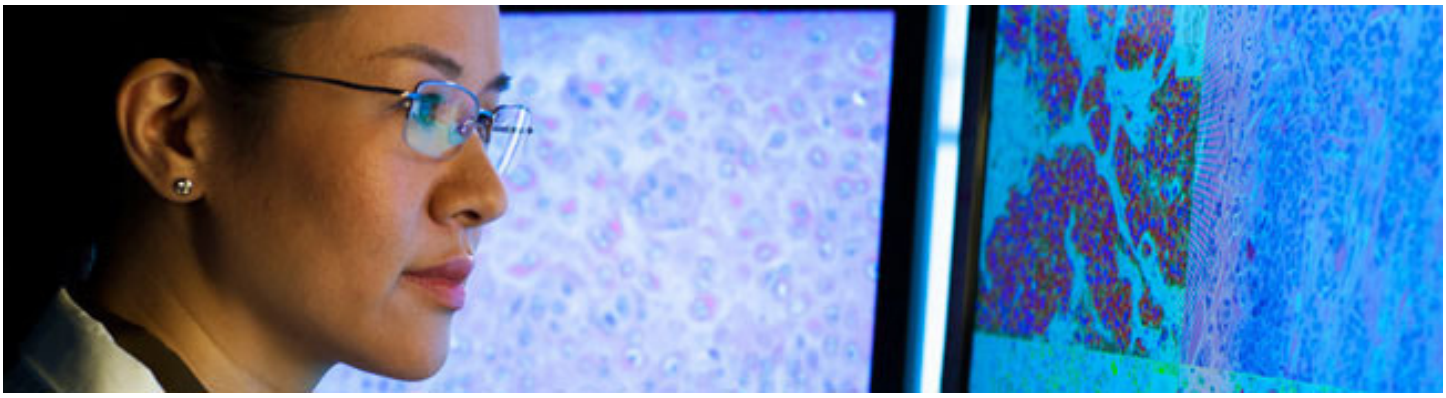


Ventana announces HER2 companion diagnostic to identify breast cancer patients for Roche's latest targeted medicines, Perjeta and Kadcyla

VENTANA HER2 (4B5) IHC assay label expansion coincides with therapy availability in many non-U.S. countries globally

Tucson, Ariz., Dec. 13, 2013 - Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, a member of the Roche Group, today announces the VENTANA HER2/neu (4B5) Rabbit Monoclonal Primary Antibody assay as a companion diagnostic*1* for detecting HER2 protein expression for patients who, in countries where they are approved, may be appropriate candidates for Perjeta® (pertuzumab) and Kadcyla™ (ado-trastuzumab emtansine). Previously, the VENTANA HER2 (4B5) test was labeled only for the identification of HER2-positive breast and gastric cancer patients for whom Herceptin® (trastuzumab) treatment is being considered.

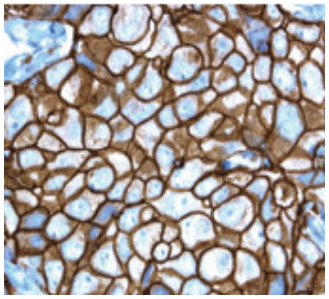
"In line with our mission to improve the lives of all patients afflicted with cancer, our HER2 assay will continue to provide important diagnostic information for breast cancer treatment decisions," says Mara G. Aspinall, President, Ventana Medical Systems, Inc. *"We are proud to be the preferred tissue diagnostics partner for our Roche Pharma colleagues. This announcement also signifies the unique ability of Roche to deliver healthcare to cancer patients worldwide."*

Breast cancer is the most common cancer worldwide for women[2] and the second leading cause of female cancer-related deaths[3]. Approximately one-fifth of breast cancers are classified as HER2-positive and if left untreated are associated with poorer clinical outcomes4. Defining HER2 status allows the treatment team to better identify which patients may be appropriate candidates for a treatment regimen with a HER2 targeted medicine.

"Ventana is a global leader in companion diagnostics. Our HER2 diagnostics portfolio, including both the VENTANA IHC and INFORM HER2 Dual ISH assays, is the market leader in terms of automation, medical value and customer adoption," says Doug Ward, Vice President, Companion Diagnostics, Ventana Medical Systems, Inc. *"We are working to enable the VENTANA HER2 (4B5) IHC companion diagnostic assay in all markets where Perjeta and Kadcyla are available for therapy, bringing this technology to physicians and patients worldwide."*

In addition to Roche, Ventana has worked with more than 45 bio-pharmaceutical partners over the past decade and is currently engaged in over 150 collaborative projects to develop and commercialize companion diagnostics globally.

Downloads



Breast carcinoma HER2 (4B5) positive, Score: 3+ Magnification: 40X

Request High Resolution Files

For more than a decade, Herceptin (trastuzumab), a HER2-directed therapy, has been approved by health authorities for people with HER2-positive breast cancer. To further help build on the progress made with Herceptin, Roche has recently introduced two additional HER2-directed therapies, Perjeta (pertuzumab) and Kadcyla (ado-trastuzumab emtansine).

Perjeta® (pertuzumab) is approved for use in combination with Herceptin® (trastuzumab) and docetaxel chemotherapy in people with HER2-positive breast cancer that has spread to different parts of the body (metastatic) and who have not received anti-HER2 therapy or chemotherapy for metastatic disease.

Kadcyla™ (ado-trastuzumab emtansine) is approved 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.

Herceptin is approved for the treatment of early-stage breast cancer that is Human Epidermal growth factor Receptor 2-positive (HER2+) and has spread into the lymph nodes, or is HER2+ and has not spread into the lymph nodes. If it has not spread into the lymph nodes, the cancer needs to be estrogen receptor/progesterone receptor (ER/PR)-negative or have one high risk feature.* Herceptin can be used in several different ways:

- As part of a treatment course including the chemotherapy drugs doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel. This treatment course is known as "AC®TH"
- With the chemotherapy drugs docetaxel and carboplatin. This treatment course is known as "TCH"
- Alone after treatment with multiple other therapies, including an anthracycline-based therapy (a type of chemotherapy)

*High risk is defined as ER/PR-positive with one of the following features: tumor size >2 cm, age <35 years, or tumor grade 2 or 3.

Herceptin has two approved uses in metastatic breast cancer:

- Herceptin in combination with the chemotherapy drug paclitaxel is approved for the first line treatment of Human Epidermal growth factor Receptor 2-positive (HER2+) metastatic breast cancer
- Herceptin alone is approved for the treatment of HER2+ breast cancer in patients who have received one or more chemotherapy courses for metastatic disease

Herceptin is approved, in combination with chemotherapy (cisplatin and either capecitabine or 5-fluorouracil), for the treatment of HER2+ metastatic cancer of the stomach or gastroesophageal junction (where the esophagus meets the stomach) in patients who have not received prior treatment for their metastatic disease.

Perjeta Important Safety Information

- Not all people have serious side effects; however, side effects with Perjeta therapy are common. It is important to know what side effects may happen and what symptoms patients should watch for
- A patient's doctor may stop treatment if serious side effects happen. Patients must contact their healthcare team right away if they have questions or are worried about any side effects

Most serious side effects:

Perjeta may cause heart problems, including those without symptoms (such as reduced heart function) and those with symptoms (such as congestive heart failure).

- A patient's doctor may run tests to monitor the patient's heart function before and during treatment with Perjeta

Receiving Perjeta during pregnancy can result in the death of an unborn baby and birth defects.

- Birth control should be used while receiving Perjeta and for 6 months after a patient's last dose of Perjeta. If a patient is a mother who is breastfeeding, the patient should talk with her doctor about either stopping breastfeeding or stopping Perjeta
- If a patient thinks she may be pregnant, the patient should contact their healthcare provider immediately

If a patient is exposed to Perjeta during pregnancy, the patient is encouraged to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720.

Other possible serious side effects:

- Perjeta should not be used in patients who are allergic to pertuzumab or to any of the ingredients in Perjeta
- Infusion-related reactions: Perjeta is a medicine that is delivered into a vein through a needle. This process can cause reactions known as infusion-related reactions. The most common infusion-related reactions when receiving Perjeta, Herceptin, and docetaxel (chemotherapy) were feeling tired, abnormal or altered taste, allergic reactions, muscle pain, and vomiting
- Severe allergic reactions: Some people receiving Perjeta may have severe allergic reactions, called hypersensitivity reactions or anaphylaxis. This reaction may be severe, may happen quickly, and may affect many areas of the body

Perjeta has only been shown to work in people with HER2-positive breast cancer. Patients must have a HER2 test to know if their breast cancer is HER2-positive before receiving an anti-HER2 treatment, such as Perjeta.

Most common side effects:

The most common side effects of Perjeta when given with Herceptin and docetaxel (chemotherapy) for treatment of breast cancer that has spread to other parts of the body (metastatic) are diarrhea, hair loss, low levels of white blood cells with or without a fever, nausea, feeling tired, rash, damage to the nerves (numbness, tingling, pain in hands/feet).

Report side effects to Genentech and the FDA. Report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. Report side effects to Genentech at (888) 835-2555.

Please see Perjeta full Prescribing Information including Most Serious Side Effect for additional Important Safety Information at www.perjeta.com.

Kadcyla Important Safety Information:

Kadcyla is not the same medicine as trastuzumab (Herceptin)

There are possible serious side effects of Kadcyla. 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. Patients must contact their doctor right away if they experience any of these symptoms.

Liver Problems

Kadcyla may cause severe liver problems that can be life-threatening. Symptoms of liver problems may include vomiting, eating disorder (anorexia), nausea, stomach pain, yellowing of the skin (jaundice), dark urine, or itching

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, rapid weight gain of greater than 5lbs in less than 24 hours, dizziness or loss of consciousness, or irregular heart beat

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 6 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 1 (800) 690-6720

If patients are mothers who are breastfeeding, they should talk with their doctor about either stopping breastfeeding or stopping 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, sensitivity to touch, lack of coordination, or muscle weakness or loss of muscle function

Skin Reactions Around the Infusion Site

Kadcyla may leak from the vein or needle and cause reactions such as redness, tenderness, skin irritation, or pain or swelling at the infusion site. If this happens, it is more likely to happen within 24 hours of the infusion

HER2 testing and Kadcyla

Patients must have a HER2 test to determine if their cancer is HER2-positive before taking Kadcyla as benefit has only been shown in patients whose tumors are HER2-positive.

Most common side effects of Kadcyla

The most common side effects seen in people taking Kadcyla were tiredness, nausea, pain that affects the bones, muscles, ligaments, and tendons; low platelet count, headache, liver problems, and constipation.

Report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. Patients and caregivers may also report side effects to Genentech at (888) 835-2555.

For full Prescribing Information and Boxed WARNINGS on Kadcyla please visit http://www.kadcyla.com.

Herceptin Important Safety Information:

Herceptin treatment can result in heart problems, including those without symptoms (such as reduced heart function) and those with symptoms (such as congestive heart failure). One patient died in an adjuvant (early) breast cancer trial from significantly weakened heart muscle. The risk and seriousness of these heart problems were highest in people who received both Herceptin and a certain type of chemotherapy (anthracycline).

Before taking the first dose of Herceptin and during treatment, a patient's doctor should check to see if there are any health conditions that may increase the patient's chance of having serious heart problems. This includes a review of the patient's health history and tests to see how well the heart muscle is working. These tests may include an echocardiogram or a MUGA scan. Some early breast cancer patients may also need to have a test done after they have finished taking Herceptin to see how well their heart muscle is working.

Some patients have had serious infusion reactions and lung problems; fatal infusion reactions have been reported. These reactions usually occur during or within 24 hours of receiving Herceptin.

The patient's doctor may need to completely stop Herceptin treatment if the patient has a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath.

Herceptin can cause harm to the fetus (unborn baby), in some cases death to the fetus, when taken by a pregnant woman. Women who could become pregnant need to use effective birth control methods during Herceptin treatment and for at least 6 months after treatment with Herceptin. Nursing mothers treated with Herceptin should discontinue nursing or discontinue Herceptin.

Worsening of low white blood cell counts associated with chemotherapy has also occurred.

Patients must have a HER2 test to determine if their breast or stomach cancer is HER2 positive before using Herceptin, as benefit has only been shown in patients that are HER2 positive.

The most common side effects associated with Herceptin in patients with breast cancer are fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, shortness of breath, rash, low white and red blood cells, and muscle pain.

The most common side effects associated with Herceptin in patients with stomach cancer are low white blood cell counts, diarrhea, fatigue, low red blood cell counts, inflammation of the lining of the mouth, weight loss, upper respiratory tract infections, fever, low platelet counts, swelling of mucus membranes, swelling of the nose and throat, and a change in taste.

Because everyone is different, it is not possible to predict what side effects any one person will have. Patients with questions or concerns about side effects should talk to their doctor.

Report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.

Patients and caregivers may also report side effects to Genentech at (888) 835-2555.

Patients should read the Herceptin Full Prescribing Information including Boxed WARNINGS, at www.herceptin.com.

About Ventana Medical Systems, Inc.

Ventana Medical Systems, Inc. ("VMSI") (SIX: RO, ROG; OTCQX: RHHBY), a member of the Roche Group, innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. VENTANA products are used in clinical histology and drug development research laboratories worldwide. The company's intuitive, integrated staining, workflow management platforms, and digital pathology solutions optimize laboratory efficiencies to reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving Personalized Healthcare through accelerated drug discovery and the development of "companion diagnostics" to identify the patients most likely to respond favorably to specific therapies.

Visit www.ventana.com to learn more.

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[1]The VENTANA HER2 (4B5) IHC assay is a CE-IVD companion diagnostic available outside the U.S. Check with your local representative for availability in your area. VENTANA HER2/neu (4B5) Rabbit Monoclonal Primary Antibody is not available or approved for use in the United States.

[2]World Health Organization

[3]National Cancer Institute

[4]Sullivan and Swain. Expert Opin. Biol. Ther. 2013. 13(5):779-90