

# Marketing and Advertising in Drug Development

Kevin Wright, PharmD

Regulatory Review Officer

Office of Prescription Drug Promotion (OPDP)

# Presentation Overview

- Mission
- Advice within FDA
- Advice to Industry
- Surveillance and Enforcement

## OPDP's Mission

- Protect the public health by ensuring prescription drug information is truthful, balanced, and accurately communicated
- To guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs

# Advice within FDA

- Professional Labeling
  - Prescribing Information
  - Package labeling
  - Tradename Review  
(Proprietary Name)
- Patient Labeling
  - Patient Package Insert
  - Medication Guide
  - Instructions for Use



# Patient Labeling – Medication Guide

<b>MEDICATION GUIDE</b> <b>TECENTRIQ® (te-SEN-trik)</b> <b>(atezolizumab)</b> injection	
<p><b>What is the most important information I should know about TECENTRIQ?</b></p> <p>TECENTRIQ is a medicine that may treat your bladder cancer or lung cancer by working with your immune system. TECENTRIQ can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death. Call or see your healthcare provider right away if you get any symptoms of the following problems or these symptoms get worse:</p>	
<p><b>Lung problems (pneumonitis).</b> Signs and symptoms of pneumonitis may include:</p> <ul style="list-style-type: none"> <li>• new or worsening cough</li> <li>• shortness of breath</li> <li>• chest pain</li> </ul>	
<p><b>Liver problems (hepatitis).</b> Signs and symptoms of hepatitis may include:</p> <ul style="list-style-type: none"> <li>• yellowing of your skin or the whites of your eyes</li> <li>• dark urine (tea colored)</li> <li>• severe nausea or vomiting</li> <li>• bleeding or bruising more easily than normal</li> <li>• pain on the right side of your stomach area (abdomen)</li> <li>• feeling less hungry than usual</li> <li>• drowsiness</li> </ul>	
<p><b>Intestinal problems (colitis).</b> Signs and symptoms of colitis may include:</p> <ul style="list-style-type: none"> <li>• diarrhea (loose stools) or more bowel movements than usual</li> <li>• blood in your stools or dark, tarry, sticky stools</li> <li>• severe stomach area (abdomen) pain or tenderness</li> </ul>	
<p><b>Hormone gland problems (especially the pituitary, thyroid, adrenal glands, and pancreas).</b> Signs and symptoms that your hormone glands are not working properly may include:</p> <ul style="list-style-type: none"> <li>• headaches that will not go away or unusual headaches</li> <li>• feeling cold</li> <li>• extreme tiredness</li> <li>• constipation</li> <li>• weight gain or weight loss</li> <li>• your voice gets deeper</li> <li>• dizziness or fainting</li> <li>• urinating more often than usual</li> <li>• feeling more hungry or thirsty than usual</li> <li>• nausea or vomiting</li> <li>• hair loss</li> <li>• stomach area (abdomen) pain</li> <li>• changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness</li> </ul>	
<p><b>Nervous system problems (neuropathy, meningitis, encephalitis).</b> Signs and symptoms of nervous system problems may include:</p> <ul style="list-style-type: none"> <li>• severe muscle weakness</li> <li>• changes in mood or behavior</li> <li>• numbness or tingling in hands or feet</li> <li>• extreme sensitivity to light</li> <li>• fever</li> <li>• neck stiffness</li> <li>• confusion</li> </ul>	
<p><b>Inflammation of the eyes.</b> Signs and symptoms may include:</p> <ul style="list-style-type: none"> <li>• blurry vision, double vision, or other vision problems</li> <li>• eye pain or redness</li> </ul>	
<p><b>Severe infections.</b> Signs and symptoms of infection may include:</p> <ul style="list-style-type: none"> <li>• fever</li> <li>• flu-like symptoms</li> <li>• cough</li> <li>• pain when urinating</li> <li>• frequent urination</li> </ul>	
<p><b>Severe infusion reactions.</b> Signs and symptoms of infusion reactions may include:</p> <ul style="list-style-type: none"> <li>• chills or shaking</li> <li>• dizziness</li> <li>• itching or rash</li> <li>• fever</li> <li>• flushing</li> <li>• feeling like passing out</li> <li>• shortness of breath or wheezing</li> <li>• back or neck pain</li> <li>• swelling of your face or lips</li> </ul>	
<p><b>Getting medical treatment right away may help keep these problems from becoming more serious.</b></p> <p>Your healthcare provider will check you for these problems during your treatment with TECENTRIQ. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment with TECENTRIQ if you have severe side effects.</p>	

# Advice to Industry

- Promotional materials
  - Professional audience
    - Press releases, sales aids and journal ads
    - Professional presentations
    - Websites and other electronic media
  - Patient audience
    - Patient brochures and journal ads
    - Television and radio advertisements
    - Websites and social media

# Consumer Print Ad

For HR+ (ER+ and/or PR+), HER2- Metastatic Breast Cancer in  
Combination With Hormone Therapy for Postmenopausal Women

THE STRUGGLE  
IS REAL.  
AND SO AM I.



"I have metastatic breast cancer.  
It doesn't have me."

**Significantly More Effective.** In a clinical trial, KISQALI + letrozole reduced the risk of disease progression by 44% vs letrozole alone. At the time of this analysis, more than half of women taking KISQALI + letrozole remained alive and progression free.

**2+ Years Without Disease Progression.** At a trial follow-up, the median time women taking KISQALI + letrozole lived without disease progression was more than 2 years (25.3 months) from the start of treatment vs 16.0 months for those taking letrozole alone.

**Targeted Treatment.** KISQALI blocks, or interferes with, substances that play a role in both healthy and cancer cell growth.

Visit [www.KISQALI.com](http://www.KISQALI.com) to learn about the personalized support you may be able to receive throughout your treatment.

Clinical trials are still ongoing to see if patients live longer with treatment.

ER+ = estrogen receptor-positive; HER2- = human epidermal growth factor receptor 2-negative; HR+ = hormone receptor-positive; PR+ = progesterone receptor-positive

## INDICATION

KISQALI® (ribociclib) is a prescription medicine used in combination with a certain type of medicine as the first hormonal-based therapy to treat women who have gone through menopause with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic).

It is not known if KISQALI is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

**What is the most important information I should know about KISQALI?**

**KISQALI may cause serious side effects, including:**

**Heart rhythm problems (QT prolongation).** KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your health care provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your health care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.

**Liver problems (hepatobiliary toxicity).** KISQALI can cause serious liver problems. Your health care provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your health care provider right away if you get any of the following signs and symptoms of liver problems:

- yellowing of your skin or the whites of your eyes (jaundice)
- feeling very tired
- pain on the right side of your stomach area (abdomen)
- dark or brown (tea-colored) urine
- loss of appetite
- bleeding or bruising more easily than normal

**Low white blood cell counts (neutropenia).** Low white blood cell counts are very common when taking KISQALI and may result in infections that may be severe. Your health care provider should check your white blood cell counts before and during treatment with KISQALI. Tell your health care provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Your health care provider may tell you to decrease your dose, temporarily stop, or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

**What should I tell my health care provider before taking KISQALI?**

Before you take KISQALI, tell your health care provider if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- have any other medical conditions

• are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby

• If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI

• Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.

• Talk to your health care provider about birth control methods that may be right for you during this time.

• If you become pregnant or think you are pregnant, tell your health care provider right away.

• are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI

**Tell your health care provider about all of the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

**What should I avoid while taking KISQALI?**

Avoid eating pomegranate or grapefruit and avoid drinking pomegranate or grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

Please see Summary of Important Information on the following page.

**The most common side effects of KISQALI include:**

- nausea
- tiredness
- diarrhea
- hair loss
- vomiting
- constipation
- headache
- back pain

KISQALI may cause fertility problems if you are male and take KISQALI. This may affect your ability to father a child. Talk to your health care provider if this is a concern for you.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KISQALI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

For information about help paying for your prescription, visit [www.KISQALI.com](http://www.KISQALI.com) or call 1-800-282-7630.

**KISQALI**<sup>®</sup>  
ribociclib 200 mg  
tablets

Keeping it Real.

# Review of Promotional Materials

- Common Promotional Problems
  - Omitting or downplaying risk information
  - Overstating the effectiveness
  - Promoting unapproved uses
  - Misleading drug comparisons



# Surveillance of Industry

- Review materials submitted to OPDP at the time of initial dissemination
- Conferences
- Complaints
  - Healthcare professionals
  - Consumers
  - Competitors

# Limitations of Surveillance

- Areas not included in surveillance activities:
  - Physician offices
  - Industry-sponsored dinner and lunch programs
- That is why we developed the **Bad Ad Program**
  - Goals of the program
    - Increase effectiveness of surveillance program
    - Raise awareness among healthcare professionals about promotional materials that may be false or misleading
    - Anyone can submit a complaint

# What will happen if you report misleading promotion to OPDP?

- Enforcement Actions
  - Contribution to ongoing OPDP surveillance activities
  - Untitled letters (Notice of Violation/NOV)
  - Warning letters
  - Injunction/consent decree
  - Seizures
  - Criminal action

# Diclegis - Social Media Post

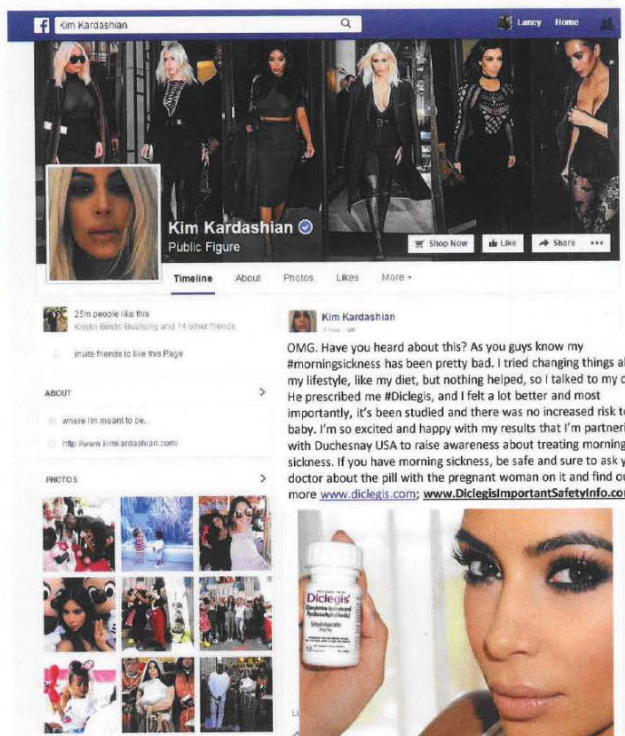
## ORIGINAL POST



Condensed version posts to Twitter with a direct link back to Instagram post

Full version is posted to Facebook page

OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more [www.diclegis.com](http://www.diclegis.com); [www.DiclegisImportantSafetyInfo.com](http://www.DiclegisImportantSafetyInfo.com)



Please note: image of Diclegis bottle will be prominent enough to read established name

2015-0069-01

# If You See Something, Say Something!



- e-mail to **BadAd@fda.gov** or
- calling **855-RX-BADAD (855-792-2323)**
- **Phone number: (301) 796-1200**
- **Fax number: (301) 847-8444**

# Questions?





# Back-up Slides

# Reminder Ad




**KISQALI**<sup>®</sup>  
 ribociclib


**NOVARTIS**

KIS-H58086



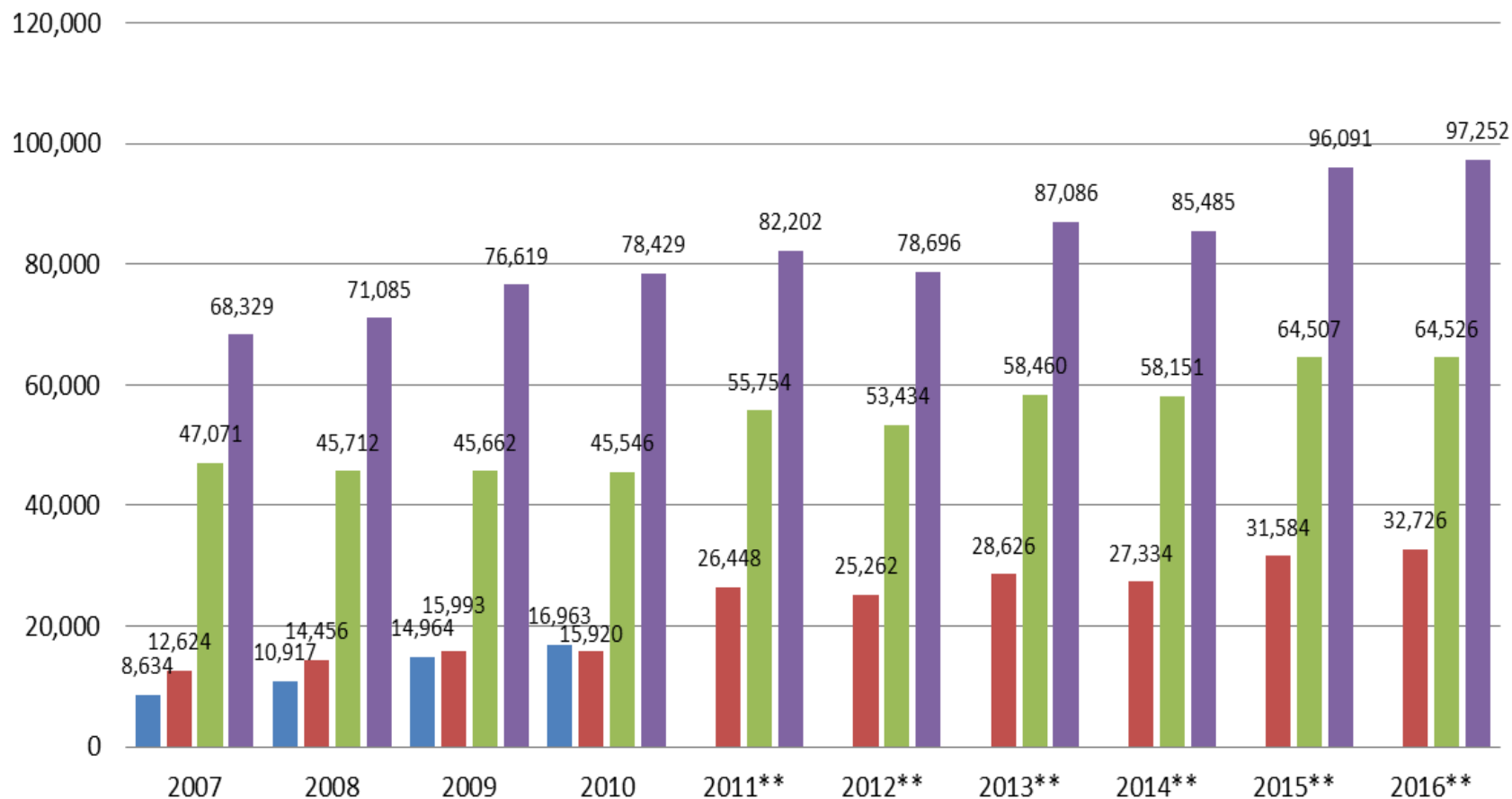
# Broadcast Advertising

- “Major Statement”
  - Information relating to the major side effects and contraindications
- “Adequate Provision”
  - Provides for dissemination of the Prescribing Information
  - Recognizes the inability of broadcast advertisements of reasonable length to present and communicate this information effectively

# Ibrance TV Ad

<https://www.ispot.tv/ad/wITp/ibrance-julies-new-normal>

## Total 2253 Promotional Pieces by Year



\*Mixed = Internet pieces, video news releases and "other" material

■ Mixed\* ■ Consumer ■ Professional ■ Total

\*\* Mixed pieces are listed as either professional or consumer