

FOR FURTHER INFORMATION CONTACT

Ausa Vickie E. Leduc or Marcia Murphy at 410-209-4885

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BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. TO PAY \$95 MILLION TO
RESOLVE OFF-LABEL PROMOTION AND KICKBACK ALLEGATIONS

Baltimore, Maryland - Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") has agreed to pay \$95 million to resolve civil liability arising from the unlawful marketing of certain pharmaceutical products, the United States Attorney for the District of Maryland announced today.

According to the agreement reached with the government, the Connecticut based company will pay \$95 million to resolve civil allegations under the False Claims Act that the company unlawfully marketed Aggrenox, Combivent and Micardis, and caused false claims to be submitted to the government health care programs. The Food and Drug Administration ("FDA") has approved Aggrenox to prevent secondary strokes, Combivent to treat continued symptoms of a bronchospasm in patients with Chronic Obstructive Pulmonary Disease ("COPD") who already are on a bronchodilator, and Micardis to treat hypertension.

Specifically, the civil settlement resolves allegations that BIPI unlawfully marketed (1) Aggrenox for a variety of uses, including for certain cardiovascular events such as myocardial infarction and peripheral vascular disease, which were not medically accepted indications and were not covered by federal health care programs, (2) Combivent for use prior to another bronchodilator in treating Chronic Obstructive Pulmonary Disease, a use that was not medically accepted and was not covered by federal health care programs and (3) Micardis for treatment of early diabetic kidney disease which was not a medically accepted indication and was not covered by federal healthcare programs.

Additionally, the settlement resolves allegations that BIPI knowingly promoted the sale and use of Combivent and Atrovent at doses that exceeded those covered by federal health care programs and that BIPI knowingly made unsubstantiated claims about the efficacy of Aggrenox, including that it was superior to Plavix. Finally, the agreement resolves allegations that the company paid kickbacks to health care professionals to induce them to prescribe Aggrenox, Atrovent, Combivent and Micardis. The federal share of the civil settlement is \$78,455,048 and the state Medicaid share of the civil settlement is \$16,544,951.

"Pharmaceutical companies cannot market drugs for unapproved uses, make unwarranted claims about their benefits, or pay kickbacks to doctors who prescribe them," added United States Attorney for the District of Maryland Rod J. Rosenstein. "Drugs

should be marketed only for purposes for which they are deemed safe and effective, and a doctor's decision to prescribe a drug should not be influenced by his personal financial interest."

The settlement resolves a whistleblower lawsuit filed under the qui tam or whistleblower provisions of the False Claims Act that is pending in the District of Maryland: U.S. ex rel. Heiden v. Boehringer Ingelheim, et al. As part of today's resolution, the whistleblower will receive payments totaling more than \$17million from the federal share of the civil recovery.

Also as part of the settlement, Boehringer Ingelheim Pharmaceuticals, Inc. has agreed to enter into an expansive Corporate Integrity Agreement that provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to the settlement.

The civil settlement was reached by the U.S. Attorney's Office for the District of Maryland and the Justice Department's Civil Division. The Corporate Integrity Agreement was negotiated by the Office of the Counsel to the Inspector General of the Department of Health and Human Services. Investigative support was provided by Department of Defense Criminal Investigative Services, the Office of Inspector General of the Department of Health and Human Services, the Federal Bureau of Investigation, the Inspector General for the Office of Personnel Management, the Office of Inspector General for Veteran's Affairs and the Office of Criminal Investigations, Food and Drug Administration. Assistance also was provided by the National Association of Medicaid Fraud Control Units and offices of various state Attorneys General. The case was handled by Assistant United States Attorneys Thomas Corcoran and Roann Nichols and Trial Attorney Brian McCabe of the Department of Justice Civil Fraud Section.