



## News Release

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### FOR IMMEDIATE RELEASE

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### **Merck Announces First-Quarter 2017 Financial Results**

- First-Quarter 2017 Worldwide Sales Were \$9.4 Billion, an Increase of 1 Percent, Including a 2 Percent Negative Impact from Foreign Exchange
- First-Quarter 2017 GAAP EPS Was \$0.56; First-Quarter Non-GAAP EPS Was \$0.88
- Company Narrows and Raises 2017 Full-Year Revenue Range to be Between \$39.1 Billion and \$40.3 Billion, Including an Approximately 1.5 Percent Negative Impact from Foreign Exchange
- Company Narrows and Raises 2017 Full-Year GAAP EPS Range to be Between \$2.51 and \$2.63; Narrows and Raises 2017 Full-Year Non-GAAP EPS Range to be Between \$3.76 and \$3.88, Including an Approximately 1.5 Percent Negative Impact from Foreign Exchange
- KEYTRUDA Development Program Advances with Two Additional Regulatory Approvals and CHMP Positive Opinion; Four sBLAs Currently Under Priority Review with PDUFA Action Dates in Second Quarter

KENILWORTH, N.J., May 2, 2017 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the first quarter of 2017.

“Merck delivered solid performance across our broad range of products that address major disease categories and the needs of global health,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “The continued momentum of KEYTRUDA in oncology, along with the strength of the vaccine and other franchises and animal health, helped to drive revenue growth in the quarter.”

## Financial Summary

\$ in millions, except EPS amounts	First Quarter	
	2017	2016
Sales	\$9,434	\$9,312
GAAP EPS	0.56	0.40
Non-GAAP EPS that excludes certain items <sup>1*</sup>	0.88	0.89
GAAP net income <sup>2</sup>	1,551	1,125
Non-GAAP net income that excludes certain items <sup>1,2*</sup>	2,437	2,492

\*Refer to table on page 7.

Worldwide sales were \$9.4 billion for the first quarter of 2017, an increase of 1 percent compared with the first quarter of 2016, including a 2 percent negative impact from foreign exchange.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) were \$0.56 for the first quarter of 2017. Non-GAAP EPS of \$0.88 for the first quarter of 2017 excludes acquisition- and divestiture-related costs, restructuring costs and certain other items.

## Pipeline Highlights

Merck continued to deliver significant progress in the development program for KEYTRUDA (pembrolizumab), an anti-PD-1 therapy, receiving key regulatory approvals or opinions and supplemental Biologics License Application (sBLA) acceptances.

- The U.S. Food and Drug Administration (FDA) [approved](#) under its Accelerated Approval program KEYTRUDA for the treatment of patients with refractory classical Hodgkin lymphoma (cHL) or for patients with cHL who have relapsed after three or more prior lines of therapy.
- The European Commission [approved](#) KEYTRUDA for the first-line treatment of non-small cell lung cancer (NSCLC) in adults whose tumors have high PD-L1 expression (tumor proportion score of 50 percent or more) with no EGFR or ALK positive tumor mutations.
- The Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) [adopted](#) a positive opinion recommending approval of KEYTRUDA for the treatment of adult patients with relapsed or refractory cHL who have failed autologous

<sup>1</sup> Merck is providing certain 2017 and 2016 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. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. For a description of the items, see Table 2a attached to this release.

<sup>2</sup> Net income attributable to Merck & Co., Inc.

stem cell transplant and brentuximab vedotin (BV), or who are transplant-ineligible and have failed BV.

- The FDA [accepted](#) for review under its Accelerated Approval program the sBLA for KEYTRUDA in combination with pemetrexed and carboplatin for the treatment of patients with metastatic or advanced NSCLC regardless of PD-L1 expression. This is the first application for regulatory approval of KEYTRUDA in combination with another treatment. The FDA granted Priority Review with a PDUFA action date of May 10, 2017.
- The FDA [accepted](#) and granted Priority Review for the sBLA for the treatment of patients with locally advanced or metastatic urothelial cancer, a type of bladder cancer, for first-line use in patients who are ineligible for cisplatin-containing therapy. The application for second-line use was also accepted for Priority Review. The PDUFA action date for both applications is June 14, 2017.
- The company recently [submitted](#) additional data and analyses to the FDA for the pending sBLA application for the treatment of previously treated patients with advanced microsatellite instability-high cancer. The PDUFA action date for this Priority Review has been extended to June 9, 2017.

The FDA and EMA [accepted](#) for review three New Drug Applications (NDAs) in the company's diabetes franchise for medicines containing ertugliflozin, an investigational SGLT2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes as part of Merck's collaboration with Pfizer Inc. The PDUFA action date from the FDA is in December 2017 for the three NDAs.

Merck presented phase 3 data across our late-stage pipeline in studies that met their primary endpoints.

- At the Conference on Retroviruses and Opportunistic Infections in February, data were [presented](#) from the ongoing "DRIVE-FORWARD" phase 3 clinical trial evaluating the safety and efficacy of doravirine (MK-1439), an investigational non-nucleoside reverse transcriptase inhibitor for previously untreated adults with HIV-1 infection. The study met its primary efficacy endpoint, demonstrating the non-inferiority of once-daily doravirine to once-daily ritonavir-boosted darunavir.
- Positive results from a study of letermovir, an investigational antiviral medicine for the prevention of cytomegalovirus infection in high-risk bone marrow transplant patients, were [presented](#) at the BMT Tandem Meetings in February.
- Merck [presented](#) data from a trial for V212, an investigational inactivated varicella zoster virus vaccine for the prevention of herpes zoster or HZ, also known as shingles. The data demonstrated a reduction in the incidence of confirmed HZ cases by an estimated

64 percent in immunocompromised patients and also were presented at the BMT Tandem Meetings.

### First-Quarter Revenue Performance

The following table reflects sales of the company's top pharmaceutical products, as well as total sales of Animal Health products.

\$ in millions	First Quarter			Change Ex-Exchange
	2017	2016	Change	
Total Sales	\$9,434	\$9,312	1%	3%
Pharmaceutical	8,185	8,104	1%	2%
JANUVIA / JANUMET	1,335	1,412	-5%	-5%
KEYTRUDA	584	249	134%	137%
ZETIA / VYTORIN	575	889	-35%	-35%
GARDASIL / GARDASIL 9	532	378	41%	41%
ZEPATIER	378	50	*	*
PROQUAD, M-M-R II and VARIVAX	355	357	0%	1%
ISENTRESS	305	340	-10%	-10%
REMICADE	229	349	-34%	-31%
ROTATEQ	224	188	19%	19%
Animal Health	939	829	13%	14%
Other Revenues	310	379	-18%	-5%

\*Growth comparison not meaningful due to ongoing product launch.

### Pharmaceutical Revenue

First-quarter pharmaceutical sales increased 1 percent to \$8.2 billion, including a 1 percent negative impact from foreign exchange. The growth was driven by oncology, hepatitis C and vaccines, largely offset by the loss of market exclusivity for several products, as well as lower sales in the diabetes franchise.

Growth in oncology was due to higher sales of KEYTRUDA as the company continues to launch the product with new indications globally.

Growth in hepatitis C was driven by ZEPATIER (elbasvir and grazoprevir), a medicine for the treatment of chronic hepatitis C virus genotypes 1 or 4 infection, due to ongoing launches globally. Sales in the United States also reflect an approximately \$40 million favorable adjustment to rebate accruals due to mix of business.

Growth in vaccines was primarily driven by higher sales of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to prevent certain cancers and other diseases caused by HPV, in the United States reflecting the timing of public sector purchases, underlying demand and increased price, as well as higher sales of PNEUMOVAX 23

(pneumococcal vaccine polyvalent) largely driven by demand in the United States. Growth in vaccines also reflects incremental sales of approximately \$65 million, of which approximately \$50 million relates to GARDASIL and GARDASIL 9, due to Merck now recording vaccine sales in the 19 European countries previously part of the Sanofi Pasteur MSD vaccines joint venture, which was terminated on Dec. 31, 2016.

Pharmaceutical sales reflect a decrease in the diabetes franchise of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl), medicines that help lower blood sugar in adults with type 2 diabetes, primarily due to the timing of customer purchases in the United States as anticipated for the quarter.

Sales growth also was offset by the loss of U.S. market exclusivity in 2016 for ZETIA (ezetimibe), a medicine for lowering LDL cholesterol; CUBICIN (daptomycin for injection), an I.V. antibiotic; and NASONEX (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; as well as by the ongoing impact of biosimilar competition in the company's marketing territories in Europe for REMICADE (infliximab), a treatment for inflammatory diseases. In the aggregate, sales of these products declined \$686 million during the first quarter of 2017 compared to the first quarter of 2016.

### **Animal Health Revenue**

Animal Health sales totaled \$939 million for the first quarter of 2017, an increase of 13 percent compared with the first quarter of 2016, including a 1 percent negative impact from foreign exchange. Growth was primarily due to sales increases in companion animal products, driven by the BRAVECTO (fluralaner) line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, as well as in ruminants, poultry and swine products. In March, Animal Health completed the acquisition of Vallée S.A., a leading privately held producer of animal health products in Brazil.

## First-Quarter Expense, EPS and Related Information

The table below presents selected expense information.

\$ in millions					
	GAAP	Acquisition- and Divestiture- Related Costs <sup>3</sup>	Restructuring Costs	Certain Other Items	Non-GAAP <sup>1</sup>
<b>First-Quarter 2017</b>					
Materials and production	\$3,015	\$855	\$63	\$--	\$2,097
Marketing and administrative	2,411	20	1	--	2,390
Research and development	1,796	11	--	--	1,785
Restructuring costs	151	--	151	--	--
Other (income) expense, net	58	(3)	--	(9)	70
<b>First-Quarter 2016</b>					
Materials and production	\$3,572	\$1,386	\$47	\$--	\$2,139
Marketing and administrative	2,318	2	3	--	2,313
Research and development	1,659	35	55	--	1,569
Restructuring costs	91	--	91	--	--
Other (income) expense, net	48	--	--	--	48

## GAAP Expense, EPS and Related Information

On a GAAP basis, the gross margin was 68.0 percent for the first quarter of 2017 compared to 61.6 percent for the first quarter of 2016. The increase in gross margin for the first quarter of 2017 was primarily driven by a lower net impact from acquisition- and divestiture-related costs and restructuring costs which reduced gross margin by 9.8 percentage points in the first quarter of 2017 as compared with 15.4 percentage points in the first quarter of 2016. The increase in gross margin also reflects the favorable effects of foreign exchange and lower inventory write-offs.

Marketing and administrative expenses were \$2.4 billion in the first quarter of 2017, a 4 percent increase compared to the first quarter of 2016. The increase primarily reflects higher health care reform fee expenses, administrative costs, and promotion and direct selling expenses.

Research and development (R&D) expenses were \$1.8 billion in the first quarter of 2017, an 8 percent increase compared to the first quarter of 2016. The increase reflects higher clinical development spending, partially offset by lower restructuring costs.

GAAP EPS was \$0.56 for the first quarter of 2017 compared with \$0.40 for the first quarter of 2016.

<sup>3</sup> Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of contingent consideration. Also includes integration, transaction and certain other costs related to business acquisitions and divestitures.

## Non-GAAP Expense, EPS and Related Information

The non-GAAP gross margin was 77.8 percent for the first quarter of 2017 compared to 77.0 percent for the first quarter of 2016. The increase in non-GAAP gross margin was largely driven by the favorable effects of foreign exchange and lower inventory write-offs.

Non-GAAP marketing and administrative expenses were \$2.4 billion in the first quarter of 2017, an increase of 3 percent compared to the first quarter of 2016. The increase was driven primarily by higher health care reform fee expenses, administrative costs, and promotion and direct selling expenses.

Non-GAAP R&D expenses were \$1.8 billion in the first quarter of 2017, a 14 percent increase compared to the first quarter of 2016. The increase primarily reflects higher clinical development spending.

Non-GAAP EPS was \$0.88 for the first quarter of 2017 compared with \$0.89 for the first quarter of 2016.

A reconciliation of GAAP to non-GAAP net income and EPS is provided in the table that follows.

\$ in millions, except EPS amounts	First Quarter	
	2017	2016
<b>EPS</b>		
GAAP EPS	\$0.56	\$0.40
Difference <sup>4</sup>	0.32	0.49
Non-GAAP EPS that excludes items listed below <sup>1</sup>	\$0.88	\$0.89
<b>Net Income</b>		
GAAP net income <sup>2</sup>	\$1,551	\$1,125
Difference	886	1,367
Non-GAAP net income that excludes items listed below <sup>1,2</sup>	\$2,437	\$2,492
<b>Decrease (Increase) in Net Income Due to Excluded Items:</b>		
Acquisition- and divestiture-related costs <sup>3</sup>	\$883	\$1,423
Restructuring costs	215	196
Other	(9)	--
Net decrease (increase) in income before taxes	1,089	1,619
Estimated income tax (benefit) expense	(203)	(252)
Decrease (increase) in net income	\$886	\$1,367

## Financial Outlook

Merck has narrowed and raised its full-year 2017 GAAP EPS range to be between \$2.51 and \$2.63. Merck has narrowed and raised its full-year 2017 non-GAAP EPS range to be between \$3.76 and \$3.88, including an approximately 1.5 percent negative impact from foreign exchange at mid-April 2017 exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs and certain other items.

<sup>4</sup> Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the period.

Merck has narrowed and raised its full-year 2017 revenue range to be between \$39.1 billion and \$40.3 billion, including an approximately 1.5 percent negative impact from foreign exchange at mid-April 2017 exchange rates.

The following table summarizes the company's 2017 financial guidance.

	<b>GAAP</b>	<b>Non-GAAP<sup>1</sup></b>
Revenue	\$39.1 to \$40.3 billion	\$39.1 to \$40.3 billion**
Operating expenses	Lower than 2016	Higher than 2016 by a low-single digit rate
Effective tax rate	22.0% to 23.0%	21.0% to 22.0%
EPS	\$2.51 to \$2.63	\$3.76 to \$3.88

\*\*The company does not have any non-GAAP adjustments to revenue.

A reconciliation of anticipated 2017 GAAP EPS to non-GAAP EPS and the items excluded from non-GAAP EPS are provided in the table below.

\$ in millions, except EPS amounts	<b>Full-Year 2017</b>
GAAP EPS	\$2.51 to \$2.63
Difference <sup>4</sup>	1.25
Non-GAAP EPS that excludes items listed below <sup>1</sup>	\$3.76 to \$3.88
Acquisition- and divestiture-related costs	\$3,600
Restructuring costs	600
Net decrease (increase) in income before taxes	4,200
Estimated income tax (benefit) expense	(750)
Decrease (increase) in net income	\$3,450

The expected full-year 2017 GAAP effective tax rate of 22.0 to 23.0 percent reflects an unfavorable impact of approximately 1 percentage point from the above items.

## **Total Employees**

As of March 31, 2017, Merck had approximately 69,000 employees worldwide.

## **Earnings Conference Call**

Investors, journalists and the general public may access a live audio webcast of the call today at 8:00 a.m. EDT on Merck's website at <http://investors.merck.com/events-and-presentations/default.aspx>. Institutional investors and analysts can participate in the call by dialing (706) 758-9927 or (877) 381-5782 and using ID code number 91134398. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 91134398. Journalists who wish to ask questions are requested to contact a member of Merck's Media Relations team at the conclusion of the call.



## **About Merck**

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](#), [Facebook](#), [YouTube](#) and [LinkedIn](#). You can also follow our Twitter conversation at \$MRK.

## **Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release 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 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 2016 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](http://www.sec.gov)).

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