News Release

FOR IMMEDIATE RELEASE

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Merck Announces First-Quarter 2019 Financial Results

- First-Quarter 2019 Worldwide Sales Were $10.8 Billion, an Increase of 8%; Sales Increased 11% Excluding Negative Impact from Foreign Exchange; Growth Driven by Oncology and Vaccines
  - Sales in China Were $725 Million in the First Quarter, an Increase of 58%; Sales in China Increased 67% Excluding Negative Impact from Foreign Exchange

- Strong GAAP and Non-GAAP EPS Growth for First-Quarter 2019
  - GAAP EPS Was $1.12 in First-Quarter 2019 Versus $0.27 in First-Quarter 2018, which Included a Charge of $1.4 Billion Related to the Formation of a Collaboration with Eisai Co., Ltd.
  - Non-GAAP EPS Was $1.22 in First-Quarter 2019 Versus $1.05 in First-Quarter 2018
  - Non-GAAP EPS Increased 16% Year-Over-Year

- Company Narrows and Raises 2019 Full-Year Revenue Range to be Between $43.9 Billion and $45.1 Billion, Including a Negative Impact from Foreign Exchange of Slightly More Than 1%

- Company Narrows and Raises 2019 Full-Year GAAP EPS Range to be Between $4.02 and $4.14; Narrows and Raises 2019 Full-Year Non-GAAP EPS Range to be Between $4.67 and $4.79, Including a Slightly Positive Impact from Foreign Exchange

- KEYTRUDA Approved by U.S. Food and Drug Administration for Use in Combination with Axitinib as First-Line Treatment for Patients with Advanced Renal Cell Carcinoma

KENILWORTH, N.J., April 30, 2019 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the first quarter of 2019.

“Our strong start to 2019, with double-digit sales and EPS growth in the first quarter, demonstrates our execution across all aspects of our business and the strength of our key growth pillars, including oncology and vaccines,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “Our investments in research and development are paying off, and we are confident in our science-driven strategy, growth prospects and ability to sustainably deliver value to patients and shareholders.”

Financial Summary

$ in millions, except EPS amounts	First Quarter			
	2019	2018	Change	Change Ex-Exchange
Sales	$10,816	$10,037	8%	11%
GAAP net income[1]	2,915	736	**	**
Non-GAAP net income that excludes certain items[1,2*]	3,175	2,844	12%	13%
GAAP EPS	1.12	0.27	**	**
Non-GAAP EPS that excludes certain items[2]	1.22	1.05	16%	18%

*Refer to table on page 9
**Greater than 100%

Worldwide sales were $10.8 billion for the first quarter of 2019, an increase of 8% compared with the first quarter of 2018; excluding the negative impact from foreign exchange, worldwide sales grew 11%. International sales represented 58% of total sales in the quarter. Performance in international markets was led by China, which had sales growth of 58% compared with the first quarter of 2018, driven by vaccines and oncology. Excluding the unfavorable effect of foreign exchange, sales in China grew by 67%.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) were $1.12 for the first quarter of 2019. Non-GAAP EPS of $1.22 for the first quarter of 2019 excludes acquisition- and divestiture-related costs, restructuring costs, a net benefit from the settlement of certain federal income tax matters, and certain other items.

Oncology Pipeline Highlights

Merck continued to advance the development programs for KEYTRUDA (pembrolizumab), the company's anti-PD-1 therapy; Lynparza (olaparib), a PARP inhibitor being co-developed and co-commercialized with AstraZeneca; and Lenvima (lenvatinib mesylate), an orally available tyrosine kinase inhibitor being co-developed and co-commercialized with Eisai Co., Ltd. (Eisai).

KEYTRUDA

- Merck announced that the U.S. Food and Drug Administration (FDA) approved KEYTRUDA for the following indications:

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

[2] Merck is providing certain 2019 and 2018 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 and 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.

  - first-line treatment in combination with axitinib for advanced renal cell carcinoma, based on the KEYNOTE-426 trial, which showed that the combination reduced the risk of death by nearly half compared to sunitinib;
  - adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection based on results from the EORTC1325/KEYNOTE-054 trial that showed significant recurrence-free survival benefit with KEYTRUDA; and
  - first-line treatment of patients with Stage III non-small cell lung cancer (NSCLC) who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS ≥1%), with no EGFR or ALK genomic tumor aberrations, based on the results of the KEYNOTE-042 trial.
- Merck announced the European approval of KEYTRUDA in combination with chemotherapy for first-line treatment of metastatic squamous NSCLC, based on data from the KEYNOTE-407 trial.
- In April 2019, the European Commission approved a six-week dosing schedule across all current monotherapy indications for KEYTRUDA.
- The National Medical Products Administration in China granted conditional approval of KEYTRUDA for the first-line treatment of metastatic nonsquamous NSCLC in combination with chemotherapy based on the KEYNOTE-189 trial. KEYTRUDA is the first anti-PD-1 therapy approved for more than one tumor type in China and the first approved in the first-line treatment setting for metastatic nonsquamous NSCLC.
- Merck announced that the FDA granted priority review for each of the following supplemental Biologics License Applications with KEYTRUDA seeking use as:
  - first-line treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) as monotherapy or in combination with chemotherapy based on the KEYNOTE-048 trial. The FDA has set a PDUFA date of June 10, 2019; and
  - third-line treatment of patients with advanced small cell lung cancer (SCLC) as monotherapy based on the KEYNOTE-158 and KEYNOTE-028 trials. The FDA has set a PDUFA date of June 17, 2019.
- Merck announced the initiation of three separate pivotal Phase 3 trials in patients with metastatic castration-resistant prostate cancer (mCRPC) evaluating KEYTRUDA in combination with: Lynparza, chemotherapy and anti-hormone agents.

Lynparza

- Merck and AstraZeneca announced European approval of Lynparza for the treatment of germline *BRCA*-mutated HER2-negative advanced breast cancer, based on the Phase 3 OlympiAD trial.

- Merck and AstraZeneca announced top-line results from the POLO study in which Lynparza reduced the risk of disease progression or death as first-line maintenance treatment in germline *BRCA*-mutated metastatic pancreatic cancer. Full results will be presented at the upcoming American Society of Clinical Oncology annual meeting.

Other Pipeline Highlights

- Merck announced FDA acceptance for priority review of a supplemental New Drug Application for ZERBAXA (ceftolozane and tazobactam) for the treatment of adult patients with nosocomial pneumonia, including ventilator-associated pneumonia caused by certain susceptible Gram-negative microorganisms, with a PDUFA date of June 3, 2019. An application also is under review for the same indication with the European Medicines Agency (EMA). These applications were based on results from the Phase 3 ASPECT-NP study which were recently presented at the European Congress of Clinical Microbiology & Infectious Diseases.
- Merck announced FDA acceptance for priority review of a New Drug Application for the company's investigational beta-lactamase inhibitor relebactam in combination with imipenem/cilastatin for the treatment of certain infections caused by certain susceptible Gram-negative bacteria, in adults with limited or no alternative therapies available. The PDUFA date is July 16, 2019. An application also is under review with the EMA.
- Merck and NGM Biopharmaceuticals, Inc. announced that Merck exercised its option to extend the research phase of the companies' collaboration to March 2022. The collaboration is focused on discovering, developing and commercializing novel biologic therapeutics across a range of therapeutic areas.
- Merck announced the EMA recently accepted the Marketing Authorization Application for V920 (rVSVΔG-ZEBOV-GP), the company's investigational vaccine for Ebola Zaire disease. A rolling submission of a Biologics License Application with the FDA is underway.

First-Quarter Revenue Performance

The following table reflects sales of the company's top pharmaceutical products, as well as sales of animal health products.

$ in millions	First Quarter			
	2019	2018	Change	Change Ex-Exchange
Total Sales	$10,816	$10,037	8%	11%
Pharmaceutical	9,663	8,919	8%	12%
KEYTRUDA	2,269	1,464	55%	60%
JANUVIA / JANUMET	1,354	1,424	-5%	-1%
GARDASIL / GARDASIL 9	838	660	27%	31%
PROQUAD, M-M-R II and VARIVAX	496	392	27%	30%
BRIDION	255	204	25%	30%
ISENTRESS / ISENTRESS HD	255	281	-9%	-3%
ZETIA / VYTORIN	238	471	-50%	-47%
NUVARING	219	216	1%	3%
ROTATEQ	211	193	10%	11%
SIMPONI	208	231	-10%	-3%
Animal Health	1,025	1,065	-4%	3%
Livestock	611	652	-6%	1%
Companion Animals	414	413	0%	6%
Other Revenues	128	53	139%	-117%

Pharmaceutical Revenue

First-quarter pharmaceutical sales were $9.7 billion, an increase of 8% compared with the first quarter of 2018; excluding the unfavorable effect of foreign exchange, sales grew 12% in the first quarter. The increase was driven primarily by growth in oncology and vaccines, partially offset by the ongoing impacts of the loss of market exclusivity for several products.

Growth in oncology was driven by a significant increase in sales of KEYTRUDA, reflecting the strong momentum for the treatment of patients with NSCLC and the company's continued launches with new indications globally. Additionally, oncology sales reflect alliance revenue of $79 million related to Lynparza and $74 million related to Lenvima, representing Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

Growth in vaccines was driven largely 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 Human Papillomavirus (HPV), primarily due to the ongoing commercial launch in China. Higher demand in Europe, driven primarily by increased vaccination rates for both boys and girls, as well as the timing of customer purchases in Latin America, also contributed to sales growth. Growth was partially offset by lower sales in the United States reflecting public sector buying patterns.

Growth in pediatric vaccines was driven by VARIVAX (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox; PROQUAD (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a combination vaccine to help protect against measles, mumps, rubella and

varicella; and M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella, reflecting government tenders in Latin America and higher demand in Europe and the United States.

Performance in hospital acute care reflects strong demand in the United States for 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; and the ongoing launch of PREVYMIS (letermovir), a medicine for the prevention of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant.

Pharmaceutical sales growth for the quarter was partially offset by the ongoing impacts from the loss of market exclusivity for ZETIA (ezetimibe) and VYTORIN (ezetimibe/simvastatin), medicines for lowering LDL cholesterol; INVANZ (ertapenem sodium), an antibiotic; CANCIDAS (caspofungin acetate for injection), an antifungal; as well as biosimilar competition for REMICADE (infliximab), a treatment for inflammatory diseases, in the company's marketing territories in Europe. In addition, sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl), medicines that help lower blood sugar in adults with type 2 diabetes, declined slightly due to continuing pricing pressure in the United States, which more than offset strong demand from international markets.

Animal Health Revenue

Animal Health sales totaled $1.0 billion for the first quarter of 2019, a decrease of 4% compared with the first quarter of 2018. Excluding the unfavorable effect from foreign exchange, Animal Health sales grew 3% in the first quarter. Sales performance reflects higher demand for companion animal products, primarily the BRAVECTO (fluralaner) line of products for parasitic control; and volume growth in livestock products, particularly from sales of new poultry and swine products, which was partially offset by lower ruminant product sales driven by distributor purchasing patterns and the delayed movement of cattle into the feedlots in the United States.

Animal Health segment profits were $415 million in the first quarter of 2019, essentially flat compared with $413 million in the first quarter of 2018[3]. In April 2019, Merck acquired Antelliq Group, a leader in digital animal identification, traceability and monitoring solutions.

[3] Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting, Merck does not allocate general and administrative expenses not directly incurred by the segment, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits.

First-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

$ in millions	GAAP	Acquisition- and Divestiture-Related Costs[4]	Restructuring Costs	Certain Other Items	Non-GAAP[2]
First-Quarter 2019					
Cost of sales	$3,052	$413	$34	$–	$2,605
Selling, general and administrative	2,425	(1)	–	–	2,426
Research and development	1,931	(31)	–	–	1,962
Restructuring costs	153	–	153	–	–
Other (income) expense, net	188	167	–	–	21
First-Quarter 2018					
Cost of sales	$3,184	$734	$6	$–	$2,444
Selling, general and administrative	2,508	8	1	–	2,499
Research and development	3,196	1	2	1,400	1,793
Restructuring costs	95	–	95	–	–
Other (income) expense, net	(291)	(10)	–	(22)	(259)

GAAP Expense, EPS and Related Information

Gross margin was 71.8% for the first quarter of 2019 compared to 68.3% for the first quarter of 2018. The increase in gross margin for the first quarter of 2019 was primarily driven by lower acquisition- and divestiture-related costs and restructuring costs, which reduced gross margin by 4.1 percentage points in the first quarter of 2019 compared with 7.4 percentage points in the first quarter of 2018. In addition, gross margin was impacted by the favorable effects of foreign exchange and product mix, partially offset by the increased amortization of intangible assets related to collaborations and the unfavorable effects of pricing pressure and royalties.

Selling, general and administrative expenses were $2.4 billion in the first quarter of 2019, a 3% decrease compared to the first quarter of 2018. The decrease primarily reflects lower promotion and selling costs and the favorable effects of foreign exchange, partially offset by higher administrative costs.

Research and development (R&D) expenses were $1.9 billion in the first quarter of 2019 compared with $3.2 billion in the first quarter of 2018. The decline was driven primarily by a $1.4 billion charge recorded in the first quarter of 2018 related to the formation of a collaboration with Eisai, partially offset by higher expenses related to clinical development, including collaborations, and investment in early drug development.

[4] Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also includes integration, transaction and certain other costs related to business acquisitions and divestitures.

Other (income) expense, net, was $188 million of expense in the first quarter of 2019 compared to $291 million of income in the first quarter of 2018. Other (income) expense, net, in the first quarter of 2019 reflects the unfavorable effects of foreign exchange losses and impairment charges. Other (income) expense, net, in the first quarter of 2018 reflects a legal settlement gain.

The effective income tax rate of 6.7% for the first quarter of 2019 reflects a net tax benefit of $360 million related to the settlement of certain federal income tax matters.

GAAP EPS was $1.12 for the first quarter of 2019 compared with $0.27 for the first quarter of 2018.

Non-GAAP Expense, EPS and Related Information

The non-GAAP gross margin was 75.9% for the first quarter of 2019, compared to 75.7% for the first quarter of 2018. The increase in non-GAAP gross margin reflects the favorable effects of foreign exchange and product mix, partially offset by the increased amortization of intangible assets related to collaborations and the unfavorable effects of pricing pressure and royalties.

Non-GAAP selling, general and administrative expenses were $2.4 billion in the first quarter of 2019, a 3% decrease compared to the first quarter of 2018. The decrease reflects lower promotion and selling costs and the favorable effects of foreign exchange, partially offset by higher administrative costs.

Non-GAAP R&D expenses were $2.0 billion in the first quarter of 2019, a 9% increase compared to the first quarter of 2018. The increase reflects higher expenses related to clinical development, including collaborations, and investment in early drug development.

Non-GAAP other (income) expense, net, was $21 million of expense in the first quarter of 2019 compared to $259 million of income in the first quarter of 2018. Non-GAAP other (income) expense, net, in the first quarter of 2018 reflects a legal settlement gain.

The non-GAAP effective income tax rate was 16.5% for the first quarter of 2019.

Non-GAAP EPS was $1.22 for the first quarter of 2019 compared with $1.05 for the first quarter of 2018.

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

$ in millions, except EPS amounts	First Quarter	
	2019	2018
EPS		
GAAP EPS	$1.12	$0.27
Difference[5]	0.10	0.78
Non-GAAP EPS that excludes items listed below[2]	$1.22	$1.05
Net Income		
GAAP net income[1]	$2,915	$736
Difference	260	2,108
Non-GAAP net income that excludes items listed below[1,2]	$3,175	$2,844
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs[4]	$548	$733
Restructuring costs	187	104
Aggregate charge related to the formation of a collaboration with Eisai	–	1,400
Other	–	(22)
Net decrease (increase) in income before taxes	735	2,215
Income tax (benefit) expense[6]	(422)	(107)
Acquisition- and divestiture-related costs attributable to noncontrolling interests	(53)	–
Decrease (increase) in net income	$260	$2,108

Financial Outlook

Merck narrowed and raised its full-year 2019 revenue range to be between $43.9 billion and $45.1 billion, including a negative impact from foreign exchange of slightly more than 1% at mid-April exchange rates.

Merck narrowed and raised its full-year 2019 GAAP EPS range to be between $4.02 and $4.14. Merck narrowed and raised its full-year 2019 non-GAAP EPS range to be between $4.67 and $4.79, including a slightly positive impact from foreign exchange at mid-April exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs, a net benefit from the settlement of certain federal income tax matters, and certain other items.

The following table summarizes the company's full year 2019 financial guidance.

	GAAP	Non-GAAP[2]
Revenue	$43.9 to $45.1 billion	$43.9 to $45.1 billion*
Operating expenses	Lower than 2018 by a mid-single digit rate	Higher than 2018 by a low- to mid-single digit rate
Effective tax rate	16.5% to 17.5%	18.5% to 19.5%
EPS**	$4.02 to $4.14	$4.67 to $4.79

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

**EPS guidance for 2019 assumes a share count (assuming dilution) of approximately 2.6 billion shares.

A reconciliation of anticipated 2019 GAAP EPS to non-GAAP EPS and the items excluded from non-GAAP EPS are provided in the table below.

[5] 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.

[6] Includes the estimated tax impact on the reconciling items. In addition, amount for 2019 includes a $360 million net tax benefit related to the settlement of certain federal income tax matters and a $67 million tax charge related to the finalization of treasury regulations for the Tax Cuts and Jobs Act of 2017.

$ in millions, except EPS amounts	**Full-Year 2019**
GAAP EPS	$4.02 to $4.14
Difference[5]	0.65
Non-GAAP EPS that excludes items listed below[2]	$4.67 to $4.79
Acquisition- and divestiture-related costs[4]	$1,900
Restructuring costs	500
Net decrease (increase) in income before taxes	2,400
Income tax (benefit) expense[6]	(725)
Decrease (increase) in net income	$1,675

The expected full-year GAAP effective tax rate of 16.5% to 17.5% reflects a net favorable impact of approximately 2.0 percentage points from the above items.

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 8493044. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 8493044. 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.

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 2018 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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