

ZIIHERA: A DUAL HER2-TARGETED TREATMENT FOR HER2-POSITIVE BTC



ZIIHERA is the first and only FDA-approved bispecific antibody* that targets HER2 in adults with previously treated unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC).

*A bispecific antibody is able to target 2 cancer-causing proteins on a tumor cell.

FDA=Food and Drug Administration; HER2=human epidermal growth factor receptor 2; IHC=immunohistochemistry.

What is ZIIHERA?

- ZIIHERA is a prescription medicine used to treat adults who have a type of bile duct (cholangiocarcinoma) or gallbladder cancer called biliary tract cancer (BTC), that is human epidermal growth factor receptor 2 (HER2)-positive (IHC 3+). ZIIHERA may be used when your BTC:
 - was previously treated **and**,
 - cannot be removed by surgery, **or**
 - has spread to other parts of your body (metastatic).

Your healthcare provider will perform a test to make sure ZIIHERA is right for you. It is not known if ZIIHERA is safe and effective in children.

ZIIHERA is approved based on response rate and how long the response lasted. Additional studies will further evaluate the benefit of ZIIHERA for this use.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZIIHERA?

ZIIHERA can cause serious side effects, including:

- **harm to your unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with ZIIHERA.**
 - **If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ZIIHERA.**
 - **Females who are able to become pregnant should use birth control (contraception) during treatment with ZIIHERA and for 4 months after the last dose.**

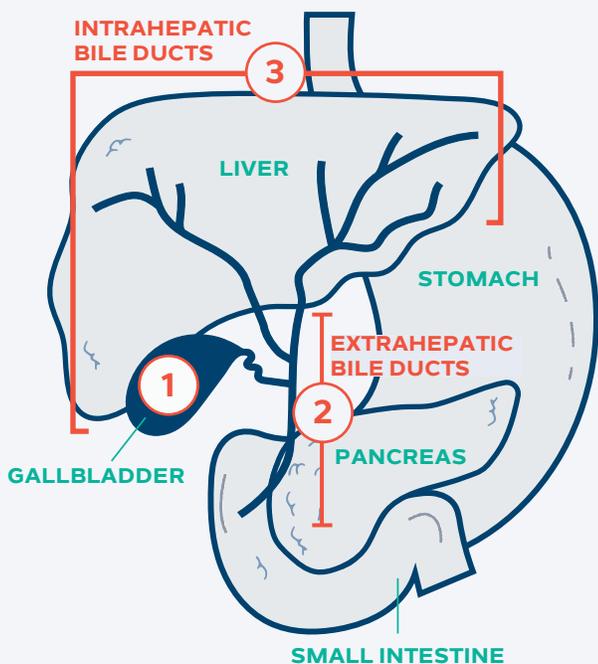
Please see additional Important Safety Information throughout and full [Prescribing Information](#), including **BOXED Warning** and Patient Leaflet, and discuss with your doctor.

Discover what ZIIHERA can do for you

WHAT IS BILIARY TRACT CANCER (BTC)?

BTC is a type of cancer that can occur in the bile ducts or gallbladder. Approximately 75% of BTCs are diagnosed at an advanced stage. There are different subtypes of BTC that affect different parts of your body.

THERE ARE 3 MAIN SUBTYPES OF BTC



- 1 Gallbladder cancer (GBC):**
Occurs in the gallbladder, which stores bile to help digest fat
 - ~30% of BTCs
- 2 Extrahepatic cholangiocarcinoma (ECC):**
Occurs in the bile ducts outside of the liver. Bile ducts are thin tubes that funnel bile from the liver to the gallbladder and small intestine
 - ~26% of BTCs
- 3 Intrahepatic cholangiocarcinoma (ICC):**
Occurs in the bile ducts inside the liver, which produces bile and helps filter toxins in the blood
 - ~23% of BTCs

IMPORTANT SAFETY INFORMATION (CONT'D)

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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of ZIIHERA?

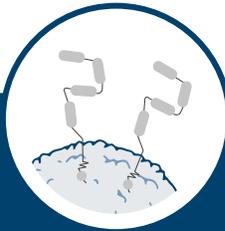
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 - irregular heartbeat
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WHAT IS HER2-POSITIVE BTC?

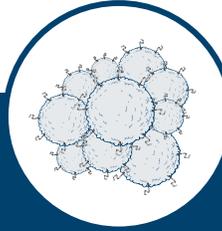
5-30% OF PEOPLE WITH BTC ARE HER2-POSITIVE

HER2 is a type of protein found on the surface of tumor cells that causes cells to grow, divide, and spread.



HER2 can become “amplified” or “overexpressed.”

Amplification means that there are extra copies of the HER2 gene, and **overexpression** means that there are too many HER2 proteins.



In HER2-expressing cancer cells, having extra copies of HER2 genes or too many HER2 proteins can make cells grow faster.



Cancers with HER2 overexpression and/or amplification are called HER2-positive.

Ask your doctor about HER2 testing and see if therapies that target HER2 can help you take control of BTC

HER2=human epidermal growth factor receptor 2.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of ZIIHERA? (cont'd)

- **Infusion-related reactions** are a serious, but common side effect that can happen during treatment with ZIIHERA. Your healthcare provider will check for side effects during your infusions. Tell your healthcare provider right away if you get any of the following symptoms during or after your infusions of ZIIHERA:
 - shortness of breath or trouble breathing
 - fever
 - chills
 - rash
 - flushing
 - nausea or vomiting
 - dizziness or feeling lightheaded
 - chest discomfort
- **Diarrhea** is a serious, but common side effect during treatment with ZIIHERA that may be severe. Your healthcare provider may prescribe an antidiarrheal medicine or other treatment, as needed.

The most common side effects of ZIIHERA include diarrhea, infusion-related reactions, stomach pain and feeling tired.

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(zanidatamab-hrii)
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HOW ZIIHERA IS THOUGHT TO WORK*

WHAT IS ZIIHERA?

ZIIHERA (zye-HAIR-ah) is a therapy designed to target HER2-positive (IHC 3+) cancer cells

It is not a chemotherapy; ZIIHERA is a bispecific antibody engineered to target HER2 on tumor cells

ZIIHERA is for people who previously received treatment

ZIIHERA IS THE FIRST AND ONLY BISPECIFIC ANTIBODY TARGETING TWO SITES ON HER2, WHICH MAY KILL OR SLOW THE GROWTH OF TUMOR CELLS



TARGETING AND BINDING:

ZIIHERA binds to 2 sites on a HER2 protein, which is on the surface of the cancer cell.



INTERNALIZATION:

Binding of ZIIHERA to HER2 results in internalization, a process where ZIIHERA and the bound HER2 protein are absorbed into the cancer cell.



REDUCTION OF HER2:

ZIIHERA being absorbed reduces the amount of HER2 proteins on the surface of the cancer cell.



IMMUNE DEFENSE:

ZIIHERA can recruit the immune system to kill the tumor cell.

*This is how ZIIHERA was shown to work in lab studies.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of ZIIHERA? (cont'd)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ZIIHERA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW ZIIHERA WAS STUDIED

ZIIHERA WAS STUDIED IN THE LARGEST PHASE 2B[†] TRIAL TO DATE OF PREVIOUSLY TREATED PEOPLE WITH HER2-POSITIVE BTC[‡]

ZIIHERA was studied in a trial of 80 adults with previously treated HER2-positive BTC, 62 of whom were IHC 3+. This trial evaluated how many people had a response to treatment (saw their tumors shrink in size) and how long these responses lasted. It also evaluated any side effects people experienced while taking ZIIHERA.

HER2 positivity was determined through 2 types of tests—ISH and IHC.



A HER2 ISH test checks the DNA or RNA of your cancer cells to see if there are extra copies of HER2.



A HER2 IHC test determines your HER2 protein levels using scores that range from 0 to 3+. The higher the score, the more HER2 is overexpressed.

People in the trial took a HER2 test to determine their HER2 status. ZIIHERA is approved to treat people with HER2-positive BTC that had a HER2 IHC score of 3+.

Your healthcare provider may use IHC or other tests to determine your HER2 levels and see if you may be eligible for ZIIHERA.



People with metastatic HER2-positive (IHC 3+) BTC received ZIIHERA by IV once every 2 weeks

[†]A Phase 2b study is designed to evaluate the effectiveness and dosing of a treatment generally over the course of several months to 2 years.

[‡]Only of FDA-approved second-line treatments. Current as of 11/2024.

BTC=biliary tract cancer; FDA=Food and Drug Administration; HER2=human epidermal growth factor receptor 2; IHC=immunohistochemistry; ISH=*in situ* hybridization; IV=intravenous.

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RESULTS WITH ZIIHERA

OF THE 62 PEOPLE WHO WERE IHC 3+



52% (32/62 people)
with a HER2 IHC 3+
score had a response

3%

(2 people) had a complete response, which means that their tumors disappeared

48%

(30 people) had a partial response, which means that their tumors shrank by 30% or more

ZIIHERA was FDA approved for this use based on clinical studies that measured how many patients responded and how long they responded. ZIIHERA is still being studied to confirm these results.

IMPORTANT SAFETY INFORMATION (CONT'D)

What is the most important information I should know about ZIIHERA? (cont'd)

- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ZIIHERA.
- Females who are able to become pregnant should use birth control (contraception) during treatment with ZIIHERA and for 4 months after the last dose.

HOW LONG PEOPLE RESPONDED TO ZIIHERA

OF THE 62 PEOPLE WHO WERE IHC 3+

 **15**
MONTHS

was the median length of time that responses lasted in the 32 people that responded, which means their tumors shrank or disappeared

OF THE 32 PEOPLE WHO RESPONDED TO ZIIHERA

 **59%**
(19 people) continued responding to ZIIHERA at ≥6 months

 **44%**
(14 people) continued responding to ZIIHERA at ≥12 months

Median is the middle number in a set of numbers.

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IMPORTANT SAFETY INFORMATION (CONT'D)

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POSSIBLE SIDE EFFECTS



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- **Heart problems** that may affect how well your heart pumps blood. Your healthcare provider will check your heart function before and during treatment with ZIIHERA. Call your healthcare provider right away if you get any of the following signs and symptoms of a heart problem:
 - new or worsening shortness of breath
 - feeling more tired than usual
 - swelling of your ankles or feet
 - loss of consciousness
 - irregular heartbeat
 - sudden weight gain
 - dizziness or feeling light-headed
- **Infusion-related reactions**, a common side effect that can happen during treatment with ZIIHERA. Your healthcare provider will check for side effects during your infusions. Tell your healthcare provider right away if you get any of the following symptoms during or after your infusions of ZIIHERA:
 - shortness of breath or trouble breathing
 - fever
 - chills
 - rash
 - flushing
 - nausea or vomiting
 - dizziness or feeling lightheaded
 - chest discomfort
- **Diarrhea**, a common side effect during treatment with ZIIHERA that may be severe. Your healthcare provider may prescribe an antidiarrheal medicine or other treatment, as needed.

Other common side effects of ZIIHERA include stomach pain and feeling tired.

Tell your healthcare 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 ZIIHERA. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.



Managing potential side effects:

- **The most common side effect of ZIIHERA is diarrhea.** Talk to your healthcare provider about any side effects you experience, and they will help you find ways to manage them

Your healthcare provider:

- will give you medicines 30 to 60 minutes before each treatment to help prevent infusion-related reactions or make them less severe
 - may slow down, temporarily stop, or permanently stop your treatment with ZIIHERA if you have certain side effects
 - may do certain tests to check you for some side effects
 - will decide how many treatments you need
- If you miss a dose, call your healthcare provider as soon as possible to reschedule your appointment

WHAT TO EXPECT WHEN TAKING ZIIHERA

ONE TREATMENT, ONCE EVERY 2 WEEKS

ZIIHERA is an intravenous (IV) infusion you will receive once every 2 weeks. Your healthcare provider will decide how long you stay on ZIIHERA and may discontinue treatment if you have uncontrolled or unmanaged side effects.

Dosing Schedule

 <p>The 1st and 2nd infusions will last 120-150 minutes</p>	<p>If past infusions are well tolerated,</p>  <p>The 3rd and 4th infusions will last 90 minutes</p>	<p>If past infusions are well tolerated,</p>  <p>Each infusion afterwards will be administered over 60 minutes</p>
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- If you miss a dose, call your healthcare provider as soon as possible to reschedule your appointment

FDA=Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (CONT'D)

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WE'RE HERE TO SUPPORT YOU

TIPS DURING TREATMENT

There are ways you can manage side effects that you may experience during treatment. The tips below should not replace your doctor's advice. Always talk to your doctor and follow their guidance on managing any side effects you may experience.



- Make sure to drink plenty of fluids each day, like water, to replace any fluids you may be losing due to diarrhea. Talk to your doctor to see what approach may be best for you



- If you experience stomach pain, try eating bland foods that won't irritate your stomach, like yogurt, rice, or clear soup. Incorporating fresh ginger into your diet can also help if you feel nauseous



- It's important to give yourself time to rest if you feel tiredness or fatigue. Try not to overextend yourself, and if you start to feel overwhelmed, ask your family or friends to help you with everyday tasks

SUPPORT GROUPS

Connect with others who understand your journey with HER2-positive BTC.



Cholangiocarcinoma
Foundation*

Cholangiocarcinoma Foundation

Support and resources for patients and caregivers: find personalized assistance and vital information to improve quality of life and treatment outcomes at www.cholangiocarcinoma.org



gi cancers
ALLIANCE

GI Cancers Alliance

The Alliance raises awareness, provides education, and advocates to prevent, treat, and cure GI cancers. Learn more at www.gicancersalliance.org

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What are the possible side effects of ZIIHERA? (cont'd)

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JazzCares is committed to helping you get access to your ZIIHERA medication.



To help you get access to ZIIHERA, JazzCares Specialists are available to assist you with:

- Understanding your insurance coverage
- Other cost and coverage questions
- Referrals to other financial assistance for which you might be eligible



JazzCares is committed to helping you reduce your out-of-pocket costs for ZIIHERA

- Savings Card—eligible, commercially insured patients can pay as little as \$10 for their ZIIHERA medication, subject to an annual maximum



Patient Assistance Program, if you are eligible

- Financial and other eligibility criteria may apply

You can learn more about JazzCares support offerings by calling 1-833-533-JAZZ (5299) Monday-Friday between 8 AM and 8 PM ET or visiting JazzCares.com

Insurance coverage and plans may vary. The JazzCares Program at Jazz Pharmaceuticals provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional. Jazz Pharmaceuticals reserves the right to terminate or modify this program at any time with or without notice. Other terms and conditions apply.

BTC=biliary tract cancer; GI=gastrointestinal; HER2=human epidermal growth factor receptor 2.

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GLOSSARY

Amplification: When cells have too many copies of a gene, like HER2. HER2 amplification can lead to HER2 overexpression.

Antibody: A protein that may be produced by the immune system to destroy bacteria or viruses or a medicine that may be used to recognize and eliminate cancer cells.

Bispecific: Treatments that are able to target 2 of the same protein such as HER2.

BTC: Biliary tract cancer. BTC can occur in the bile ducts or gallbladder.

CR: Complete response, or when tumors shrink or disappear completely.

ECC: Extrahepatic cholangiocarcinoma. ECC occurs in the bile ducts outside of the liver. Bile ducts are thin tubes that funnel bile from the liver to the gallbladder and small intestine.

GBC: Gallbladder cancer. The gallbladder stores bile to help digest fat.

HER2: Human epidermal growth factor receptor 2. These are proteins found on the surface of all cells.

ICC: Intrahepatic cholangiocarcinoma. ICC occurs in the bile ducts inside the liver, which produces bile and helps filter toxins in the blood.

IHC: Immunohistochemistry. A test that determines HER2 protein levels using scores that range from 0 to 3+. The higher the score, the more HER2 is overexpressed.

Immune system: An internal defense system that protects the body from antigens—toxins or foreign substances, such as bacteria or viruses.

ISH: *In situ* hybridization. A test that checks the DNA or RNA of cancer cells to see if there are extra copies of HER2.

IV: Intravenous.

Median: The middle number in a set of numbers.

Metastatic: When cancer spreads to other parts of the body.

Overexpression: When an abnormal amount of proteins, like HER2, are present on cells. This can cause tumors to grow.

PR: Partial response, or when tumors shrink by 30% or more.

Response: When a person experiences a CR or PR and sees their tumors shrink during treatment.

Targeted therapy: A treatment that specifically focuses on what may be causing tumors to grow.

APPROVED USE & IMPORTANT SAFETY INFORMATION

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Talk to your doctor about HER2 testing and see if ZIIHERA is right for you



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US-ZAN-2400023

