AbbVie Reports Second-Quarter 2013 Financial Results

- Raises 2013 Adjusted EPS Guidance to \$3.07-\$3.13, GAAP EPS Guidance of \$2.66-\$2.72
- Reports Second-Quarter Adjusted EPS of \$0.82, GAAP EPS of \$0.66

- Delivers Revenue of \$4.692 Billion, an Increase of 4.4 Percent (Up 5.1 Percent Excluding Foreign Exchange)

- Revenue Growth Reflects 12.1 Percent Global Reported Sales Growth from HUMIRA (Up 12.8 Percent Excluding Foreign Exchange) and Double-Digit Growth from Several Other Key Products

- Significant Advancements in Pipeline: Phase 3 HCV Enrollment Now Complete; HCV Combination Granted Breakthrough Designation; Extended Galapagos Collaboration to Include Crohn's Disease; Initiated Phase 3 Program for Atrasentan; Entered Collaboration to Develop Novel Compound for Celiac Disease

NORTH CHICAGO, III., July 26, 2013 -- AbbVie (NYSE: ABBV) today announced financial results for the second quarter ended June 30, 2013.

"AbbVie has delivered strong performance in both the second quarter and the first six months as an independent company," said Richard A. Gonzalez, chairman and chief executive officer, AbbVie. "Our first-half performance, including better-than-expected sales growth, has allowed us to increase our earnings-per-share guidance for the year. We also reached a number of key pipeline milestones this quarter, and remain very encouraged by the progress of our mid- and late-stage development programs."

Second-Quarter Results

- Worldwide sales were \$4.692 billion in the second quarter, up 4.4 percent. On an operational basis, sales increased 5.1 percent, excluding a 0.7 percent unfavorable impact from foreign exchange rate fluctuations. Sales increased in the quarter despite the decline in TriCor/Trilipix sales due to the loss of exclusivity. Excluding TriCor/Trilipix sales and foreign exchange, sales increased 10.3 percent in the second quarter.
- Sales growth was driven primarily by the continued strength of HUMIRA. Global HUMIRA sales increased 12.1 percent, or 12.8 percent on an operational basis, excluding the impact of foreign exchange rate fluctuations. U.S. HUMIRA sales grew 16.0 percent due to growth in dermatology and gastroenterology, as well as the launch of the ulcerative colitis indication. Total company sales growth was also driven by double-digit growth from key products including Synthroid, Creon, Zemplar and Duodopa.
- Second-quarter adjusted gross margin ratio was 80.7 percent, excluding intangible asset amortization and other specified items. The gross margin ratio under U.S. generally accepted accounting principles (GAAP) was 77.5 percent.
- Adjusted selling, general and administrative (SG&A) expense was 27.9 percent of sales in the second quarter, reflecting continued investment in our growth brands. On a GAAP basis, SG&A was 30.0 percent of sales.
- Adjusted research and development (R&D) was 14.8 percent of sales in the second quarter, reflecting funding actions in support of our emerging mid- and late-stage pipeline assets and the continued pursuit of additional HUMIRA indications. On a GAAP basis, R&D was 15.1 percent of sales.
- Net interest expense was \$75 million in the second quarter, and adjusted other income was \$7 million. On a GAAP basis, other income was \$4 million.
- The adjusted tax rate was 22.3 percent in the quarter. On a GAAP basis, the second-quarter tax rate was 21.9 percent.
- Second-quarter diluted earnings per share were \$0.66 on a GAAP basis. Adjusted diluted earnings per share, excluding intangible asset amortization expense and other specified items, were \$0.82, above the company's previous guidance range.

Key Events from the Second Quarter

• Recently completed enrollment in all registrational studies in AbbVie's Phase 3 genotype 1 hepatitis C virus

(HCV) program. Received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for AbbVie's investigational direct-acting antiviral combination with and without ribavirin. We expect our Phase 3 studies to begin to read out later this year and into early 2014.

- Announced preliminary results from a Phase 1 study of ABT-199, AbbVie's first-in-class BcL-2 inhibitor in development in partnership with Roche/Genentech, in patients with high-risk relapsed/refractory chronic lymphocytic leukemia (CLL), and in patients with relapsed/refractory non-Hodgkin's lymphoma (NHL). We recently initiated a potentially registrational Phase 2 single-agent, single-arm study in relapsed/refractory CLL patients with the 17P chromosome deletion. We also expect to begin a Phase 3 comparative, combination study in relapsed/refractory CLL in the next six to nine months.
- Initiated a Phase 3 study to assess the effects of the investigational compound atrasentan, when added to standard of care, on progression of kidney disease in patients with stage 2 to 4 chronic kidney disease and type 2 diabetes. The initiation of the Phase 3 study follows results from Phase 2b studies, which were recently presented at the 2013 European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Congress.
- AbbVie and Galapagos announced an extension of their GLPG0634 clinical development collaboration to include Crohn's disease. Galapagos will fund and complete a Phase 2 program in Crohn's disease, which is designed to facilitate rapid progression into Phase 3. Additionally, safety and efficacy data from a Phase 2a study of GLPG0634 in rheumatoid arthritis was recently presented at the European League Against Rheumatism (EULAR) Annual Congress.
- HUMIRA received approval in Japan for two additional gastroenterology indications, including ulcerative colitis and intestinal Behçet's disease. HUMIRA is the first and only biologic treatment available for Behçet's in the country.
- AbbVie and Alvine Pharmaceuticals announced a global collaboration to develop a novel oral treatment for patients with celiac disease, currently in Phase 2 development. This collaboration builds on AbbVie's expertise and leadership in the field of gastroenterology.
- Along with partner Bristol-Myers Squibb, AbbVie announced updated efficacy and safety data from a randomized Phase 2, open-label study in patients with previously-treated multiple myeloma. Results demonstrated median progression-free survival of 33 months and an objective response rate of 92 percent among patients treated with the investigational monoclonal antibody elotuzumab (10 mg/kg) in combination with lenalidomide and low-dose dexamethasone.
- On June 20, the board of directors of AbbVie declared a quarterly cash dividend of \$0.40 per share, payable Aug. 15, 2013 to stockholders of record at the close of business on July 15, 2013. AbbVie was named to the S&P 500 Dividend Aristocrats Index.

Raising Full-Year 2013 Outlook

AbbVie is raising its diluted earnings-per-share guidance for the full-year 2013 to \$3.07 to \$3.13 (from \$3.03 to \$3.13) on an adjusted basis, or \$2.66 to \$2.72 on a GAAP basis. The company's 2013 adjusted diluted earnings-per-share guidance excludes \$0.41 per share of intangible asset amortization expense, acquired in-process research and development, and other specified items primarily associated with certain separation-related costs and ongoing restructuring activities.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. In 2013, AbbVie employs approximately 21,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit <u>www.abbvie.com</u>. Follow <u>@abbvie</u> on Twitter or view careers on our <u>Facebook</u> or <u>LinkedIn</u> page.

Conference Call

AbbVie will host an investor conference call today at 8:00 a.m. Central time to discuss our second-quarter performance. Participating on the call will be Rick Gonzalez, chairman and chief executive officer; Bill Chase, executive vice president and chief financial officer; Laura Schumacher, executive vice president of business development, external affairs and general counsel; Scott Brun, vice president of clinical development; and Larry Peepo, vice president of investor relations. The call will be webcast through AbbVie's Investor Relations Web site

at <u>www.abbvieinvestor.com</u>. An archived edition of the call will be available after 11:00 a.m. Central time.

Non-GAAP Financial Results

Financial results for 2013 are presented on both a reported and a non-GAAP basis. Reported results were prepared in accordance with GAAP and include all revenue and expenses recognized during the period. Non-GAAP results adjust for certain non-cash items and for factors that are unusual or unpredictable, and exclude those costs, expenses, and other specified items presented in the reconciliation tables later in this release. AbbVie's management believes non-GAAP financial measures provide useful information to investors regarding AbbVie's results of operations and assist management, analysts, and investors in evaluating the performance of the business. Non-GAAP financial measures should be considered in addition to, and not as a substitute for, measures of financial performance prepared in accordance with GAAP. The company's 2013 financial guidance is also being provided on both a reported and a non-GAAP basis.

Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's 2012 Annual Report on Form 10-K/A, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

| | | | | % Change vs. 2Q12 | | | | | |
|-----------------|---------------------|---------------|--------------|-------------------|----------------------|--------|--------------------|-----------------|--|
| | Sales (in millions) | | | | Interna | tional | Total | | |
| | <u>U.S.</u> | <u>Int'l.</u> | <u>Total</u> | <u>U.S.</u> | Operational Reported | | <u>Operational</u> | Reported | |
| TOTAL SALES | \$2,625 | \$2,067 | \$4,692 | 2.3% | 8.9% | 7.3% | 5.1% | 4.4% | |
| Humira | 1,224 | 1,382 | 2,606 | 16.0 | 10.1 | 8.8 | 12.8 | 12.1 | |
| Kaletra | 66 | 212 | 278 | (5.7) | 4.9 | 3.4 | 2.2 | 1.1 | |
| AndroGel | 258 | | 258 | (6.5) | n/a | n/a | (6.5) | (6.5) | |
| Niaspan | 232 | | 232 | 10.0 | n/a | n/a | 10.0 | 10.0 | |
| Lupron | 144 | 55 | 199 | 2.1 | (8.3) | (8.3) | (1.0) | (1.0) | |
| Synthroid | 153 | | 153 | 24.4 | n/a | n/a | 24.4 | 24.4 | |
| Sevoflurane | 19 | 118 | 137 | | (9.7) | (11.9) | (8.5) | (10.5) | |
| TriCor/Trilipix | 107 | | 107 | (65.6) | n/a | n/a | (65.6) | (65.6) | |
| Zemplar | 63 | 44 | 107 | 12.5 | 12.8 | 12.8 | 12.6 | 12.6 | |
| Creon | 106 | | 106 | 20.5 | n/a | n/a | 20.5 | 20.5 | |
| Synagis | | 70 | 70 | n/a | 20.3 | 9.4 | 20.3 | 9.4 | |
| Duodopa | | 44 | 44 | n/a | 22.9 | 25.7 | 22.9 | 25.7 | |

AbbVie Inc. Key Product Sales Quarter Ended June 30, 2013 (Unaudited)

Note: "Operational" growth reflects the percentage change over the prior year excluding the impact of exchange rate fluctuations. n/a = not applicable

AbbVie Inc. Key Product Sales Six Months Ended June 30, 2013 (Unaudited)

| | % Change vs. 6M | % Change vs. 6M12 | | | | |
|---------------------|-----------------|-------------------|--|--|--|--|
| Sales (in millions) | International | Total | | | | |

| | <u>U.S.</u> | <u>Int'l.</u> | <u>Total</u> | <u>U.S.</u> | Operational | Reported | Operational | Reported |
|-----------------|-------------|---------------|--------------|-------------|--------------------|-----------------|--------------------|-----------------|
| TOTAL SALES | \$4,747 | \$4,274 | \$9,021 | 1.1% | 9.9% | 7.7% | 5.1% | 4.1% |
| Humira | 2,180 | 2,670 | 4,850 | 19.3 | 11.5 | 9.8 | 14.8 | 13.9 |
| AndroGel | 498 | | 498 | (2.0) | n/a | n/a | (2.0) | (2.0) |
| Kaletra | 118 | 379 | 497 | (5.6) | 3.8 | 2.2 | 1.4 | 0.2 |
| Niaspan | 418 | | 418 | 4.0 | n/a | n/a | 4.0 | 4.0 |
| Synagis | | 415 | 415 | n/a | 8.5 | 1.2 | 8.5 | 1.2 |
| Lupron | 269 | 111 | 380 | (4.6) | (5.1) | (5.9) | (4.8) | (5.0) |
| Sevoflurane | 35 | 239 | 274 | 6.1 | (11.6) | (13.4) | (9.7) | (11.3) |
| Synthroid | 272 | | 272 | 7.9 | n/a | n/a | 7.9 | 7.9 |
| TriCor/Trilipix | 235 | | 235 | (58.4) | n/a | n/a | (58.4) | (58.4) |
| Creon | 196 | | 196 | 25.6 | n/a | n/a | 25.6 | 25.6 |
| Zemplar | 104 | 84 | 188 | (4.6) | 10.5 | 10.5 | 1.6 | 1.6 |
| Duodopa | | 83 | 83 | n/a ′ | 15.5 | 16.9 | 15.5 | 16.9 |

Note: "Operational" growth reflects the percentage change over the prior year excluding the impact of exchange rate fluctuations. n/a = not applicable

AbbVie Inc. Consolidated Statements of Earnings Quarter and Six Months Ended June 30, 2013 and 2012 (Unaudited) (In millions, except per share data)

| | Second Quarter Ended June 30 | | Six Months Ended June 30 | |
|----------------------------------------------|---------------------------------|---------|-----------------------------|---------|
| | 2013 | 2012 | 2013 | 2012 |
| Net sales | \$4,692 | \$4,493 | \$9,021 | \$8,666 |
| Cost of products sold | 1,054 | 1,073 | 2,207 | 2,229 |
| Selling, general and administrative | 1,406 | 1,246 | 2,643 | 2,493 |
| Research and development | 709 | 642 | 1,343 | 1,284 |
| Acquired in-process research and development | 70 | 110 | 70 | 260 |
| Total operating cost and expenses | 3,239 | 3,071 | 6,263 | 6,266 |
| Operating earnings | 1,453 | 1,422 | 2,758 | 2,400 |
| Interest (income) expense, net | 75 | (2) | 141 | (3) |
| Net foreign exchange (gain) loss | 14 | 11 | 29 | 21 |
| Other (income) expense, net | (4) | 11 | (19) | (26) |
| Earnings before income tax | 1,368 | 1,402 | 2,607 | 2,408 |
| Income tax expense | 300 | 135 | 571 | 258 |
| Net earnings | \$1,068 | \$1,267 | \$2,036 | \$2,150 |
| Diluted earnings per share | \$0.66 | \$0.80 | \$1.27 | \$1.36 |
| Average diluted shares outstanding | 1,609 | 1,577 | 1,605 | 1,577 |

Note: On January 1, 2013, Abbott Laboratories distributed 1,577 million shares of AbbVie common stock to Abbott's shareholders in connection with the separation of AbbVie from Abbott. The computation of diluted earnings per share for the quarter and six months ended June 30, 2012 was calculated using the shares distributed on January 1, 2013.

AbbVie Inc. Reconciliation of GAAP Reported to Non-GAAP Adjusted Information Quarter Ended June 30, 2013 (Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

| | 2Q13 | | | | |
|-------------------------------|---------|-----------|--------|--|--|
| | Earning | Earnings | | | |
| | Pre-tax | After-tax | EPS | | |
| As reported (GAAP) | \$1,368 | \$1,068 | \$0.66 | | |
| Adjusted for specified items: | | | | | |
| Intangible asset amortization | 136 | 98 | 0.06 | | |
| Separation costs | 67 | 42 | 0.03 | | |
| Acquired IPR&D | 70 | 70 | 0.04 | | |
| Restructuring/Other | 57 | 41 | 0.03 | | |
| As adjusted (non-GAAP) | \$1,698 | \$1,319 | \$0.82 | | |

Intangible asset amortization reflects costs recognized as a result of licensing and acquisition activities. Separation costs are expenses related to the separation of AbbVie from Abbott. Acquired IPR&D reflects the upfront payment related to the previously announced collaboration with Alvine Pharmaceuticals. Restructuring/Other is primarily associated with ongoing restructuring activities.

2. The impact of the specified items by line item was as follows:

| | | | | 2Q13 | |
|-------------------------------|------------------|---------|-------|----------|----------------|
| | Cost of products | 0004 | | Acquired | Other (income) |
| | sold | SG&A | R&D | IPR&D | expense |
| As reported (GAAP) | \$1,054 | \$1,406 | \$709 | \$70 | (\$4) |
| Adjusted for specified items: | | | | | |
| Intangible asset amortization | (136) | | | | |
| Separation costs | (4) | (60) | (3) | | |
| Acquired IPR&D | | | | (70) | |
| Restructuring/Other | (7) | (36) | (11) | | (3) |
| As adjusted (non-GAAP) | \$907 | \$1,310 | \$695 | | (\$7) |

3. The adjusted tax rate for the second quarter was 22.3 percent, as detailed below:

| | 2Q13 | | | | |
|------------------------|----------------|-------|----------|--|--|
| | Pre-tax Income | | | | |
| | income | taxes | Tax rate | | |
| As reported (GAAP) | \$1,368 | \$300 | 21.9% | | |
| Specified items | 330 | 79 | 23.9% | | |
| As adjusted (non-GAAP) | \$1,698 | \$379 | 22.3% | | |

SOURCE AbbVie Inc.

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