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FDA Approves Genentech's Kadcyla (Ado-Trastuzumab Emtansine), the First Antibody-Drug Conjugate for Treating Her2-Positive Metastatic Breast Cancer

New Personalized Medicine Helped People in Phase III Study Live Longer, Compared to Standard Treatment

South San Francisco, Calif. -- February 22, 2013 -- Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) has approved Kadcyla (ado-trastuzumab emtansine or T-DM1) for the treatment of people with HER2-positive metastatic breast cancer (mBC) who have received prior treatment with Herceptin® (trastuzumab) and a taxane chemotherapy. Kadcyla is the fourth medicine from Genentech to receive FDA approval for people with advanced cancers within the past two years.

An antibody-drug conjugate (ADC) is a new kind of targeted cancer medicine that can attach to certain types of cancer cells and deliver chemotherapy directly to them. Kadcyla is the first FDA-approved ADC for treating HER2-positive mBC, an aggressive form of the disease.

"Kadcyla is an antibody-drug conjugate representing a completely new way to treat HER2-positive metastatic breast cancer, and it helped people in the EMILIA study live nearly six months longer," said Hal Barron, M.D., chief medical officer

and head, Global Product Development. "We currently have more than 25 antibody-drug conjugates in our pipeline and hope this promising approach will help us deliver more medicines to fight other cancers in the future."

Kadcyla is made up of the antibody, trastuzumab, and the chemotherapy, DM1, joined together using a stable linker. Kadcyla combines the mechanisms of action of both trastuzumab and DM1, and it is the first Genentech ADC approved by the FDA. Genentech has studied ADC science for more than a decade and has eight ADCs in Phase I or Phase II studies for different types of cancer.

Kadcyla will be available to people in the United States within two weeks. As part of this approval, Genentech plans to initiate patient assistance programs for people taking Kadcyla through Genentech Access Solutions. These programs help people who might not be able to afford this medicine. People who do not have health insurance, or who have reached the lifetime limit set by their insurance company, might qualify to receive Kadcyla free of charge. For people with insurance, Genentech Access Solutions offers co-pay assistance programs to help with the out-of-pocket costs of their medicine, including a co-pay card for those with private insurance. The card pays 80 percent of out-of-pocket costs for people who qualify (up to $9,000 or $24,000 per year, depending on the person's income).

Doctors can contact Genentech Access Solutions at (888) 249-4918. More information is also available at http://www.Genentech-Access.com.

Roche has also submitted a Marketing Authorization Application to other regulatory authorities around the world, including the European Medicines Agency (EMA), for Kadcyla for the treatment of people with HER2-positive mBC. This application is currently under review by the EMA.

Kadcyla Efficacy in HER2-positive mBC

The FDA approval of Kadcyla is based on results from EMILIA (TDM4370g/BO21977), an international, Phase III, randomized, open-label study comparing Kadcyla alone to lapatinib in combination with Xeloda® (capecitabine) in 991 people with HER2-positive locally advanced breast cancer or mBC who had previously been treated with Herceptin and a taxane chemotherapy. Results include:

- The study met both co-primary efficacy endpoints of overall survival and progression-free survival (PFS; as assessed by an independent review committee).
- People who received Kadcyla lived a median of 5.8 months longer (overall survival) than those who received the combination of lapatinib and Xeloda, the standard of care in this setting (median overall survival: 30.9 months vs. 25.1 months).
- People receiving Kadcyla experienced a 32 percent reduction in the risk of dying compared to people who received lapatinib and Xeloda (HR=0.68; p=0.0006).
- People who received Kadcyla lived significantly longer without their disease getting worse (PFS) compared to those who received lapatinib plus Xeloda (HR=0.65, 35 percent reduction in risk of disease worsening or death, p No new safety signals were observed and adverse events (AEs) were consistent with those seen in previous studies, with fewer people who received Kadcyla experiencing Grade 3 or higher (severe) AEs than those who received lapatinib plus Xeloda (43.1 percent vs. 59.2 percent).
- For people receiving Kadcyla, the most common (occurring in more than 2 percent of participants) Grade 3 or higher AEs were low platelet count (14.5 percent), increased levels of enzymes released by the liver and other organs (8.0 percent), low red blood cell count (4.1 percent), low levels of potassium in the blood (2.7 percent), nerve problems (2.2 percent) and tiredness (2.5 percent).

About Kadcyla (pronounced kad SIGH luh); ado-trastuzumab emtansine (pronounced ADD oh traz TOO zuh mab em TAN zine)

medicine Genentech has developed for the treatment of HER2-positive breast cancer.

Like Herceptin, Kadcyla binds to HER2-positive cells and is thought to block out-of-control signals that make the cancer grow while also calling on the body's immune system to attack the cancer cells. Once Kadcyla is taken up by those cells, it is designed to destroy them by releasing the DM1 inside the cells.

Genentech licenses technology for Kadcyla under an agreement with ImmunoGen, Inc.

Kadcyla Indication Statement

Kadcyla (ado-trastuzumab emtansine) is approved as a single medicine for the treatment of people with HER2-positive metastatic breast cancer (mBC) who have received prior treatment with Herceptin® (trastuzumab) and a taxane chemotherapy. People should either:

- Have already been treated for their metastatic cancer, or
- Have had their early-stage cancer come back during or within six months after they completed a course of treatment following surgery.

Important Safety Information

Kadcyla is not the same medicine as Herceptin.

There are possible serious side effects of Kadcyla. Patients must contact their doctor right away if they experience any of these symptoms. The patient's doctor may do tests before starting Kadcyla and before each dose to monitor for these side effects. Kadcyla treatment may be stopped or the dose may be lowered if the patient experiences any of these side effects.

Liver Problems

- Kadcyla may cause severe liver problems that can be life-threatening. Symptoms of liver problems may include vomiting, nausea, stomach pain,

Heart Problems

- Kadcyla may cause heart problems, including those without symptoms (such as reduced heart function) and those with symptoms (such as congestive heart failure). Symptoms may include swelling of the ankles or legs, shortness of breath, cough or rapid weight gain of greater than five pounds in less than 24 hours.

Pregnancy

- Receiving Kadcyla during pregnancy can result in the death of an unborn baby and birth defects. Birth control should be used while patients receive Kadcyla and for six months after their last dose of Kadcyla.

- If patients are exposed to Kadcyla during pregnancy, they must contact their healthcare provider right away; they are also encouraged to enroll in the MotHER Pregnancy Registry by contacting (800) 690-6720.

- If patients are mothers who are breastfeeding, they should talk with their doctor about either stopping breastfeeding or stopping treatment with Kadcyla.

Additional Possible Serious Side Effects of Kadcyla

Lung Problems

- Kadcyla may cause lung problems, including inflammation of the lung tissue, which can be life-threatening. Signs of lung problems may include trouble breathing, cough, tiredness and fluid in the lungs.

Infusion-Related Reactions

- Symptoms of an infusion-related reaction may include one or more of the following: the skin getting hot or red (flushing), chills, fever, trouble breathing, low blood pressure, wheezing, tightening of the muscles in the chest around the airways or a fast heartbeat. The patient's doctor will monitor the patient for infusion-related reactions.

Low Platelet Count

- Low platelet count may happen during treatment with Kadcyla. Platelets are cells in the blood that help the blood clot.

Nerve Damage

- Symptoms may include numbness and tingling, burning or sharp pain,

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