



News Release

FOR IMMEDIATE RELEASE

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Merck Announces Third-Quarter 2016 Financial Results

- Third-Quarter 2016 Worldwide Sales Were \$10.5 Billion, an Increase of 5 Percent, Including a 1 Percent Negative Impact from Foreign Exchange
- Third-Quarter 2016 GAAP EPS Was \$0.78; Third-Quarter Non-GAAP EPS Was \$1.07
- Company Updates EPS Guidance: Full-Year 2016 GAAP EPS to be Between \$2.02 and \$2.09; Full-Year 2016 Non-GAAP EPS to be Between \$3.71 and \$3.78
- Advanced KEYTRUDA Development Program
 - FDA Approved KEYTRUDA for Previously Untreated Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC) Whose Tumors Have High PD-L1 Expression (Tumor Proportion Score [TPS] of 50 Percent or More)
 - New Data Were Included in Labeling for KEYTRUDA Showing Improved Survival Compared to Chemotherapy in Previously Treated Patients with NSCLC Whose Tumors Express PD-L1 (TPS of 1 Percent or More)
 - FDA Approved KEYTRUDA to Treat Previously Treated Recurrent or Metastatic Head and Neck Cancer
 - KEYNOTE-045 Study Evaluating KEYTRUDA in Previously Treated Advanced Bladder Cancer (Urothelial Cancer) Met Primary Endpoint of Overall Survival and Stopped Early

KENILWORTH, N.J., Oct. 25, 2016 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the third quarter of 2016.

“The latest achievements for KEYTRUDA and other recent regulatory approvals across our portfolio show that our innovation strategy is working,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “We are confident that our focus on the science, along with continued commercial execution, will drive long-term results for the company and our shareholders.”

Financial Summary

| \$ in millions, except EPS amounts | Third Quarter | |
|---------------------------------------------------------------------|---------------|----------|
| | 2016 | 2015 |
| Sales | \$10,536 | \$10,073 |
| GAAP EPS | 0.78 | 0.64 |
| Non-GAAP EPS that excludes items listed below ¹ | 1.07 | 0.96 |
| GAAP net income ² | 2,184 | 1,826 |
| Non-GAAP net income that excludes items listed below ^{1,2} | 2,989 | 2,720 |

Worldwide sales were \$10.5 billion for the third quarter of 2016, an increase of 5 percent compared with the third quarter of 2015, including a 1 percent negative impact from foreign exchange. Sales in the third quarter of 2016 include an estimated benefit of approximately \$150 million of additional sales in Japan resulting from the timing of shipments in anticipation of a resource planning system Merck is implementing in the fourth quarter of 2016.

GAAP (generally accepted accounting principles) earnings per share (EPS) assuming dilution were \$0.78 for the third quarter. Non-GAAP EPS of \$1.07 for the third quarter excludes acquisition- and divestiture-related costs and restructuring costs. GAAP and non-GAAP EPS in the third quarter include an estimated benefit of approximately \$0.04 from the timing of shipments in Japan noted above.

Pipeline Highlights

Merck significantly advanced the clinical development program for KEYTRUDA (pembrolizumab), an anti-PD-1 therapy. KEYTRUDA is now approved in the United States for the treatment of previously untreated metastatic NSCLC in patients whose tumors express high levels of PD-L1 (TPS of 50 percent or more) and previously treated metastatic NSCLC in patients whose tumors express PD-L1 (TPS of 1 percent or more), as well as advanced melanoma and previously treated recurrent or metastatic head and neck cancer (HNSCC). Earlier this month at the European Society for Medical Oncology (ESMO) 2016 Congress, data were presented from 30 studies evaluating the use of KEYTRUDA as a monotherapy and in combination in 23 cancers.

Lung Cancer

- Yesterday the U.S. Food and Drug Administration (FDA) [approved](#) two supplemental Biologics License Applications (sBLA) for KEYTRUDA in lung cancer.

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. 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.

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

- Based on the KEYNOTE-024 study, KEYTRUDA was approved for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression (TPS of 50 percent or more) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. The data from KEYNOTE-024 [were published](#) in *The New England Journal of Medicine* and highlighted at ESMO.
- The FDA also approved a sBLA 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 (TPS of 1 percent or more) as determined by an FDA-approved test.
- Data [were presented](#) at ESMO from KEYNOTE-021, Cohort G, showing superior efficacy of KEYTRUDA plus chemotherapy compared to chemotherapy alone as a first-line treatment for patients with metastatic non-squamous NSCLC regardless of PD-L1 expression. These data were simultaneously published in *The Lancet Oncology*.
- The European Commission [approved](#) KEYTRUDA for the treatment of locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 and who have received at least one prior chemotherapy regimen.

Head and Neck Cancer

- The FDA [approved](#) a sBLA for KEYTRUDA for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

Bladder Cancer

- On Friday the company [announced](#) that the KEYNOTE-045 trial investigating the use of KEYTRUDA in patients with previously treated advanced bladder cancer (urothelial cancer) met its primary endpoint. In the study, KEYTRUDA met the primary endpoint of overall survival and was superior compared to investigator choice chemotherapy.
- Interim Phase 2 data [were presented](#) at ESMO for the first time investigating the use of KEYTRUDA in previously untreated patients with advanced bladder cancer.

Last week the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices voted to recommend a 2-dose vaccination regimen for GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), a vaccine to prevent certain cancers and other diseases caused by HPV, in certain girls and boys 9 through 14 years of age, which followed the FDA's [approval](#) of a 2-dose regimen in this adolescent population earlier this month.

The FDA [accepted](#) for review the New Drug Application (NDA) for MK-1293, an investigational follow-on biologic insulin glargine candidate for the treatment of people with type 1 and type 2 diabetes that is being developed in collaboration with and partially funded by Samsung Bioepis.

The FDA accepted for review a supplemental NDA for a once-daily formulation of ISENTRESS (raltegravir) in combination with other antiretroviral therapies for the treatment of HIV-1 infection in previously untreated patients or patients whose virus remains suppressed after treatment with an initial regimen of 400 mg of ISENTRESS twice-daily. The FDA granted a PDUFA action date of May 27, 2017.

Merck [announced](#) last week that the pivotal Phase 3 study of letermovir, an investigational antiviral medicine for prevention of cytomegalovirus infection in high-risk bone marrow transplant patients, met its primary endpoint; Merck will submit results from the study for presentation at a future scientific conference.

Third-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 | Third Quarter | | Change | Change Ex-Exchange |
|------------------------------|---------------|----------|--------|--------------------|
| | 2016 | 2015 | | |
| Total Sales | \$10,536 | \$10,073 | 5% | 6% |
| Pharmaceutical | 9,443 | 8,925 | 6% | 6% |
| JANUVIA / JANUMET | 1,554 | 1,576 | -1% | -2% |
| ZETIA / VYTORIN | 944 | 936 | 1% | — |
| GARDASIL / GARDASIL 9 | 860 | 625 | 38% | 38% |
| PROQUAD / M-M-R II / VARIVAX | 496 | 390 | 27% | 28% |
| ISENTRESS | 372 | 377 | -1% | 1% |
| KEYTRUDA | 356 | 159 | 124% | 128% |
| CUBICIN | 320 | 325 | -2% | -2% |
| REMICADE | 311 | 442 | -30% | -28% |
| Animal Health | 865 | 827 | 5% | 7% |
| Other Revenues | 228 | 321 | -29% | 10% |

Pharmaceutical Revenue

Third-quarter pharmaceutical sales increased 6 percent to \$9.4 billion, reflecting higher sales in vaccines, oncology, the cardiovascular franchise and hospital acute care.

Growth in vaccines resulted from higher sales of GARDASIL 9 and GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], vaccines to prevent certain cancers and other diseases caused by HPV, primarily due to the timing of public sector purchases and increased pricing and demand in the United States; and higher sales of PROQUAD (Measles, Mumps, Rubella and Varicella Vaccine Live), driven by the timing of sales activity in the third quarter of 2015 related to the Pediatric Vaccine Stockpile of the U.S. CDC.

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

Higher sales in the cardiovascular portfolio were driven by an increase in sales of ADEMPAS (riociguat), a medicine for treating pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, which the company is now promoting and distributing in Europe; and ZETIA (ezetimibe), a medicine for lowering LDL cholesterol, primarily driven by higher sales in Japan due to the timing of shipments. U.S. sales of ZETIA were \$411 million for the third quarter of 2016; in December 2016 the company will lose market exclusivity in the United States for ZETIA and anticipates a significant decline in U.S. ZETIA sales thereafter.

Growth in hospital acute care primarily resulted from higher sales 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, which had worldwide sales of \$139 million for the quarter that were driven by the ongoing launch in the United States, higher sales in Europe and the timing of shipments in Japan.

Pharmaceutical sales growth also reflects the continued launch of ZEPATIER (elbasvir and grazoprevir), a medicine for the treatment of chronic hepatitis C virus genotypes 1 or 4 infection, which had sales of \$164 million in the third quarter.

Third-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.

U.S. sales of CUBICIN (daptomycin for injection), an I.V. antibiotic, were \$264 million in the third quarter. The company has lost U.S. patent protection for CUBICIN and anticipates a significant decline in U.S. CUBICIN sales going forward.

Animal Health Revenue

Animal Health sales totaled \$865 million for the third quarter of 2016, an increase of 5 percent compared with the third quarter of 2015, including a 2 percent negative impact from foreign exchange. Sales growth was primarily driven by an increase in sales of companion animal and poultry products, particularly the BRAVECTO (fluralaner) line of products that kill fleas and ticks in dogs and cats for up to 12 weeks.

Earlier this month, the company [announced](#) that the U.S. Department of Agriculture approved a license for Nobivac Canine Flu Bivalent vaccine, the first vaccine to aid in the control of disease associated with both canine influenza virus H3N2 and canine influenza virus H3N8.

Third-Quarter Expense, EPS and Related Information

The table below presents selected expense information.

| \$ in millions | | Acquisition- and Divestiture- Related Costs ³ | Restructuring Costs | Certain Other Items | Non- GAAP ¹ |
|------------------------------|---------|----------------------------------------------------------------------|------------------------|---------------------------|---------------------------|
| | GAAP | | | | |
| Third-Quarter 2016 | | | | | |
| Materials and production | \$3,409 | \$773 | \$36 | \$— | \$2,600 |
| Marketing and administrative | 2,393 | 36 | 1 | — | 2,356 |
| Research and development | 1,664 | 13 | 14 | — | 1,637 |
| Restructuring costs | 161 | — | 161 | — | — |
| Other (income) expense, net | 22 | 12 | — | (6) | 16 |
| Third-Quarter 2015 | | | | | |
| Materials and production | \$3,761 | \$1,184 | \$70 | \$— | \$2,507 |
| Marketing and administrative | 2,472 | 26 | 17 | — | 2,429 |
| Research and development | 1,500 | (71) | 17 | — | 1,554 |
| Restructuring costs | 113 | — | 113 | — | — |
| Other (income) expense, net | (170) | 7 | — | (283) | 106 |

GAAP Expense, EPS and Related Information

On a GAAP basis, the gross margin was 67.6 percent for the third quarter of 2016 compared to 62.7 percent for the third quarter of 2015. The increase in gross margin for the third quarter of 2016 was primarily driven by lower acquisition- and divestiture-related costs, which negatively affected gross margin by 7.7 percentage points in the third quarter of 2016 compared with 12.4 percentage points for the third quarter of 2015. The increase in gross margin also reflects the favorable effects of product mix.

Marketing and administrative expenses were \$2.4 billion in the third quarter of 2016, a 3 percent decrease compared to the third quarter of 2015. The decline primarily reflects lower selling and promotional expenses as a result of prioritizing investments in key brands, the favorable impact of foreign exchange and lower restructuring costs, partially offset by higher acquisition- and divestiture-related costs.

Research and development (R&D) expenses were \$1.7 billion in the third quarter of 2016, an 11 percent increase compared to the third quarter of 2015. The increase primarily reflects higher clinical development spending, as well as a reduction in the third quarter of 2015 of the estimated fair value of liabilities for contingent consideration.

Other (income) expense, net, was \$22 million of expense in the third quarter of 2016 compared to \$170 million of income in the third quarter of 2015, reflecting a gain of \$250 million in the third quarter of 2015 on the divestiture of certain migraine clinical development programs, as well as lower foreign exchange losses in the third quarter of 2016.

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.

GAAP EPS was \$0.78 for the third quarter of 2016 compared with \$0.64 for the third quarter of 2015.

Non-GAAP Expense, EPS and Related Information

The non-GAAP gross margin was 75.3 percent for the third quarter of 2016 compared to 75.1 percent for the third quarter of 2015. The increase in non-GAAP gross margin for the third quarter of 2016 reflects the favorable impact of product mix.

Non-GAAP marketing and administrative expenses were \$2.4 billion in the third quarter of 2016, a 3 percent decline compared to the third quarter of 2015. The decline reflects lower selling costs and promotional spending as a result of prioritizing investments in key brands and the favorable impact of foreign exchange.

Non-GAAP R&D expenses were \$1.6 billion in the third quarter of 2016, a 5 percent increase compared to the third quarter of 2015. The increase primarily reflects higher clinical development spending.

Non-GAAP EPS was \$1.07 for the third quarter of 2016 compared with \$0.96 for the third quarter of 2015.

Non-GAAP other (income) expense, net, was \$16 million of expense in the third quarter of 2016 compared to \$106 million of expense in the third quarter of 2015, reflecting lower foreign exchange losses.

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 | Third Quarter | |
|-----------------------------------------------------------------------|----------------------|-------------|
| | 2016 | 2015 |
| EPS | | |
| GAAP EPS | \$0.78 | \$0.64 |
| Difference ⁴ | 0.29 | 0.32 |
| Non-GAAP EPS that excludes items listed below ¹ | \$1.07 | \$0.96 |
| Net Income | | |
| GAAP net income ² | \$2,184 | \$1,826 |
| Difference | 805 | 894 |
| Non-GAAP net income that excludes items listed below ^{1,2} | \$2,989 | \$2,720 |
| Decrease (Increase) in Net Income Due to Excluded Items: | | |
| Acquisition- and divestiture-related costs ³ | \$834 | \$1,146 |
| Restructuring costs | 212 | 217 |
| Gain on divestiture of certain migraine clinical development programs | – | (250) |
| Other | (6) | (33) |
| Net decrease (increase) in income before taxes | 1,040 | 1,080 |
| Income tax (benefit) expense ⁵ | (235) | (186) |
| Decrease (increase) in net income | \$805 | \$894 |

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.

Financial Outlook

Merck has narrowed and raised its full-year 2016 GAAP EPS to be between \$2.02 and \$2.09. The company has narrowed and raised its full-year 2016 non-GAAP EPS to be between \$3.71 to \$3.78, including an approximately 1 percent negative impact from foreign exchange at mid-October exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs.

Merck has narrowed and raised its full-year 2016 revenue range to be between \$39.7 billion and \$40.2 billion, including an approximately 2 percent negative impact from foreign exchange at mid-October exchange rates.

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

| | GAAP | Non-GAAP¹ |
|---------------------------------------|--------------------------|-----------------------------|
| Revenue | \$39.7 to \$40.2 billion | \$39.7 to \$40.2 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 | \$2.02 to \$2.09 | \$3.71 to \$3.78 |

*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.

| \$ in millions, except EPS amounts | Full-Year 2016 |
|------------------------------------------------------------|-----------------------|
| GAAP EPS | \$2.02 to \$2.09 |
| Difference ⁴ | 1.69 |
| Non-GAAP EPS that excludes items listed below ¹ | \$3.71 to \$3.78 |
| 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 Sept. 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 87561377. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 87561377. 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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