results summary:

	2021	2020	Change	Change Ex-FX
Sales	\$48.7	\$41.5	+17%	+16%
Operating Expenses	\$21.9	\$22.4	-2%	-3%
Tax Rate	11.0%	22.9%	-11.9pts	N/A
GAAP EPS	\$4.86	\$1.78	+>100%	+>100%

## 2021 continuing operations non-GAAP financial results summary: Delivered strong revenue and EPS growth

	2021	2020	Change	Change Ex-FX
Sales	\$48.7	\$41.5	+17%	+16%
Non-GAAP Gross Margin <sup>1</sup>	76.1%	76.3%	-0.2pts	-0.3pts
Operating Expenses	\$19.4	\$17.7	+9%	+8%
Tax Rate	11.2%	15.2%	-4.0pts	N/A
Non-GAAP EPS that excludes certain items <sup>1</sup>	\$6.02	\$4.53	+33%	+32%

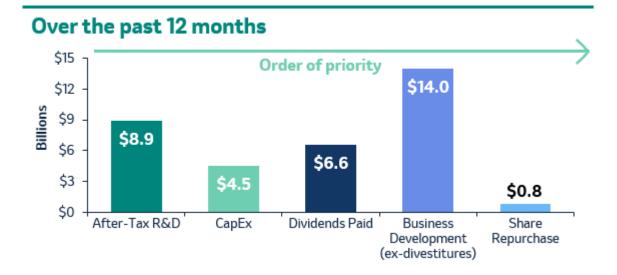
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## 2021: key pillars driving strong growth over the past four years<sup>1</sup>



## Capital allocation: Trailing twelve months



### **Capital investments**

2021 to 2025

~\$20B

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

Well positioned balance sheet with capacity to fund additional value-enhancing business development opportunities

#### Commitment to the dividend





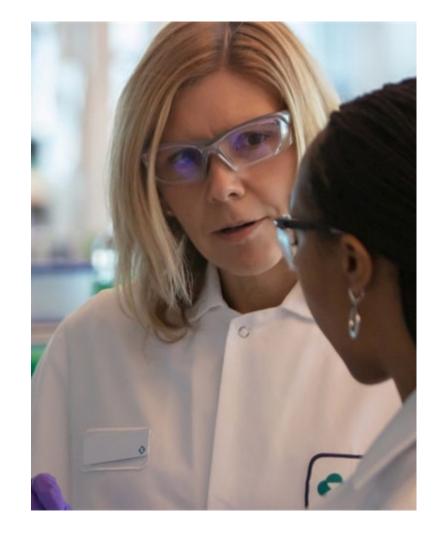
## Driving value for patients and shareholders by progressing our pipeline

## Key regulatory milestones since the last earnings call:

- In the U.S., received approval for KEYTRUDA as adjuvant therapy for certain patients with RCC based on KN-564 and as adjuvant treatment for patients with stage IIB and IIC melanoma based on KN-716
- Received FDA Emergency Use Authorization for molnupiravir as well as authorization in other markets
- FDA granted priority review for VAXNEUVANCE in the pediatric setting and for Lynparza in certain early-stage breast cancers based on OlympiA
- In the EU, received approvals for KEYTRUDA in adjuvant RCC based on KN-564, for KEYTRUDA+lenvatinib<sup>1</sup> in advanced RCC based on KN-581 and in endometrial cancer based on KN-775, as well as for VAXNEUVANCE in adults
- In Japan, received approvals for KEYTRUDA in esophageal cancer based on KN-590 and endometrial cancer based on KN-775 as well as gefapixant

## Key data and presentations since the last earnings call:

- Presented data for KEYTRUDA at SMR, SITC and ASCO GI, for MK-2140 (ROR1-ADC) at ASH, for molnupiravir at ASTMH, and for MK-0616 (oral PCSK9 inhibitor) at AHA
- Initiated Phase 3 trial studying Verquvo in patients with chronic heart failure and reduced ejection fraction who have not had a recent worsening heart failure event
- Announced topline results for KEYTRUDA as adjuvant treatment for patients with NSCLC based on KN-091



## Broad and innovative pipeline to solve significant unmet medical needs

Phase 2				Phase 3		Under regulatory review	
Oncology					Oncology		Oncology
Advanced Solid Tumors LYNPARZA (MK-7339) Advanced Solid Tumors  MK-6440 (ladiratuzumab vedotin) Breast NSCLC SCLC HNSCC Esophageal Gastric Prostate Melanoma  MK-1026 Hematological Malignancies	MK-4280 (favezelimab) NSCLC Hematological Malignancies LENVIMA (MK-7902) Biliary Tract Glioblastoma Prostate SCLC Pancreas MK-7684A (vibostolimab/pembrolizumab Biliary Cervical Esophageal Breast HNSCC HCC Endometrial Prostate Hematological Malignancies	V937 Melanoma Breast CSCC HNSCC Solid Tumors MK-4280A (favezelimab/pembrolizumab RCC SCLC WELIREG (MK-6482) D) Rare Cancers CRC Pancreatic Biliary HCC Certain VHL tumors (EU)	MK-1308A (quavonlimab/ pembrolizumab) Advanced Solid Tumors HCC CRC SCLC Melanoma ) TUKYSA (MK-7119) Advanced Solid Tumors Colorectal Gastric Endometrial NSCLC Bladder Biliary Cervical	MK-2140 Breast NSCLC Heme  MK-4830 NSCLC SCLC RCC  MK-0482 NSCLC  MK-1308 NSCLC  MK-1308 NSCLC  MK-7684 Melanoma	KEYTRUDA (MK-3475) Biliary Tract cSCC (EU) Gastric (EU) Hepatocellular (EU) Mesothelioma Ovarian Prostate SCLC  MK-1308A RCC  MK-7684A NSCLC  MK-4280A CRC	LENVIMA (MK-7902) HNSCC Melanoma CRC Esophageal NSCLC Gastric LYNPARZA (MK-7339) NSCLC SCLC CRC WELIREG (MK-6482) RCC TUKYSA (MK-7119) Breast MK-3475 subcutaneous NSCLC	KEYTRUDA (MK-3475) MSI-H or dMMR Endometrial (US) TMB-H (JPN) Adjuvant RCC (JPN) Melanoma (EU) High-risk early stage TNBC (EU, JPN) Cervical (EU, JPN)  LENVIMA (MK-7902) 1L HCC (US) Advanced unresectable RCC (JPN)  LYNPARZA (MK-7339) Prostate cancer (EU) Adjuvant breast cancer (US, EU)  Vaccines V114 Pneumoconjugate Vaccine, adult (JPN), pediatric (US)
Vaccines	Neurosc	ience	General medicine	ļ	MK-8591A (doravirine/isl	latravir) <sup>1</sup>	General medicine
V116 Pneumococcal, adult	MK-8189 Schizophrenia	a	MK-7075 Overgrowth Syndrome		Islatravir (MK-8591) <sup>1</sup> HIV-1 prevention		Gefapixant (MK-7264) Cough (US, EU)
V184 Chikungunya Virus	·	s diseases	MK-1942 Treatment Resistant Dep	ression	Vaccines		CUBICIN (MK-3009) cSST & Sepsis, pediatric (JPN)
Cardiovascular	MK-8591B (is HIV-1 Infection	slatravir/MK-8507) <sup>1</sup> on	MK-3655 NASH		MK-1654 Respiratory Syncytial Vir	IIS	
1K-5475 Iulmonary Arterial Hypertens	sion MK-8591D (is	slatravir/lenacapavir) <sup>1</sup> on	MK-6024 NASH			us	
1K-2060 ardiovascular					Cardiovascular Sotatercept (MK-7962) Pulmonary Arterial Hype	ertension	
On clinical hold							As of February 2, 2022