



Merck Q3 2021 Earnings

October 28, 2021



Agenda



Strategy and Business Update

Rob Davis
Chief Executive Officer



Human Health Results

Frank Clyburn
President, Merck
Human Health



Animal Health and Financial Results

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 products, including if the Acceleron acquisition is consummated, Acceleron’s 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; uncertainties as to the timing of the offer and subsequent merger with Acceleron; uncertainties as to how many of Acceleron’s stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the merger and the offer contemplated thereby may not be satisfied or waived; the effects of disruption from the transactions contemplated by the merger agreement and the impact of the announcement and pendency of the transactions on Acceleron’s business; the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability; 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

Chief Executive Officer



Delivered on our key strategic priorities in 3Q 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

Merck's investigational antiviral treatment has potential to have meaningful impact on the COVID-19 pandemic

- Demonstrated a 50% reduction in risk of hospitalization or death in phase 3 MOVE-OUT trial in at risk, non-hospitalized adults with mild-to-moderate COVID-19
- Submitted EUA and engaging with FDA as the agency reviews application. Announced EMA rolling submission.
- Governments and health systems around the world recognizing potential and committing to orders upon regulatory approval
- Rapidly building supply to meet expected demand



Acceleron acquisition adds strong external science and potential long-term growth driver in sotatercept

- Transaction aligns well with innovation-driven business development strategy
- Sotatercept is a first-in-class, late-stage asset with potential to be foundational pulmonary hypertension add-on therapy
- Potential multi-billion dollar commercial opportunity with ability to drive long-term revenue growth
- Significant potential to positively impact patients and create shareholder value



Exceptional Q3 2021 sales and earnings growth



Worldwide Sales

\$13.2B
+19%



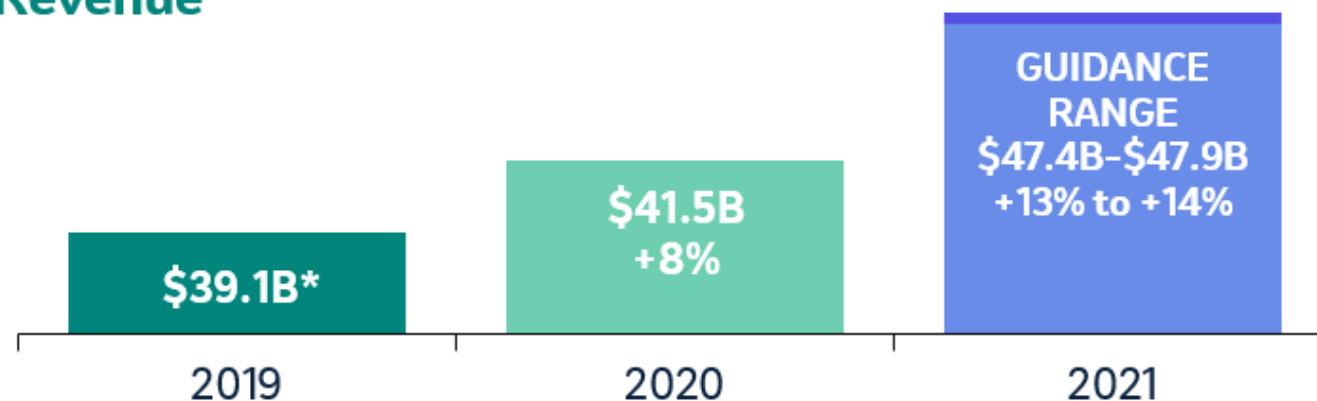
Non-GAAP EPS

\$1.75
+26%

Growth rates exclude the impact of foreign exchange.

* Growth rate not available as restated 2018 results are not provided

Revenue



EPS



ESG priority areas grounded in the core values that guide Merck's mission

-
- Access to medicine
 - Product quality and safety
 - Public health risks



-
- Climate change

-
- Employee health and safety
 - Employee engagement and diversity

-
- Business ethics
 - Ethics in R&D
 - Data security and privacy
 - Governance structures and mechanisms



Human Health Results

Frank Clyburn

President, Merck Human Health



Human health delivered continued strong performance in Q3

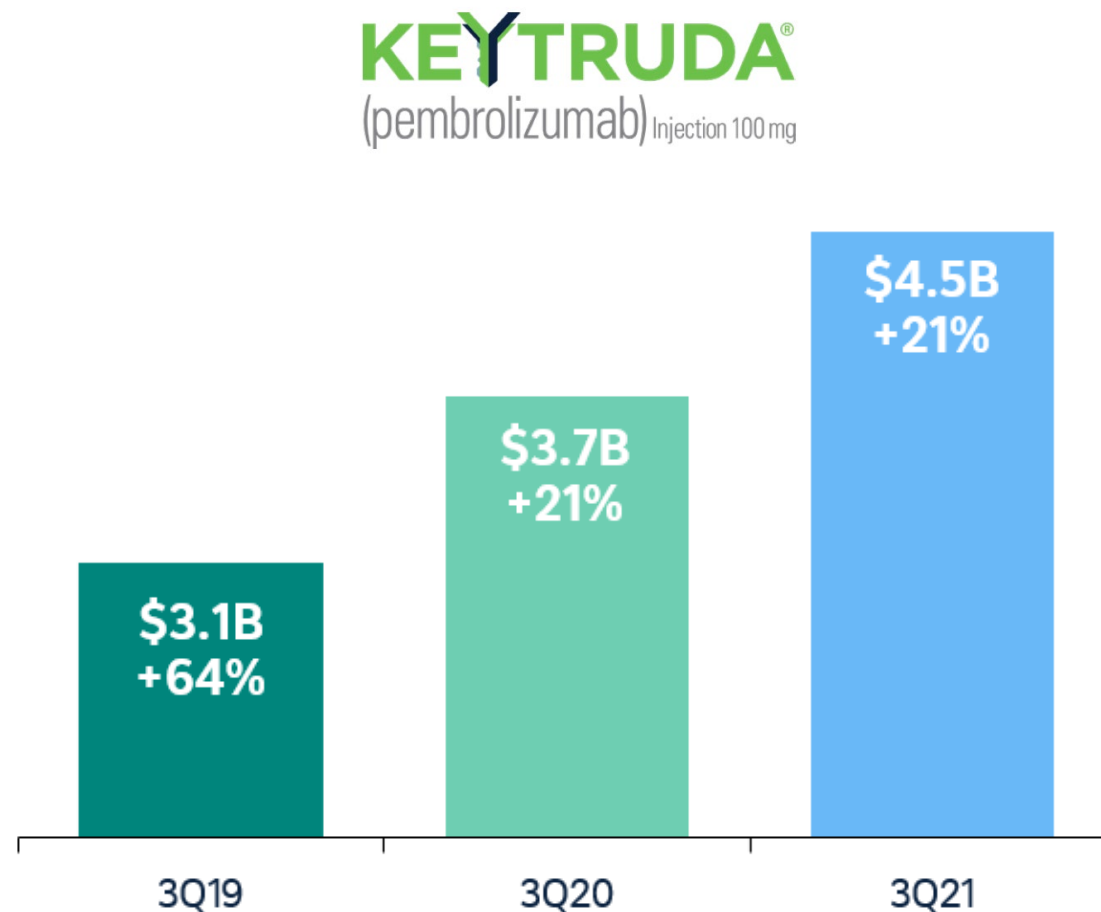


Total Human Health
\$11.5B, +17%

- Sustained business momentum driven by strong underlying demand and commercial execution
- Continue to invest in patient activation programs
- Lingering effects from the pandemic remain a modest headwind

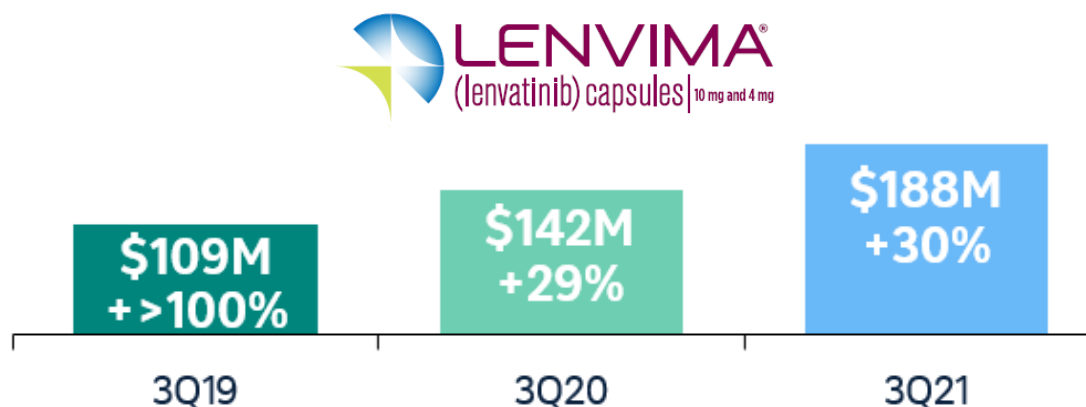
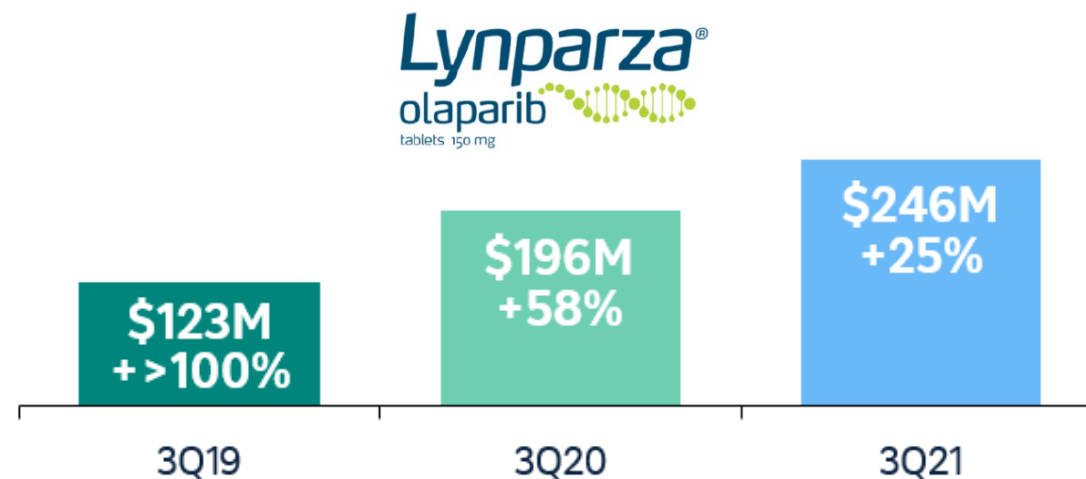
Oncology: KEYTRUDA drives continued momentum

- KEYTRUDA sales of \$4.5B increased 21% year-over-year, driven by momentum across key tumor types and recent launches
 - In the U.S., sales of \$2.6B driven by growth across all key tumor types, including continued leadership in lung, as well as RCC, TNBC, MSI-H, esophageal, and H&N
 - Ex-U.S., 24% growth was driven by global uptake in lung as well as RCC and H&N
- KEYTRUDA will continue to expand into earlier lines of therapy
 - In the U.S., more than half of KEYTRUDA's growth will come from indications in earlier-stage treatment settings through 2025, and will represent roughly 30% of total KEYTRUDA sales



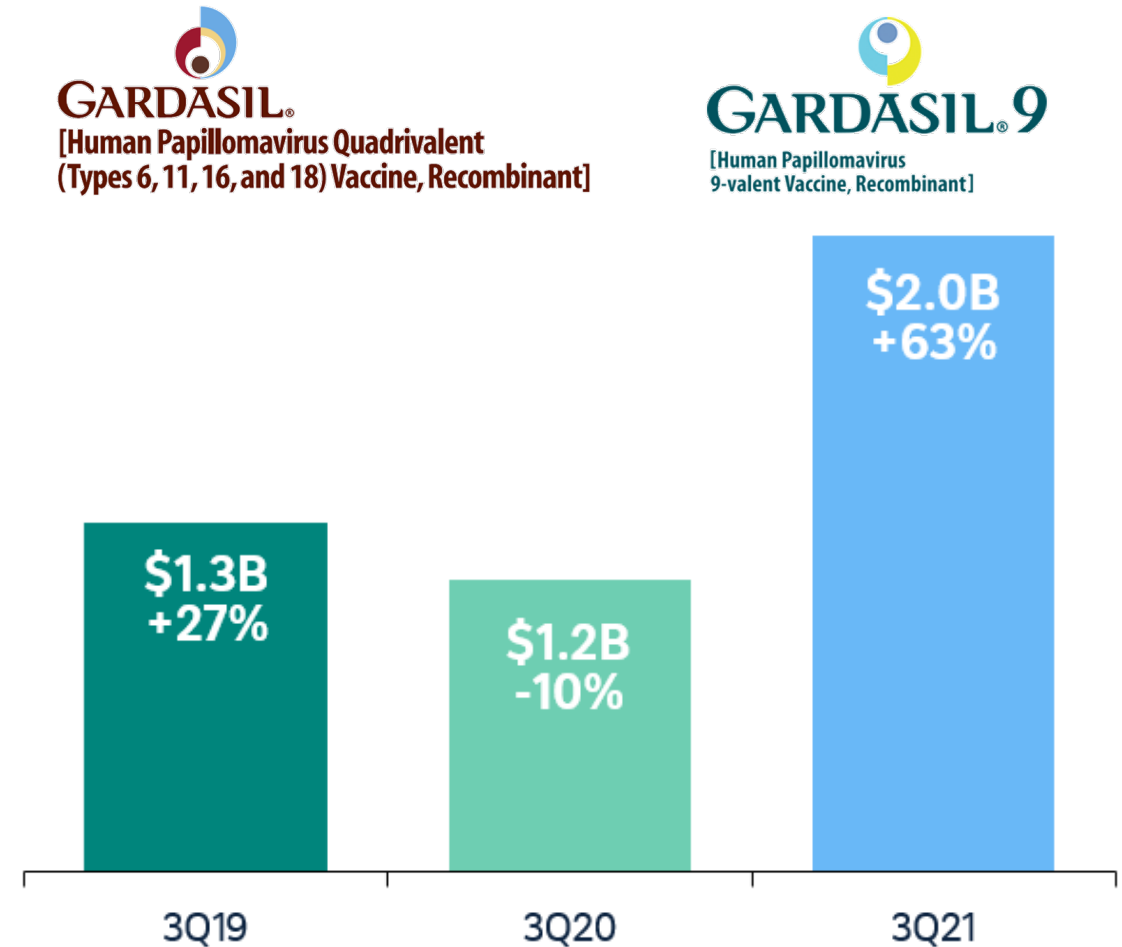
Oncology: Additional current and future growth drivers

- Lynparza sales increased 25%, with growth driven by breast and continued uptake in other approved indications, including ovarian and prostate
- Lenvima sales grew 30%; growth in the U.S. driven by RCC and EC; ex-US growth driven by NRDL listing in China
- WELIREG launch off to a strong start with approval in patients with certain VHL-associated tumors, potential to expand to broader RCC indications in the future



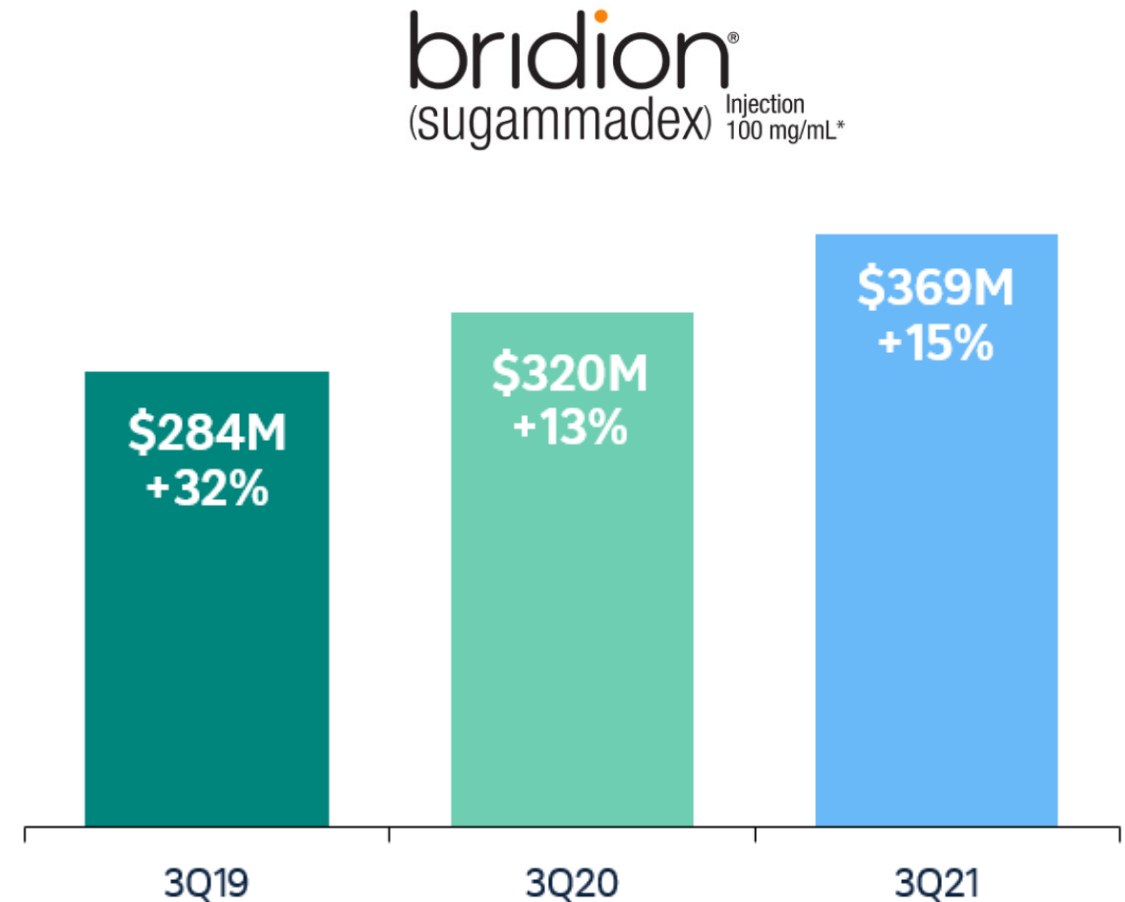
Vaccines: GARDASIL robust global demand

- GARDASIL sales of \$2.0B, increased 63% year-over-year, driven by strong global demand and increased supply
 - U.S. growth benefited from timing of CDC purchases and underlying demand
 - Ex-U.S., growth was driven by robust demand, increased supply and reallocation of doses



Hospital: BRIDION strong performance

- BRIDION sales of \$369M increased 15% year-over-year, driven by increased share of the growing neuromuscular blockade reversal market
- Continued uptake in PREVYMIS, driven by ongoing launches
- ZERBAXA expected to return to market in Q4



Trends to watch: GARDASIL and Oncology

GARDASIL

- Sustained robust underlying demand, particularly in ex-US markets such as China
- Normal business seasonality will make Q3 the largest quarter of sales in 2021
- Global HPV vaccination levels remain low in eligible patient cohort
- Continue to benefit from investments in manufacturing productivity and capacity which will better position us to meet long-term global demand

Oncology

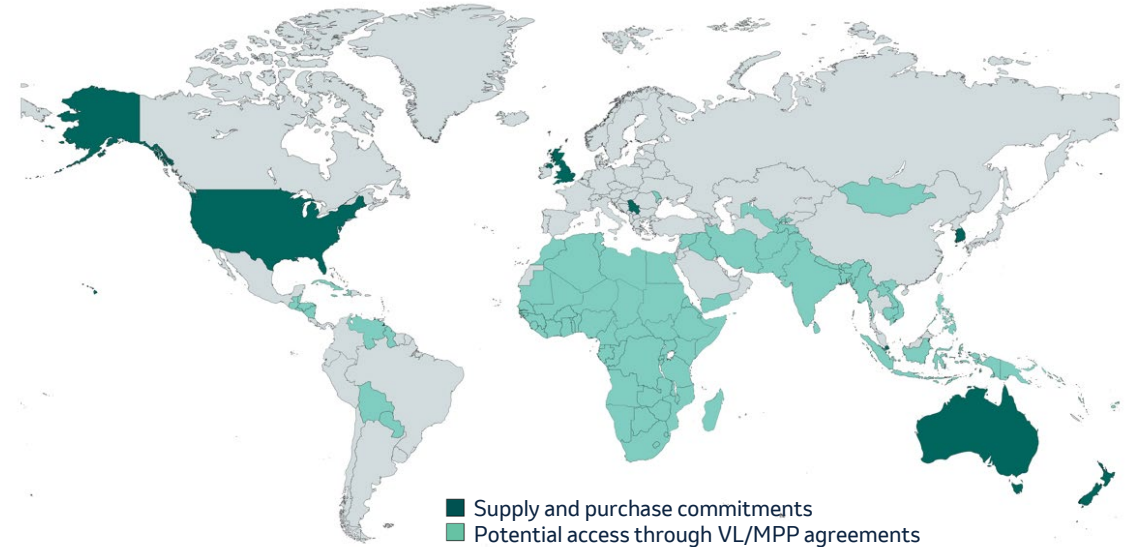
- KEYTRUDA maintains very strong IO class leadership
- KEYTRUDA growth from new indication launches, offsetting continued softness in new patient starts as a result of the pandemic
- Confident in the underlying demand across our broad and innovative Oncology portfolio
- Indications in early-stage disease will account for greater than half of KEYTRUDA's growth through 2025

Trends to watch: Molnupiravir commercial considerations

Key Considerations

- Potential first oral treatment option authorized for mild or moderate COVID-19
- Enable greater access by entering into agreements with voluntary license manufacturers and Medicines Patent Pool covering >100 countries, and by using a tier-based pricing approach
- Announced several supply and purchase commitments
- Ongoing discussions with other governments around the world

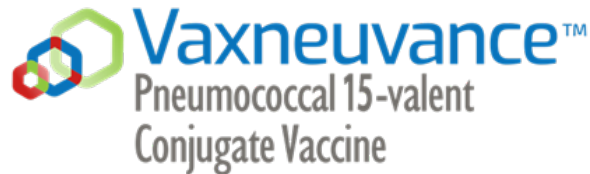
Enabling Broad Global Access



- **Supply and purchase commitments** with Australia, Korea, New Zealand, Serbia, Singapore, United Kingdom and United States

Trends to watch: Pneumococcal vaccine franchise

✓ CDC's ACIP votes to provisionally recommend the regimen of **VAXNEUVANCE + PNEUMOVAX 23** as an option for appropriate adults at increased risk of invasive pneumococcal disease* (IPD)



PNEUMOVAX²³
(Pneumococcal Vaccine Polyvalent)

**Burden of disease
for key serotypes**

**Strong immune response
for serotypes in vaccine**

**Robust immune response
data across recommended
cohorts**

**Broad serotype coverage to
help protect against
majority of IPD cases**

VAXNEUVANCE elicits **robust immune response** to the serotypes in the vaccine, including superior immunogenicity vs. PCV13 to serotype 3, the #1 disease-causing serotype in U.S. adults

Together with PNEUMOVAX23, this regimen covers key IPD-causing serotypes and provides the **broadest available serotype coverage** among adult pneumococcal vaccines

* Final recommendations are subject to review by CDC director and Department of Health and Human Services, and are pending publication in CDC's Morbidity and Mortality Weekly Report (MMWR)

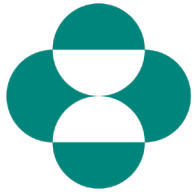


Financial Results

Caroline Litchfield
Chief Financial Officer



Strong Q3 2021 sales growth



Merck

WORLDWIDE SALES¹

\$13.2B

+20% growth
+19% ex-exchange



Human Health

\$11.5B

+18% growth
+17% ex-exchange



Animal Health

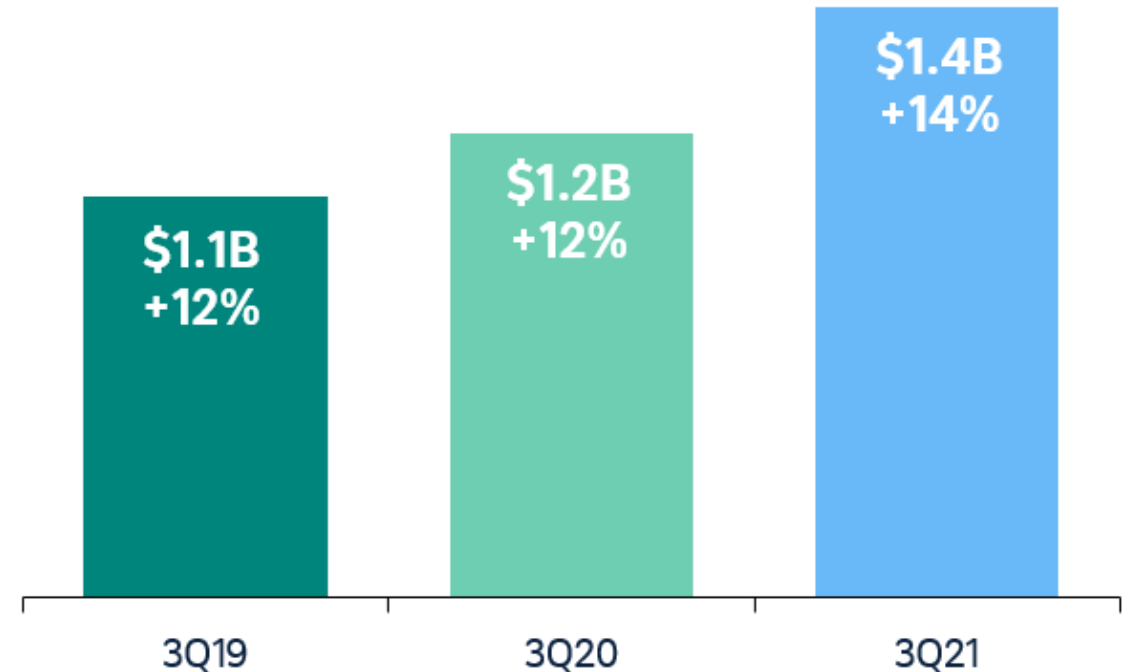
\$1.4B

+16% growth
+14% ex-exchange

1. Worldwide Sales includes Other Revenue.

Animal Health: durable growth across portfolio

- Animal Health sales increased 14% to \$1.4B, reflecting growth across geographies and species
 - Companion Animal sales increased 18%, driven by the BRAVECTO parasiticide line of products and vaccines
 - Livestock sales increased 12%, reflecting higher global demand for ruminant and poultry products, including Animal Health Intelligence products



Growth rates exclude the impact of foreign exchange.

Q3 2021 non-GAAP financial results summary:

Delivered strong revenue and EPS growth

\$ in billions, except EPS amounts

	Q3 2021	Q3 2020	Change	Change Ex-FX
Sales	\$13.2	\$10.9	+20%	+19%
Non-GAAP Gross Margin¹	76.8%	76.5%	+0.3pts	+0.3pts
Operating Expenses	\$4.7	\$4.2	+12%	+11%
Tax Rate	13.0%	14.4%	-1.4pts	N/A
Non-GAAP EPS that excludes certain items¹	\$1.75	\$1.37	+28%	+26%

1. 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.

Updated full-year 2021 guidance¹

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$46.4 to \$47.4B +12% to +14% (+10% to +12% ex-FX)	\$47.4 to \$47.9B +14% to +15% (+13% to +14% ex-FX)	- Now assumes 1.5% positive FX impact - Assumes ~3% negative impact due to COVID-19, particularly during the first half of 2021
Non-GAAP Gross Margin Rate²	76.0-77.0%	~76.5%	
Non-GAAP Operating Expenses³	Increase by high single-digit rate	Increase by high single-digit rate	Increased promotional spend and patient activation as well as increased investment in the pipeline
Other (Income) / Expense	~\$300M of expense	~\$450M of expense	Increase driven by pension settlement costs
Tax Rate⁴	~14.5-15.5%	~14.0-14.5%	Driven by discrete items
Shares Outstanding	~2.53B	~2.54B	Assumes very modest repurchase
GAAP EPS⁵	\$4.24 to \$4.34	\$4.71 to \$4.76	
Non-GAAP EPS⁵	\$5.47 to \$5.57 +21% to +23% (+19% to +21% ex-FX)	\$5.65 to \$5.70 +25% to +26% (+23% to +24% ex-FX)	Assumes ~2% positive FX impact

1. Guidance assumes the Acceleron transaction will close during the fourth quarter. Guidance does not include the impact of the potential launch of molnupiravir.

2. GAAP Gross Margin Rate: Higher than 2020 by a low single-digit rate. 3. GAAP Operating Expenses: Lower than 2020 by a mid-single-digit rate. 4. GAAP Tax Rate: ~14.5% - 15.0%

5. The GAAP to non-GAAP reconciliation is available in Merck's Q3 2021 earnings release

Modeling assumptions & outlook

Molnupiravir

- Potential sales or earnings for molnupiravir not included in 2021 guidance
 - Merck shares profits equally with Ridgeback
 - Merck records revenues and costs
 - Profit share reflected in Cost of Sales
- Assuming EUA in December, expect global opportunity of ~\$5 to \$7B through 2022, including ~\$0.5 to \$1.0B in 2021

GARDASIL

- Expect robust growth for GARDASIL in the 4th quarter and full year driven by strong demand and increased supply
 - 4Q 2021 sales will be lower than 3Q 2021, due to normal seasonality and timing effects
 - Recall, \$120M benefit in 4Q 2020 from CDC stockpile replenishment
- Expect strong long-term demand-driven growth
 - Enabled by increased capacity

Animal Health

- Exceptional quarterly growth in 2021 driven in part by increased pet adoption and pet spending due to the pandemic
- Expect 4Q 2021 growth to be more normalized as these trends stabilize

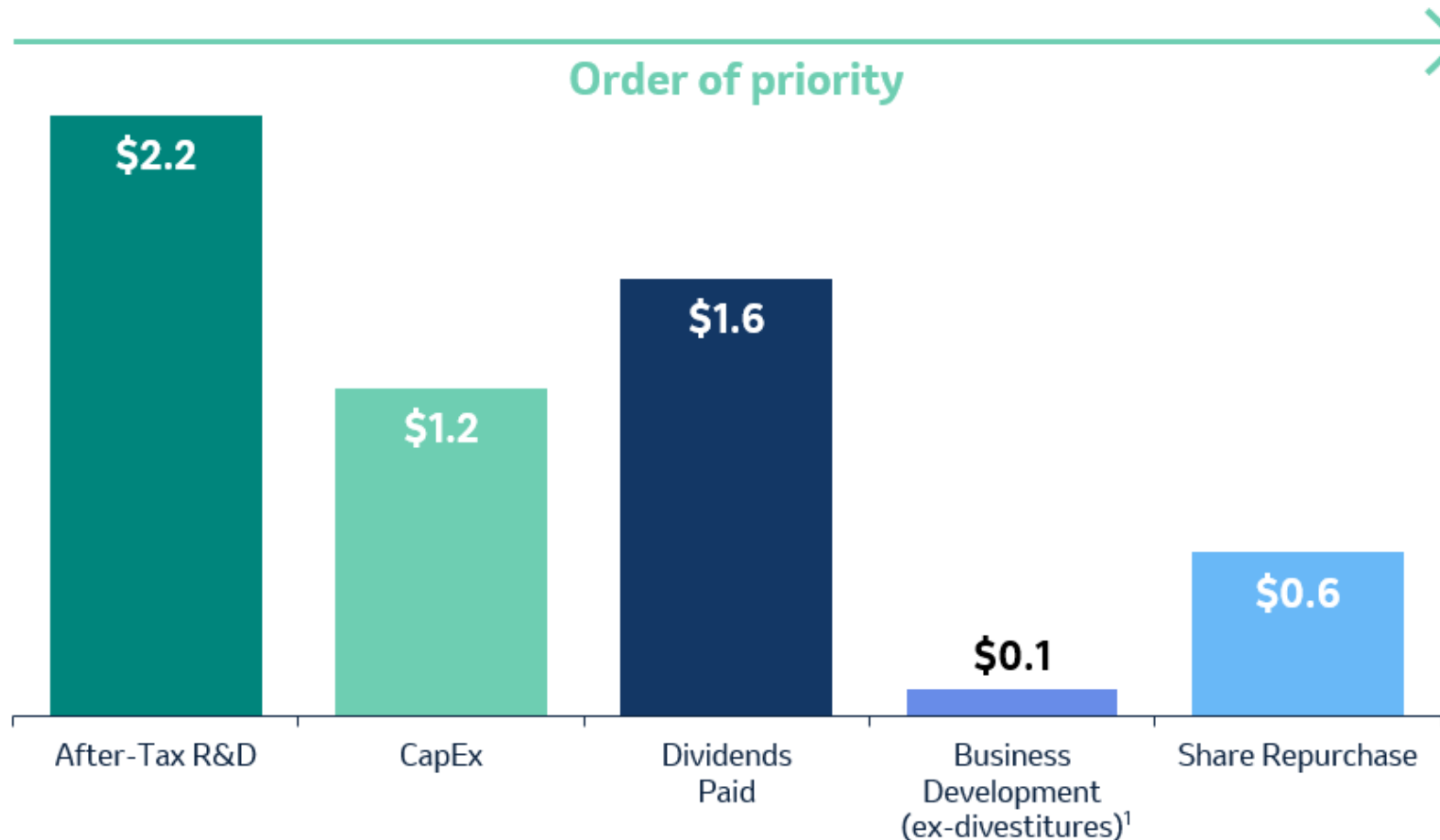
Operating Margin

- 3Q operating margin benefitted from strong revenue growth and normal seasonality of vaccines
- Expect operating margins to normalize due to this seasonality and phasing of spend
- Continue to expect operating margins of >42% in 2024

Balanced approach to capital allocation in Q3

\$ Billions

Order of priority



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

1. The business development figure reflects a milestone payment from our oncology collaboration with Eisai.



Research Update

Dr. Dean Li

President, Merck Research Laboratories



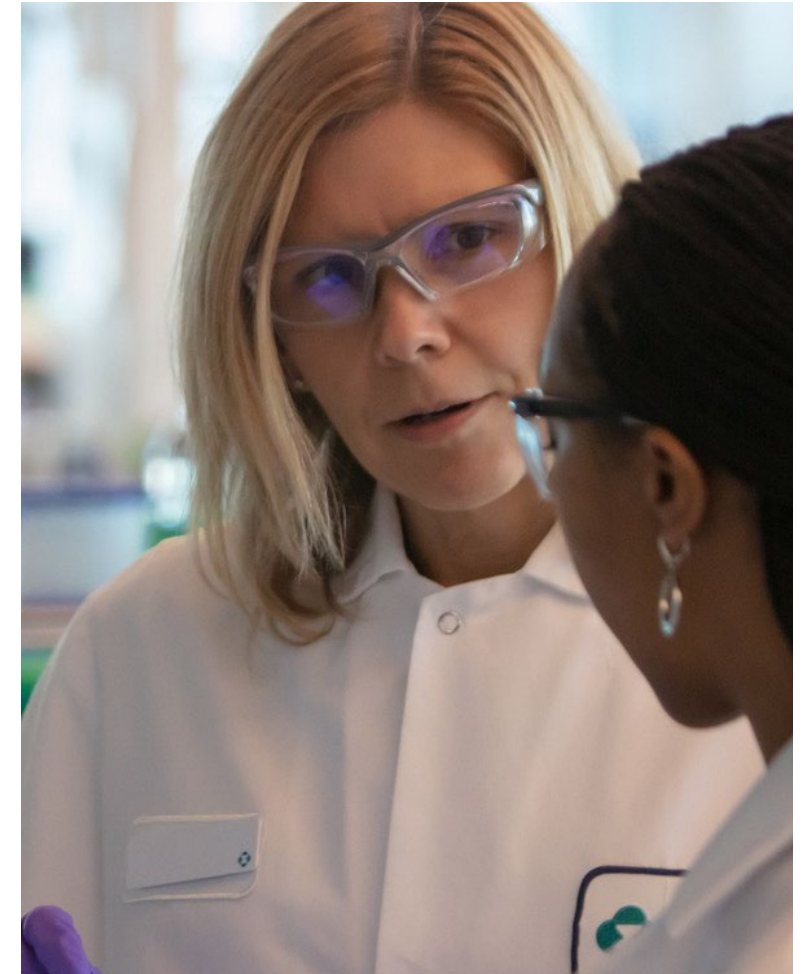
Driving value for patients and shareholders by progressing our pipeline

Key regulatory milestones since the last earnings call:

- In the U.S., received approval for KEYTRUDA in cervical cancer based on KN-826, KEYTRUDA+Lenvima in RCC based on KN-581, and WELIREG in certain types of VHL-associated tumors. FDA granted priority review for KEYTRUDA as adjuvant therapy both in melanoma based on KN-716 and in RCC based on KN-564. FDA accepted for review an sBLA for KEYTRUDA in endometrial carcinoma based on KN-158
- In the EU, received approval for KEYTRUDA in TNBC based on KN-355 as well as received positive CHMP opinion for KEYTRUDA for RCC based on KN-581 and endometrial based on KN-775 and for VAXNEUVANCE in adults
- In China, received approval for KEYTRUDA in esophageal or GEJ cancer based on KN-590
- In Japan, received approval for KEYTRUDA in TNBC based on KN-355 and in MSI-H colorectal cancer based on KN-177

Key data presentations since the last earnings call:

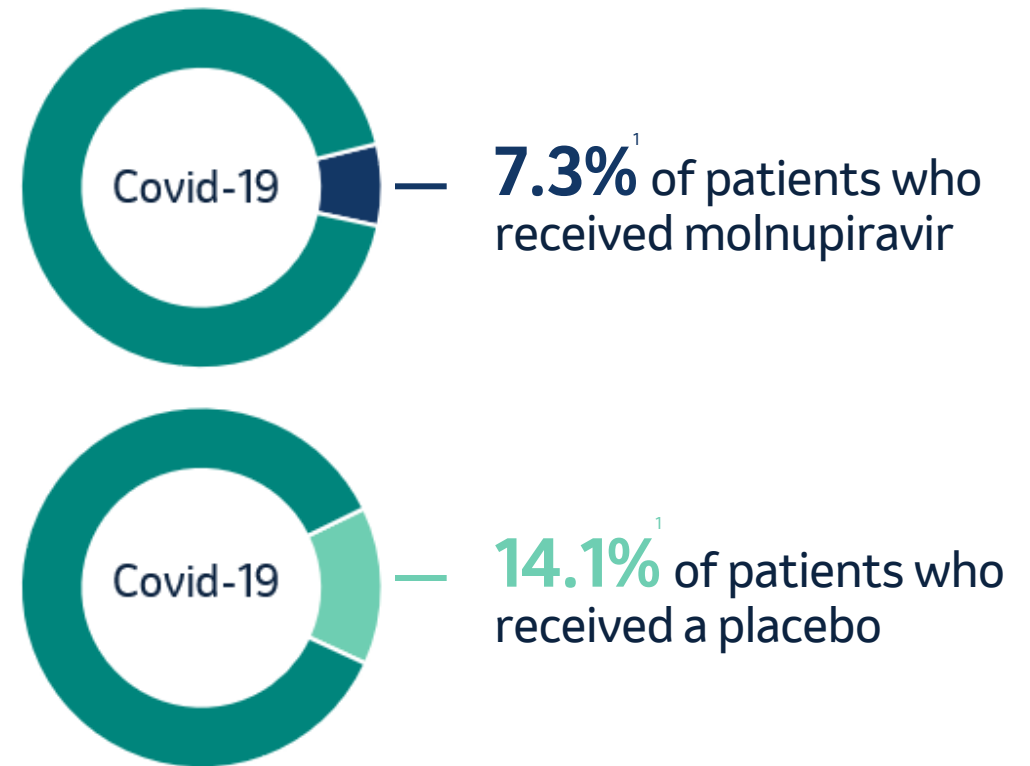
- Announced data from broad oncology portfolio at ESMO, including KEYTRUDA (KN-716, KN-826, KN-355, KN-564, KN-775, KN-158, KN365, and KN-522), Lynparza (OReO) and WELIREG in VHL associated RCC
- Presented data from the Phase 2b trial studying once-daily oral combination of doravirine and islatravir for the treatment HIV at EACS
- Toplined data for the combination of doravirine and islatravir for the treatment of HIV in the switch setting from Protocols 17 and 18
- Announced positive results for KEYTRUDA in Asian patients with HCC based on KN-394 and Lynparza in metastatic castration resistant prostate cancer based on PROpel
- Toplined pivotal results for VAXNEUVANCE in infants based on the PNEU-PED trial, as well as for molnupiravir in at-risk, non-hospitalized adult patients with mild-to-moderate COVID-19 based on the MOVE-OUT trial



Molnupiravir MOVE-OUT trial

- **Global study** with planned interim analysis that evaluated 775 patients with at least one risk factor for severe disease
- **Reduced the risk of hospitalization or death by ~50%** compared to placebo for at risk patients with mild or moderate COVID-19
- Based on the participants with available viral sequencing data, demonstrated **consistent efficacy** across viral variants Gamma, Delta, and Mu
- Being evaluated for **post-exposure prophylaxis** to prevent spread of COVID-19 within households in Phase 3 study, MOVE-AHEAD
- **Zero deaths reported** compared to eight deaths on placebo through Day 29

Patients with mild-to-moderate COVID-19 who experienced hospitalization or death:



¹ 7.3% represents 28/385 patients; 14.1% represents 53/377 patients

Sotatercept is highly complementary to and strengthens our existing cardiovascular portfolio and pipeline

	Heart Failure	Pulmonary Hypertension			Anti-thrombotic	Atherosclerosis
	 Verquvo [®] (vericiguat) tablets 2.5 mg, 5 mg, 10 mg	 Adempas [®] riociguat tablets 0.5mg 1mg 1.5mg 2mg 2.5mg	sotatercept	MK-5475	MK-2060	MK-0616
Status	Approved; additional studies planned	Approved	Phase 3	Phase 2/3	Phase 2	Phase 1
Mechanism of Action	Oral sGC stimulator	Oral sGC stimulator	Activin receptor type IIA fusion protein	Inhaled sGC stimulator	Factor XI	Oral PCSK9
Disease Area	HFrEF	PAH, CTEPH	PAH, PH-LHD	PAH	Thrombosis	Atherosclerosis

HIV and Vaccines highlights

HIV

- Doravirine and islatravir demonstrated continued **maintenance of viral suppression** in Phase 2 study through week 144
- Positive top-line results from **pivotal** Phase 3 study evaluating a **once daily oral** regimen of doravirine and islatravir in switch setting
- Initiated Phase 2 study evaluating a **once weekly oral** combination of islatravir and lenacapavir in partnership with Gilead

Pneumococcal Disease

- Positive CHMP opinion for VAXNEUVANCE
- **ACIP unanimously voted to provisionally recommend** VAXNEUVANCE in series with PNEUMOVAX 23 as an option for pneumococcal vaccination pending CDC adoption
 - Two dose regimen provides broadest serotype coverage with **4 unique serotypes**
 - **Only newly licensed PCV** evaluated in a high-risk immunocompromised patient population
- Positive top-line pivotal results for VAXNEUVANCE in the **pediatric setting** and **submitted filing** to FDA

Oncology highlights

Women's Cancers

- Approval of KEYTRUDA + chemotherapy in recurrent or **metastatic cervical cancer** [KN-826]
- Presented significant new and updated data at ESMO:
 - Final results of KEYTRUDA + chemotherapy in **metastatic triple negative breast cancer** [KN-355]
 - Data in expanded population across **endometrial cancer** [KN-775 and KN-158]

Prostate Cancer

- Positive top-line results in **metastatic castration-resistant prostate cancer** for Lynparza + abiraterone in front line setting [PROpel]
- Robust **Phase 3 clinical development program** evaluating KEYTRUDA in combination in multiple settings:
 - KEYTRUDA + Lynparza 2nd / 3rd line mCRPC [KL-10]
 - KEYTRUDA + docetaxel 1st / 2nd line mCRPC [KN-921]
 - KEYTRUDA + enzalutamide 1st line mCRPC [KN-641]
 - KEYTRUDA + enzalutamide+ADT in mHSPC [KN-991]

Broad based program in renal cell carcinoma

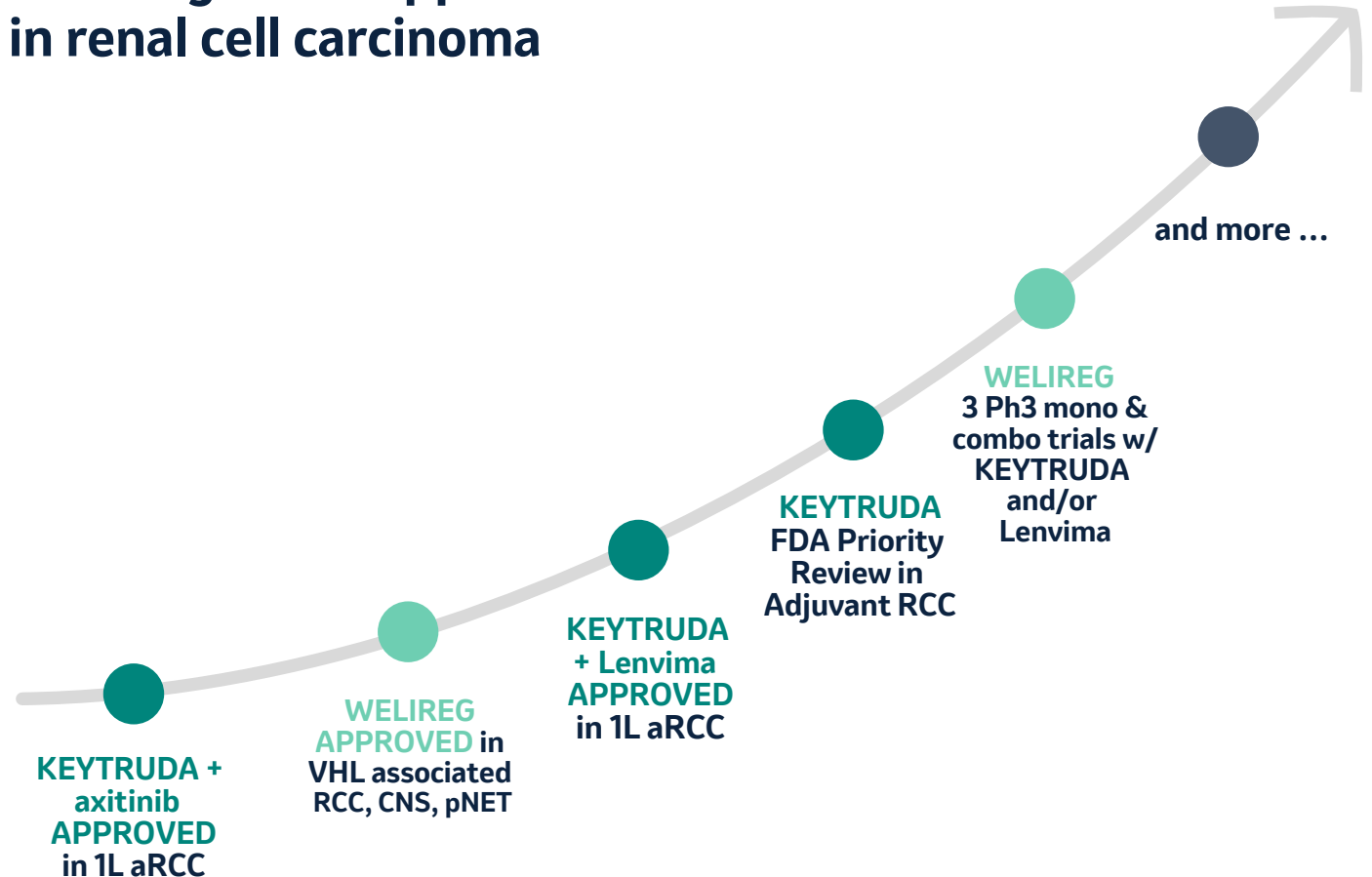
WELIREG

- **APPROVED as first-in-class** HIF-2 α inhibitor therapy targeting a gene transcription factor
- **3 pivotal clinical trials** in progress assessing efficacy alone and in combination with TKI & IO in advanced renal cell carcinoma

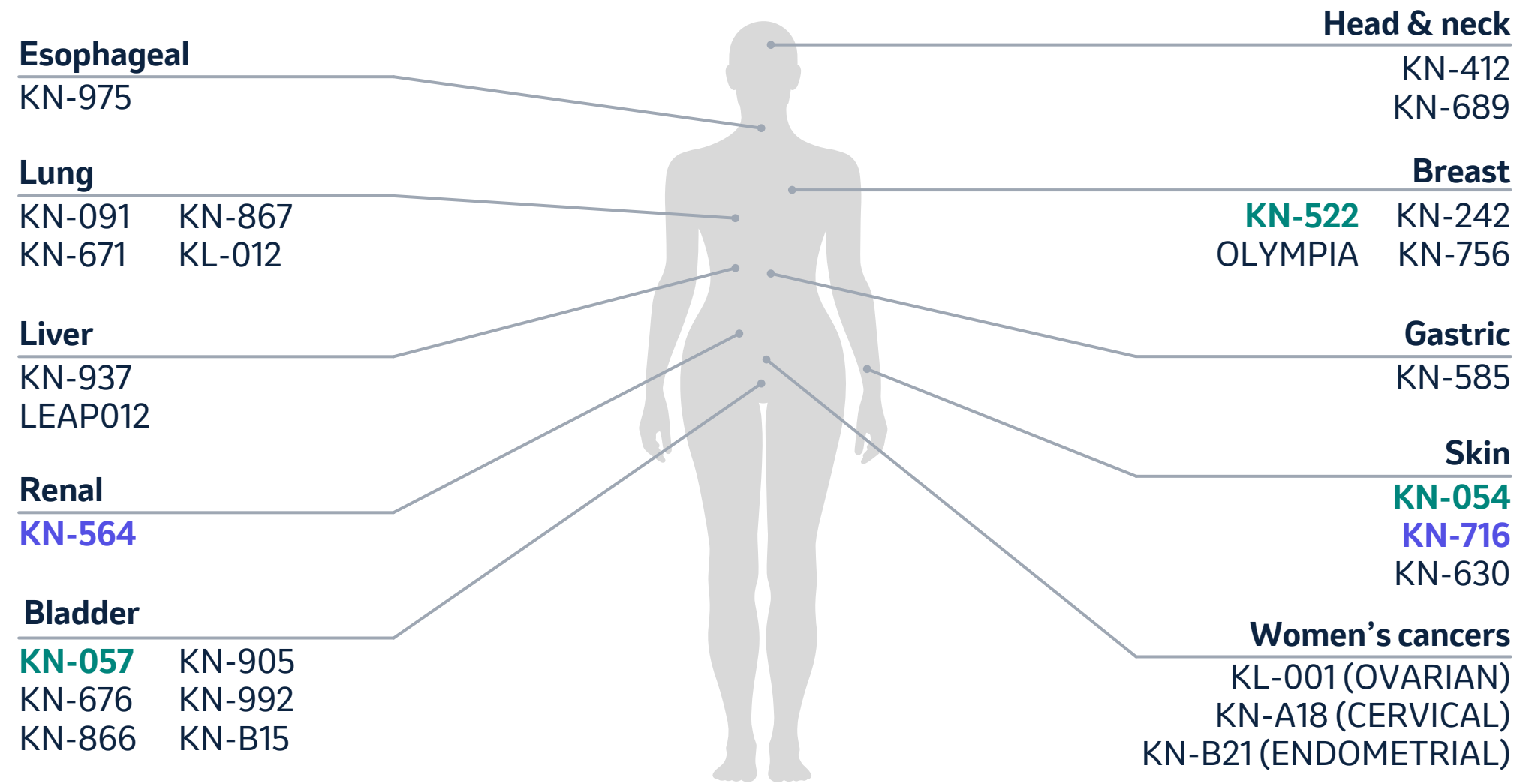
KEYTRUDA

- **1L advanced RCC Approvals:**
 - KEYTRUDA + Lenvima [KN-581]
 - KEYTRUDA + axitinib [KN-426]
- **Adjuvant RCC in Priority Review:**
 - KEYTRUDA [KN-564]

Future growth opportunities in renal cell carcinoma



Potential foundational early-stage disease program across many tumor types



Approved Indication FDA Granted Priority Review



Q&A



Rob Davis
Chief Executive Officer



Frank Clyburn
President, Merck Human Health



Caroline Litchfield
Chief Financial Officer



Dr. Dean Li
President, Merck Research Laboratories



Peter Dannenbaum
Vice President, Investor Relations



Appendix

Q3 2021 GAAP financial results summary:

\$ in billions, except EPS amounts

	Q3 2021	Q3 2020	Change	Change Ex-FX
Sales	\$13.2	\$10.9	+20%	+19%
Operating Expenses	\$4.8	\$5.4	-12%	-12%
Tax Rate	13.2%	14.0%	-0.8pts	N/A
GAAP EPS from continuing operations	\$1.80	\$0.92	+96%	+93%

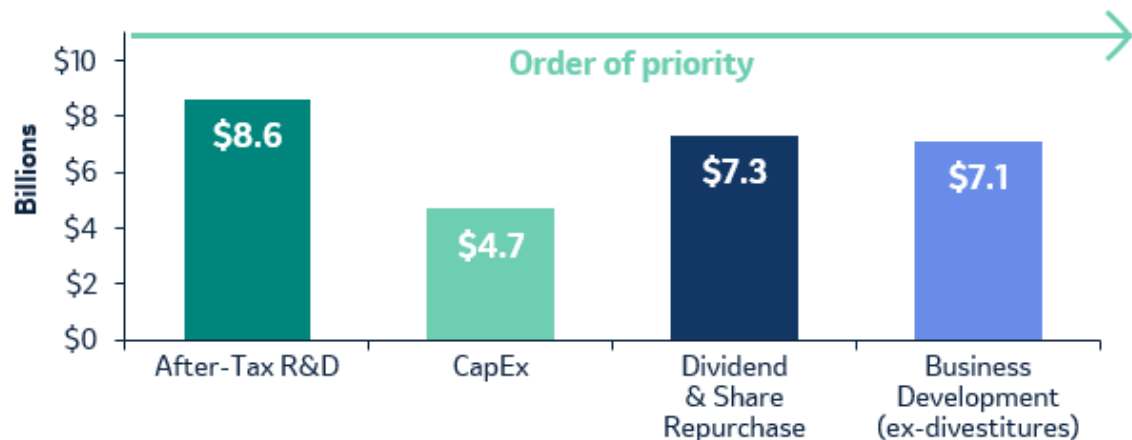
Broad and innovative pipeline to solve significant unmet medical needs

Phase 2					Phase 3	Under regulatory review
Oncology					Oncology	Oncology
KEYTRUDA (MK-3475) Advanced Solid Tumors	MK-4280 NSCLC Hematological Malignancies	V937 Melanoma Breast CSCC HNSCC Solid Tumors	MK-1308A (quavonlimab/ pembrolizumab) Advanced Solid Tumors HCC CRC SCLC Melanoma	MK-2140 Breast NSCLC	KEYTRUDA (MK-3475) Biliary Tract Cervical (EU) cSCC (EU) Gastric (EU) Hepatocellular (EU) Mesothelioma Ovarian Prostate SCLC	KEYTRUDA (MK-3475) MSI-H or dMMR Endometrial (US) TMB-H (JPN) Adjuvant RCC (US, EU, JPN) Advanced Unresectable Metastatic Esophageal (JPN) Melanoma (US, EU) High-risk early stage TNBC (EU, JPN) Cervical (JPN)
LYNPARZA (MK-7339) Advanced Solid Tumors	LENVIMA (MK-7902) Biliary Tract Glioblastoma Prostate SCLC Pancreas	MK-4280A (favezelimab/ pembrolizumab) RCC SCLC	TUKYSA (MK-7119) Advanced Solid Tumors Colorectal Gastric Endometrial NSCLC Bladder Biliary Cervical	MK-4830 NSCLC SCLC	LENVIMA (MK-7902) HNSCC Melanoma CRC Esophageal NSCLC Gastric	LENVIMA (MK-7902) 1L HCC (US) Advanced unresectable RCC (EU, JPN) Advanced endometrial (EU, JPN)
MK-6440 Breast NSCLC SCLC HNSCC Esophageal Gastric Prostate Melanoma	MK-7684A (vibostolimab/ pembrolizumab) Biliary Cervical Esophageal Breast Endometrial Prostate Hematological Malignancies	WELIREG (MK-6482) Rare Cancers CRC Pancreatic Biliary Certain VHL tumors (EU)	MK-0482 NSCLC	MK-1308 NSCLC	LYNPARZA (MK-7339) NSCLC SCLC CRC	
MK-1026 Hematological Malignancies			MK-5890 NSCLC SCLC	MK-7684 NSCLC	WELIREG (MK-6482) RCC	Vaccines
			MK-7684 Melanoma		TUKYSA (MK-7119) Breast	V114 Pneumoconjugate Vaccine, adult (EU, JPN)
					MK-3475 subcutaneous NSCLC	
Vaccines					Infectious diseases	General medicine
V116 Pneumococcal, adult					MK-8591A (doravirine/islatravir) HIV-1 Infection	Gefapixant (MK-7264) Cough (US, JPN, EU)
V184 Chikungunya Virus					Islatravir (MK-8591) HIV-1 prevention	CUBICIN (MK-3009) cSST & Sepsis, pediatric (JPN)
MK-1654 Respiratory Syncytial Virus						NOXAFIL (MK-5592) Invasive aspergillosis (EU)
	Neuroscience		General medicine			Infectious diseases
	MK-8189 Schizophrenia		MK-7075 Overgrowth Syndrome			Molnupiravir (MK-4482) COVID-19 (US, EU)
	Infectious diseases		MK-1942 Treatment Resistant Depression			
	MK-8591B (islatravir/MK-8507) HIV-1 Infection		MK-3655 NASH			
	MK-8591D (islatravir/lenacapavir) HIV-1 Infection		MK-6024 NASH			
	Cardiovascular					
	MK-5475 Pulmonary Arterial Hypertension					
	MK-2060 Cardiovascular					

As of October 27, 2021

Capital allocation: TTM

Over the past 12 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

