# A potential treatment option for **people with bladder cancer**

Bladder cancer is type of cancer of the urinary system. While it's more common in men than women, bladder cancer can happen to anyone.

## What is the RC48G001 Study?

The purpose of this clinical research study is to learn if the investigational drug (disitamab vedotin) works to treat bladder cancer when it is used alone and when it is used in combination with an anticancer drug (Keytruda). This study is enrolling patients with the type of bladder cancer that has measurable levels of HER2, a protein that has been associated with many types of cancer. For this reason, all participants must have cancer cells that make HER2 to enroll in this study. The study team will check to see if your cancer cells make HER2 before you can enroll in the study.

## What is the investigational drug?

Disitamab vedotin is a type of drug called an antibody drug conjugate (ADC). ADCs work by preferentially binding to the cancer cells in your body to help kill them. They can also bind to some non-cancer cells in your body. Disitamab vedotin is designed to bind to cancer cells that make HER2.

This is an open-label study. Everyone who participates in the study will receive the investigational drug, disitamab vedotin.

Some participants in the study will also receive another anticancer drug, Keytruda, in combination with disitamab vedotin. Keytruda is an anticancer drug called an immune checkpoint inhibitor (CPI). It is a standard treatment for bladder cancer. The study doctor will let participants know if they are receiving one or both drugs.

# What is a **clinical research study?**

Clinical research studies are designed to examine the effects of potential new medical treatments. The RC48G001 Study will help researchers learn more about the safety and effectiveness of disitamab vedotin, potentially providing a new treatment option for people with bladder cancer.

Participation in this clinical research study is completely voluntary. You may stop participation at any time and for any reason. If you withdraw your consent to participate in the study, the study team will not contact you again.

**The use of disitamab vedotin in this study is experimental. Because of that, not all risks are known. It is also not known if it will work in treating bladder cancer. This is why we are conducting the study.**

**http://www.clinicaltrials.seagen.com/study/?pid=RC48G001**

**Learn more about the RC48G001 Study**

To learn more, call the Seagen Trial Information Hotline at 866-333-7436 or contact our study team today.

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RC48G001 – PFM – Recruitment Brochure – US/ENG – V1.0
30Aug2022 – USM/DV/2022/0021

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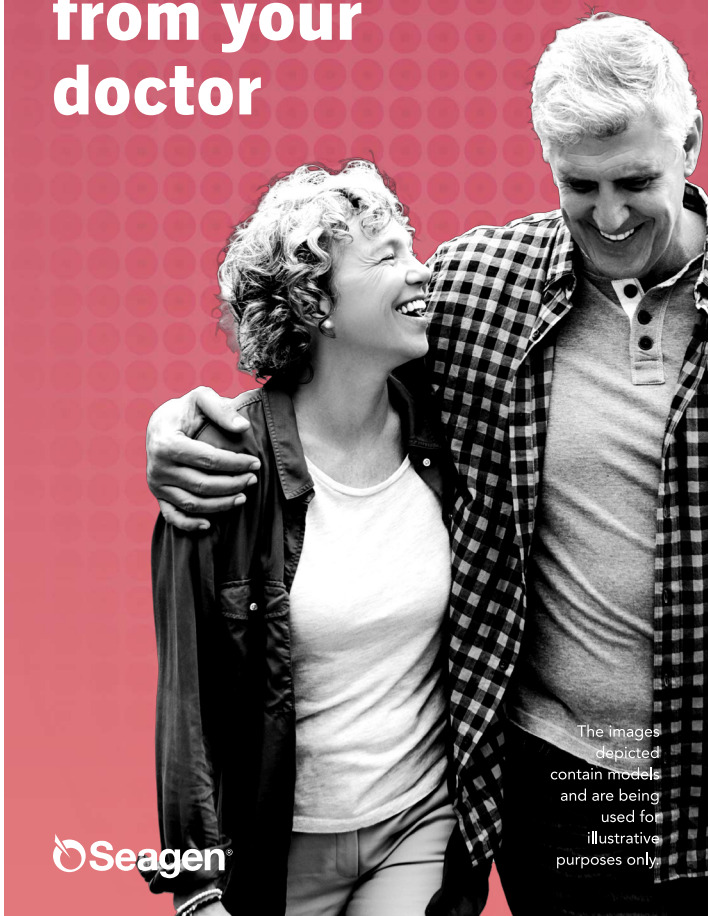
# Looking for a research study targeting bladder cancer? **Learn more about the RC48G001 Study from your doctor**



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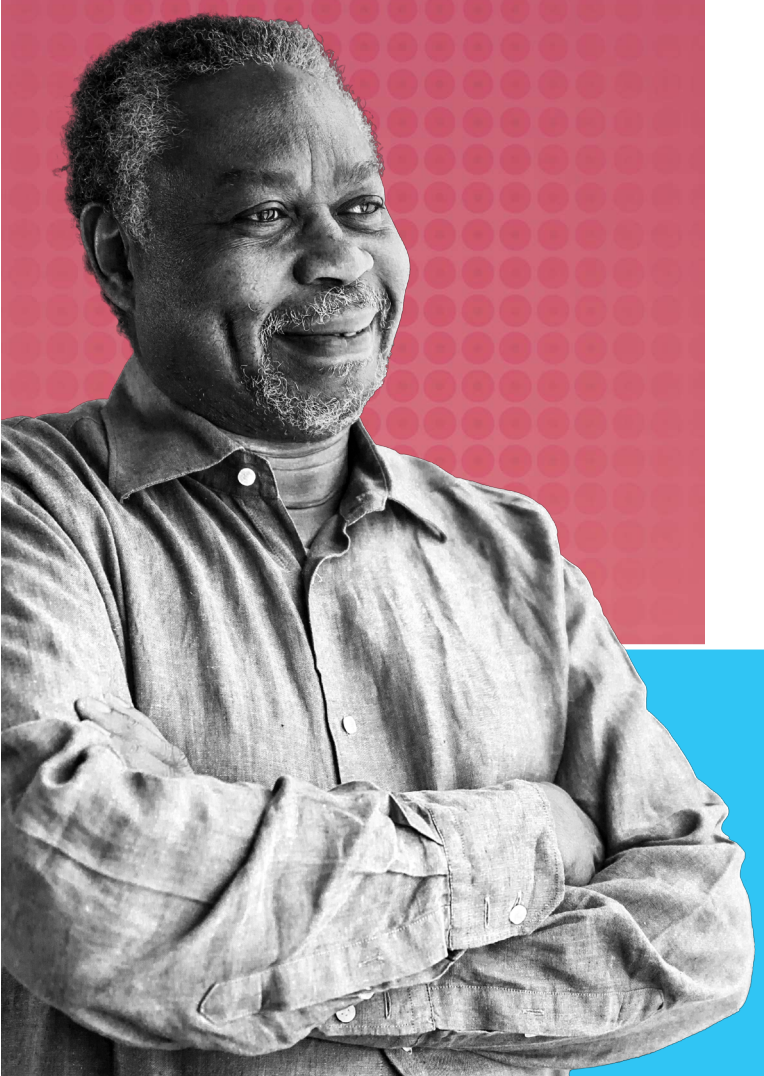
The images depicted contain models and are being used for illustrative purposes only.

## How do I **enroll in the study?**

If you are interested in learning more about the study, speak to your doctor. You can talk about the study with them and ask any questions you may have. If you are still interested in joining the study, you will sign an Informed Consent Form and attend clinic visits with the study doctor to learn if you are eligible to participate. These visits may involve some tests and procedures. If the study doctor determines you are eligible and you choose to participate, you may begin the study.



## A closer look at the **RC48G001 Study**

If you qualify for the study and decide to enroll, your participation in the study may last up to 3 years. Participants in the study will be enrolled in one of three cohorts, A, B and C:

+ All participants in Cohorts A and B will receive disitamab vedotin.
+ Participants in Cohort C will either receive disitamab vedotin alone or in combination with Keytruda.

**The study is divided into the following periods:**

### Cohorts A & B

**Screening period (up to 4 weeks)**

+ Participants will have some tests and procedures to see if they can be in the study. This will include a test to make sure their cancer makes HER2.
+ These tests will be done during 1 or 2 office visits.

**Treatment period (2-week study cycles)**

+ Participants will receive disitamab vedotin into the arm by an intravenous (IV) infusion on the first day of each 2-week study cycle.
+ Participants will have a scan to check their cancer every 6 weeks until week 72 and then every 12 weeks until the end of the study.
+ Participants may continue study cycles as long as their cancer is stable or getting better.

**End-of-treatment visit (30 days after last treatment)**

+ During this visit, participants will have an exam and some tests and answer questions about their cancer.

**Long-term follow-up period (ongoing)**

+ Participants will continue to have scans every 6 weeks until week 72 and then every 12 weeks until the end of the study.
+ If their cancer gets worse, participants will receive phone calls every 3 months, but will not have any more scans.

### Cohort C

**Screening period (up to 4 weeks)**

+ Participants will have some tests and procedures to see if they can be in the study. This will include a test to make sure their cancer makes HER2.
+ These tests will be done during 1 or 2 office visits.

**Treatment period (6-week study cycles)**

+ Participants will receive disitamab vedotin into the arm by an IV infusion on Days 1, 15 and 29 of each 6-week cycle.
+ Some participants will receive Keytruda into the arm by an IV infusion on Day 1 of each 6-week cycle.
+ Participants will have a scan to check their cancer every 8 weeks until week 72 and then every 12 weeks until the end of the study.
+ Participants may continue study cycles as long as their cancer is stable or getting better.

**End-of-treatment visit (30 days after last treatment)**

+ During this visit, participants will have an exam and some tests and answer questions about their cancer.

**Long-term follow-up period (ongoing)**

+ Participants will continue to have scans every 8 weeks until week 72 and then every 12 week until the end of the study.
+ If their cancer gets worse, participants will receive phone calls every 3 months, but will not have any more scans.

For more information about the investigational drug, tests or assessments, please speak with a member of the study team

## Who is eligible to participate?

**You may be eligible to participate in the RC48G001 Study if:**

+ **You are age 18 or older**
+ **You have been diagnosed with bladder cancer**
+ **The cancer has spread to nearby tissue or other parts of the body**

**If you are interested in joining the study, the study doctor or staff will assess you to see if you meet further eligibility criteria.**

## What is included in study participation?

**All eligible study participants will receive the following at no cost:**

+ **The investigational drug, disitamab vedotin and Keytruda (if applicable)**
+ **Study-related visits, assessments and tests**

**Participants may also be reimbursed for reasonable expenses, such as travel costs, for attending study visits.**