RC48
G001

Looking for a research study targeting bladder cancer?

# Learn more about the RC48G001 Study from your doctor

**For more information about the investigational drug, tests or assessments, please speak with your treating physician or the study physician.**

## Who is eligible to participate?

### You may be eligible for 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 the purpose of 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).

## Study details

If you qualify for the study and decide to enroll, study participation 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 alone.
+ 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 checking their cancer to ensure it makes the protein 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.
+ 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.
+ These tests will be done during 1 or 2 office visits and will include checking their cancer to ensure it makes the protein HER2.

**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 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.

**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.**

**You may stop participation in the study 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.**

**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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