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Wyeth Breast Cancer 03 16

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TO BUSINESS, HEALTH AND MEDICAL EDITORS:

Wyeth Pharmaceuticals Announces Termination of Phase 3 Clinical Program with

Oral Temsirolimus in Women with Metastatic Breast Cancer

Ongoing Phase 3 Studies With I.V. Temsirolimus in Renal Cell Carcinoma and

Mantle Cell Lymphoma Continue

MADISON, N.J., March 16 /PRNewswire-FirstCall/ -- Wyeth Pharmaceuticals, a

division of Wyeth (NYSE: WYE), announced today its decision to discontinue the

HORIZON phase 3 clinical trial program of Wyeth's investigational drug

temsirolimus oral tablets in combination with letrozole (Femara(R)), a

currently approved breast cancer therapy, for first-line use in postmenopausal

women with hormone-receptor positive metastatic breast cancer. This decision

was based upon the recommendation of an Independent Data Monitoring Committee

(IDMC) after review of data from a planned interim analysis.

The HORIZON study compared the combination of temsirolimus oral tablets

and letrozole versus letrozole alone. The IDMC advised that continuation of the trial was unlikely to achieve the targeted level of efficacy for the combination therapy compared to letrozole alone. The IDMC concluded, therefore, that the risk/benefit ratio for treatment of metastatic breast cancer did not favor continuation and recommended that the trial be discontinued.

"While not the anticipated outcome, it is unfortunately not unusual for cancer drugs to work in some tumor types and not others, or even work in only some specific subpopulations of cancer patients," says Gary L. Stiles, M.D., FACC, Executive Vice President and Chief Medical Officer, Wyeth Pharmaceuticals. "We remain committed to studying temsirolimus in other cancer indications."

While the phase 3 trial for women with hormone-receptor positive metastatic breast cancer involved an oral formulation of temsirolimus, two other phase 3 clinical trials studying temsirolimus in renal cell carcinoma and mantle cell lymphoma using an intravenous formulation are continuing. After a recent review of the data, the IDMC for the renal cancer study indicated that study continue as planned.

About the IDMC and the Interim Analysis

The IDMC consists of independent experts in medical oncology, statistics and medical ethics, who are not participating in the clinical trials, whose primary responsibility is to monitor, on a periodic basis, the data emerging from a clinical trial and to provide recommendations to the sponsor on whether a study should be modified or discontinued.

About Temsirolimus

Temsirolimus is a targeted investigational drug that specifically inhibits mTOR (mammalian target of rapamycin) kinase, a protein critical for tumor growth and cell survival. Enrollment continues as planned with other ongoing clinical trials with temsirolimus in the oncology setting. In addition to Wyeth's ongoing renal cell carcinoma and mantle cell lymphoma phase 3 trials, independent investigators are evaluating temsirolimus in clinical trials in prostate cancer, and head and neck cancer. These and other early oncology trials with temsirolimus are being conducted through a cooperative research and development agreement with the National Cancer Institute. Anti-tumor activity with this agent has been previously reported in phase 1 and phase 2 studies.

Wyeth Pharmaceuticals

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events that involve risks and uncertainties including, without limitation, risks

associated with the inherent uncertainty of the timing and success of pharmaceutical research, product development, manufacturing, commercialization, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade-buying patterns, wars or terrorist acts, product liability and other types of lawsuits, the impact of legislation and regulatory compliance and obtaining reimbursement, favorable drug pricing, access and other approvals, environmental liabilities, and patent, and other risks and uncertainties, including those detailed from time to time in the Company's periodic reports, including current reports on Form 8-K, quarterly reports on Form 10-Q and the annual report on Form 10-K, filed with the Securities and Exchange Commission. Actual results may vary materially from the forward-looking statements. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

SOURCE Wyeth

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