



News Release

FOR IMMEDIATE RELEASE

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Merck Announces Second-Quarter 2017 Financial Results

- Second-Quarter 2017 Worldwide Sales Were \$9.9 Billion, an Increase of 1 Percent, Including a 1 Percent Negative Impact from Foreign Exchange
- Second-Quarter 2017 GAAP EPS Was \$0.71; Second-Quarter Non-GAAP EPS Was \$1.01
- Company Narrows and Raises 2017 Full-Year Revenue Range to be Between \$39.4 Billion and \$40.4 Billion, Including an Approximately 1 Percent Negative Impact from Foreign Exchange
- Company Reduces 2017 Full-Year GAAP EPS Range to be Between \$1.60 and \$1.72; Continues to Expect 2017 Full-Year Non-GAAP EPS Range to be Between \$3.76 and \$3.88, Including an Approximately 1 Percent Negative Impact from Foreign Exchange
- KEYTRUDA Development Program Significantly Advances with Several Key Regulatory Approvals
- Merck Enters Global Strategic Oncology Collaboration with AstraZeneca

KENILWORTH, N.J., July 28, 2017 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the second quarter of 2017.

“We continued to deliver strong results in the second quarter, driven by robust momentum for KEYTRUDA and good progress with other products in our portfolio,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “The company continues to invest in innovative science that addresses the critical needs of population health, which benefits patients while creating long-term value for shareholders.”

Financial Summary

	Second Quarter	
	2017	2016
\$ in millions, except EPS amounts		
Sales	\$9,930	\$9,844
GAAP net income ¹	1,946	1,205
Non-GAAP net income that excludes items listed below ^{1,2}	2,778	2,587
GAAP EPS	0.71	0.43
Non-GAAP EPS that excludes items listed below ²	1.01	0.93

Worldwide sales were \$9.9 billion for the second quarter of 2017, an increase of 1 percent compared with the second quarter of 2016, including a 1 percent negative impact from foreign exchange.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) were \$0.71 for the second quarter of 2017. Non-GAAP EPS of \$1.01 for the second quarter of 2017 excludes acquisition- and divestiture-related costs, restructuring costs and certain other items. Year-to-date results can be found in the attached tables.

Pipeline Highlights

Merck made significant advances in the development program for KEYTRUDA (pembrolizumab), an anti-PD-1 therapy, receiving key regulatory approvals and a supplemental Biologics License Application (sBLA) acceptance.

- The U.S. Food and Drug Administration (FDA) approved KEYTRUDA under its Accelerated Approval program:
 - In combination with pemetrexed and carboplatin for the [treatment](#) of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC) regardless of PD-L1 expression. This is the first regulatory approval of KEYTRUDA in combination with another treatment. The National Cancer Care Network (NCCN) also recommended the combination for the treatment of patients with metastatic nonsquamous NSCLC.
 - For the [treatment](#) of previously treated patients with advanced microsatellite instability-high cancers.

¹ Net income attributable to Merck & Co., Inc.

² 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.

- For the [treatment](#) of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer, for first-line use in patients who are ineligible for cisplatin-containing therapy.
- The FDA [approved](#) KEYTRUDA for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma in the second-line setting for patients who have disease progression during or following platinum-containing chemotherapy.
- The European Commission [approved](#) KEYTRUDA for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant and brentuximab vedotin (BV), or who are transplant-ineligible and have failed BV.
- 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 certain patients with locally advanced or metastatic urothelial carcinoma, with a final decision expected in the third quarter of 2017.
- The FDA [accepted](#) for review the sBLA for KEYTRUDA for the treatment of patients with recurrent or advanced gastric or gastroesophageal junction adenocarcinoma who have already received two or more lines of chemotherapy. The FDA granted Priority Review with a PDUFA action date of Sept. 22, 2017.
- The FDA granted Breakthrough Therapy Designation for KEYTRUDA in combination with axitinib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma.

The company previously announced that the pivotal Phase 3 KEYNOTE-040 [trial](#) investigating KEYTRUDA in previously treated patients with recurrent or metastatic head and neck squamous cell carcinoma did not meet its primary endpoint of overall survival (HR, 0.82 [95% CI, 0.67-1.01]; one-sided p = 0.03). The safety profile observed in KEYNOTE-040 was consistent with that observed in previously reported studies of KEYTRUDA without new safety signals identified. The final data from KEYNOTE-040 will be presented at an upcoming medical meeting.

At the 77th Scientific Sessions of the American Diabetes Association, Merck in partnership with Pfizer [presented](#) data from two Phase 3 studies of ertugliflozin, an investigational oral SGLT-2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes, which met their primary endpoints. Three New Drug Applications for medicines containing ertugliflozin are currently under review with the FDA and EMA.

Phase 3 results from the REVEAL (Randomized EVAluation of the Effects of Anacetrapib through Lipid modification) outcomes [study](#) of anacetrapib met its primary endpoint, significantly reducing major coronary events (defined as the composite of coronary death, myocardial infarction, and coronary revascularization) compared to placebo in patients at risk for cardiac events who are already receiving an effective LDL-C lowering regimen. The safety profile of anacetrapib in the early analysis was generally consistent with that demonstrated in previous studies of the drug, including accumulation of anacetrapib in adipose tissue, as has been previously reported. Merck plans to review the results of the trial with external experts, and will consider whether to file new drug applications with the FDA and other regulatory agencies.

New data from the company's HIV portfolio and pipeline were presented at the 9th IAS Conference on HIV Science.

- Week 96 [results](#) from the pivotal Phase 3 ONCEMRK study evaluating the efficacy and safety of ISENTRESS HD, a 1200 mg once-daily dose of the company's integrase inhibitor, ISENTRESS (raltegravir), met its primary efficacy endpoint of non-inferiority to twice-daily ISENTRESS, with a similar safety and tolerability profile, reaffirming the comparable efficacy and safety of ISENTRESS HD. ISENTRESS HD is now approved in the United States and European Union.
- 48 week [data](#) from DRIVE-AHEAD, the second of two pivotal Phase 3 studies evaluating doravirine (MK-1439), an investigational non-nucleoside reverse transcriptase inhibitor, for the treatment of HIV-1 infection showed that a once-daily single tablet, fixed-dose combination of doravirine, lamivudine and tenofovir disoproxil fumarate met its primary endpoint. Based on these findings the company plans to file regulatory applications in the fourth quarter of 2017.
- Results from a Phase 1 study of MK-8591, Merck's investigational nucleoside reverse transcriptase translocation inhibitor in adult patients with HIV-1 infection.

Merck entered into an exclusive worldwide license [agreement](#) with Teijin Pharma for the development, manufacture and commercialization of an investigational preclinical antibody candidate targeting the protein tau. Changes in tau are associated with a number of diseases affecting the nervous system, including Alzheimer's disease.

Recent Developments

Merck entered a global strategic oncology collaboration with AstraZeneca to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib), a PARP inhibitor, and investigational medicine selmetinib, a MEK inhibitor, as monotherapy and in combination treatments for

multiple cancer types. Merck and AstraZeneca will independently develop and commercialize Lynparza and selumetinib in combinations with the companies' respective PD-1 and PD-L1 immuno-oncology medicines KEYTRUDA and Imfinzi (durvalumab). The companies will share development and marketing costs equally, as well as gross profits from Lynparza and selumetinib.

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			
	2017	2016	Change	Change Ex-Exchange
Total Sales	\$9,930	\$9,844	1%	2%
Pharmaceutical	8,759	8,700	1%	2%
JANUVIA / JANUMET	1,511	1,634	-8%	-7%
KEYTRUDA	881	314	180%	183%
ZETIA / VYTORIN	549	994	-45%	-44%
ZEPATIER	517	112	*	*
GARDASIL / GARDASIL 9	469	393	19%	20%
PROQUAD,				
M-M-R II and VARIVAX	399	383	4%	5%
ISENTRESS / ISENTRESS HD	282	338	-17%	-15%
REMICADE	208	339	-39%	-36%
SINGULAIR	203	229	-11%	-10%
Animal Health	955	900	6%	7%
Other Revenues	216	244	-11%	-5%

*Growth comparison not meaningful due to ongoing product launch.

Pharmaceutical Revenue

Second-quarter pharmaceutical sales increased 1 percent to \$8.8 billion, including a 1 percent negative impact from foreign exchange. The growth was primarily driven by product launches 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. Strong momentum from NSCLC, as KEYTRUDA is the only anti-PD-1 approved in the first-line setting, contributed significantly to KEYTRUDA's overall growth.

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.

Additionally, the ongoing launch of BRIDION (sugammadex) Injection 100 mg/mL, a medicine for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults undergoing surgery, generated sales of \$163 million and also contributed to growth during the second quarter of 2017.

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, reflecting strong demand in Asia Pacific and the timing of sales in Brazil. Growth in vaccines also reflects higher sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, largely driven by volume growth and pricing in the United States. Additionally, vaccines sales growth reflects incremental sales of approximately \$70 million, of which approximately \$40 million relates to GARDASIL and GARDASIL 9, due to the recording of vaccine sales from 19 European countries that were part of the Sanofi Pasteur MSD (SPMSD) vaccines joint venture, which was terminated on Dec. 31, 2016.

Pharmaceutical sales reflect a decrease in the diabetes franchise of JANUVIA and JANUMET (sitagliptin and metformin HCl), medicines that help lower blood sugar in adults with type 2 diabetes, primarily due to lower sales in the United States, reflecting continued pricing pressure and lower customer inventory levels that were partially offset by continued volume growth. Pharmaceutical sales growth also was offset by the loss of U.S. market exclusivity for ZETIA (ezetimibe) in late 2016 and VYTORIN (ezetimibe/simvastatin) in April 2017, medicines for lowering LDL cholesterol, and the ongoing impacts of generic competition for CUBICIN (daptomycin for injection), an I.V. antibiotic, and biosimilar competition for REMICADE (infliximab), a treatment for inflammatory diseases, in the company's marketing territories in Europe. In the aggregate, sales of these products declined \$830 million during the second quarter of 2017 compared to the second quarter of 2016.

Animal Health Revenue

Animal Health sales totaled \$955 million for the second quarter of 2017, an increase of 6 percent compared with the second 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, and the NOBIVAC Canine Flu Bivalent vaccine, as well as sales increases in ruminants products, reflecting the positive impact of the Vallée S.A. acquisition.

Second-Quarter Expense, EPS and Related Information

The table below presents selected expense information.

	GAAP	Acquisition- and Divestiture- Related Costs ³	Restructuring Costs	Non-GAAP ²
Second-Quarter 2017				
Materials and production	\$3,080	\$827	\$33	\$2,220
Marketing and administrative	2,438	9	2	2,427
Research and development	1,749	7	9	1,733
Restructuring costs	166	--	166	--
Other (income) expense, net	58	39	--	19
Second-Quarter 2016				
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	--
Other (income) expense, net	19	--	--	19

GAAP Expense, EPS and Related Information

On a GAAP basis, the gross margin was 69.0 percent for the second quarter of 2017 compared to 63.7 percent for the second quarter of 2016. The increase in gross margin for the second quarter of 2017 was primarily driven by lower acquisition- and divestiture-related costs and restructuring costs, which reduced gross margin by 8.6 percentage points in the second quarter of 2017 compared with 12.0 percentage points in the second quarter of 2016. The increase also reflects the favorable effects of product mix and lower inventory write-offs.

Marketing and administrative expenses were \$2.4 billion in the second quarter of 2017, a 1 percent decrease compared to the second quarter of 2016. The decrease primarily reflects lower restructuring costs partially offset by higher administrative costs including costs associated with the company now operating its European vaccines business in the countries that were part of the SPMSD vaccines joint venture, which was terminated on Dec. 31, 2016, and higher promotion expenses related to product launches.

³ 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.

Research and development (R&D) expenses were \$1.7 billion in the second quarter of 2017, a 19 percent decrease compared to the second quarter of 2016. The decrease primarily reflects lower intangible asset impairment charges and licensing costs.

GAAP EPS was \$0.71 for the second quarter of 2017 compared with \$0.43 for the second quarter of 2016.

Non-GAAP Expense, EPS and Related Information

The non-GAAP gross margin was 77.6 percent for the second quarter of 2017 compared to 75.7 percent for the second quarter of 2016. The increase in non-GAAP gross margin was largely driven by the favorable effects of product mix and lower inventory write-offs.

Non-GAAP marketing and administrative expenses were \$2.4 billion in the second quarter of 2017, an increase of 3 percent compared to the second quarter of 2016. The increase was driven primarily by higher administrative costs, including costs associated with the company now operating its European vaccines business in the countries that were previously part of the SPMSD vaccines joint venture, and higher promotion expenses related to product launches.

Non-GAAP R&D expenses were \$1.7 billion in the second quarter of 2017, an 8 percent decrease compared to the second quarter of 2016. The decrease primarily reflects lower licensing costs.

Non-GAAP EPS was \$1.01 for the second quarter of 2017 compared with \$0.93 for the second 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		Second Quarter	
		2017	2016
EPS			
GAAP EPS		\$0.71	\$0.43
Difference ⁴		0.30	0.50
Non-GAAP EPS that excludes items listed below ²		\$1.01	\$0.93
Net Income			
GAAP net income ¹		\$1,946	\$1,205
Difference		832	1,382
Non-GAAP net income that excludes items listed below ^{1,2}		\$2,778	\$2,587
Decrease (Increase) in Net Income Due to Excluded Items:			
Acquisition- and divestiture-related costs ³		\$882	\$1,345
Restructuring costs		210	351
Net decrease (increase) in income before taxes		1,092	1,696
Income tax (benefit) expense ⁵		(260)	(314)
Decrease (increase) in net income		\$832	\$1,382

Financial Outlook

On June 27, 2017, the company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. While the company does not yet know the magnitude of the impact of the disruption, which remains ongoing in certain operations, it continues to work to minimize the effects.

The company is in the process of restoring its manufacturing operations. To date, Merck has largely restored its packaging operations and has partially restored its formulation operations. The company is in the process of restoring its Active Pharmaceutical Ingredient operations but is not yet producing bulk product. The company's external manufacturing was not impacted. Throughout this time, Merck has continued to fulfill orders and ship product.

The company is confident in the continuous supply of key products such as KEYTRUDA, JANUVIA and ZEPATIER. In addition, Merck does not currently expect a significant impact to sales of its other top products; however, the company anticipates that it will have temporary delays in fulfilling orders for certain other products in certain markets.

The financial outlook below reflects the current state of the company's manufacturing operations as well as its plans to restore those operations and potential costs associated with the remediation efforts.

Merck has reduced its full-year 2017 GAAP EPS range to be between \$1.60 and \$1.72. The change in the GAAP EPS range reflects the inclusion of licensing expenses related to the collaboration with AstraZeneca. Merck has maintained its full-year 2017 non-GAAP EPS range

⁴ 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.

⁵ Includes the estimated tax impact on the reconciling items based on applying the statutory rate of the originating territory of the non-GAAP adjustments, as well as a benefit of \$88 million related to the settlement of a state income tax issue.

to be between \$3.76 and \$3.88, including an approximately 1 percent negative impact from foreign exchange at mid-July 2017 exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs and certain other items, including licensing expenses related to the collaboration with AstraZeneca as shown in the table below.

Merck has narrowed and raised its full-year 2017 revenue range to be between \$39.4 billion and \$40.4 billion, including an approximately 1 percent negative impact from foreign exchange at mid-July 2017 exchange rates.

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

	GAAP	Non-GAAP ²
Revenue	\$39.4 to \$40.4 billion	\$39.4 to \$40.4 billion**
Operating expenses	Lower than 2016	Higher than 2016 by a mid-single digit rate
Effective tax rate	32.0% to 33.0%	21.0% to 22.0%
EPS	\$1.60 to \$1.72	\$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	Full-Year 2017
GAAP EPS	\$1.60 to \$1.72
Difference ⁴	2.16
Non-GAAP EPS that excludes items listed below ¹	\$3.76 to \$3.88
Acquisition- and divestiture-related costs	\$3,600
Restructuring costs	600
Licensing expense relating to AstraZeneca collaboration	2,350
Net decrease (increase) in income before taxes	6,550
Estimated income tax (benefit) expense	(610)
Decrease (increase) in net income	\$5,940

The expected full-year 2017 GAAP effective tax rate of 32.0 to 33.0 percent reflects an unfavorable impact of approximately 11 percentage points from the above items.

Total Employees

As of June 30, 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 36593115. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 36593115. 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 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).

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