

HEALTH

Breast-Cancer Drug Gains Traction

*Early Use of Herceptin
May Expand in Europe;
Access Is Sought in U.S.*

By JEANNE WHALEN

AN EXPENSIVE DRUG that has proven effective at fighting early breast cancer is likely to be more widely available in Europe soon, pleasing patients who have been lobbying hard for the treatment but increasing pressure on Europe's cash-strapped health-care budgets.

Late last week, Europe's main medical regulator recommended that the drug, Herceptin, be approved to treat the early stages of a particularly aggressive kind of tumor that produces the protein HER-2. The regulator's recommendations need to be endorsed by the European Commission, the European Union's executive body, which typically signs off on them within a few months.

Patients in the U.S. have also been pushing for earlier access to Herceptin, which has been on the market for several years as a late-stage treatment for HER-2 breast cancer. In February, the drug's makers asked the Food and Drug Administration to approve Herceptin for early-stage use, and the FDA granted the application "priority review" status, which means the agency must make a decision within six months.

About 20% to 30% of women with breast cancer have this form of the disease. Herceptin costs tens of thousands of dollars a year per person. Herceptin is sold by Genentech Inc. of South San Francisco, Calif., and Roche Holding AG of Basel, Switzerland.

The drug has long been prescribed to women with advanced HER-2 breast cancer, but new research published last year showed that Herceptin, in combination with chemotherapy, reduced the risk of cancer recurring by 52%, compared with chemotherapy alone, in the early stages of disease. This news prompted many physicians world-wide to begin prescribing Herceptin for earlier stages of the disease.

In the fragmented U.S. health-care market, where many patients are covered by a variety of health-care providers, it isn't clear how widely Herceptin is covered for early breast-cancer use. But the drug's sales have more than doubled since news of Herceptin's effectiveness against early-stage breast cancer was first reported last spring. In this year's first quarter, Herceptin had U.S. sales of \$290 million, com-

pared with \$130 million in the first quarter of 2005, according to Genentech.

"We do know there has been early uptake [of Herceptin] in the early adjuvant setting. I just don't know what that's involved from an insurance standpoint," a Genentech spokeswoman said. She added that the drug would likely be universally insured for early-stage use if it receives FDA approval.

In Europe, meanwhile, the new request for treatment for early-stage breast cancer has sparked a debate about the high cost of cancer therapies.

In Britain, the taxpayer-funded health service has declined to provide Herceptin free of charge to many women with early-stage cancer in recent months, even after their physicians prescribed the drug. Some hospitals said they were declining the request because the medicine hadn't been licensed by the European Medicines Agency for early-stage use. Doctors have the right to prescribe medicines on an "off-label" basis, for conditions for which the drugs aren't yet licensed.

While no hospitals have explicitly refused to supply Herceptin for cost reasons, most patients say they believe cost has been a big factor. Many of the National Health Service's regional units are either in debt or barely breaking even, particularly as price tags rise on a dizzying array of new medical treatment. Suzanne Digwood, a breast-cancer patient who was recently denied Herceptin by her health authority in Shropshire county, England, says she believes officials are

"using any excuse at all not to fund" the medication because of its expense.

Ms. Digwood and several other women in her county have resorted to raising money from friends and family to pay for their own Herceptin treatment, which costs between £21,000 and £47,000 (\$38,300 and \$85,700) a year in the United Kingdom, according to cancer patients and Roche. The Shropshire women set up a Web site—www.ShropshireSix.com—to publicize their predicament. Other women have re-mortgaged their homes or spent their pension savings to pay for Herceptin, according to Clara Mackay, director of policy and research at Breast Cancer Care, a charity in London.

At least one woman has filed a lawsuit against the National Health Service. Last month, Ann Marie Rogers won a court case against her local health-service unit. An appeals court ruled that the health service had acted illegally in declining to provide Ms. Rogers with Herceptin. It is unclear whether that ruling is forcing other health-service units to provide the drug free of charge.

Herceptin's licensing in Europe as an early-stage treatment should make it easier for patients to get the drug from their national health services. But in Britain, the drug must jump through an additional hoop: It must also be endorsed by the National Institute for Health and Clinical Excellence, or NICE, which weighs benefits versus costs of all drugs before allowing NHS doctors to prescribe them. A NICE spokesman said the agency should make a preliminary decision on Herceptin for early breast cancer by August.