Summary of Results for Laypersons

Astellas is grateful to the patients who took part in this clinical study. Thank you.

What was the Study Called?

Efficacy and Safety of two Anti-T-lymphocyte Immune Globulin (ATG-F) Induction Regimens in de novo Kidney Transplant Patients – a multicenter, randomized, parallel group study

Why was this Study Needed?

The immune system is part of the body that fights foreign objects or infections. After organ transplantation, the immune system recognizes the new organ as a foreign object. ATG-F (also known as anti-T-lymphocyte immune globulin, ATG-Fresenius or Grafalon) is an experimental medicine that is used together with other medicines to reduce the strength of the immune system ("immunosuppressants"). These medicines prevent the body from rejecting organ transplants. Patients receive ATG-F as an intravenous infusion for several days. For the infusion, a catheter (thin tube) is inserted into a vein of their arm. It may be easier if ATG-F can be given once to patients. Therefore, there was a need to study the effect of a single dose of ATG-F in patients with transplants.

This study was conducted in patients who had a kidney transplant. This study compared treatment failure between patients who took 1 or 5 doses of study medicine. Treatment failure means that the body rejected the transplant, the transplant no longer worked like it should or the patient died. It was also important to find out what unwanted effects these patients had from the study medicine.

The study started in May 2013 and ended in December 2015. When the study ended, the sponsor of this study (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

This was an "open-label" study. This means that all patients and the study doctors knew which study medicine the patients took (ATG-F).

This study included adult women and men aged 18 to 65 years with end stage kidney disease. This means that their kidneys could no longer filter out wastes and extra salt and fluid from the blood. To stay alive, they needed a kidney transplant or dialysis (a treatment to filter the blood).

During the study, the study doctor did a check-up of the patients at several study visits. At the first visit, patients were checked to see if they could be in the study. Patients who could be in the study were picked for a treatment (1 or 5 doses of ATG-F) by chance alone.

- 1 Dose of ATG-F: Patients received a single intravenous infusion of ATG-F (between 7 and 9 mg per kg body weight). After the infusion, the blood flow to their kidney transplant was started.

- 5 Doses of ATG-F: Patients received daily intravenous infusions of ATG-F (2 mg per kg body weight) for 5 days.

One year after the kidney transplant surgery, the patients were checked for treatment failure.

This study took place at 19 clinics in China. 280 patients were in the study. Out of these patients, 276 patients took ATG-F.

	Number of Patients	
	1 Dose of ATG-F (out of 135 patients)	**5 Doses of ATG-F (out of 141 patients)**
Age Group		
Aged 18 to 63 years	135	141
Sex		
Men	97	104
Women	38	37

What Were the Study Results?

This study in patients with kidney transplants compared treatment failure 1 year after their transplant surgery between patients who took 1 or 5 doses of ATG-F.

116 patients took 1 dose of ATG-F and completed the study. Treatment failure happened in 20 out of 116 patients (17.24%). Out of the 20 patients, the body rejected the transplants in 14 patients, the transplants of 2 patients no longer worked like it should and 4 patients died.

117 patients took 5 doses of ATG-F and completed the study. Treatment failure happened in 27 out of 117 patients (23.08%). Out of the 27 patients, the body rejected the transplants in 25 patients and 2 patients died.

The difference in treatment failure was not likely to be due to chance. The study showed that after 1 dose of ATG-F, the results were not worse than after 5 doses of ATG-F.

What Adverse Events did Patients Have?

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

The table below shows the most common adverse events experienced by patients who took ATG-F in this study.

Adverse Event	1 Dose of ATG-F (out of 135 patients)	5 Doses of ATG-F (out of 141 patients)
Any adverse event	111 (82.22%)	123 (87.23%)
Increased blood levels of liver enzymes	27 (20.00%)	17 (12.06%)
Lung infection	25 (18.52%)	25 (17.73%)
Increased blood sugar level	24 (17.78%)	33 (23.40%)
Lack of enough red blood cells (anemia)	23 (17.04%)	25 (17.73%)
Decreased number of a type of blood cell that helps to clot blood (platelet)	19 (14.07%)	11 (7.80%)
Increase in the total number of white blood cells (leukocytes)	19 (14.07%)	13 (9.22%)
Fever	15 (11.11%)	9 (6.38%)
Rejection of the kidney transplant by the body	14 (10.37%)	22 (15.60%)

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

95 patients (34.42%, or 95 out of 276 patients) experienced serious adverse events:
45 patients who took 1 dose of ATG-F and 50 patients who took 5 doses of ATG-F.

Six patients died during the study: 4 patients who took 1 dose of ATG-F and 2 patients who took 5 doses of ATG-F.

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study and reflects the information available as of November 2016. You can find this summary and more information about this study online at http://www.astellasclinicalstudyresults.com.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse events they might cause. This summary only shows the results of this 1 study. If you have questions about ATG-F, please discuss these with your doctor.

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