News Release

FOR IMMEDIATE RELEASE

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Merck Announces First-Quarter 2021 Financial Results

- First-Quarter 2021 Sales Were $12.1 Billion, In-Line with First-Quarter 2020; Excluding the Impact from Foreign Exchange, Sales Declined 1%
- First-Quarter 2021 Sales Reflect Strong Underlying Performance of KEYTRUDA, Lynparza, BRIDION and Animal Health, Which Was Offset by COVID-19 Pandemic Impacts to Patient Access, Particularly for Vaccines
- First-Quarter 2021 GAAP EPS Was $1.25; First-Quarter Non-GAAP EPS Was $1.40
- Entered into HIV Collaboration with Gilead Sciences, Inc. and Completed Acquisition of Pandion Therapeutics, Inc.
- Merck Will Host an Investor Event Featuring Organon on May 3; Organon Spinoff is Expected to be Completed on June 2, with First Day of Trading Scheduled for June 3
- 2021 Financial Outlook
    - Continues to Expect Sales Growth of 8% to 12%; Full-Year 2021 Sales Estimated to be Between $51.8 Billion and $53.8 Billion, Including a Positive Impact from Foreign Exchange of Less Than 2%, Assuming Organon is Part of Merck for the Full Year
    - Expects Full-Year 2021 GAAP EPS to be Between $5.05 and $5.25; Continues to Expect Non-GAAP EPS to be Between $6.48 and $6.68, Including a Positive Impact from Foreign Exchange of Less Than 3%, Assuming Organon is Part of Merck for the Full Year
    - Assuming the Completion of the Organon Spinoff, Expects Full-Year 2021 Sales from Continuing Operations to be Between $45.8 Billion and $47.8 Billion

KENILWORTH, N.J., April 29, 2021 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the first quarter of 2021.

"While our results this quarter were impacted by the pandemic, the underlying demand for our innovative products remains strong and we remain confident in our future growth prospects," said Kenneth C. Frazier, chairman and CEO, Merck. "We are also taking the right steps to evolve Merck's operating model to continue to create value for patients, shareholders and society."

"As I transition into the CEO role, one of my immediate priorities is to ensure that our experienced leadership team continues to build on our solid foundation," said Robert M. Davis, president, Merck. "Our company is well positioned for strong long-term performance, with scientific innovation remaining the source of our company's energy and value creation."

Financial Summary

	First Quarter			
$ in millions, except EPS amounts	**2021**	**2020**	**Change**	**Change Ex-Exchange**
Sales	$12,080	$12,057	0%	-1%
GAAP net income[1]	3,179	3,219	-1%	-3%
Non-GAAP net income that excludes certain items[1,2]*	3,556	3,851	-8%	-9%
GAAP EPS	1.25	1.26	-1%	-3%
Non-GAAP EPS that excludes certain items[2]*	1.40	1.51	-7%	-9%

*Refer to table on page 11.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was $1.25 for the first quarter of 2021. Non-GAAP EPS of $1.40 for the first quarter of 2021 excludes acquisition- and divestiture-related costs, restructuring costs, income and losses from investments in equity securities 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

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

[2] Merck is providing certain 2021 and 2020 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. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. As previously disclosed, beginning in 2021, Merck changed the treatment of certain items for purposes of its non-GAAP reporting. Prior periods have been recast to conform to the current presentation. For a description of the non-GAAP adjustments, see Table 2a attached to this release.

orally available tyrosine kinase inhibitor being co-developed and co-commercialized with Eisai Co., Ltd. (Eisai), in addition to other notable developments as follows:

- Merck announced the following regulatory actions for KEYTRUDA:
    - Approval by the U.S. Food and Drug Administration (FDA) in combination with platinum- and fluropyrimidine-based chemotherapy for the first-line treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation, based on results from the Phase 3 KEYNOTE-590 trial.
    - Approval by the European Commission (EC) for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option, based on results from the Phase 3 KEYNOTE-204 trial.
    - Approval by the EC for the first-line treatment of adult patients with metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient colorectal cancer based on results from the Phase 3 KEYNOTE-177 trial.
    - A Complete Response Letter was received from the FDA regarding Merck's supplemental Biologics License Application for the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC), in combination with chemotherapy as neoadjuvant (pre-operative) treatment, then continuing as a single agent as adjuvant (post-operative) treatment after surgery.
    - A voluntary withdrawal in the United States for the treatment of patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. This withdrawal does not affect other indications for KEYTRUDA.
- Merck announced that an interim analysis from the pivotal Phase 3 KEYNOTE-564 trial evaluating KEYTRUDA met its primary endpoint of disease-free survival for the potential adjuvant treatment of patients with renal cell carcinoma (RCC) following nephrectomy or following nephrectomy and resection of metastatic lesions. Data will be presented at the 2021 American Society for Clinical Oncology (ASCO) Annual Meeting.
- Merck announced that the FDA has accepted and granted priority review for a New Drug Application (NDA) for the hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, belzutifan, a novel investigational candidate in Merck's oncology pipeline, for the potential treatment of

certain patients with von Hippel-Lindau (VHL) disease-associated RCC, not requiring immediate surgery. The FDA has set a PDUFA date of Sept. 15, 2021.

- Merck and Eisai announced the first presentation of new investigational data from the pivotal Phase 3 CLEAR study (KEYNOTE-581/Study 307) at the 2021 Genitourinary Cancers Symposium (ASCO GU) and simultaneously published in the *New England Journal of Medicine*. The combination of KEYTRUDA plus Lenvima significantly improved the primary endpoint of progression-free survival (PFS) and key secondary endpoint of overall survival (OS) versus sunitinib in first-line treatment of patients with advanced RCC.
- Merck and Eisai announced the first presentation of investigational data from the pivotal Phase 3 KEYNOTE-775/Study 309 trial at the Society of Gynecologic Oncology (SGO) 2021 Annual Meeting. The combination of KEYTRUDA plus Lenvima significantly improved the dual primary endpoints of PFS and OS versus chemotherapy for the treatment of patients with advanced endometrial cancer following one prior platinum-based regimen in any setting.
- Merck and AstraZeneca announced that the Phase 3 OlympiA trial for Lynparza will move to early primary analysis and reporting following a recommendation from the Independent Data Monitoring Committee (IDMC). Based on the planned interim analysis, the IDMC concluded that the trial crossed the superiority boundary for its primary endpoint of invasive disease-free survival versus placebo in the adjuvant treatment of germline *BRCA*-mutated (g*BRCA*m), high-risk human epidermal growth factor receptor 2 (HER2)-negative early-stage breast cancer following definitive local treatment and neoadjuvant or adjuvant chemotherapy. The trial will continue to evaluate the key secondary endpoints of OS and distant disease-free survival. Data will be presented at the 2021 ASCO Annual Meeting.
- Merck began enrollment for the Phase 3 study evaluating vibostolimab, its investigational anti-TIGIT antibody, in combination with KEYTRUDA in non-small cell lung cancer patients whose tumors express PD-L1.

Business Development and Other Pipeline Highlights

- Merck and Gilead Sciences, Inc. (Gilead) announced that they have entered into an agreement to co-develop and co-commercialize long-acting treatments in HIV that combine Gilead's investigational capsid inhibitor, lenacapavir, and Merck's investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI), islatravir, into a two-drug regimen in oral and injectable formulations with the potential to provide new, meaningful treatment options for people living with HIV.

- Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, on April 1, 2021.
- Merck announced that a Phase 2/3 trial of molnupiravir (EIDD-2801/MK-4482), an investigational oral antiviral agent being developed in collaboration with Ridgeback Biotherapeutics, for the treatment of outpatients diagnosed with COVID-19, will proceed to Phase 3. Interim results from Phase 2/3 studies evaluating molnupiravir in both outpatients and inpatients will be shared with the scientific community at an upcoming medical meeting.
- Merck announced results from a Phase 1 study evaluating the safety, tolerability and pharmacokinetics (PK) of the company's investigational subdermal drug-eluting implant with potential for extended administration of islatravir, an investigational NRTTI, for pre-exposure prophylaxis (PrEP) of HIV-1 infection. Study results demonstrated that the implant achieved active drug concentrations above the pre-specified PK threshold at 12 weeks across the three doses of islatravir studied (48 mg, 52 mg and 56 mg), and is projected to provide drug concentrations likely above threshold for one year at the 56 mg dose. Based on these findings, Merck plans to initiate a Phase 2 trial to further explore the potential of a subdermal implant containing islatravir as a long-acting option for PrEP for up to 12 months.
- Merck announced that the FDA has accepted for review the company's NDA for gefapixant, an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough or unexplained chronic cough in adults based on results from the COUGH-1 and COUGH-2 studies. This application for gefapixant will be discussed at an upcoming advisory committee meeting. The FDA has set a PDUFA date of Dec. 21, 2021.
- Merck announced that supply for VAXELIS (Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine) in the United States will be available in June 2021. Developed as part of a joint-partnership between Sanofi and Merck, VAXELIS is the first and only hexavalent combination vaccine approved in the United States to help protect infants and children 6 weeks through 4 years of age against diseases caused by six infectious agents: diphtheria, tetanus, pertussis (whooping cough), poliomyelitis, hepatitis B and invasive disease due to *Haemophilus influenzae* type b.

Organon Highlights

- Merck filed a Form 10 registration statement with the United States Securities and Exchange Commission (SEC) in connection with the intended spinoff of its women's health, biosimilars

and established brands businesses into a standalone, publicly-traded company, Organon & Co. (Organon).

- In April 2021, Organon Finance 1 LLC issued senior secured notes of €1.25 billion aggregate principal amount of 2.875% senior secured notes due 2028, $2.1 billion aggregate principal amount of 4.125% senior secured notes due 2028 and $2.0 billon aggregate principal amount of 5.125% senior unsecured notes due 2031, in connection with the intended spinoff of Organon from Merck.
- Merck announced a definitive agreement pursuant to which, after the intended spinoff of Organon, Organon will acquire Alydia Health. Alydia Health is a commercial-stage medical device company focused on preventing maternal morbidity and mortality caused by postpartum hemorrhage or abnormal postpartum uterine bleeding.
- Merck will host an investor event featuring Organon on May 3. The Organon spinoff is expected to be completed on June 2, with first day of trading scheduled for June 3.

Corporate Developments

- Merck announced goals to achieve carbon neutrality in its operations (Scopes 1 & 2 emissions) by 2025 through ongoing innovation to increase efficiency and reduce carbon emissions, applying sustainable building standards and continuing to transition away from fossil fuel use. Remaining Scope 1 emissions will be offset each year with a portfolio of high-quality carbon credits, including carbon removals. Merck has also set a goal of achieving a 30% reduction in its value chain emissions by 2030 (Scope 3 emissions).

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			
	2021	**2020**	**Change**	**Change Ex-Exchange**
Total Sales	$12,080	$12,057	0%	-1%
Pharmaceutical	10,675	10,655	0%	-3%
KEYTRUDA	3,899	3,284	19%	16%
JANUVIA / JANUMET	1,295	1,277	1%	-2%
GARDASIL / GARDASIL 9	917	1,097	-16%	-20%
PROQUAD, M-M-R II and VARIVAX	449	435	3%	2%
BRIDION	340	299	14%	11%
Lynparza*	228	145	57%	51%
SIMPONI	214	215	0%	-8%
ISENTRESS / ISENTRESS HD	209	245	-15%	-15%
PNEUMOVAX 23	171	256	-33%	-36%
ROTATEQ	158	222	-29%	-29%
Animal Health	1,418	1,214	17%	15%
Livestock	819	739	11%	9%
Companion Animals	599	475	26%	24%
Other Revenues**	(13)	188	-107%	-21%

*Alliance revenue for this product represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

**Other revenues are comprised primarily of third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities. The revenue hedging activities resulted in negative revenue in the first quarter of 2021.

Pharmaceutical Revenue

First-quarter pharmaceutical sales of $10.7 billion were in-line with the first quarter of 2020. Excluding the favorable effect of foreign exchange, sales declined by 3%. Sales performance reflects underlying strength in the business, offset by negative impacts of the COVID-19 pandemic, and the ongoing impacts of the loss of market exclusivity for several products. With respect to the COVID-19 pandemic, the estimated negative impact to Merck's first quarter pharmaceutical revenue was approximately $600 million. Continued reduced access to health care providers, combined with the prioritization of COVID-19 vaccines has negatively impacted the sales of certain products, notably vaccines in the United States.

Pharmaceutical revenue reflects growth in oncology, largely driven by higher sales of KEYTRUDA, which rose 19% to $3.9 billion in the quarter, although the COVID-19 pandemic had a dampening effect on growing demand due to a decline in the number of new patients starting treatment. Global sales growth of KEYTRUDA reflects continued strong momentum from the non-small-cell lung cancer indications as well as continued uptake in other indications, including adjuvant melanoma, RCC, bladder, head and neck squamous cell carcinoma

(HNSCC) and MSI-H cancers, as well as uptake following the recent launch of the 400mg every 6 weeks adult dosing regimen in the United States, partially offset by pricing pressure in Europe and Japan. Also contributing to growth in oncology was 57% growth in Lynparza alliance revenue, reflecting continued uptake in approved indications in the United States, Europe and China.

The decline in vaccine sales was primarily driven by GARDASIL (Human Papillomavirus Quadrivalent [Types 6,11,16 and 18] Vaccine, Recombinant)/GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to prevent certain cancers and other diseases caused by HPV, primarily attributable to buying patterns in the United States and the timing of shipments in China, which in total negatively affected the year over year GARDASIL/GARDASIL 9 sales comparison by approximately $230 million. The COVID-19 pandemic also negatively affected sales for GARDASIL/GARDASIL 9, particularly in the United States and Europe.

Also contributing to the decline in vaccine sales were lower sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, primarily reflecting the impact of the COVID-19 pandemic on demand in the United States, partially offset by higher volumes in international markets.

Vaccines sales were also negatively affected by lower sales of ROTATEQ (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, largely due to the timing of shipments in China and lower demand in the United States.

Pharmaceutical sales in the quarter were negatively affected by the ongoing impacts from the loss of market exclusivity, including for ZETIA (ezetimibe) and NOXAFIL (posaconazole), as well as certain products in diversified brands.

Performance in hospital acute care primarily reflects the decline in sales of ZERBAXA (ceftolozane and tazobactam) for injection, a combination cephalosporin antibacterial and beta-lactamase inhibitor for the treatment of adults with certain bacterial infections due to the temporary suspension of sales and product recall in the fourth quarter of 2020. Hospital acute care performance also reflects higher demand globally 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 continued uptake of PREVYMIS (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant.

Animal Health Revenue

Animal Health sales totaled $1.4 billion for the first quarter of 2021, an increase of 17% compared with the first quarter of 2020; excluding the favorable effect from foreign exchange, Animal Health sales grew 15%. Sales growth reflects higher demand globally for companion animal products, including parasiticide lines of products, primarily BRAVECTO (fluralaner), as well as higher sales of companion animal vaccines. Sales growth in livestock products reflects higher demand in international markets for ruminant, poultry and swine products, as well as higher demand globally for Animal Intelligence products.

First-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

$ in millions **First-Quarter 2021**	**GAAP**	**Acquisition- and Divestiture-Related Costs**[3]	**Restructuring Costs**	**(Income) Loss from Investments in Equity Securities**	**Certain Other Items**	**Non-GAAP**[2]
Cost of sales	$3,670	$517	$27	$−	$188	$2,938
Selling, general and administrative	2,633	218	3	−	−	2,412
Research and development	2,465	18	7	−	−	2,440
Restructuring costs	298	−	298	−	−	−
Other (income) expense, net	(448)	(28)	−	(561)	−	141
First-Quarter 2020						
Cost of sales	$3,312	$407	$68	$−	$−	$2,837
Selling, general and administrative	2,555	278	11	−	−	2,266
Research and development	2,209	40	17	−	−	2,152
Restructuring costs	72	−	72	−	−	−
Other (income) expense, net	71	(11)	–	(87)	−	169

[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 liabilities for contingent consideration. Also includes integration, transaction and certain other costs related to acquisitions and divestitures.

GAAP Expense, EPS and Related Information

Gross margin was 69.6% for the first quarter of 2021 compared to 72.5% for the first quarter of 2020. The decrease reflects higher costs associated with COVID-19 development programs, including a charge related to the discontinuation of certain COVID-19 development programs, as well as higher acquisition- and divestiture-related costs, and pricing pressure, partially offset by favorable product mix.

Selling, general and administrative expenses were $2.6 billion in the first quarter of 2021, an increase of 3% compared to the first quarter of 2020. The increase primarily reflects higher promotion and administrative costs, the unfavorable effects of foreign exchange and higher costs related to the company's planned spinoff of Organon, partially offset by lower selling costs due in part to the COVID-19 pandemic.

Research and development expenses were $2.5 billion in the first quarter of 2021, an increase of 12% compared with the first quarter of 2020. The increase was primarily driven by higher expenses related to clinical development, including investment in COVID-19 development programs, as well as increased investment in discovery research and early drug development, partially offset by lower licensing costs.

Other (income) expense, net, was $448 million of income in the first quarter of 2021 compared to $71 million of expense in the first quarter of 2020, primarily reflecting higher income from investments in equity securities in 2021 compared with 2020.

The effective income tax rate of 8.0% for the first quarter of 2021 reflects a net tax benefit of $237 million related to the settlement of certain federal income tax matters.

GAAP EPS was $1.25 for the first quarter of 2021 compared with $1.26 for the first quarter of 2020.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 75.7% for the first quarter of 2021 compared to 76.5% for the first quarter of 2020. The decrease in non-GAAP gross margin reflects higher costs associated with COVID-19 development programs, as well as pricing pressure, partially offset by favorable product mix.

Non-GAAP selling, general and administrative expenses were $2.4 billion in the first quarter of 2021, an increase of 6% compared to the first quarter of 2020. The increase primarily reflects higher promotion and administrative costs and the unfavorable effects of foreign exchange, partially offset by lower selling costs due in part to the COVID-19 pandemic.

Non-GAAP R&D expenses were $2.4 billion in the first quarter of 2021, a 13% increase compared to the first quarter of 2020. The increase primarily reflects higher expenses related to clinical development, including investment in COVID-19 development programs, as well as increased investment in discovery research and early drug development, partially offset by lower licensing costs.

Non-GAAP other (income) expense, net, was $141 million of expense in the first quarter of 2021 compared to $169 million of expense in the first quarter of 2020.

The non-GAAP effective income tax rate was 14.1% for the first quarter of 2021.

Non-GAAP EPS was $1.40 for the first quarter of 2021 compared with $1.51 for the first quarter of 2020.

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	
	2021	**2020**
EPS		
GAAP EPS	$1.25	$1.26
Difference	0.15	0.25
Non-GAAP EPS that excludes items listed below[2]	$1.40	$1.51
Net Income		
GAAP net income[1]	$3,179	$3,219
Difference	377	632
Non-GAAP net income that excludes items listed below[1,2]	$3,556	$3,851
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs[3]	$725	$714
Restructuring costs	335	168
(Income) loss from investments in equity securities	(561)	(87)
Charge for the discontinuation of COVID-19 development programs	188	-
Net decrease (increase) in income before taxes	687	795
Income tax (benefit) expense[4]	(310)	(163)
Decrease (increase) in net income	$377	$632

Financial Outlook

The guidance provided below is based on the assumption that the Organon business will be part of Merck for all of 2021; however, the Company expects that the Organon spinoff will

[4] Includes the estimated tax impact on the reconciling items. In addition, the amount for 2021 includes a $237 million net tax benefit related to the settlement of certain federal income tax matters.

occur on June 2, 2021. If the spinoff occurs, these financial estimates will be updated. Initial information related to revenue from continuing operations is provided below.

Merck continues to experience strong global underlying demand across its business. Consequently, at mid-April 2021 exchange rates, Merck continues to expect sales growth of 8% to 12% in 2021 with full-year 2021 revenue estimated to be between $51.8 billion and $53.8 billion, including a positive impact from foreign exchange of less than 2%. Merck now estimates that the pandemic will have a net unfavorable impact to 2021 revenues of approximately 3%, all of which relates to the pharmaceutical segment.

Merck continues to believe that global health systems and patients have largely adapted to the impacts of COVID-19 disease, but that negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales in the United States, which is expected to be partially offset by the re-allocation of GARDASIL 9 doses to markets outside of the United States to address continued strong demand.

Merck now expects full-year 2021 GAAP EPS to be between $5.05 and $5.25.

Merck continues to expect full-year 2021 non-GAAP EPS to be between $6.48 and $6.68, including a positive impact from foreign exchange of less than 3%. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs, income and losses from investments in equity securities and certain other items.

For full-year 2021, Merck expects the pandemic to have a negligible impact on operating expenses, as spending on the development of its COVID-19 antiviral programs is expected to largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

Neither the sales nor the EPS guidance ranges provided above include the impact of the potential launch of Merck's COVID-19 antiviral drug candidate.

The following table summarizes the company's full-year 2021 financial guidance.

	GAAP	**Non-GAAP**[2]
Revenue	$51.8 to $53.8 billion	$51.8 to $53.8 billion*
Operating expenses	Lower than 2020 by a mid-single digit rate	Higher than 2020 by a mid- to high-single digit rate
Effective tax rate	15% to 16%	15% to 16%
EPS**	$5.05 to $5.25	$6.48 to $6.68

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

**EPS guidance for 2021 assumes a share count (assuming dilution) of approximately 2.53 billion shares.

A reconciliation of anticipated 2021 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 2021**
GAAP EPS	$5.05 to $5.25
Difference	$1.43
Non-GAAP EPS that excludes items listed below[2]	$6.48 to $6.68
Acquisition- and divestiture-related costs	$2,500
Restructuring costs	700
(Income) loss from investments in equity securities	(1,000)
Charge for the discontinuation of COVID-19 development programs	188
Charge for the acquisition of Pandion	1,800
Net decrease (increase) in income before taxes	4,188
Income tax (benefit) expense[4]	(565)
Decrease (increase) in net income	$3,623

Impact of Planned Spinoff of Organon

Merck expects the spinoff of Organon to be completed on June 2, 2021. Merck continues to expect the transaction to create two companies with enhanced strategic and operational focus, improved agility, simplified operating models, optimized capital structures and improved financial profiles. Merck believes the transaction will deliver significant benefits for both Merck and Organon and create value for Merck shareholders.

On a pro forma basis, assuming it operated as an independent company for the full year, Organon is expected to generate $6.1 billion to $6.4 billion in revenue in 2021. Organon is expected to have $9.5 billion in initial debt and is expected to pay a special tax-free dividend to Merck of approximately $9.0 billion.

For Merck, the spinoff of Organon will allow it to increase its focus on key growth pillars, achieve higher revenue and EPS growth rates and enable incremental operating efficiencies of approximately $1.5 billion, which are expected to be achieved ratably over three years, with approximately $500 million realized during 2021. Merck will continue to incur overhead costs previously allocated to the Organon products, which are estimated to be approximately $400 million on a full-year basis. These costs are expected to be reduced over time and are netted into the overall efficiency target. Merck expects to use the special tax-free dividend from Organon for business development and/or share repurchases.

As a result of the stronger growth Organon is expected to achieve as a standalone company and the benefit of operating efficiencies at Merck enabled by the spinoff, Merck expects combined non-GAAP EPS of the two companies to be higher within 12-24 months post-spinoff versus what would have been achieved assuming no transaction. Due to the higher relative profitability of Organon's products, Merck's operating margin from continuing operations is expected to initially be slightly lower in 2021 versus what it was prior to the spinoff. With the incremental operating efficiencies enabled by the spinoff, Merck's operating margins are expected to be higher within 12-24 months versus where they would have been in the absence of the spinoff and to be greater than 42% in 2024.

Finally, assuming the completion of the Organon spinoff, Merck anticipates full-year 2021 revenue from continuing operations to be between $45.8 billion and $47.8 billion. Continuing operations for Merck exclude Organon results for the full year. Further details, including post-spinoff GAAP and non-GAAP EPS guidance, will be announced in conjunction with Merck's second-quarter 2021 earnings release.

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 https://investors.merck.com/events-and-presentations/default.aspx. Institutional investors and analysts can participate in the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 7279283. Members of the media are invited to monitor the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 7279283. 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 130 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information,

visit www.merck.com and connect with us on Twitter, Facebook, Instagram, 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; uncertainties as to the timing of the proposed spinoff; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); 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 2020 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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