### INDICATIONS:

HER2+ Adjuvant and Metastatic Breast Cancer, Metastatic Gastric Cancer.

# IAM #HER PATIENT BROCHURE

## This is Your Guide to

Stock photo. Not actual patients Societation (trastuzumab-dkst)

## **IMPORTANT SAFETY INFORMATION**

### What are the possible Serious Side Effects with OGIVRI?

OGIVRI is not for everyone. Be sure to contact your doctor if you are experiencing any of the following potentially life-threatening side effects:

HEART PROBLEMS These include congestive heart failure or reduced heart function—with or without symptoms. The risk for and seriousness of these heart problems were highest in people who received both a trastuzumab product and a certain type of chemotherapy (anthracycline). In a study of adjuvant (early) breast cancer, one patient died of significantly weakened heart muscle. Your doctor will check for signs of heart problems before, during, and after treatment with OGIVRI.

### **INFUSION REACTIONS, including:**

Fever and chills, feeling sick to your stomach (nausea), throwing up (vomiting), pain (in some cases at tumor sites), headache, dizziness, shortness of breath.

These signs usually happen within 24 hours after receiving OGIVRI.

### Visit ogivri.com to learn more

Please see complete Important Safety Information on pages 10-11 and the accompanying <u>Full Prescribing Information</u>, including Boxed WARNING.



# I AM #HER

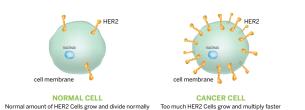
Moving forward, from HER2+ breast cancer diagnosis through treatment, is a personal challenge but you are not alone. Biocon Biologics is on this journey with you by offering a treatment option with OGIVRI. In this brochure, you'll learn how Biocon Biologics also supports your OGIVRI regimen with access services through its My Biocon Biologics<sup>™</sup> program. Biocon Biologics believes you deserve this kind of dedicated support. Because you are not just anybody—

## YOU ARE #HER

## About HER2+ Breast Cancer

HER2+ breast cancer is a breast cancer that tests positive for a protein called <u>H</u>uman <u>E</u>pidermal growth factor <u>R</u>eceptor <u>2</u>-positive (HER2+), which promotes the growth of cancer cells.

A plus sign means the cancer has the protein.



1 out of every 5 breast cancers have extra copies of the gene that make the HER2 protein

# **OGIVRI® AND YOU**

Your doctor has prescribed OGIVRI-

**the first FDA-approved biosimilar to Herceptin**<sup>®</sup> **(trastuzumab)**-for the treatment of your HER2+ breast cancer. OGIVRI is proven to be as safe and effective as Herceptin. OGIVRI is an important part of the fuller collaboration between you, your doctor, and your extended care team.



## What is OGIVRI®?

## ADJUVANT BREAST CANCER

OGIVRI is a prescription medicine used for the treatment of adjuvant breast cancer in adults. OGIVRI is used for the treatment of early-stage breast cancer that is **H**uman **E**pidermal growth factor **R**eceptor **2**-positive (**HER2+**) and has spread into the lymph nodes or is HER2-positive 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 highrisk feature. 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.

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## What is OGIVRI®?

## ADJUVANT BREAST CANCER (continued)

OGIVRI 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 (doxorubicin) based therapy (a type of chemotherapy).



# WHAT IS A BIOSIMILAR?

Biosimilars are **FDA-approved** biologic medications used for treating many illnesses, including cancer. They are made with the same types of natural sources as the original or reference biologic they were compared to (in this case, Herceptin® (trastuzumab)) and **provide the same treatment benefits.** Biosimilars must meet the FDA's rigorous approval standards. This means patients and healthcare professionals can rely upon the safety and effectiveness of the biosimilar, just as they would the original product.

## Biosimilar & Original Biologic

- Same treatment benefits
- Same potential side effects
- Same strength & dosage
- Given the same way





Both biologics and biosimilars are created in living cells

Biologic Biosimilar Biosimilars are highly similar to their

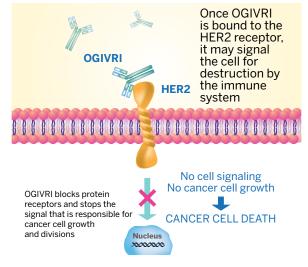
reference biologics



Biosimilars and biologics have the same treatment benefits

# HOW OGIVRI® WORKS

OGIVRI<sup>®</sup> attaches to HER2\* receptors on cells. This may stop the cancer cells from growing and multiplying.



### In an international study, OGIVRI was proven to be as safe and effective as Herceptin for the treatment of HER2+ metastatic breast cancer.

\*Normal cells also have HER2, so HER2 targeted therapies like OGIVRI may also affect healthy cells which may cause serious side effects.

## What is OGIVRI®? (continued)

### METASTATIC BREAST CANCER

OGIVRI has 2 approved uses in metastatic breast cancer in adults:

- OGIVRI 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
- OGIVRI alone is approved for the treatment of HER2positive breast cancer in patients who have received one or more chemotherapy courses for metastatic disease

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## What is OGIVRI®? (continued)

### GASTRIC CANCER

OGIVRI is approved in adults, in combination with chemotherapy (cisplatin and either capecitabine or 5-fluorouracil), for the treatment of HER2-positive 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.

Patients are selected for therapy based on an FDAapproved test for trastuzumab.



# MY OGIVRI<sup>®</sup> TREATMENT

- OGIVRI is administered through an IV infusion once a week for 12 weeks and may be administered in combination with chemotherapy.
- One week after the last weekly dose of OGIVRI, you will continue to receive OGIVRI once every three weeks for as long as your healthcare provider recommends.\*
- Infusion time with OGIVRI is approximately 90 minutes for the initial dose and 30-90 minutes for subsequent doses.



# TREATMENT DAYS

# What to consider bringing on your treatment days:

- A family member or trusted friend, especially on your first day of treatment.
- Your favorite music with headphones, a book, a sweater or pillow anything that will help make you feel more comfortable.
- A list of questions or concerns you may have for your healthcare provider. Be sure to let your healthcare provider know about any changes in your health or your medications, including over-the-counter drugs, vitamins, dietary supplements and/or herbs.

\*Your treatment plan outline may differ depending on the decisions of your healthcare team.

### **IMPORTANT SAFETY INFORMATION**

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Your doctor will check for signs of heart problems before, during, and after treatment with OGIVRI.

## **IMPORTANT SAFETY INFORMATION (continued)**

### INFUSION REACTIONS, including:

Fever and chills, feeling sick to your stomach (nausea), throwing up (vomiting), pain (in some cases at tumor sites), headache, dizziness, shortness of breath.

These signs usually happen within 24 hours after receiving OGIVRI.

### Tell your doctor if you:

# Are a woman who could become pregnant or may be pregnant.

OGIVRI may result in the death of an unborn baby or birth defects.

Contraception should be used while receiving OGIVRI and for seven months after your

last dose of OGIVRI.

Tell your doctor right away if you are exposed to OGIVRI during pregnancy or within 7 months of becoming pregnant.



# IMPORTANT INFORMATION **TO SHARE**

Before starting OGIVRI®, tell your healthcare provider if you

- Are a woman who could become pregnant or may be pregnant
- If you are exposed to OGIVRI during pregnancy or within 7 months of becoming pregnant
- Have any signs of SEVERE LUNG PROBLEMS
- Have LOW WHITE BLOOD CELL COUNTS
- Have any other medical conditions that your healthcare provider is not aware of



### **IMPORTANT SAFETY INFORMATION (continued)**

### What are the possible Serious Side Effects with **OGIVRI? (continued)**

### Have any signs of SEVERE LUNG PROBLEMS, including:

Severe shortness of breath, fluid in or around the lungs, weakening of the valve between the heart and the lungs, not enough oxygen in the body, swelling of the lungs, and scarring of the lungs. Your doctor may check for signs of severe lung problems.

### Have LOW WHITE BLOOD CELL COUNTS

Low white blood cell counts can be life threatening. Low white blood cell counts were seen more often in patients receiving trastuzumab plus chemotherapy than in patients receiving chemotherapy alone. Your doctor may test your blood and check for signs of low white blood cell counts.



# **Providing patient access** support for OGIVRI®

## Your My Biocon Biologics team is here for you

The company's commitment also extends to patient access support through My Biocon Biologics, where a team of dedicated patient access specialists is available to answer calls and address questions you and your providers may have regarding:

### Insurance coverage verification and out-of-pocket costs

- Check patient insurance plan coverage status.
- Determine the patient's deductible and out-ofpocket costs.



### **Copay Assistance**

- Commercially insured patients may be able to access OGIVRI for as little as \$0 copay.
- There are no income restrictions.
- Certain limits and restrictions apply.

## **D** Patient Assistance

- Patients without insurance coverage for OGIVRI who cannot afford their medication may be able to receive their medication free of charge.
- Eligibility requirements apply based on residency, income, and other factors. Contact My Biocon Biologics for more information.

## **Alternate Coverage Identification**

My Biocon Biologics can help identify other resources, such as state programs or thirdparty charitable foundations, that may be able to assist you.

Contact your My Biocon Biologics Specialist or visit www.mybioconbiologicsportal.com

## Experienced and caring My Biocon Biologics patient access specialists are available

Monday - Friday, 9:00 AM to 8:00 PM ET

Phone: 1 (833) 695-2623 💾 Fax: 1 (833) 247-2756

Patient support services and resources are available 24 hours a day, 7 days a week, via the My Biocon Biologics at www.mybioconbiologicsportal.com

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### What are the possible more common side effects of OGIVRI? Side Effects Seen Most Often With OGIVRI

Some patients receiving trastuzumab products, like OGIVRI, for breast cancer had the following side effects:

Fever, feeling sick to your stomach (nausea), throwing up (vomiting), infusion reactions, diarrhea, infections, increased cough, headache, feeling tired, shortness of breath, rash, low white and red blood cell counts, and muscle pain.

# Some patients receiving trastuzumab products, like OGIVRI, for metastatic stomach cancer had the following side effects:

Low white blood cell counts, diarrhea, feeling tired, low red blood cell counts, swelling of the mouth lining, weight loss, upper respiratory tract infections, fever, low platelet counts, swelling of the mucous membranes, swelling of the nose and throat, and change in taste.

These are not all the possible side effects of Ogivri. For more information, ask your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088.** 



# NOTES



This Patient Brochure is meant to help you understand your condition and your treatment. Please use this space to write down information from your healthcare provider and any questions you may have for your healthcare provider.

<sup>S</sup> Ogi	ivri <sup>.</sup>
	umab-dkst) 420mg   150mg

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# YOU ARE #HER

Stock photo. Not actual patient.

# Biocon Biologics is with you on your journey

Biocon Biologics is a proud leader in the advancement of biosimilars. As we continue to drive innovation and invest in the future, our mission is singularly focused on the development, manufacturing, distribution, and commercialization of the highest quality biosimilars in the world. This journey continues with Biocon Biologics biosimilar to Herceptin<sup>®</sup> (trastuzumab), formulations of which are available as an alternate treatment option to patients in over 40 countries.

## www.bioconbiologicsus.com

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