News Release

Merck Announces Second-Quarter 2023 Financial Results

- Sales Reflect Sustained Underlying Growth, Particularly in Oncology and Vaccines
- Total Worldwide Sales Were $15.0 Billion, an Increase of 3% From Second Quarter 2022; Excluding LAGEVRIO, Growth Was 11%; Excluding LAGEVRIO and the Impact of Foreign Exchange, Growth Was 14%
    - KEYTRUDA Sales Grew 19% to $6.3 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 21%
    - GARDASIL/GARDASIL 9 Sales Grew 47% to $2.5 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 53%
    - LAGEVRIO Sales Declined 83% to $203 Million; Excluding the Impact of Foreign Exchange, Sales Declined 82%
- GAAP Loss per Share Was $2.35; Non-GAAP Loss per Share Was $2.06; GAAP and Non-GAAP Loss per Share Include a Charge of $4.02 per Share for the Acquisition of Prometheus
- Presented Compelling Data in Earlier Stages of Cancer at 2023 ASCO Annual Meeting, Including:
    - Positive Phase 3 Results From KEYNOTE-671 Trial
    - Promising New Data From Phase 2b KEYNOTE-942/mRNA-4157-P201 Trial in Collaboration With Moderna
- Announced Positive Results From Two Phase 3 Trials Evaluating V116
- Submitted Biologics License Application to the U.S. FDA for Sotatercept
- Full-Year 2023 Financial Outlook
    - Raises and Narrows Expected Worldwide Sales Range To Be Between $58.6 Billion and $59.6 Billion, Including Negative Impact of Foreign Exchange of Approximately 2 Percentage Points; Outlook Includes Approximately $1.0 Billion of LAGEVRIO Sales
    - Now Expects Non-GAAP EPS To Be Between $2.95 and $3.05, Including the Negative Impact of Foreign Exchange of Approximately 5 Percentage Points; Outlook Reflects Negative Impact From One-Time Charge of $10.2 Billion, or $4.02 per Share, for the Acquisition of Prometheus

RAHWAY, N.J., Aug. 1, 2023 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the second quarter of 2023.

"We continue to make great progress as we advance our broad and deep pipeline, raise the bar of innovation, and bring forward leading-edge science to save and improve lives around the world," said Robert M. Davis, chairman and chief executive officer, Merck. "We delivered robust underlying growth during the second quarter and are well positioned to achieve strong

full-year results. I am proud of our talented, diverse and dedicated global team that continues to focus on creating value for patients and all our stakeholders now and well into the future."

Financial Summary

	Second Quarter			
$ in millions, except EPS amounts	2023	2022	Change	Change Ex-Exchange
Sales	$15,035	$14,593	3%	7%
GAAP net (loss) income[1]	(5,975)	3,944	**N/M	N/M
Non-GAAP net (loss) income that excludes certain items[1,2*]	(5,220)	4,743	N/M	N/M
GAAP EPS	(2.35)	1.55	N/M	N/M
Non-GAAP EPS that excludes certain items[2*]	(2.06)	1.87	N/M	N/M

*Refer to table on page 6.
**Not meaningful

Generally Accepted Accounting Principles (GAAP) loss / earnings per share (EPS) assuming dilution was a loss per share of $2.35 for the second quarter of 2023. Non-GAAP loss per share was $2.06 for the second quarter of 2023. Both GAAP and non-GAAP loss per share were due to a charge for the acquisition of Prometheus Biosciences, Inc. (Prometheus) of $4.02 per share. Additionally, both GAAP and non-GAAP loss per share in the second quarter of 2023 were unfavorably affected by lower sales of LAGEVRIO and the impact of foreign exchange compared with the second quarter of 2022.

Non-GAAP EPS excludes acquisition- and divestiture-related costs and costs related to restructuring programs, as well as income and losses from investments in equity securities.

Year-to-date results can be found in the attached tables.

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

[2] Merck is providing certain 2023 and 2022 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 because management uses non-GAAP results to assess performance. Management uses non-GAAP 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 a non-GAAP pre-tax income metric. 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 non-GAAP adjustments, see Table 2a attached to this release.

Second-Quarter Sales Performance

The following table reflects sales of the company's top products and significant performance drivers.

	Second Quarter				
$ in millions	2023	2022	Change	Change Ex-Exchange	Commentary
Total Sales	$15,035	$14,593	3%	7%	
Pharmaceutical	13,457	12,756	6%	8%	Increase driven by growth in oncology, vaccines and hospital acute care, partially offset by lower sales in virology due to LAGEVRIO, and in diabetes. Excluding LAGEVRIO, growth of 14%. Excluding LAGEVRIO and unfavorable impact of foreign exchange, growth of 17%.
KEYTRUDA	6,271	5,252	19%	21%	Growth from continued strong global momentum in metastatic indications, including certain types of non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), head and neck squamous cell carcinoma and triple-negative breast cancer (TNBC), and increased uptake across earlier-stage indications, including certain types of neoadjuvant/adjuvant TNBC in the U.S.
GARDASIL / GARDASIL 9	2,458	1,674	47%	53%	Growth largely due to strong global demand, particularly in China.
JANUVIA / JANUMET	864	1,233	-30%	-28%	Decline primarily due to generic competition in several international markets, particularly in Europe, and lower demand and pricing in the U.S.
PROQUAD, M-M-R II and VARIVAX	582	578	1%	1%	Relatively flat compared with prior year.
BRIDION	502	426	18%	19%	Growth primarily due to increased demand, particularly in the U.S., reflecting an increase in market share among neuromuscular blockade reversal agents.
Lynparza*	310	275	13%	15%	Growth driven primarily by increased demand in certain international markets.
Lenvima*	242	231	5%	6%	Growth primarily due to higher demand in the U.S., partially offset by lower demand in China.
LAGEVRIO	203	1,177	-83%	-82%	Decrease largely attributable to lower sales in Japan and nonrecurrence of sales in the U.K.
SIMPONI	180	181	-1%	-1%	Relatively flat compared with prior year.
VAXNEUVANCE	168	12	***N/M	N/M	Growth driven largely by continued uptake in pediatric indication following launch in the U.S.
Animal Health	1,456	1,467	-1%	2%	Excluding unfavorable impact of foreign exchange, growth primarily driven by higher pricing in both Livestock and Companion Animal product portfolios.
Livestock	807	826	-2%	2%	Excluding unfavorable impact of foreign exchange, growth due to higher pricing, as well as higher demand for swine and poultry products, partially offset by lower demand for ruminant products, due in part to reduced herd sizes.
Companion Animal	649	641	1%	2%	Growth driven by higher pricing, including for the BRAVECTO line of products, partially offset by supply challenges for certain companion animal vaccines. Sales of

$ in millions	Second Quarter 2023	2022	Change	Change Ex-Exchange	Commentary
					BRAVECTO were $326 million and $309 million in the current and prior quarters, respectively, which represented growth of 5% or 7% excluding unfavorable impact of foreign exchange.
Other Revenues**	122	370	-67%	-19%	Decline primarily due to impact of revenue hedging. Excluding unfavorable impact of foreign exchange, decline due to lower royalties and milestone payments received for out-licensing arrangements.

*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 revenues from third-party manufacturing arrangements and miscellaneous corporate revenues, including revenue-hedging activities.

***Not meaningful

Second-Quarter Expense, EPS and Related Information

The table below presents selected expense information.

$ in millions	GAAP	Acquisition- and Divestiture-Related Costs[3]	Restructuring Costs	(Income) Loss From Investments in Equity Securities	Non-GAAP[2]
Second Quarter 2023					
Cost of sales	$4,024	$467	$32	$-	$3,525
Selling, general and administrative	2,702	25	52	-	2,625
Research and development	13,321	9	1	-	13,311
Restructuring costs	151	-	151	-	-
Other (income) expense, net	172	(3)	-	194	(19)
Second Quarter 2022					
Cost of sales	$4,216	$451	$67	$-	$3,698
Selling, general and administrative	2,512	65	27	-	2,420
Research and development	2,798	12	22	-	2,764
Restructuring costs	142	-	142	-	-
Other (income) expense, net	438	2	-	234	202

GAAP Expense, EPS and Related Information

Gross margin was 73.2% for the second quarter of 2023 compared with 71.1% for the second quarter of 2022. The increase was primarily due to lower LAGEVRIO sales, which have a low gross margin, as well as the favorable impact of product mix. The gross margin increase was partially offset by the unfavorable impact of foreign exchange.

Selling, general and administrative (SG&A) expenses were $2.7 billion in the second quarter of 2023, an increase of 8% compared with the second quarter of 2022. The increase

[3] Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions of businesses, 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 associated with acquisitions and divestitures, as well as amortization of intangible assets related to collaborations and licensing arrangements.

was primarily due to higher administrative costs, including higher compensation and benefit costs, and higher promotional spending, partially offset by lower acquisition- and divestiture-related costs and the favorable impact of foreign exchange.

Research and development (R&D) expenses were $13.3 billion in the second quarter of 2023 compared with $2.8 billion in the second quarter of 2022. The increase was primarily due to a $10.2 billion charge for the acquisition of Prometheus. The remaining increase was driven by higher compensation and benefit costs, reflecting in part increased headcount, higher investments in discovery research and early drug development, and higher clinical development spending.

Other (income) expense, net, was $172 million of expense in the second quarter of 2023 compared with $438 million of expense in the second quarter of 2022, primarily due to lower net losses from investments in equity securities and lower pension settlement costs.

The income tax provision for the second quarter of 2023 was $637 million on a pretax loss of $5.3 billion, resulting in an effective tax rate of (11.9)%. This effective tax rate includes a 25.1 percentage point unfavorable impact of the charge for the acquisition of Prometheus, for which no tax benefit was recorded.

GAAP loss per share was $2.35 for the second quarter of 2023 compared with earnings per share of $1.55 for the second quarter of 2022.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 76.6% for the second quarter of 2023 compared with 74.7% for the second quarter of 2022. The increase was primarily due to lower LAGEVRIO sales, which have a low gross margin, as well as the favorable impact of product mix. The gross margin increase was partially offset by the unfavorable impact of foreign exchange.

Non-GAAP SG&A expenses were $2.6 billion in the second quarter of 2023, an increase of 8% compared with the second quarter of 2022. The increase was primarily due to higher administrative costs, including higher compensation and benefit costs, and higher promotional spending, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were $13.3 billion in the second quarter of 2023 compared with $2.8 billion in the second quarter of 2022. The increase was primarily due to a $10.2 billion charge for the acquisition of Prometheus. The remaining increase was driven by higher compensation and benefit costs, reflecting in part increased headcount, higher investments in discovery research and early drug development, and higher clinical development spending.

Non-GAAP other (income) expense, net, was $19 million of income in the second quarter of 2023 compared with $202 million of expense in the second quarter of 2022, primarily due to lower pension settlement costs.

The non-GAAP income tax provision for the second quarter of 2023 was $810 million on a pretax loss of $4.4 billion, resulting in a non-GAAP effective tax rate of (18.4)%. This effective tax rate includes a 32.5 percentage point unfavorable impact of the charge for the acquisition of Prometheus, for which no tax benefit was recorded.

Non-GAAP loss per share was $2.06 for the second quarter of 2023 compared with earnings per share of $1.87 for the second quarter of 2022.

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

	Second Quarter	
$ in millions, except EPS amounts	**2023**	**2022**
EPS		
GAAP EPS	$(2.35)	$1.55
Difference	0.29	0.32
Non-GAAP EPS that excludes items listed below[2]	$(2.06)	$1.87
Net (Loss) Income		
GAAP net (loss) income[1]	$(5,975)	$3,944
Difference	755	799
Non-GAAP net (loss) income that excludes items listed below[1,2]	$(5,220)	$4,743
Excluded Items:		
Acquisition- and divestiture-related costs[3]	$498	$530
Restructuring costs	236	258
Loss from investments in equity securities	194	234
Increase to net loss / decrease to net income before taxes	928	1,022
Estimated income tax (benefit) expense	(173)	(223)
Increase to net loss / decrease to net income	$755	$799

Pipeline and Portfolio Highlights

Merck's expansive research efforts resulted in continued progress across its broad pipeline and portfolio. In oncology, the company reached regulatory milestones across different stages of cancer and shared positive results from a range of clinical trials. Notably, Merck presented data on four approved medicines and two pipeline candidates in more than 25 types of cancer at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, including investigational data for KEYTRUDA that demonstrates its progress in earlier stages of disease.

Further, in vaccines, Merck announced positive topline results demonstrating that V116, an investigational 21-valent pneumococcal conjugate vaccine specifically designed for adults, met key immunogenicity and safety endpoints in two Phase 3 trials. In cardiovascular, Merck submitted a Biologics License Application to the U.S. Food and Drug Administration (FDA) for sotatercept, Merck's novel investigational activin signaling inhibitor for the treatment of adults with pulmonary arterial hypertension (World Health Organization Group 1). In chronic cough, Merck received an acceptance from the FDA for the resubmission of the New Drug Application for gefapixant and assigned a target action date of Dec. 27, 2023.

Merck also completed the acquisition of Prometheus, which will accelerate the company's growing presence in immunology and add diversity to its pipeline. Prometheus' leading clinical candidate, MK-7240, formerly known as PRA-023, creates an opportunity for Merck to transform the treatment of immune-mediated diseases.

Notable recent news releases on Merck's pipeline and portfolio are provided in the table that follows.

Oncology	FDA Approved Lynparza Plus Abiraterone and Prednisone or Prednisolone for Treatment of Adult Patients With BRCA-Mutated Metastatic Castration-Resistant Prostate Cancer	(Read Announcement)
	FDA Accepted Application for Merck's KEYTRUDA Plus Chemotherapy as Treatment for Advanced or Unresectable Biliary Tract Cancer	(Read Announcement)
	Merck's KEYTRUDA Plus Chemotherapy Before Surgery and Continued as a Single Agent After Surgery Reduced the Risk of Event-Free Survival Events by 42% Versus Pre-Operative Chemotherapy in Resectable Stage II, IIIA or IIIB NSCLC	(Read Announcement)
	Merck and Moderna Initiated Phase 3 Study Evaluating V940 (mRNA-4157) In Combination With KEYTRUDA for Adjuvant Treatment of Patients With Resected High-Risk (Stage IIB-IV) Melanoma	(Read Announcement)
	Merck and Moderna Announced mRNA-4157 (V940) in Combination With KEYTRUDA Demonstrated a Statistically Significant and Clinically Meaningful Improvement in Distant Metastasis-Free Survival in Patients With High-Risk Stage III/IV Melanoma Following Complete Resection Versus KEYTRUDA	(Read Announcement)
	KEYTRUDA Plus Chemotherapy Significantly Improved Overall Survival Versus Chemotherapy Alone as First-Line Treatment for Unresectable Advanced Pleural Mesothelioma	(Read Announcement)
	KEYTRUDA Plus Lenvima Demonstrated Long-Term, Durable Survival Benefit Versus Sunitinib as First-Line Treatment for Patients With Advanced RCC	(Read Announcement)
	Merck Announced Phase 3 KEYNOTE-A18 Trial Met Primary Endpoint of Progression-Free Survival (PFS) in Patients With Newly Diagnosed High-Risk Locally Advanced Cervical Cancer	(Read Announcement)
	KEYTRUDA Plus Trastuzumab and Chemotherapy Met Primary Endpoint of PFS as First-Line Treatment in Patients With HER2-Positive Advanced Gastric or Gastroesophageal Junction Adenocarcinoma	(Read Announcement)
Vaccines	Merck Announced V116, an Investigational, 21-Valent Pneumococcal Conjugate Vaccine Specifically Designed for Adults, Met Key Immunogenicity and Safety Endpoints in Two Phase 3 Trials	(Read Announcement)
Other Pipeline Updates	FDA Approved New Indication for Merck's PREVYMIS for Prevention of Cytomegalovirus Disease in High-Risk Adult Kidney Transplant Recipients	(Read Announcement)
	Merck Presented Phase 2a Data for Efinopegdutide (MK-6024), an Investigational GLP-1/Glucagon Receptor Co-agonist, in Patients With Nonalcoholic Fatty Liver Disease, at EASL 2023; Additionally, Efinopegdutide Was Granted Fast Track Designation by the FDA for the Treatment of Nonalcoholic Steatohepatitis (NASH)	(Read Announcement)
	Merck Received Positive European Union Committee for Medicinal Products for Human Use (CHMP) Opinion for Gefapixant	(Read Announcement)

Full-Year 2023 Financial Outlook

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

Sales*	$58.6 to $59.6 billion
Non-GAAP Gross margin[2]	Approximately 77%
Non-GAAP Operating expenses[2]**	$34.0 to $34.6 billion
Non-GAAP Other (income) expense, net[2]	Approximately $100 million
Non-GAAP Effective tax rate[2]***	30.5% to 31.5%
Non-GAAP EPS[2]****	$2.95 to $3.05
Share count (assuming dilution)	2.55 billion

*Includes approximately $1.0 billion of LAGEVRIO sales. The company does not have any non-GAAP adjustments to sales.
**Includes an aggregate $11.6 billion of R&D expenses related to the Prometheus and Imago BioSciences, Inc. (Imago) acquisitions and upfront payment for the license and collaboration agreement with Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd). Outlook does not assume any additional significant potential business development transactions.
***Includes a negative impact of 15 percentage points from the one-time charge for the acquisition of Prometheus.
****Includes $4.53 of one-time charges related to the Prometheus and Imago acquisitions and upfront payment to Kelun-Biotech.

Merck has not provided a reconciliation of forward-looking non-GAAP gross margin, non-GAAP operating expenses, non-GAAP other (income) expense, net, non-GAAP effective tax rate and non-GAAP EPS to the most directly comparable GAAP measures, given it cannot predict with reasonable certainty the amounts necessary for such a reconciliation, including intangible asset impairment charges, legal settlements, and gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds, without unreasonable effort. These items are inherently difficult to forecast and could have a significant impact on the company's future GAAP results.

Merck continues to experience strong global demand for key growth products, particularly in oncology and vaccines. As a result, Merck is raising and narrowing its full-year sales outlook. Merck now expects full-year sales to be between $58.6 billion and $59.6 billion, including a negative impact of foreign exchange of approximately 2 percentage points, at mid-July 2023 exchange rates. This full-year outlook continues to include approximately $1.0 billion of LAGEVRIO sales.

Merck's full-year non-GAAP effective income tax rate is expected to be between 30.5% and 31.5%, including an unfavorable impact of approximately 15 percentage points from the non-tax deductible one-time charge for the acquisition of Prometheus.

Merck now expects its full-year non-GAAP EPS to be between $2.95 and $3.05, including a negative impact of foreign exchange of approximately 5 percentage points, at mid-July 2023 exchange rates. This revised non-GAAP EPS range reflects the following, which were not previously included in the outlook:

- Additional strength in the business of approximately $0.24 per share.
- A charge of $10.2 billion, or $4.02 per share, for the acquisition of Prometheus.
- Estimated 2023 expense of approximately $0.14 per share to be incurred to finance the Prometheus acquisition and to advance the acquired assets.

- A less than 1%, or approximately $0.02 per share, incremental negative impact of foreign exchange.

The non-GAAP EPS range excludes acquisition- and divestiture-related costs and costs related to restructuring programs, as well as income and losses from investments in equity securities, and a previously disclosed charge related to settlements with certain plaintiffs in the Zetia antitrust litigation.

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the earnings conference call on Tuesday, Aug. 1, at 8 a.m. ET via this weblink. A replay of the webcast, along with the sales and earnings news release, supplemental financial disclosures, prepared remarks and slides highlighting the results, will be available at www.merck.com.

All participants may join the call by dialing (888) 769-8514 (U.S. and Canada Toll-Free) or (517) 308-9208 and using the access code 8206435.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. 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., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, 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 candidates that the candidates 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 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 Annual Report on Form 10-K for the year ended December 31, 2022, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Appendix

Generic product names are provided below.

Pharmaceutical

BRIDION *(sugammadex)*
GARDASIL (*Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant*)
GARDASIL 9 *(Human Papillomavirus 9-valent Vaccine, Recombinant)*
JANUMET *(sitagliptin and metformin HCl)*
JANUVIA *(sitagliptin)*
KEYTRUDA *(pembrolizumab)*
LAGEVRIO *(molnupiravir)*
Lenvima *(lenvatinib)*
Lynparza *(olaparib)*
M-M-R II *(Measles, Mumps and Rubella Virus Vaccine Live)*
PREVYMIS (*letermovir*)
PROQUAD *(Measles, Mumps, Rubella and Varicella Virus Vaccine Live)*
SIMPONI *(golimumab)*
VARIVAX *(Varicella Virus Vaccine Live)*
VAXNEUVANCE (*Pneumococcal 15-valent Conjugate Vaccine*)

Animal Health

BRAVECTO *(fluralaner)*

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Media Contacts:

Robert Josephson
(203) 914-2372

Investor Contacts:

Peter Dannenbaum
(732) 594-1579

robert.josephson@merck.com

peter.dannenbaum@merck.com

Michael Levey
(215) 872-1462
michael.levey@merck.com

Steven Graziano
(732) 594-1583
steven.graziano@merck.com