

U.S. FDA grants priority review for Femara for new indication as first ever post-tamoxifen treatment for early breast cancer in postmenopausal women

Agency expected to give decision before end of year

Basel, June 29, 2004 — Novartis Oncology announced today that its supplementary New Drug Application for Femara® (letrozole) has been granted priority review by the U.S. Food and Drug Administration (FDA) for an indication in the extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy.

The FDA grants priority review to products that appear to represent a significant advance for serious or life-threatening diseases. The application was filed at the end of April 2004. The priority review establishes an action date no later than six months after the filing date. Femara received its first approval for this new indication from the Mexican health authorities earlier this month. Novartis Oncology has also submitted marketing applications for this new indication in the European Union, Canada and Switzerland among other countries.

“We are pleased the FDA recognizes the potential for Femara to fulfill an important unmet medical need of postmenopausal women to reduce their risk of recurrence of breast cancer following completion of therapy with tamoxifen,” said Diane Young, MD, vice president, global head, Clinical Development, Novartis Oncology.

In women with early breast cancer, adjuvant therapy with tamoxifen has not been shown to provide additional benefit after five years and, traditionally, most women have not received treatment after completion of adjuvant tamoxifen therapy. More than half of the recurrences of breast cancer occur after the completion of standard adjuvant therapy with tamoxifen. Recurrence of breast cancer after initial treatment places patients at greater risk of developing distant metastases and of dying of the disease.

There is currently no post-tamoxifen therapy available for the approximately 100,000 women who complete tamoxifen therapy in the United States each year. Upon completion of tamoxifen therapy, many of these women are potential candidates for treatment with Femara.

The filing for this new indication was based on data from the landmark MA-17 trial. MA-17 is the first study that has provided clinical evidence to support the use of a medication, Femara, to reduce the risk of breast cancer recurrence during this extended adjuvant (post-tamoxifen) period. Coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario and supported by Novartis, the MA-17 study evaluated extended adjuvant treatment with Femara vs. placebo in over 5,100 postmenopausal women with early breast cancer. Interim results from MA-17 received an expedited review from the *New England Journal of Medicine* and were published in October 2003. Updated results of the study were presented earlier this month at the annual meeting of the American Society of Clinical Oncology held in New Orleans.

About Femara

Femara, an aromatase inhibitor, is an oral once-a-day first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. It is also approved for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is currently available in more than 80 countries worldwide. Not all indications are available in every country.

Femara Contraindications and Adverse Events

In the interim MA-17 analysis, the most common adverse events were hot flashes, sweating, edema, hypercholesterolemia, headache, arthralgia, myalgia, fatigue, constipation and dizziness, in greater than 10% of patients in either arm of the study. Of these, hot flashes, arthralgia, and myalgia were more common in those receiving Femara than placebo ($P < 0.05$). Vaginal bleeding was more common in those taking placebo ($P = 0.01$). The MA-17 researchers noted a trend toward newly diagnosed cases of osteoporosis in women taking Femara vs. placebo (5.7 vs. 4.5%; $P = 0.07$) and, at two years there was a mean decrease in bone mineral density in the hip from baseline as compared to placebo (3.0 vs. 0.4%; $P = 0.048$).

Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. Femara is generally well tolerated and adverse reaction rates in the first-line study in which Femara was compared with tamoxifen were similar with those seen in second-line studies. The most commonly reported adverse events for Femara vs. tamoxifen were bone pain (22% vs. 21%), hot flashes (19% vs. 16%), back pain (18% vs. 19%), nausea (17% vs. 17%), dyspnea or labored breathing (18% vs. 17%), arthralgia (16% vs. 15%), fatigue (13% vs. 13%), coughing (13% vs. 13%), constipation (10% vs. 11%), chest pain (6% vs. 6%) and headache (8% vs. 6%). Femara may cause fetal harm when administered to pregnant women. The incidence of peripheral thromboembolic events, cardiovascular events, and cerebrovascular events was 3-4% in each treatment arm.

The foregoing release contains forward-looking statements that can be identified by terminology such as "landmark," "first ever," "potential," "appear to represent a significant advance" or similar expressions, or by express or implied discussions regarding potential new indications for Femara or potential future sales of Femara, or regarding the long-term impact of a patient's use of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market. Nor can there be any guarantee regarding potential future sales of Femara. Neither can there be any guarantee regarding the long-term impact of a patient's use of Femara. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78,500 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

Additional information regarding Femara or Novartis Oncology can contact the websites www.femara.com or www.novartisoncology.com or additional media information can be found at www.novartisoncologyvpo.com.

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