



News Release

FOR IMMEDIATE RELEASE

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Merck Announces First-Quarter 2016 Financial Results

- First-Quarter 2016 GAAP EPS was \$0.40; First-Quarter Non-GAAP EPS Increased by 5 Percent to \$0.89
- Company Continues to Expect 2016 Full-Year GAAP EPS to be Between \$1.96 and \$2.23; Narrows and Raises 2016 Full-Year Non-GAAP EPS to be Between \$3.65 and \$3.77
- First-Quarter 2016 Worldwide Sales Were \$9.3 Billion, a Decrease of 1 Percent, Including a 4 Percent Negative Impact from Foreign Exchange
- Obtained FDA Approval of ZEPATIER in the Treatment of Chronic Hepatitis C Genotypes 1 or 4 Infection
- Advanced KEYTRUDA Development Program
 - sBLA Accepted for Recurrent or Metastatic Head and Neck Cancer
 - Breakthrough Therapy Designation Granted for Classical Hodgkin Lymphoma

KENILWORTH, N.J., May 5, 2016 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the first quarter of 2016.

“Our first quarter’s performance sets us on a good course for the year,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “We remain focused on advancing our pipeline and driving the commercial success of our key launches and inline medicines and vaccines.”

Financial Summary

\$ in millions, except EPS amounts	First Quarter	
	2016	2015
Sales	\$9,312	\$9,425
GAAP EPS	0.40	0.33
Non-GAAP EPS that excludes items listed below ¹	0.89	0.85
GAAP net income ²	1,125	953
Non-GAAP net income that excludes items listed below ^{1,2}	2,492	2,426

¹ Merck is providing certain 2016 and 2015 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 performance. This information should be considered in addition to, but not in lieu of, information prepared in accordance with GAAP. For description of the items, see Table 2a, including the related footnotes, attached to this release.

² Net income attributable to Merck & Co., Inc.

Non-GAAP (generally accepted accounting principles) earnings per share (EPS) of \$0.89 for the first quarter exclude acquisition- and divestiture-related costs and restructuring costs.

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

\$ in millions, except EPS amounts

	First Quarter	
	2016	2015
EPS		
GAAP EPS	\$0.40	\$0.33
Difference ³	0.49	0.52
Non-GAAP EPS that excludes items listed below ¹	\$0.89	\$0.85

Net Income

GAAP net income ²	\$1,125	\$953
Difference	1,367	1,473
Non-GAAP net income that excludes items listed below ^{1,2}	\$2,492	\$2,426

Decrease (Increase) in Net Income Due to Excluded Items:

Acquisition- and divestiture-related costs ⁴	\$1,423	\$1,526
Restructuring costs	196	225
Net decrease (increase) in income before taxes	1,619	1,751
Estimated income tax (benefit) expense	(252)	(278)
Decrease (increase) in net income	\$1,367	\$1,473

Additional Executive Commentary

“Business development is a top priority, and we are actively pursuing the best external science through licensing or bolt-on acquisitions to bolster our pipeline and grow our company,” said Frazier.

“The Global Human Health business performed well in the first quarter. The JANUVIA franchise demonstrated strong growth, and we remain pleased with the ongoing launch of KEYTRUDA in markets around the world,” said Adam Schechter, president, Global Human Health. “Additionally, we are already seeing positive signs in the launch of ZEPATIER in the United States.”

“Merck Research Laboratories advanced several clinical development programs in the first quarter of 2016. We continued to accelerate the development of KEYTRUDA with an additional supplemental filing in head and neck cancer, and by securing a fourth Breakthrough

³ 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.

⁴ 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.

Therapy Designation in classical Hodgkin lymphoma,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories.

“We demonstrated strong performance with a leveraged P&L, growing sales and EPS, excluding the impact of foreign exchange. We benefited from the contribution of new product launches, while continuing to sustain growth in our key franchises and driving operational improvements across the company,” said Robert Davis, chief financial officer.

Select Business Highlights

Worldwide sales were \$9.3 billion for the first quarter of 2016, a decrease of 1 percent compared with the first quarter of 2015, including a 4 percent negative impact from foreign exchange.

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	Change Ex-Exchange
	2016	2015		
Total Sales	\$9,312	\$9,425	-1%	3%
Pharmaceutical	8,104	8,266	-2%	2%
JANUVIA / JANUMET	1,412	1,393	1%	4%
ZETIA / VYTORIN	889	887	0%	4%
GARDASIL / GARDASIL 9	378	359	5%	7%
PROQUAD, M-M-R II and VARIVAX	357	348	3%	4%
REMICADE	349	501	-30%	-26%
ISENTRESS	340	385	-12%	-8%
CUBICIN	292	187*	56%*	57%*
KEYTRUDA	249	83	**	**
SINGULAIR	237	245	-3%	-1%
NASONEX	229	289	-21%	-19%
Animal Health	829	829	0%	9%
Other Revenues	379	330	15%	23%

*First quarter of 2015 reflects approximately two months of sales following the acquisition of Cubist Pharmaceuticals, Inc. (Cubist) by Merck on Jan. 21, 2015. Percentages reflect comparison to full quarter of sales in 2016.

**≥ 100%

Commercial and Pipeline Highlights

During the first quarter of 2016, the company continued to focus on advancing its pipeline, and achieved regulatory and clinical milestones for multiple products in its portfolio.

- Merck advanced its development program for KEYTRUDA (pembrolizumab), an anti-PD-1 therapy for the treatment of metastatic non-small cell lung cancer (NSCLC) in previously treated patients whose tumors express PD-L1, as well as advanced melanoma.
 - The U.S. Food and Drug Administration (FDA) [accepted](#) for review a supplemental Biologics License Application (sBLA) for KEYTRUDA for the treatment of patients with

recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy. The FDA granted Priority Review with a PDUFA action date of Aug. 9, 2016; the sBLA will be reviewed under the FDA's Accelerated Approval program.

- KEYTRUDA received Breakthrough Therapy Designation from the FDA for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma. It is the fourth Breakthrough Therapy Designation granted for KEYTRUDA.
- The FDA also accepted for review a sBLA for KEYTRUDA to include data from the pivotal KEYNOTE-010 study in which KEYTRUDA showed superior overall survival compared to chemotherapy in patients with previously treated advanced NSCLC whose tumors express PD-L1. In accordance with the accelerated approval process, the data from KEYNOTE-010 was intended to serve as the confirmatory trial for receiving full approval, establishing the clinical benefit by demonstrating improved survival over standard chemotherapy.
- The KEYTRUDA clinical development program includes patients with more than 30 tumor types in more than 250 clinical trials, including more than 100 trials that combine KEYTRUDA with other cancer treatments. Registration-enabling trials of KEYTRUDA are currently enrolling patients with melanoma, NSCLC, head and neck cancer, bladder cancer, gastric cancer, colorectal cancer, esophageal cancer, breast cancer, ovarian cancer, Hodgkin lymphoma, non-Hodgkin lymphoma, multiple myeloma, nasopharyngeal cancer, and other tumors, with further trials in planning for other cancers.
- The FDA approved ZEPATIER (elbasvir and grazoprevir), a once-daily, fixed-dose combination tablet for the treatment of adult patients with chronic hepatitis C virus genotype (GT) 1 or GT4 infection, with or without ribavirin.
- The FDA accepted for review the Biologics License Application (BLA) for MK-8237, the company's investigational house dust mite sublingual allergy immunotherapy tablet.
- The Antimicrobial Drugs Advisory Committee of the FDA has scheduled a meeting on June 9, 2016 to discuss the BLA for ZINPLAVA (bezlotoxumab), an investigational antitoxin for the prevention of *Clostridium difficile* (*C. difficile*) infection recurrence, which was accepted by the FDA for Priority Review with a PDUFA action date of July 23, 2016.

Pharmaceutical Revenue Performance

First-quarter pharmaceutical sales declined 2 percent to \$8.1 billion, including a 4 percent negative impact from foreign exchange. Excluding the impact of exchange, growth reflects higher sales in oncology, hospital acute care and diabetes. Growth in oncology was

driven by higher sales of KEYTRUDA as the company continues to launch the product with new indications and in new markets. Growth in hospital acute care was driven by sales of the Cubist portfolio and sales growth of certain inline brands. Pharmaceutical sales also reflect an increase 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, driven by strong growth in the United States and Europe, partially offset by lower sales in emerging markets.

First-quarter pharmaceutical sales reflect a decrease in REMICADE (infliximab), a treatment for inflammatory diseases, due to the accelerating impact of biosimilar competition in the company's marketing territories in Europe. Pharmaceutical sales also reflect declines in NASONEX (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, and ZOSTAVAX (zoster vaccine live), a vaccine for the prevention of herpes zoster. Pharmaceutical sales were unfavorably affected in the first quarter of 2016 by the company's reduced operations in Venezuela.

A generic version of NASONEX became available in the United States in March 2016; as a result, the company anticipates significant losses of future NASONEX sales. Additionally, in June 2016 the company will lose U.S. patent protection for CUBICIN (daptomycin for injection), an I.V. antibiotic, and significant losses of CUBICIN sales are expected to occur thereafter.

Animal Health Revenue Performance

Animal Health sales, which totaled \$829 million for the first quarter of 2016, were in line with sales from the first quarter of 2015. Excluding the impact of foreign exchange, Animal Health sales grew 9 percent, primarily driven by BRAVECTO (fluralaner), a chewable tablet that kills fleas and ticks in dogs for up to 12 weeks.

First-Quarter 2016 Expense and Other Information

The tables that follow present selected expense information.

\$ in millions	Included in expenses for the period			
	GAAP	Acquisition- and Divestiture-Related Costs ⁴	Restructuring Costs	Non-GAAP ¹
First Quarter 2016				
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	—

First Quarter 2015				
Materials and production	\$3,569	\$1,250	\$105	\$2,214
Marketing and administrative	2,601	227	36	2,338
Research and development	1,737	63	2	1,672
Restructuring costs	82	–	82	–

The gross margin was 61.6 percent for the first quarter of 2016 compared to 62.1 percent for the first quarter of 2015, reflecting 15.4 and 14.4 unfavorable percentage point impacts, respectively, from the acquisition- and divestiture-related costs and restructuring costs noted above.

Research and development (R&D) expenses, on a non-GAAP basis, were \$1.6 billion in the first quarter of 2016, a 6 percent decrease compared to the first quarter of 2015, primarily driven by lower licensing expenses.

Financial Outlook

Merck continues to expect its full-year 2016 GAAP EPS to be between \$1.96 and \$2.23. The company has narrowed and raised its full-year 2016 non-GAAP EPS to be between \$3.65 and \$3.77, including an approximately 2 percent negative impact from foreign exchange at mid-April exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs. The change in the non-GAAP EPS range reflects recent favorability in foreign exchange rates, partially offset by the earlier than expected entry of a generic version of NASONEX in the United States.

At mid-April exchange rates, Merck now anticipates full-year 2016 revenues to be between \$39.0 billion and \$40.2 billion, including an approximately 2 percent negative impact from foreign exchange.

In addition, the company continues to expect full-year 2016 non-GAAP marketing and administrative expenses to be below 2015 levels and R&D expenses to be modestly above 2015 levels.

The company continues to anticipate its full-year 2016 non-GAAP tax rate will be in the range of 21.5 to 22.5 percent, including a 2016 R&D tax credit.

A reconciliation of anticipated 2016 EPS, as reported in accordance with GAAP to non-GAAP EPS that excludes certain items, is provided in the table below.

\$ in millions, except EPS amounts	Full Year 2016
GAAP EPS	\$1.96 to \$2.23
Difference ³	1.69 to 1.54
Non-GAAP EPS that excludes items listed below	\$3.65 to \$3.77
Acquisition- and divestiture-related costs	\$4,700 to \$4,400
Restructuring costs	900 to 700
Net decrease (increase) in income before taxes	5,600 to 5,100
Estimated income tax (benefit) expense	(900) to (805)
Decrease (increase) in net income	\$4,700 to \$4,295

Total Employees

As of March 31, 2016, Merck had approximately 68,000 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/investors/webcasts-and-presentations>. Institutional investors and analysts can participate in the call by dialing (706) 758-9927 or (877) 381-5782 and using ID code number 75256428. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 75256428. 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 125 years, Merck has been a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. 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. For more information, visit 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 2015 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).

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