



# JP Morgan Healthcare Conference

January 9, 2023





# Strategy and Business Update

**Rob Davis**

Chairman and Chief Executive Officer



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

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This presentation of Merck & Co., Inc., Rahway, 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 Annual Report on Form 10-K for the year ended December 31, 2021 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site ([www.sec.gov](http://www.sec.gov)).

# Significant advancements across key strategic priorities

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## Advancing

The pipeline to meet patient unmet needs

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## Executing

Strategic business development to enhance pipeline

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## Achieving

Strong commercial and financial performance

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## Creating

Long-term value for patients and shareholders



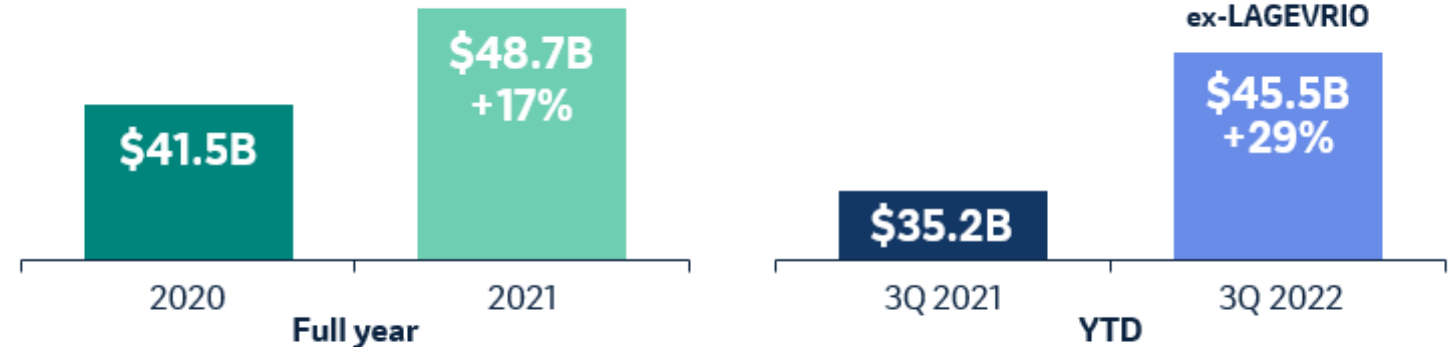
# Strong commercial and operational execution driving revenue and EPS growth

## Excellent commercial execution across key growth pillars:

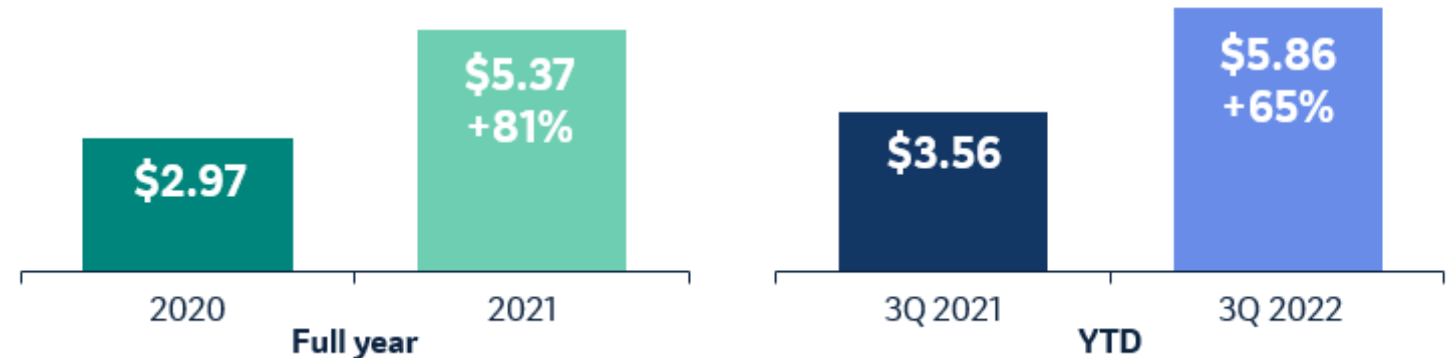
- Oncology
- Vaccines
- Hospital
- Animal Health

## Strong underlying growth excluding LAGEVRIO

### Revenue



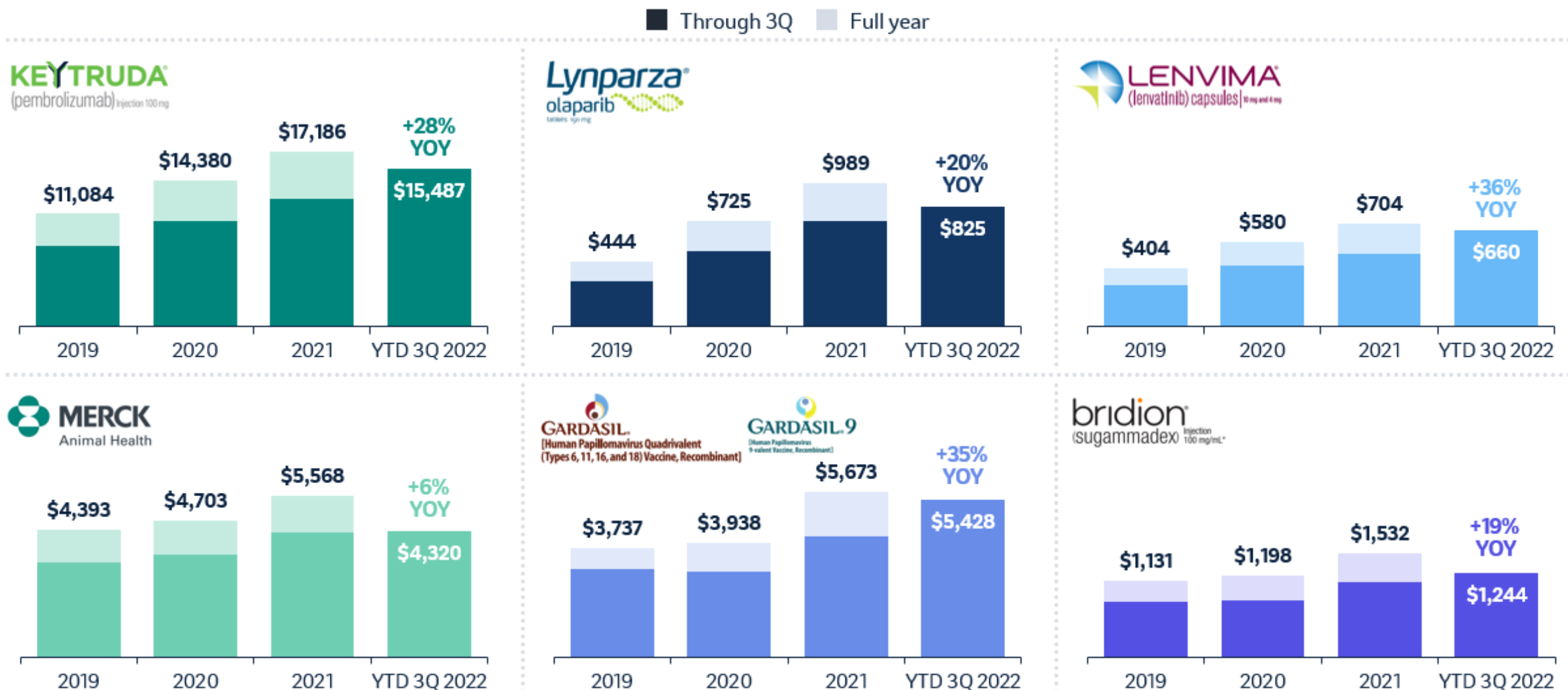
### Non-GAAP EPS



Growth rates include the impact of foreign exchange.

For 2020, non-GAAP results have been recast to include \$4.2 billion of incremental R&D expenses, which reduced previously reported non-GAAP EPS by \$1.56. For 2021, non-GAAP results have been recast to include \$1.7 billion of incremental R&D expense, which reduced previously reported non-GAAP EPS by \$0.65. For 3Q 2022, Non-GAAP results include \$690 million of R&D expense for collaborations and licensing agreements with Moderna, Orna and Orion, or an estimated \$0.22 of negative impact to EPS.

# Sustained strong performance across key growth pillars

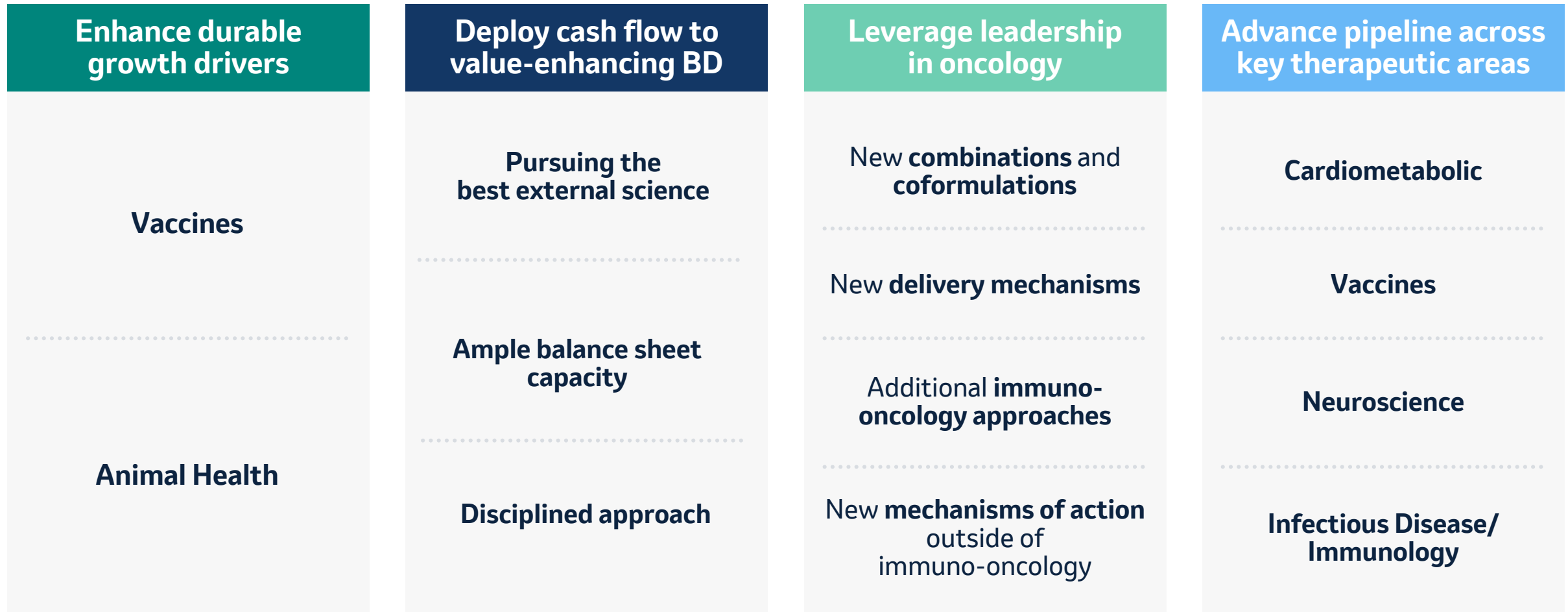


All growth rates exclude the impact of foreign exchange. All growth rates represent 3Q YTD growth.

\$ In millions.

Lynparza in collaboration with AstraZeneca. Lenvima in collaboration with Eisai.

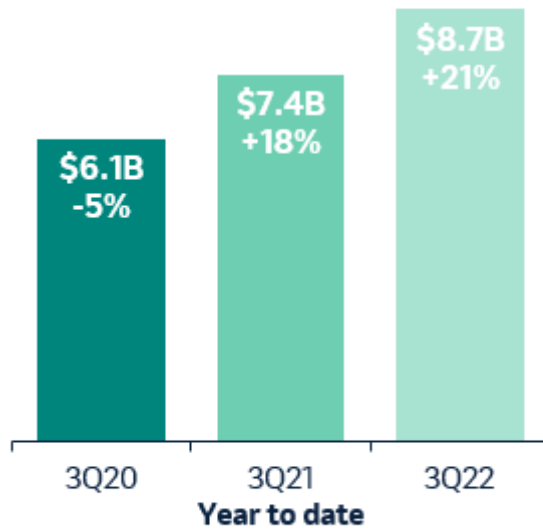
# Advancing key levers to drive success into the next decade



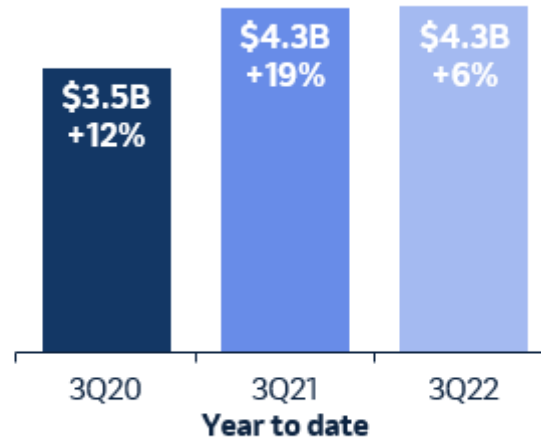
# Durable growth drivers provide a strong foundation

## Sustained results driven by robust underlying demand and strong commercial execution

### Vaccines



### Animal Health



### Vaccines

- **GARDASIL** sales expected to double off a 2021 base by 2030, driven by strong global demand and increased ability to supply
- Potential suite of population-specific **pneumococcal conjugate vaccines** addressing large and growing market
- Established presence in **pediatric vaccines**
- Promising pipeline in **RSV** and **Dengue**

### Animal Health

- **Broad global portfolio** to continue to deliver above market growth
- **Innovative pipeline** across both Companion Animal and Livestock
- Promising **monitoring technology** with potential to expand livestock offerings and advance pet health

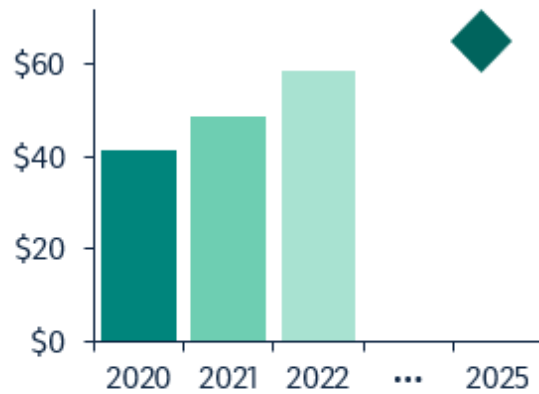
Growth rates excluding the impact of foreign exchange.



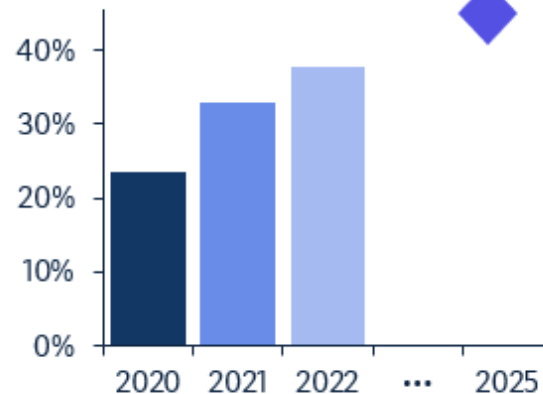
# Prioritizing strategic business development to augment the pipeline

## Delivering visible de-risked revenue growth and operating margins of >43% by 2025

Revenue  
\$ in billions



Non-GAAP  
Operating margin



### Strategic priority

Seeking the best external science to augment the pipeline, unbounded by therapeutic area

### Ample balance sheet capacity

Financial flexibility to evaluate the full breadth of the business development landscape

### Disciplined approach

Pursuing opportunities that will create sustainable value for shareholders

Results from continuing operations attributable to Merck & Co., Inc

**2022+ not actuals**; 2022 values reflect the midpoint of guidance.

Beginning in 2022, Merck no longer excludes expenses for upfront and milestone payments related to collaborations and licensing agreements, or charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions from its non-GAAP results

# Enhanced pipeline with important business development in 2022



Announced **acquisition** expected to expand hematology presence with bomedemstat (LSD1 inhibitor)



Advanced **collaboration** to develop SKB-264 (TROP2 ADC) and 7 investigational preclinical ADCs



**Collaboration** to evaluate mRNA-4157/V940 (personalized cancer vaccine) in multiple tumor types



**Collaboration** on ODM-208 (CYP11A1 inhibitor) complements strategy in prostate cancer



**Collaboration** to develop circular RNA technology in multiple areas, including infectious diseases and oncology



**Collaboration** for the discovery and development of novel peptide drug conjugates



**Acquisition** complements broad Animal Health portfolio with virtual fencing technology

# \$36.5B

on BD  
over the last  
5 years<sup>1</sup>

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



# Research Update

**Dr. Dean Li**

President, Merck Research Laboratories



# Significant pipeline advancements across therapeutic areas in 2022

## Oncology

- **KEYTRUDA:**
  - Received approval for advanced endometrial cancer that is MSI-H or dMMR (KN-158)
  - FDA accepted for review KN-091 for the adjuvant treatment of patients with stage IB, II or IIIA NSCLC
  - Announced positive topline results for HER2- gastric or GEJ adenocarcinoma (KN-859)
- **Lynparza:** Received approval for adjuvant treatment of adults with gBRCAm, HER2- high-risk early breast cancer (OlympiA)
- **MRNA-4157/V940:** Announced positive topline data for Phase 2b trial in adjuvant melanoma

## Cardiometabolic

- **Sotatercept:** Announced positive topline data for Phase 3 STELLAR trial in PAH
- **MK-0616:** Completed Phase 2 trial in patients with hypercholesterolemia
- **MK-2060:** Received Fast Track designation for the reduction in risk of major thrombotic cardiovascular events in patients with ESRD
- **MK-5475:** Initiated Phase 2 study in patients with PH-COPD

## Vaccines

- **VAXNEUVANCE:** Received approval in the pediatric setting
- **V116:** Received Breakthrough Therapy Designation and advanced into Phase 3 trials for the prevention of invasive pneumococcal disease in adults
- **V181:** Merck collaborator Instituto Butantan (IB) announced positive topline results from IB's Phase 3 dengue vaccine candidate. Results to inform next steps for V181 program<sup>1</sup>

## Infectious Disease

- **Islatravir:** Reinitiated development program in the HIV treatment setting
- **MK-8527:** Initiated Phase 1b study of internal novel NRTTI for HIV PrEP
- **LAGEVRIO:** Initiated Phase 2 trial for the treatment of RSV

1. Both Merck and IB's investigational vaccines are derived from materials licensed from the U.S. National Institutes of Health and both institutions are evaluating formulations analogous to the NIH TV003 formulation.

# Leveraging leadership in oncology with robust portfolio and innovative pipeline

Further establish KEYTRUDA as a foundational anti-PD-1 cancer treatment in monotherapy and in combination regimens

**KEYTRUDA**  
(pembrolizumab) Injection 100 mg

Diversify through collaborations with PARPi, VEGF TKI, HER2 TKI, LIV-1 ADC, TROP-2 ADC, CYP11A1, personalized cancer vaccine



Diversify through acquisitions of LSD1, BTK, HIF-2α, ROR-1 ADC assets

**Bomedemstat**<sup>1</sup>

LSD1i

**Nemtabrutinib**  
(MK-1026)

rBTKi

**WELIREG**  
(belzutifan) 40 mg tablets

HIF-2α

**Zilovetamab Vedotin**  
(MK-2140)

anti-ROR-1 ADC

Expand the IO-IO strategy through combinations with internal assets

**Quavonlimab/pembro**  
(MK-1308A)  
anti-CTLA-4

**Vibostolimab/pembro**  
(MK-7684A)  
anti-TIGIT

**Favezelimab/pembro**  
(MK-4280A)  
anti-LAG-3

**anti-ILT-4**  
(MK-4830)

**anti-ILT-3**  
(MK-0482)

Expand into cell-based therapies & T/NK cell engagers

**Dragonfly**

**artiva**

**Biotherapeutics**

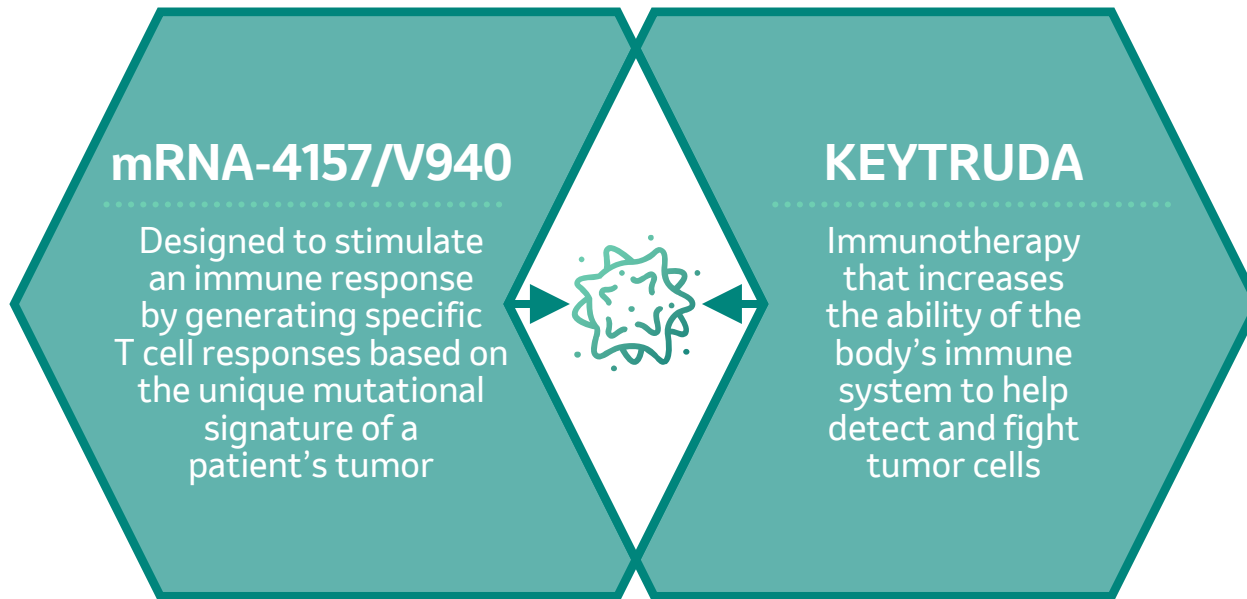
**JANUX**

1. Transaction expected to close in 1Q 2023



# Collaboration with Moderna to leverage expertise in mRNA and immuno-oncology to improve outcomes for patients with cancer

**Combining mRNA-4157/V940 with KEYTRUDA may provide a synergistic effect and enhance T cell-mediated destruction of tumor cells**



## Positive Phase 2b results

- Phase 2 trial for the adjuvant treatment of patients with stage III/IV melanoma with high risk of recurrence following complete resection
- Demonstrated a statistically significant and clinically meaningful improvement in RFS versus KEYTRUDA alone
- Combination **reduced** the risk of recurrence or death by **44%** (HR=0.56 [95% CI, 0.31-1.08]; one-sided p-value=0.0266)

## Development strategy

- To discuss Phase 2b results with regulatory authorities and initiate a **Phase 3 study in melanoma in 2023**
- Planning additional studies in other forms of cancer

# Broad pipeline advancing across key therapeutic areas

## Cardiometabolic

### PAH

sotatercept (ligand trap, Phase 3)

### Chronic Heart Failure (without worsening event)

Verquvo (sGC stimulator, Phase 3)

### PAH

MK-5475 (Inhaled sGC stimulator, Phase 2/3)

### Lipid Lowering

MK-0616 (Oral PCSK9 inhibitor, Phase 2)

### Thrombosis

MK-2060 (Factor XI inhibitor, Phase 2)

### NASH

MK-6024 (GLP-1/glucagon receptor dual agonist, Phase 2)

## Vaccines

### Pneumococcal Disease: Adults

V116 (PCV, Phase 3)

### RSV

Clesrovimab (mAb, Phase 3)

### Dengue

V181 (LATV, Phase 2)

### Pneumococcal Disease: Pediatrics

V117 (PCV, Phase 1)

## Neuroscience

### Schizophrenia

MK-8189 (PDE10A, Phase 2)

### Treatment-Resistant Depression

MK-1942 (not yet disclosed, Phase 2)

### Alzheimers Disease

MK-1942 (not yet disclosed, Phase 2)

MK-2214 (Anti-Tau mAb, Phase 1)

## Infectious Disease/ Immunology

### HIV: Treatment

Islatravir<sup>1</sup> (NRTTI, Phase 3)

### RSV

Molnupiravir (antiviral, Phase 2)

### HIV: PrEP

MK-8527 (NRTTI, Phase 1)

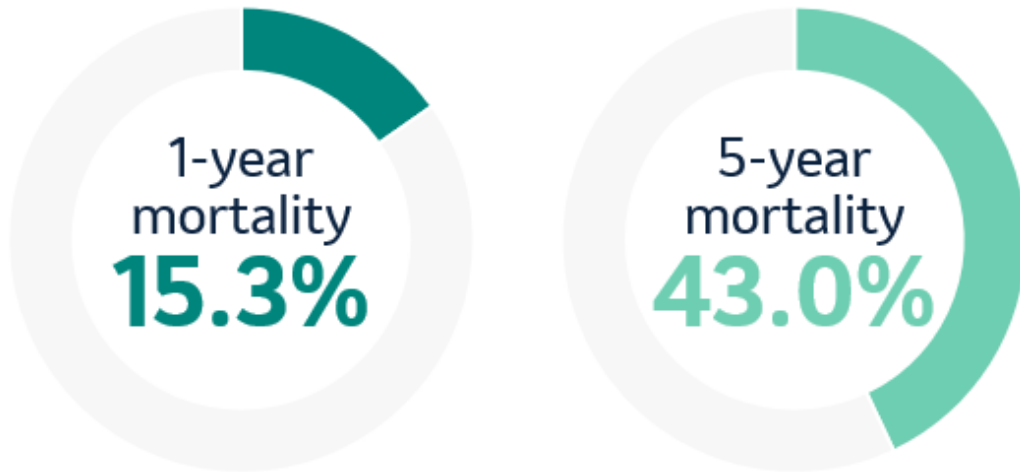
### Immunology

MK-6194 (IL-2 mutein, Phase 1b)

1. Announced plans to initiate a new once daily oral Phase 3 clinical program in the treatment setting with a lower dose of islatravir in combination with doravirine.

# Sotatercept has the potential to transform the treatment of patients with PAH

## PAH is a rare, rapidly progressive and fatal disease



## Positive results for Phase 3 STELLAR trial

- Demonstrated a profound effect on improvement in six-minute walk distance from baseline at 24 weeks
- Met 8 of 9 secondary endpoints
- Targeting filing with regulatory authorities in 1Q 2023

## Data presentation

- STELLAR data will be presented at ACC in March
- Merck to host investor meeting at ACC to discuss trial results

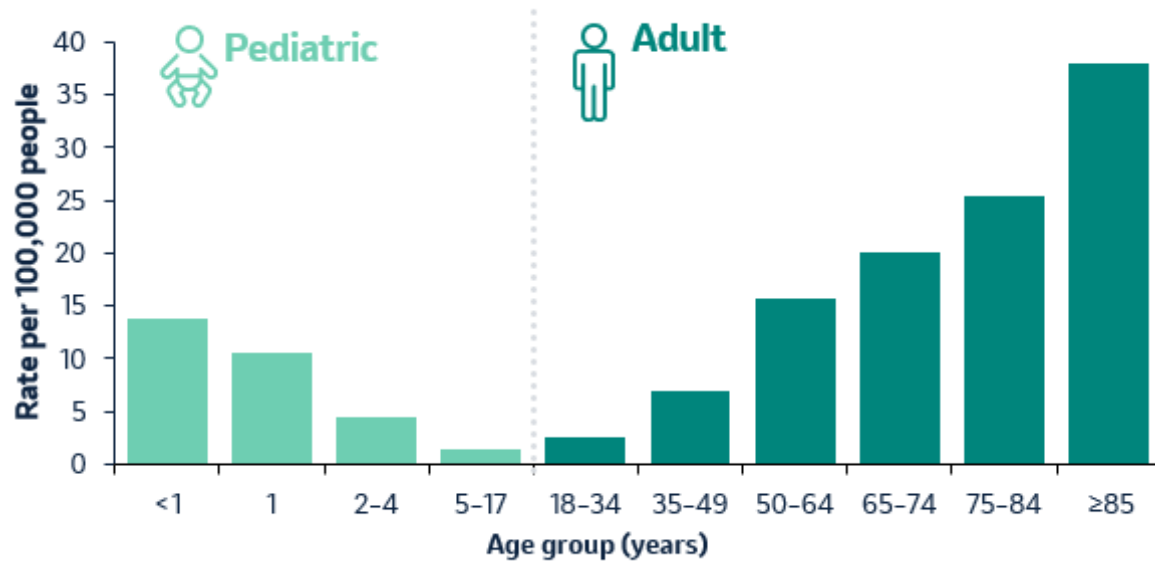
## Development strategy

- Phase 3 HYPERION, ZENITH and SOTERIA trials in PAH are ongoing



# Advancing population-specific approach to pneumococcal disease

## The serotypes that cause pediatric disease differ significantly from those that cause adult disease



## VAXNEUVANCE

Expanding coverage while maintaining protection against historically invasive disease-causing serotypes in children, including during the first year of life, which represents nearly half of all IPD for children under 17 years old

### V116

Phase 3 investigational candidate specifically targeting adult disease by covering serotypes that account for 85% of all IPD in U.S. adults ages ≥65<sup>1</sup> as of 2019

### V117

Phase 1 investigational candidate specifically targeting serotypes associated with pediatric disease

Active Bacterial Core Surveillance (ABCs) report emerging infections program network streptococcus pneumoniae, 2019. Available: [SPN Surveillance Report 2019.pdf \(cdc.gov\)](https://www.cdc.gov/spn-surveillance/reports/index.html).

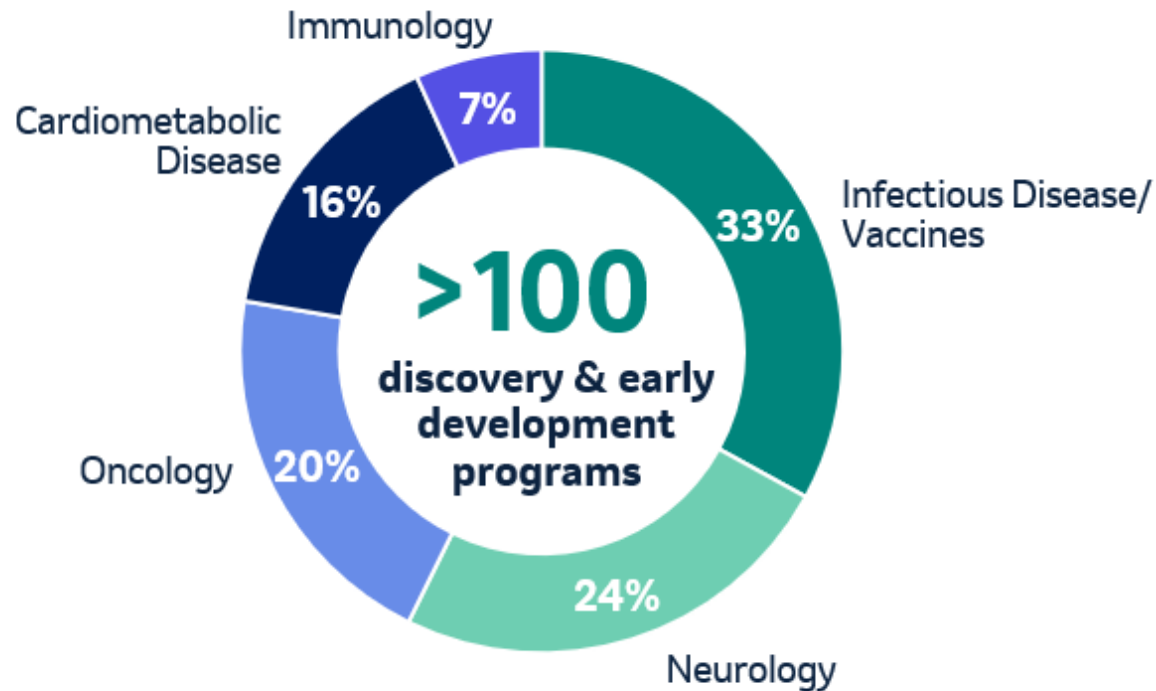
Source: Epidemiology of pneumococcal disease and pneumococcal vaccine coverage in US children, Ryan Gierke, MPH.

Advisory Committee on Immunization Practices, February 24<sup>th</sup>, 2022.

1. Centers for Disease Control and Prevention, IPD serotype data 2019, as compiled from data provided through Active Bacterial Core surveillance (ABCs).

# Extensive discovery research efforts and clinical expertise to generate future breakthroughs

## Broad research efforts across multiple therapeutic areas and modalities



## Investing in key technologies

- Vaccines
  - Circular RNA technology
  - Personalized cancer vaccine
- Cyclic Peptide Technology
- Antibody Drug Conjugates
- Cell Based Therapies
  - Bi- and tri-specific T & NK cell engagers
  - Allogeneic cell therapy
- Molecularly Targeted Therapies

## Clinical development expertise

- Proven track record of bringing promising innovation to patients



# Building a sustainable engine to drive success into the next decade

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Enhance durable  
growth drivers

Deploy cash flow to  
value-enhancing BD

Leverage leadership  
in oncology

Advance pipeline  
across key  
therapeutic areas

Achieved **meaningful progress** across each lever in 2022

Increased confidence in our **sustainable engine** to drive success into the next decade

Potential for **>\$10B from cardiovascular pipeline** approaching the mid-2030s

Potential for **>\$10B from new mechanisms in oncology** approaching the mid-2030s

- Includes ADCs (e.g. TROP-2, ROR-1) and small molecules (e.g. inhibitors of CYP11A1, LSD-1, KRAS, BTK)

# Q&A



**Rob Davis**  
Chairman and Chief Executive Officer



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



# Appendix

# Full year continuing operations

## GAAP to Non-GAAP financial results reconciliation

\$ in billions, except EPS amounts

		GAAP	Acquisition and Divestiture-Related Costs <sup>(1)</sup>	Restructuring Costs <sup>(2)</sup>	(Income) Loss from Investments in Equity Securities	Certain Other Items <sup>(3)</sup>	Non-GAAP
2021	Cost of sales	\$13,626	1,607	160		221	\$11,638
	Selling, general and administrative	9,634	322	19			9,293
	Research and development	12,245	479	28			11,738
	Restructuring costs	661		661			-
	Earnings per Common Share Assuming Dilution from Continuing Operations	\$4.86	(0.80)	(0.30)	0.58	0.01	\$5.37
2020	Cost of sales	\$13,618	3,355	175		260	\$9,828
	Selling, general and administrative	8,955	225	47			8,683
	Research and development	13,397	12	83		45	13,257
	Restructuring costs	575		575			-
	Earnings per Common Share Assuming Dilution from Continuing Operations	\$1.78	(1.19)	(0.31)	0.40	(0.09)	\$2.97

# 3Q YTD continuing operations

## GAAP to Non-GAAP financial results reconciliation

\$ in billions, except EPS amounts

		GAAP	Acquisition and Divestiture- Related Costs <sup>(1)</sup>	Restructuring Costs <sup>(2)</sup>	(Income) Loss from Investments in Equity Securities	Certain Other Items <sup>(3)</sup>	Non-GAAP
YTD 2022	Cost of sales	\$13,530	1,577	167			\$11,786
	Selling, general and administrative	7,355	137	74			7,144
	Research and development	9,773	936	30			8,807
	Restructuring costs	288		288			-
	Earnings per Common Share Assuming Dilution from Continuing Operations	\$4.53	(0.76)	(0.18)	(0.39)		\$5.86
YTD 2021	Cost of sales	\$9,752	1,188	113		225	\$8,226
	Selling, general and administrative	6,804	96	9			6,699
	Research and development	9,177	82	21			9,074
	Restructuring costs	487		487			-
	Earnings per Common Share Assuming Dilution from Continuing Operations	\$3.36	(0.46)	(0.22)	0.46	0.02	\$3.56



# Full year and 3Q YTD Continuing operations

## GAAP to Non-GAAP financial results reconciliation (cont'd)

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1. Amounts included in cost of sales primarily reflect expenses for the amortization of intangible assets. Amount in full year 2020 cost of sales also reflects a \$1.6 billion intangible asset impairment charge related to ZERBAXA. Amounts included in selling, general and administrative expenses reflect integration, transaction and certain other costs related to acquisitions and divestitures. Amounts included in research and development expenses primarily reflect the amortization of intangible assets, as well as \$275 million and \$887 million of intangible asset impairment charges related to the ArQule, Inc. acquisition in the full year 2021 and the third quarter year-to-date 2022 period, respectively.
2. Amounts primarily include employee separation costs and accelerated depreciation associated with facilities to be closed or divested related to activities under the Company's formal restructuring programs.
3. Amounts in cost of sales and research and development expenses reflect charges for the discontinuation of COVID-19 development programs. EPS impacts in 2021 also reflect a net tax benefit of \$207 million related to the settlement of certain federal income tax matters.