

## Plain Language Summary of Study Results

Astellas is grateful to the people who  
took part in this clinical study.

***Thank you!***

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**Study Sponsor: Astellas Pharma Global Development, Inc**

**Medicine Studied: Bleselumab (ASKP1240)**

**Study Number: 7163-CL-3201**

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### What was the study called?

A study about bleselumab in preventing focal segmental glomerulosclerosis coming back in people who have recently had a kidney transplant

### Why was the study needed?

Focal segmental glomerulosclerosis, or FSGS, is a term used to describe damage to the kidneys. FSGS occurs when scar tissue develops on the filters of the kidney. FSGS can happen on its own, without a known or obvious cause, or it can be caused by other conditions or even medications.

While some people can take medication to control the progression of the disease and prevent further damage to their kidneys, some people with FSGS need to have a kidney transplant.

Unfortunately, despite receiving a kidney transplant, FSGS comes back in around half of people whose original diagnosis of FSGS had no known cause. So, researchers are looking for better ways to stop FSGS coming back in people who have kidney transplants.

The researchers in this study had reason to believe that bleselumab, also called ASKP1240, may help prevent FSGS coming back after a kidney transplant. A study was needed to confirm this.

The study started in May 2017 and ended in May 2021. Astellas reviewed all the study information and created a report of the results. This is a summary of that report.

## What were the main question this study helped answer?

- Does bleseelumab prevent FSGS coming back after a kidney transplant?

## What kind of study was this and who took part in it?

This was a phase 2 study. The aim of a phase 2 study is to gather information about whether a treatment works as intended and learn about any medical problems people had while taking the treatment. This phase 2 study was done in a “randomized” and “open-label” way.

This means:

- The treatment group each person was assigned to was chosen by chance
- People knew which treatment they were taking

Randomized studies help make the results fair and unbiased.

The study included men and women between the ages of 20 and 77 who had been diagnosed with FSGS, and recently had a kidney transplant.

67 people took part in the study. Of these, 63 people had a kidney transplant and received study treatment.

This study had 2 groups:

<b>Group 1</b> <b>Bleseelumab</b>	<b>Group 2</b> <b>Standard medical care</b>
People received: basiliximab, tacrolimus, steroids <b>and bleseelumab</b>	People received: basiliximab, tacrolimus, steroids <b>and mycophenolate mofetil</b>
27 people took part	33 people took part
18 men (66.7%) 9 women (33.3%)	21 men (63.6%) 12 women (36.4%)

## Where did the study take place?

This study took place at 25 clinics in the USA and Canada.

## What happened during the study?

At the first study visit, the study doctors:

- checked who could take part
- did a chest X-ray
- checked the peoples' heart health
- took blood and urine samples

During the study, people:

- received an injection of basiliximab before or during their transplant surgery and another a few days later
- took tacrolimus capsules 48 hours after their transplant surgery and then daily throughout the study
- received a steroid injection on the day of surgery, then daily for 3 days
- took steroid tablets daily throughout the study

In addition to the above, people in Group 1 were given bleseelumab, and people in Group 2 were given mycophenolate mofetil, as follows:

<b>Group 1</b> <b>Bleseelumab</b>	<b>Group 2</b> <b>Standard medical care</b>
bleseelumab	mycophenolate mofetil
Given directly into a vein on the day of the transplant surgery, 1 week later, then every 2 weeks for 3 months, then every 4 weeks until the end of the study	Given directly into a vein or as a tablet up to 12 hours before the transplant surgery, and then daily until the end of the study

## What were the study results?

### Does bleselumab prevent FSGS coming back after a kidney transplant?

At 3, 6 and 12 months after their kidney transplant, FSGS came back in fewer people treated with bleselumab than in those who received standard medical care.

Group 1 Bleselumab	Group 2 Standard medical care
FSGS came back in 6 people treated with bleselumab	FSGS came back in 11 people treated with standard medical care

The differences were not large enough to continue developing bleselumab to prevent FSGS from coming back.

## What medical problems did these people have during the study?

### What adverse reactions did people have in this study?

A lot of research is needed to know whether a medicine causes a medical problem. When new medicines are being studied, researchers keep track of all medical problems that people have while they are in the study. These problems are called adverse events and are recorded whether or not they might be caused by the treatment taken.

An adverse reaction is any medical problem or adverse event that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

In this study, 15 out of 29 people (51.7%) in Group 1 had adverse reactions to bleselumab. The most common was a higher-than-normal reading from blood tests that were done to check how the liver functions. These readings were seen in 6 people. In Group 2, 21 out of 34 people (61.8%) had adverse reactions to standard medical care. The most common reactions were a low white blood cell count, diarrhea, and involuntary shaking.

## Did any of the people in this study have serious adverse reactions?

An adverse reaction is considered serious when it is life-threatening, causes lasting problems or needs hospital care.

In this study, 14 people had serious adverse reactions:

- 8 people were in Group 1
- 6 people were in Group 2

The most common serious adverse reactions were kidney disorders and infections.

No people passed away during the study.

## Where can I learn more about this study?

This document is a short summary of the main results from this study.

The full name for the study is “A Phase 2a, Randomized, Open-Label, Active Control, Multi-Center Study to Assess the Efficacy and Safety of Bleselumab in Preventing the Recurrence of Primary Focal Segmental Glomerulosclerosis (pFSGS) in de novo Kidney Transplant Recipients.”

You can find this summary and more information about this study at

- <https://www.trialssummaries.com> and searching for the study number **7163-CL-3201**

Further information can be found at the following website:

- <https://clinicaltrials.gov/> and searching for the study number **NCT02921789**

**Please remember** that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

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