



## News Release

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### FOR IMMEDIATE RELEASE

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### **Merck Announces Second-Quarter 2016 Financial Results**

- Second-Quarter 2016 Worldwide Sales Were \$9.8 Billion, an Increase of 1 Percent, Including a 2 Percent Negative Impact from Foreign Exchange
- Second-Quarter 2016 GAAP EPS Was \$0.43; Second-Quarter Non-GAAP EPS Was \$0.93
- Company Updates EPS Guidance: Full-Year 2016 GAAP EPS Range to be Between \$1.98 and \$2.08; Full-Year 2016 Non-GAAP EPS Range of \$3.67 to \$3.77
- Advanced KEYTRUDA Development Program
  - KEYTRUDA Demonstrated Superior Progression-Free Survival and Overall Survival Compared to Chemotherapy in Patients with Previously Untreated Advanced Non-Small Cell Lung Cancer (NSCLC) Whose Tumors Expressed PD-L1 in KEYNOTE-024 Study
  - Merck Received Positive Opinion from Committee for Medicinal Products for Human Use of the European Medicines Agency for KEYTRUDA for the Treatment of Previously Treated Advanced NSCLC in Patients Whose Tumors Express PD-L1

KENILWORTH, N.J., July 29, 2016 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the second quarter of 2016.

“Our results this quarter reflect our strategic focus on key launches, including KEYTRUDA and ZEPATIER, as well as our priority inline programs,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “We remain committed to advancing our pipeline, delivering a balanced and differentiated portfolio, and achieving long-term, sustainable growth.”

## Financial Summary

\$ in millions, except EPS amounts	Second Quarter	
	2016	2015
Sales	\$9,844	\$9,785
GAAP EPS	0.43	0.24
Non-GAAP EPS that excludes items listed below <sup>1</sup>	0.93	0.86
GAAP net income <sup>2</sup>	1,205	687
Non-GAAP net income that excludes items listed below <sup>1,2</sup>	2,587	2,441

Worldwide sales were \$9.8 billion for the second quarter of 2016, an increase of 1 percent compared with the second quarter of 2015, including a 2 percent negative impact from foreign exchange.

GAAP (generally accepted accounting principles) earnings per share (EPS) were \$0.43 for the second quarter. Non-GAAP EPS of \$0.93 for the second quarter excludes acquisition- and divestiture-related costs and restructuring costs.

## Pipeline Highlights

In the second quarter of 2016, the company advanced its late-stage pipeline in multiple priority areas and executed on key launches, including KEYTRUDA (pembrolizumab), an anti-PD-1 therapy for the treatment of metastatic NSCLC in previously treated patients whose tumors express PD-L1, as well as advanced melanoma; and 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.

- The company advanced its clinical development program for KEYTRUDA.
  - The company [announced](#) topline results from the KEYNOTE-024 trial investigating the use of KEYTRUDA in patients with previously untreated advanced NSCLC whose tumors expressed high levels of PD-L1 (tumor proportion score of 50 percent or more).
    - In this study, KEYTRUDA was superior compared to chemotherapy for the primary endpoint of progression-free survival and the secondary endpoint of overall survival.
    - Based on these results, an independent Data Monitoring Committee recommended that the trial be stopped and that patients receiving chemotherapy in KEYNOTE-024 be offered the opportunity to receive KEYTRUDA.

<sup>1</sup> 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. 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.

- The U.S. Food and Drug Administration (FDA) [accepted](#) for review a supplemental Biologics License Application 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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) [adopted](#) a positive opinion recommending approval of KEYTRUDA for the treatment of locally advanced or metastatic NSCLC in adults whose tumors express PD-L1 and who have received at least one prior chemotherapy regimen.
- At the 52<sup>nd</sup> Annual Meeting of the American Society of Clinical Oncology in June, data [were presented](#) evaluating the use of KEYTRUDA as a monotherapy and in combination with other therapies in more than 15 different cancers, including melanoma, NSCLC, head and neck cancer, classical Hodgkin lymphoma, multiple myeloma, colorectal cancer and esophageal cancer. Data evaluating KEYTRUDA in new tumor types were presented for the first time in cervical, endometrial, pancreatic, salivary and thyroid cancers.
- The KEYTRUDA research program includes more than 300 clinical trials evaluating KEYTRUDA across more than 30 tumor types. To date, clinical activity has been shown in more than 20 tumor types.
- Last week, the European Commission approved ZEPATIER for the treatment of chronic HCV in adult patients, allowing marketing of ZEPATIER in all 28 European Union (EU) member states. The company continues to work to supply the EU market, with product launches estimated to begin between the fourth quarter of 2016 and the first quarter of 2017. Product launches are expected to continue across the EU through 2017.
- At the 76<sup>th</sup> Scientific Sessions of the American Diabetes Association in June, Merck and Pfizer [announced](#) that two pivotal Phase 3 studies of ertugliflozin, an investigational oral SGLT-2 inhibitor for the treatment of patients with type 2 diabetes, met their primary endpoints, showing significant reductions in A1C (a measure of average blood glucose). The companies continue to expect to submit New Drug Applications to the FDA for ertugliflozin as a monotherapy and two fixed-dose combination tablets (ertugliflozin plus JANUVIA [sitagliptin], and ertugliflozin plus metformin) by the end of 2016.

### **Business Development Highlights**

Business development remains a critical component of Merck's strategy, and the company is actively engaged in seeking external opportunities to complement and strengthen its

pipeline and portfolio. The company recently engaged in the following scientific collaborations and acquisitions:

- Earlier this week, the company completed its [acquisition](#) of Afferent Pharmaceuticals, a leader in the development of investigational therapeutic candidates for the treatment of common, poorly managed, neurogenic conditions, such as chronic cough.
- The company [announced](#) a new collaboration with Moderna Therapeutics to develop and commercialize personalized cancer vaccines, combining KEYTRUDA and Moderna's messenger-RNA technology.
- Merck Animal Health [announced](#) it will acquire a controlling interest in Vallée S.A., a privately held producer of animal health products in Brazil with a portfolio of more than 100 products for livestock, horses and companion animals.

## Second-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	Second Quarter		Change	Change Ex-Exchange
	2016	2015		
Total Sales	\$9,844	\$9,785	1%	3%
Pharmaceutical	8,700	8,564	2%	2%
JANUVIA / JANUMET	1,634	1,598	2%	2%
ZETIA / VYTORIN	994	955	4%	4%
GARDASIL / GARDASIL 9	393	427	-8%	-7%
PROQUAD / M-M-R II / VARIVAX	383	358	7%	10%
CUBICIN	357	293	22%	22%
REMICADE	339	455	-26%	-26%
ISENTRESS	338	375	-10%	-9%
KEYTRUDA	314	110	*	*
Animal Health	898	840	7%	10%
Other Revenues	246	381	-36%	-2%

\* >100%

## Pharmaceutical Revenue

Second-quarter pharmaceutical sales increased 2 percent to \$8.7 billion, reflecting higher sales in oncology, hospital acute care, the cardiovascular franchise and vaccines.

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

Growth in hospital acute care reflects higher sales of CUBICIN (daptomycin for injection), an I.V. antibiotic, partially due to price increases in the United States, and the U.S. launch of BRIDION (sugammadex) Injection 100 mg/mL, an agent for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults

undergoing surgery. In June 2016, the company lost U.S. patent protection for CUBICIN, and, going forward, the company anticipates a significant decline in CUBICIN sales.

Higher sales in the cardiovascular portfolio were primarily driven by an increase in sales of ZETIA (ezetimibe), a medicine for lowering LDL cholesterol, largely due to price increases in the United States, and ADEMPAS (riociguat), a medicine for treating pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, which the company is now promoting and distributing in Europe.

Growth in vaccines resulted largely from higher sales of pediatric vaccines, partially offset by lower sales in the franchise of GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], vaccines to prevent cancers and other diseases caused by HPV, due to the timing of public sector purchases.

Pharmaceutical sales growth also reflects the launch of ZEPATIER, which had sales of \$112 million in the quarter.

Second-quarter pharmaceutical sales reflect a decline in REMICADE (infliximab), a treatment for inflammatory diseases, due to the impact of biosimilar competition in the company's marketing territories in Europe. Pharmaceutical sales also reflect a decrease in sales of NASONEX (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, due to loss of exclusivity in the United States.

### **Animal Health Revenue**

Animal Health sales totaled \$898 million for the second quarter of 2016, an increase of 7 percent compared with the second quarter of 2015, including a 3 percent negative impact from foreign exchange. Excluding the impact of exchange, sales across all species grew, particularly in products for companion animals, led by BRAVECTO (fluralaner), a chewable tablet that kills fleas and ticks in dogs for up to 12 weeks.

In the second quarter, the company [received](#) marketing approval from the EMA for BRAVECTO Spot-On Solution for cats and dogs; last week, the company [received](#) approval in the United States to market the product under the tradename BRAVECTO Topical (fluralaner topical solution) for cats and dogs.

### **Second-Quarter Expense, EPS and Related Information**

The tables below present selected expense information.

\$ in millions		<b>Acquisition- and Divestiture- Related Costs<sup>3</sup></b>	<b>Restructuring Costs</b>	<b>Non-GAAP<sup>1</sup></b>
	<b>GAAP</b>			
<b>Second-Quarter 2016</b>				
Materials and production	\$3,578	\$1,120	\$66	\$2,392
Marketing and administrative	2,458	18	87	2,353
Research and development	2,151	207	64	1,880
Restructuring costs	134	–	134	–
<b>Second-Quarter 2015</b>				
Materials and production	\$3,754	\$1,241	\$105	\$2,408
Marketing and administrative	2,624	136	17	2,471
Research and development	1,670	71	15	1,584
Restructuring costs	191	–	191	–

### GAAP Expense, EPS and Related Information

On a GAAP basis, the gross margin was 63.7 percent for the second quarter of 2016 compared to 61.6 percent for the second quarter of 2015. The increase for the second quarter of 2016 reflects the favorable impacts of foreign exchange; product mix; lower acquisition- and divestiture-related costs; and lower restructuring costs. Acquisition- and divestiture-related costs and restructuring costs negatively affected gross margin by 12.0 and 13.8 percentage points for the second quarters of 2016 and 2015, respectively.

Marketing and administrative expenses were \$2.5 billion in the second quarter of 2016, a 6 percent decrease compared to the second quarter of 2015. The decline reflects lower acquisition- and divestiture-related costs, as well as lower administrative costs, such as legal defense reserves, partially offset by higher restructuring costs.

Research and development (R&D) expenses were \$2.2 billion in the second quarter of 2016, a 29 percent increase compared to the second quarter of 2015. The increase primarily reflects higher licensing costs, increased clinical development spending and intangible asset impairment charges.

Other (income) expense, net, was \$19 million of expense in the second quarter of 2016 compared to \$739 million of expense in the second quarter of 2015. The second quarter of 2015 includes foreign exchange losses of \$715 million related to the devaluation of the company's net monetary assets in Venezuela.

GAAP EPS was \$0.43 for the second quarter of 2016 compared with \$0.24 for the second quarter of 2015.

<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 75.7 percent for the second quarter of 2016 compared to 75.4 percent for the second quarter of 2015. The increase for the second quarter of 2016 reflects the favorable impacts of foreign exchange and product mix.

Non-GAAP marketing and administrative expenses were \$2.4 billion in the second quarter of 2016, a 5 percent decline compared to the second quarter of 2015. The decline reflects lower administrative costs, such as legal defense reserves.

Non-GAAP R&D expenses were \$1.9 billion in the second quarter of 2016, a 19 percent increase compared to the second quarter of 2015. The increase primarily reflects higher licensing costs and increased clinical development spending.

Non-GAAP EPS was \$0.93 for the second quarter of 2016 compared with \$0.86 for the second quarter of 2015.

A reconciliation of GAAP to non-GAAP net income and EPS is provided in the table that follows. Year-to-date results can be found in the attached tables.

\$ in millions, except EPS amounts	Second Quarter	
	2016	2015
<b>EPS</b>		
GAAP EPS	\$0.43	\$0.24
Difference <sup>4</sup>	0.50	0.62
Non-GAAP EPS that excludes items listed below <sup>1</sup>	\$0.93	\$0.86
<b>Net Income</b>		
GAAP net income <sup>2</sup>	\$1,205	\$687
Difference	1,382	1,754
Non-GAAP net income that excludes items listed below <sup>1,2</sup>	\$2,587	\$2,441
<b>Decrease (Increase) in Net Income Due to Excluded Items:</b>		
Acquisition- and divestiture-related costs <sup>3</sup>	\$ 1,345	\$1,448
Restructuring costs	351	328
Foreign exchange losses related to Venezuela	—	715
Net decrease (increase) in income before taxes	1,696	2,491
Income tax (benefit) expense <sup>5</sup>	(314)	(737)
Decrease (increase) in net income	\$ 1,382	\$1,754

## Financial Outlook

Merck has lowered its full-year 2016 GAAP EPS range to be between \$1.98 and \$2.08, reflecting the impact of intangible asset impairment charges and higher restructuring costs incurred in the second quarter of 2016. The company has raised the bottom end of its full-year 2016 non-GAAP EPS range and is now targeting a range of \$3.67 to \$3.77, including an

<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.

<sup>5</sup> Includes the estimated tax impact on the reconciling items. In addition, amount for the second quarter of 2015 includes a net benefit of \$370 million related to the settlement of certain federal income tax issues.

approximately 1 percent negative impact from foreign exchange at current exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs.

Merck has narrowed its full-year 2016 revenue range to be between \$39.1 billion and \$40.1 billion, including an approximately 2 percent negative impact from foreign exchange at current exchange rates.

The following table summarizes the company's 2016 financial guidance.

	<b>GAAP</b>	<b>Non-GAAP<sup>1</sup></b>
Revenue	\$39.1 to \$40.1 billion	\$39.1 to \$40.1 billion**
Marketing and administrative expenses	Lower than 2015	Lower than 2015
R&D expenses	Higher than 2015	Higher than 2015
Effective tax rate	26.0% to 27.0%	21.5% to 22.5%
EPS	\$1.98 to \$2.08	\$3.67 to \$3.77

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

A reconciliation of anticipated 2016 GAAP EPS to non-GAAP EPS and the items excluded from non-GAAP EPS are provided in the table below.

<b>\$ in millions, except EPS amounts</b>	<b>Full-Year 2016</b>
GAAP EPS	\$1.98 to \$2.08
Difference <sup>4</sup>	1.69
Non-GAAP EPS that excludes items listed below <sup>1</sup>	\$3.67 to \$3.77
Acquisition- and divestiture-related costs	\$4,750
Restructuring costs	900
Net decrease (increase) in income before taxes	5,650
Estimated income tax (benefit) expense	(955)
Decrease (increase) in net income	\$4,695

The expected full-year 2016 GAAP effective tax rate of 26.0 to 27.0 percent reflects an unfavorable impact of approximately 4.5 percentage points from the above items.

## **Total Employees**

As of June 30, 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/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 34462082. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 34462082. 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](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 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](http://www.sec.gov)).

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