



News Release

FOR IMMEDIATE RELEASE

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Merck Announces Fourth-Quarter and Full-Year 2015 Financial Results

- Fourth-Quarter 2015 GAAP EPS was \$0.35; Fourth-Quarter Non-GAAP EPS was \$0.93, an Increase of 7 Percent; Full-Year 2015 GAAP EPS was \$1.56; Full-Year 2015 Non-GAAP EPS was \$3.59, an Increase of 3 Percent
- Fourth-Quarter 2015 Worldwide Sales Were \$10.2 Billion, a Decrease of 3 Percent, Including a 7 Percent Negative Impact from Foreign Exchange and 3 Percent Net Favorable Impact from Acquisitions and Divestitures
- Full-Year 2015 Worldwide Sales Were \$39.5 Billion, a Decrease of 6 Percent, Reflecting a 6 Percent Negative Impact from Foreign Exchange and a 3 Percent Net Unfavorable Impact from Acquisitions and Divestitures
- 2016 Financial Outlook
 - Expects Full-Year 2016 GAAP EPS to be Between \$1.96 and \$2.23; Expects Non-GAAP EPS to be Between \$3.60 and \$3.75, Including an Approximately 4 Percent Negative Impact from Foreign Exchange
 - Anticipates Full-Year 2016 Worldwide Sales to be Between \$38.7 Billion and \$40.2 Billion, Including an Approximately 3 Percent Negative Impact from Foreign Exchange
- Advanced KEYTRUDA Program
 - sBLA Approval for Treatment of Previously Treated Patients with Metastatic Non-Small Cell Lung Cancer Whose Tumors Express PD-L1
 - Expanded Indication for First-Line Treatment of Patients with Unresectable or Metastatic Melanoma
- Obtained FDA Approval of ZEPATIER in the Treatment of Chronic Hepatitis C

KENILWORTH, N.J., Feb. 3, 2016 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter and full year of 2015.

“The past year was one of considerable progress and execution for Merck,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “I’m excited by the near-term opportunities, as we continue launching important new products like ZEPATIER and KEYTRUDA while augmenting and advancing our pipeline.”

Financial Summary

	Fourth Quarter		Year Ended	
	2015	2014	Dec. 31, 2015	Dec. 31, 2014
\$ in millions, except EPS amounts				
Sales	\$10,215	\$10,482	\$39,498	\$42,237
GAAP EPS	0.35	2.54	1.56	4.07
Non-GAAP EPS that excludes items listed below ¹	0.93	0.87	3.59	3.49
GAAP net income ²	976	7,316	4,442	11,920
Non-GAAP net income that excludes items listed below ^{1,2}	2,608	2,504	10,195	10,215

Non-GAAP (generally accepted accounting principles) earnings per share (EPS) of \$0.93 for the fourth quarter and \$3.59 for the full year of 2015 exclude acquisition- and divestiture-related costs, restructuring costs and certain other items, as well as a net charge to settle Vioxx shareholder class action litigation.

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

	Fourth Quarter		Year Ended	
	2015	2014	Dec. 31, 2015	Dec. 31, 2014
\$ in millions, except EPS amounts				
EPS				
GAAP EPS	\$0.35	\$2.54	\$1.56	\$4.07
Difference ³	0.58	(1.67)	2.03	(0.58)
Non-GAAP EPS that excludes items listed below ¹	\$ 0.93	\$0.87	\$3.59	\$3.49
Net Income				
GAAP net income ²	\$976	\$7,316	\$4,442	\$11,920
Difference	1,632	(4,812)	5,753	(1,705)
Non-GAAP net income that excludes items listed below ^{1,2}	\$2,608	\$2,504	\$10,195	\$10,215

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

Acquisition- and divestiture-related costs ⁴	\$ 1,264	\$1,394	\$5,398	\$5,946
Restructuring costs	340	619	1,110	1,978
Net charge to settle Vioxx shareholder class action litigation	680	–	680	–
Foreign exchange losses related to Venezuela	161	–	876	–
Loss on extinguishment of debt	–	628	–	628
Additional year of health care reform fee	–	–	–	193
Gain on divestiture of certain ophthalmic products	(147)	(84)	(147)	(480)
Gain on divestiture of certain migraine clinical development programs	–	–	(250)	–
Gain on sale of Merck Consumer Care	–	(11,209)	–	(11,209)
Gain on AstraZeneca option exercise	–	–	–	(741)
Other	13	(14)	(34)	(9)
Net decrease (increase) in income before taxes	2,311	(8,666)	7,633	(3,694)
Income tax (benefit) expense ⁵	(679)	3,854	(1,880)	2,045
Acquisition- and divestiture-related costs attributable to non-controlling interests	–	–	–	(56)
Decrease (increase) in net income	\$1,632	\$(4,812)	\$5,753	\$(1,705)

¹ Merck is providing certain 2015 and 2014 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 Tables 2a and 2b, including the related footnotes, attached to this release.

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

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 recognized as a result of acquisitions, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also includes integration costs, as well as transaction and certain other costs related to business acquisitions and divestitures.

⁵ Includes the estimated tax impact on the reconciling items. In addition, amounts for fourth-quarter and full-year 2015 include net benefits of \$40 million and \$410 million, respectively, related to the settlement of certain federal income tax issues. Additionally, amount for full-year 2014 includes a net benefit of \$517 million recorded in connection with AstraZeneca's option exercise, as well as a benefit of approximately \$300 million associated with a capital loss generated in the first quarter.

Additional Executive Commentary

“In 2016 we will build upon the strong foundation we established last year. We will continue to invest resources to launch and grow our strongest brands, support the most promising internal assets, enhance our pipeline with the best available external science and maintain a balanced and differentiated portfolio, with the goal of delivering long-term growth and shareholder value,” said Frazier.

“Global Human Health delivered a solid performance in 2015,” said Adam Schechter, president, Global Human Health, Merck. “In 2016 we will continue to prioritize resources focusing on JANUVIA, on our key launches, including KEYTRUDA and ZEPATIER, and on our hospital acute care and vaccines businesses.”

“We will pursue numerous filings and approvals in 2016,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “For example, we view KEYTRUDA as foundational in the next-generation treatment of malignant disease, and hence have embarked upon an exceptionally broad development program for this agent, with registration-enabling studies underway in more than a dozen tumor types. We will also pursue more than 100 studies involving combinations of KEYTRUDA with other drugs.”

“The fourth quarter was a strong finish to a solid year of execution. We expect this momentum to continue into 2016, as we further innovate in our labs, invest behind our launches and continue our focus on disciplined resource allocation and continuous productivity to deliver a leveraged P&L and shareholder returns,” said Robert Davis, chief financial officer, Merck.

Select Business Highlights

Worldwide sales were \$10.2 billion for the fourth quarter of 2015, a decrease of 3 percent compared with the fourth quarter of 2014, including a 7 percent negative impact from foreign exchange and a 3 percent net positive impact primarily from the acquisition of Cubist Pharmaceuticals, Inc. (Cubist). Full-year 2015 worldwide sales were \$39.5 billion, a decrease of 6 percent compared with the full year of 2014, including a 6 percent negative impact from foreign exchange and a 3 percent net negative impact resulting from the divestiture of the Consumer Care business and select products, partially offset by the Cubist acquisition.

The following table reflects sales of the company’s top pharmaceutical products, as well as total sales of Animal Health and Consumer Care products.

\$ in millions	Fourth Quarter		Change	Change Ex-Exchange	Year Ended		Change	Change Ex-Exchange
	2015	2014			Dec. 31, 2015	Dec. 31, 2014		
Total Sales	\$10,215	\$10,482	-3%	4%	\$39,498	\$42,237	-6%	0%
Pharmaceutical	9,027	9,370	-4%	4%	34,782	36,042	-3%	4%
JANUVIA / JANUMET	1,447	1,652	-12%	-6%	6,014	6,002	0%	7%
ZETIA / VYTORIN	999	1,032	-3%	4%	3,777	4,166	-9%	-2%
GARDASIL / GARDASIL 9	497	356	40%	42%	1,908	1,738	10%	11%
PROQUAD, M-M-R II and VARIVAX	409	366	12%	14%	1,505	1,394	8%	10%
REMICADE	396	557	-29%	-18%	1,794	2,372	-24%	-10%
ISENTRESS	374	418	-11%	-4%	1,511	1,673	-10%	-2%
CUBICIN	322	7*	**	**	1,127	25*	**	**
SINGULAIR	273	319	-14%	-7%	931	1,092	-15%	-5%
ZOSTAVAX	246	285	-14%	-11%	749	765	-2%	0%
NASONEX	231	268	-14%	-8%	858	1,099	-22%	-16%
KEYTRUDA	214	50	**	**	566	55	**	**
Animal Health	830	885	-6%	8%	3,324	3,454	-4%	9%
Consumer Care***	–	16	**	**	3	1,547	**	**
Other Revenues	358	211	69%	19%	1,389	1,194	16%	-33%

*Reflects licensing agreement with Cubist in Japan prior to acquisition by Merck on Jan. 21, 2015

**≥100%

***divested on Oct. 1, 2014

Commercial and Pipeline Highlights

The company continued to make steady progress in advancing its late-stage pipeline, achieving key regulatory approvals and expanded indications for multiple products across its portfolio.

- The U.S. Food and Drug Administration (FDA) [approved](#) ZEPATIER (elbasvir and grazoprevir), a once-daily, fixed-dose combination tablet for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with or without ribavirin. ZEPATIER was approved for use in a broad range of chronic HCV patients, including those with compensated cirrhosis, renal impairment of any degree and HIV-1/HCV co-infection.
- Merck significantly 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 FDA [approved](#) KEYTRUDA for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy across both squamous and non-squamous metastatic NSCLC.
 - The FDA [approved](#) an expanded indication for KEYTRUDA for the first-line treatment of patients with unresectable or metastatic melanoma regardless of BRAF status and an update to the product labeling for KEYTRUDA for the treatment of patients with ipilimumab-refractory advanced melanoma.
 - KEYTRUDA [received](#) a third Breakthrough Therapy Designation from the FDA for the treatment of patients with microsatellite instability high metastatic colorectal cancer.

- Results from the pivotal KEYNOTE-010 study [were published](#) in *The Lancet* and presented at the European Society for Medical Oncology Asia 2015 Congress, showing superior overall survival compared to chemotherapy in patients with previously treated advanced NSCLC whose tumors express PD-L1. Based on these data, the company has submitted a supplemental Biologics License Application to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).
- During the fourth quarter of 2015, the company entered into collaborations with [GSK](#) and [Amgen](#). Additionally, the company extended an [existing collaboration](#) with Eli Lilly and Company (Lilly) and entered into a [new collaboration](#) with Lilly to study KEYTRUDA in combination settings.
- The KEYTRUDA clinical trials program currently includes more than 30 tumor types in more than 200 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, Hodgkin lymphoma, multiple myeloma and breast cancer, and further trials are being planned for other malignancies.
- The company strengthened its oncology pipeline by [acquiring](#) IOmet Pharma Ltd (IOmet) in early 2016. IOmet is a drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism.
- BRIDION (sugammadex) Injection 100 mg/mL was [approved](#) by the FDA for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.
- The Biologics License Application for bezlotoxumab, an investigational antitoxin for the prevention of *Clostridium difficile* (*C. difficile*) infection recurrence, was [accepted](#) by the FDA for priority review with a PDUFA action date of July 23, 2016. The company also has filed a MAA for bezlotoxumab with the EMA that is currently under review.

Pharmaceutical Revenue Performance

Fourth-quarter pharmaceutical sales declined 4 percent to \$9.0 billion, including an 8 percent negative impact from foreign exchange. Excluding the impact of exchange, growth was driven by sales in hospital acute care, oncology and vaccines. Growth in hospital acute care was driven by the addition of the Cubist portfolio and sales growth of certain inline brands. Growth in oncology reflects higher sales of KEYTRUDA. Growth in vaccines reflects higher sales of GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), a vaccine to prevent cancers and other diseases caused by HPV, reflecting an increase in sales in the United States primarily due to public sector purchases, and higher sales of PROQUAD (Measles, Mumps,

Rubella and Varicella Vaccine Live) driven by the timing of sales activity related to the Pediatric Vaccine Stockpile of the U.S. Centers for Disease Control and Prevention.

Fourth-quarter pharmaceutical sales reflect a decrease in PNEUMOVAX 23 (pneumococcal vaccine polyvalent), due to near-term market dynamics in the United States and the timing of vaccinations linked to the National Immunization Program in Japan, as well as lower sales in the diabetes franchise of JANUVIA (sitagliptin)/JANUMET (sitagliptin and metformin HCl), medicines that help lower blood sugar in adults with type 2 diabetes, driven in large part by an expected decline due to the timing of customer purchases in the third quarter of 2015. Pharmaceutical sales also reflect declines in REMICADE (infliximab), a treatment for inflammatory diseases, due to loss of exclusivity and the accelerating impact of biosimilar competition in the company's marketing territories in Europe, and PEGINTRON (peginterferon alfa-2b), a medicine to treat chronic HCV.

Full-year 2015 pharmaceutical sales declined 3 percent to \$34.8 billion, including a 7 percent negative impact from foreign exchange. Excluding the impact of exchange, growth was driven by sales in hospital acute care, oncology, diabetes and vaccines.

Animal Health Revenue Performance

Animal Health sales totaled \$830 million for the fourth quarter of 2015, a decrease of 6 percent compared with the fourth quarter of 2014, including a 14 percent negative impact from foreign exchange. Worldwide sales for the full year of 2015 were \$3.3 billion, a decrease of 4 percent, including a 13 percent negative impact from foreign exchange. Excluding the impact of exchange, growth in both periods was primarily driven by an increase in sales of companion animal products, including continued strong growth from BRAVECTO (fluralaner), a chewable tablet that kills fleas and ticks in dogs for up to 12 weeks, and aqua and swine products.

Fourth-Quarter and Full-Year 2015 Expense and Other Information

The tables below present selected expense information for the fourth quarter and full year of 2015.

\$ in millions	Included in expenses for the period			
	GAAP	Acquisition- and Divestiture-Related Costs ⁴	Restructuring Costs	Non-GAAP ¹
Fourth Quarter 2015				
Materials and production	\$3,850	\$1,194	\$81	\$2,575
Marketing and administrative	2,615	47	8	2,560
Research and development	1,797	(24)	18	1,803
Restructuring costs	233	–	233	–
Fourth Quarter 2014				
Materials and production	\$3,749	\$984	\$105	\$2,660
Marketing and administrative	2,924	81	57	2,786
Research and development	2,283	329	108	1,846
Restructuring costs	349	–	349	–

\$ in millions	Included in expenses for the period				
	GAAP	Acquisition- and Divestiture- Related Costs ⁴	Restructuring Costs	Certain Other Items	Non-GAAP ¹
Year Ended Dec. 31, 2015					
Materials and production	\$14,934	\$4,869	\$361	\$-	\$9,704
Marketing and administrative	10,313	436	78	-	9,799
Research and development	6,704	39	52	-	6,613
Restructuring costs	619	-	619	-	-
Year Ended Dec. 31, 2014					
Materials and production	\$16,768	\$5,254	\$482	\$-	\$ 11,032
Marketing and administrative	11,606	234	200	193	10,979
Research and development	7,180	365	283	-	6,532
Restructuring costs	1,013	-	1,013	-	-

The gross margin was 62.3 percent for the fourth quarter of 2015 compared to 64.2 percent for the fourth quarter of 2014, reflecting 12.5 and 10.4 unfavorable percentage point impacts, respectively, from the acquisition- and divestiture-related costs and restructuring costs noted above. The gross margin was 62.2 percent for the full year of 2015 compared to 60.3 percent for the full year of 2014, reflecting 13.2 and 13.6 unfavorable percentage point impacts, respectively, from the acquisition- and divestiture-related costs and restructuring costs noted above. The rate increases in non-GAAP gross margin for the fourth quarter and full year of 2015 reflect the favorable impact of foreign exchange and lower inventory write-offs.

Marketing and administrative expenses, on a non-GAAP basis, were \$2.6 billion in the fourth quarter of 2015, a decrease from \$2.8 billion in the same period of 2014, which was primarily driven by the favorable impact of foreign exchange and operational efficiencies, partially offset by investments in key brands. Full-year 2015 marketing and administrative expenses, on a non-GAAP basis, were \$9.8 billion, a decrease from \$11.0 billion in 2014, which was primarily driven by the favorable impact of foreign exchange and the sale of the Consumer Care business, partially offset by investments in key brands.

Research and development (R&D) expenses, on a non-GAAP basis, were \$1.8 billion in the fourth quarter of 2015, a 2 percent decrease compared to the fourth quarter of 2014. Full-year R&D expenses in 2015, on a non-GAAP basis, were \$6.6 billion, an increase from \$6.5 billion in 2014.

Other (income) expense, net, was \$905 million of expense in the fourth quarter of 2015 compared to \$10.6 billion of income in the fourth quarter of 2014 and \$1.5 billion of expense for the full year of 2015 compared to \$11.6 billion of income for the full year of 2014. Other (income) expense, net for the fourth quarter and full year of 2015 includes \$161 million and \$876 million, respectively, of foreign exchange losses related to the revaluation of the company's net monetary assets in Venezuela and a \$680 million net charge to settle Vioxx shareholder class action litigation. Other (income) expense, net in both the fourth quarter and full year of 2014 includes an

\$11.2 billion gain on the divestiture of the Consumer Care business and a \$628 million loss on the extinguishment of debt.

The GAAP effective tax rates of (20.4) percent for the fourth quarter of 2015 and 17.4 percent for the full year of 2015 reflect the impacts of acquisition- and divestiture-related costs, restructuring costs and certain other items, including the impact of the net charge to settle Vioxx shareholder class action litigation being fully deductible at combined U.S. federal and state tax rates, as well as the unfavorable impact of non-deductible foreign exchange losses related to Venezuela. In addition, the GAAP effective tax rates for the fourth quarter and full year of 2015 include net benefits of \$40 million and \$410 million, respectively, related to the settlement of certain federal tax issues. The non-GAAP effective tax rates, which exclude these items, were 16.4 percent for the fourth quarter and 21.7 percent for the full year of 2015. Both the GAAP and non-GAAP effective tax rates for the fourth quarter and full year of 2015 include the favorable impact of tax legislation, including the renewal of the R&D tax credit, enacted in the fourth quarter of 2015.

Financial Outlook

Merck expects its full-year 2016 GAAP EPS to be between \$1.96 and \$2.23. Merck expects its full-year 2016 non-GAAP EPS to be between \$3.60 and \$3.75, including an approximately 4 percent negative impact from foreign exchange. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs.

At mid-January 2016 exchange rates, Merck anticipates full-year 2016 revenues to be between \$38.7 billion and \$40.2 billion, including an approximately 3 percent negative impact from foreign exchange.

In addition, the company expects 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 anticipates 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	1.64 to 1.52
Non-GAAP EPS that excludes items listed below	\$3.60 to \$3.75
Acquisition- and divestiture-related costs	\$4,600 to \$4,400
Restructuring costs	900 to 700
Net decrease (increase) in income before taxes	5,500 to 5,100
Estimated income tax (benefit) expense	(935) to (860)
Decrease (increase) in net income	\$4,565 to \$4,240

Total Employees

As of Dec. 31, 2015, 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. EST on Merck's website at <http://www.merck.com/investors/events-and-presentations/home.html>. Institutional investors and analysts can participate in the call by dialing (706) 758-9927 or (877) 381-5782 and using ID code number 4404803. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 4404803. 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

Today's Merck is 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](#).

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 2014 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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