

# Clinical Trial RESULTS



**Research Sponsor:** F. Hoffman-La Roche, Ltd., and Genentech, Inc.

**Drug Studied:** Etrolizumab (rhuMAB Beta7)

**National Clinical Trial #:** NCT01336465

**Protocol #:** ABS4986g [Eucalyptus]

**Study Date:** September 2011 to January 2013

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## *Thank you!*

As a participant in a clinical study, you belong to a large community around the world. Your participation helps researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the study drug etrolizumab (rhuMAB Beta7). The study you participated in began in September 2011 and finished in January 2013 and examined the use of etrolizumab in patients with ulcerative colitis. You and 123 other patients helped researchers begin to understand how etrolizumab works for people with moderate to severe ulcerative colitis.

F. Hoffman–La Roche and Genentech, the sponsors of this study, think it is important for you to know the results. The sponsors asked an independent nonprofit organisation called CISCRP to prepare this summary of the results for you. Please note that the results described here only apply to the study you participated in and new information regarding etrolizumab may become available in other studies.

We hope it helps you understand and feel proud of your key role in medical research. If you have questions about the results, please speak with the doctor, research nurse, or other team member at your study site.

## WHAT KIND OF STUDY WAS THIS?

In your study, researchers studied etrolizumab to see if it was effective and learn more about how safe it is. This was a “double-blind” study, which means none of the patients or study staff knew who was taking the study drug and who was taking a placebo. A placebo looks like the study drug, but does not contain any study medicine. Researchers use a placebo to learn if the study medicine works better than no medicine at all and make sure the study results are accurate.

The entire study took almost 2 years to finish and included patients from 11 countries around the world. A total of 124 patients received at least one dose of the study drug, etrolizumab, or placebo. The sponsor published the results from this study in July 2014.

## WHY WAS THE RESEARCH DONE?

Researchers were looking for a new way to treat ulcerative colitis, a disease that causes inflammation and sores in the colon. In your study, researchers were testing a drug called etrolizumab. The drug is designed to stop inflammation in the colon and keep it from coming back. When this happens, it is called “remission.” It means the disease is no longer active.

In your study, researchers wanted to learn:

- How many patients taking etrolizumab were in remission after 10 weeks of treatment?
- How many patients were getting better at weeks 6 and 10?
- How many patients had fewer signs of active ulcerative colitis at week 10?

All the patients in your study were between 18 and 75 years old and more than half had taken a biologic before. They were diagnosed with moderate to severe ulcerative colitis at least 12 weeks before starting the study, and the ulcerative colitis had not gotten better with other medicines.

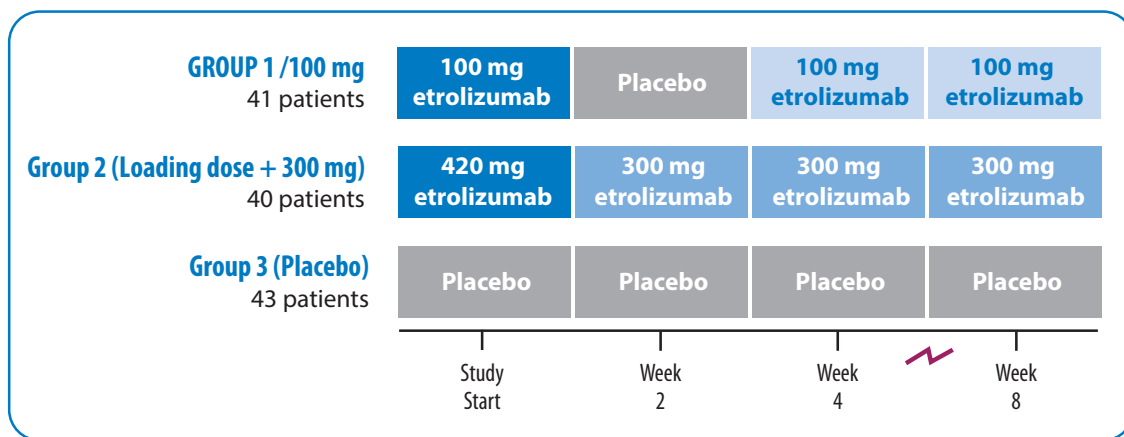
Patients had to stop taking some ulcerative colitis medicines before the study started. They could keep taking some corticosteroid medicines, but they had to decrease the dose gradually and stop taking these medicines by the end of the study.

## WHAT HAPPENED DURING THE STUDY?

You were one of 124 patients who received etrolizumab or the placebo for 10 weeks. The researchers stayed in contact with you for 12 more weeks to check for any medical problems. If you were taking etrolizumab and it helped your ulcerative colitis, you were eligible to keep taking it for up to 240 weeks.

No matter when you stopped taking etrolizumab, researchers stayed in contact with you after the last dose. They did this to check for side effects including a very rare disease called progressive multifocal leukoencephalopathy, or PML. No one in your study got this disease.

There were 3 groups in the study. Patients in 2 of the groups received etrolizumab and patients in 1 group received the placebo. Patients in each group had an injection (shot) at the start of the study and at weeks 2, 4, and 8. The time line below shows the groups and injections, as well as how many patients were in each group.



During the study, researchers regularly checked patients' health. Patients had physical examinations and tests on blood, urine, and bowel movements. Patients also had examinations of the colon, tissue samples taken from the colon, and electrocardiogrammes (ECGs) to measure heartbeat. Patients were also evaluated using a 12-point rating scale to measure ulcerative colitis activity.

Researchers also kept track of all medical problems that patients had. These are known as "adverse events" and may or may not be caused by the study drug.

## WHAT WERE THE STUDY RESULTS?

Below is a summary of the medical questions that were asked in this study and the study results. A total of 5 patients (2 in Group 1, 1 in Group 2, and 2 in Group 3) were not included in the summary because their level of colon inflammation was milder than required for the study.

### *How many patients taking etrolizumab had some improvement after treatment?*

Researchers measured how many patients were feeling better or had less active disease compared to when the study started. The table below shows how many patients in each group reported fewer symptoms at weeks 6 and 10.

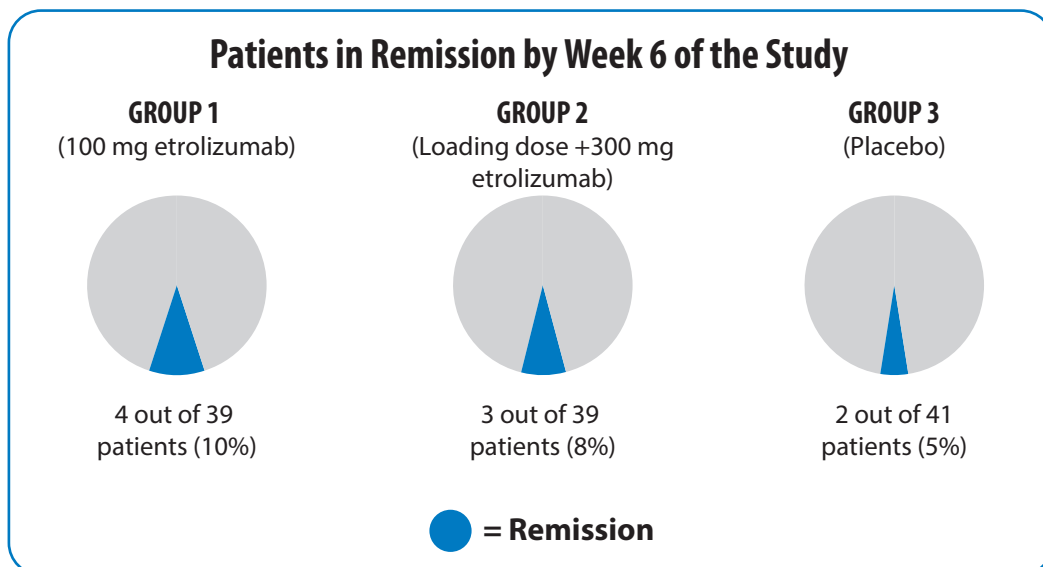
**How Many Patients Scored Lower on a Test of Ulcerative Colitis Symptoms?**

	<b>GROUP 1 (100 mg of etrolizumab) 39 Patients</b>	<b>GROUP 2 (Loading dose + 300 mg of etrolizumab) 39 Patients</b>	<b>GROUP 3 (Placebo) 41 Patients</b>
<b>Week 6</b>	19 Patients (49%)	15 Patients (38%)	14 Patients (34%)
<b>Week 10</b>	13 Patients (33%)	15 Patients (38%)	12 Patients (29%)

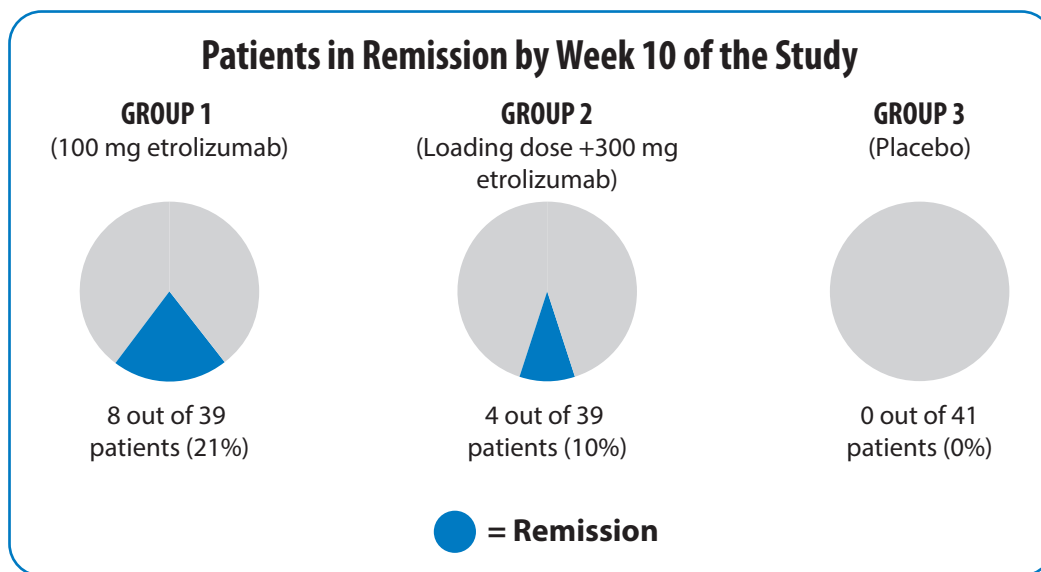
### *How many patients taking etrolizumab were in remission after treatment?*

In this study, remission meant having near complete or complete improvement of their active disease.

The chart below shows how many patients in each group were in remission by week 6. The results at week 6 were about the same for patients treated with etrolizumab and placebo.



By week 10, several patients in the etrolizumab groups (Groups 1 and 2) went into remission, but no patients in the placebo group did. The chart below show how many patients were in remission by week 10.



*How many patients taking etrolizumab had no rectal bleeding and improvement of colon damage after treatment?*

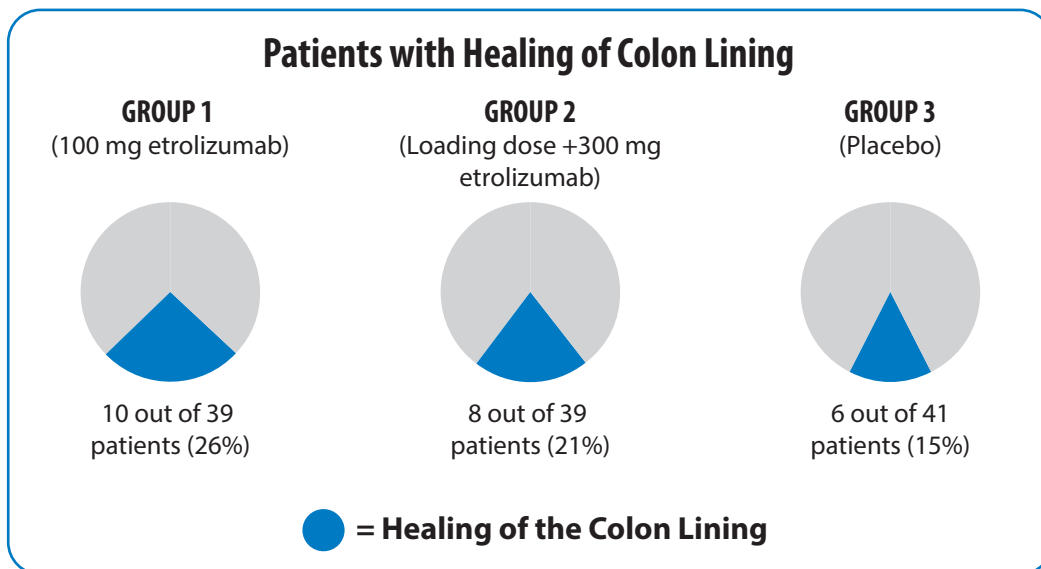
Researchers also measured how much rectal bleeding patients had and how much colon damage the study doctor could see by endoscopy. The table below shows how many patients in each group had no rectal bleeding and very little or no colon damage at weeks 6 and 10.

**How Many Patients Had No Rectal Bleeding and Little or No Colon Damage?**

	<b>GROUP 1 (100 mg of etrolizumab) 39 Patients</b>	<b>GROUP 2 (Loading dose + 300 mg of etrolizumab) 39 Patients</b>	<b>GROUP 3 (Placebo) 41 Patients</b>
<b>Week 6</b>	3 Patients (8%)	1 Patient (3%)	1 Patient (2%)
<b>Week 10</b>	4 Patients (10%)	3 Patients (8%)	0 Patients (0%)

*How many patients taking etrolizumab had healing of the colon lining?*

Patients in each group had healing of the colon lining by week 10 of the study. The study doctors looked for healing by endoscopy. The chart below shows these results



**WHAT ADVERSE EVENTS DID PATIENTS HAVE?**

A lot of research is needed to know whether a drug causes a medical problem. So when new drugs are being studied, researchers keep track of all medical problems. The medical problems are called “adverse events”, and may or may not be caused by the study drug. This section tells you about the adverse events in your study.

*What serious adverse events did patients have?*

An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care. Researchers counted the adverse events that happened to all 124 patients who started the study. The table below shows how many serious events happened in each group. No patients died in the study.

**How Many Patients Had a Serious Adverse Event?**

GROUP 1 (100 mg of etrolizumab) 41 Patients	GROUP 2 (Loading dose + 300 mg of etrolizumab) 40 Patients	GROUP 3 (Placebo) 43 Patients
5 Patients (12%)	2 Patients (5%)	5 Patients (12%)

A total of 12 patients had serious adverse events. Five of these (42%) were worsening of ulcerative colitis.

### *What were the most common adverse events in the study?*

For all patients who started the study, the most common adverse events were the ulcerative colitis, colds, joint pain, and headaches. Patients who took etrolizumab had more rashes, flu-like illness, and joint pain than patients who took the placebo. The table below shows the most common adverse events in each group.

**Most Common Adverse Events**

	<b>GROUP 1 (100 mg of etrolizumab) 41 Patients</b>	<b>GROUP 2 (Loading dose + 300 mg of etrolizumab) 40 Patients</b>	<b>GROUP 3 (Placebo) 43 Patients</b>	<b>Total 124 Patients</b>
<b>Ulcerative colitis</b>	7 Patients (17%)	9 Patients (23%)	8 Patients (19%)	24 Patients (19%)
<b>Colds</b>	4 Patients (10%)	6 Patients (15%)	8 Patients (19%)	18 Patients (15%)
<b>Headache</b>	5 Patients (12%)	4 Patients (10%)	5 Patients (12%)	14 Patients (11%)
<b>Joint pain</b>	6 Patients (15%)	2 Patients (5%)	4 Patients (9%)	12 Patients (10%)
<b>Tiredness</b>	2 Patients (5%)	2 Patients (5%)	4 Patients (9%)	8 Patients (6%)
<b>Cough</b>	2 Patients (5%)	2 Patients (5%)	2 Patients (5%)	6 Patients (5%)
<b>Nausea</b>	2 Patients (5%)	2 Patients (5%)	2 Patients (5%)	6 Patients (5%)
<b>Rash</b>	3 Patients (7%)	1 Patients (3%)	1 Patient (2%)	5 Patients (4%)
<b>Weakness</b>	0 Patients	0 Patients	4 Patients (9%)	4 Patients (3%)
<b>Dizziness</b>	1 Patient (3%)	0 Patients	3 Patients (7%)	4 Patients (3%)
<b>Flu-like illness</b>	3 Patients (8%)	0 Patients	1 Patient (2%)	4 Patients (3%)
<b>Low iron in the blood</b>	0 Patients	2 Patients (5%)	2 Patients (5%)	4 Patients (3%)
<b>Stomach flu (Gastroenteritis)</b>	1 Patient (2%)	1 Patients (3%)	2 Patients (5%)	4 Patients (3%)
<b>Fever</b>	2 Patients (5%)	0 Patients	2 Patients (5%)	4 Patients (3%)
<b>Throat pain</b>	2 Patients (5%)	0 Patients	2 Patients (5%)	4 Patients (3%)
<b>Belly pain</b>	1 Patient (2%)	0 Patients	2 Patients (5%)	3 Patients (2%)
<b>Feelings of irregular heartbeat</b>	1 Patient (2%)	0 Patients	2 Patients (5%)	3 Patients (2%)
<b>Upper respiratory tract infection</b>	2 Patients (5%)	0 Patients	1 Patient (2%)	3 Patients (2%)

\* The full list of adverse events for your trial can be found on the U.S. government's clinical trial website at <http://clinicaltrials.gov/ct2/show/study/NCT01336465>

### *Did any patients stop receiving etrolizumab because of adverse events?*

Four patients stopped receiving etrolizumab because of adverse events, including headache, rash, chest pain, liver problems already detected prior to taking etrolizumab, and ulcerative colitis problems.

## WHERE CAN I LEARN MORE ABOUT THIS STUDY?

The summary of the clinical study results is available online at [www.ciscrp.org/NCT01336465](http://www.ciscrp.org/NCT01336465). At that web page, you will also find links to more information about the scientific results. If you have questions about the results, please speak with the doctor, research nurse, or other team member at your study site.

**Researchers look at the results of many studies to decide which drugs work best and are safest for patients. It takes participants in many trials all around the world to advance medical science.**

Address and telephone number for the sponsor of this trial:

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## *Thank you*

It is said that the greatest gift is one that is given anonymously, given when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge. Thank you for the gift of your participation in clinical research.



The Centre for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organisation focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting patients for clinical trials, nor is it involved in conducting clinical trials.