CLINICAL TRIAL RESULTS

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Hospira Inc, a Pfizer company

Medicine Studied: Retacrit® (epoetin alfa-epbx)

Protocol Number: ZIN-EPO-1503

Dates of Trial: 13 July 2015 to 16 July 2016

Title of this Trial: The PIEDA Study: A Phase 3b Investigation of Erythropoietin Drugs Using A Specified Dosing Algorithm: A Randomized Open Label Dosing Study in Adult Chronic Kidney Disease Subjects on Hemodialysis

Date of this Report: 17 August 2018

– Thank You –

Hospira Inc, a Pfizer company, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

WHY WAS THIS STUDY DONE?

Anemia is a condition when a person has a low amount of red blood cells in their body. Anemia is common in patients with chronic kidney disease because their bodies may not make enough erythropoietin, a hormone that is needed to make red blood cells. Patients who have anemia can feel weak or very tired, have trouble breathing, or have headaches.

There are a variety of ways to treat anemia. One (1) medicine that is used is called Epogen® (epoetin alfa). Epogen may help the body make red blood cells.

Retacrit® (epoetin alfa-epbx) is a new medicine for anemia. Retacrit was made to be similar to Epogen. The reason for making a drug that is similar to Epogen is to help give patients access to a comparable but less expensive medicine. At the time of this study, Retacrit was still being tested and was not yet approved for use. Retacrit is now approved for use in Europe and the United States.

The purpose of this study was to learn more about switching from Epogen to Retacrit for patients with anemia and chronic kidney disease.

Patients who take medicines like Epogen or Retacrit must have blood tests regularly. These tests measure the amount of a protein in the blood called "hemoglobin", which tells doctors how well the medicine is working. Hemoglobin contains iron and helps to carry oxygen from the lungs to the body.

Usually, doctors look for a hemoglobin "target range" of 9 to 11 g/dL. Patients with hemoglobin levels below this range often have anemia symptoms.

For this study, researchers wanted to know:

Over the last 8 weeks of the study, what proportion of time were hemoglobin levels in the target range, for patients who took Retacrit **compared to those who took** Epogen**?**

WHAT HAPPENED DURING THE STUDY?

This study compared 2 groups of patients to learn more about switching from Epogen to Retacrit.

All patients in this study were adults with anemia and chronic kidney disease who were receiving a treatment called dialysis. Dialysis is used to remove extra water and waste from the body when the kidneys don't work well. At the time the study started, all patients were also receiving Epogen.

The first group of patients continued receiving Epogen throughout the study. There were 206 patients in this group. The second group of patients stopped taking Epogen and took Retacrit throughout the study. There were 212 patients in this group.

Both Epogen and Retacrit were given as an injection. Study doctors used a standard formula to determine the appropriate dose of Epogen or Retacrit for each patient.

Patients were picked for each treatment by chance alone. This is known as a "randomized" study. Randomized studies are done to make the treatment groups more similar for things like age and the number of men and women. Reducing differences between the groups makes comparing the groups more fair. Both the researchers and the patients knew who was receiving which study treatment.

Each patient in this study was supposed to be treated for about 24 weeks. However, it took about 1 year for all the patients to complete the study. Patients joined the study at 46 locations in the United States and Puerto Rico. It began 13 July 2015 and ended 16 July 2016. A total of 234 men and 184 women participated. Patients were between 21 and 94 years old.

Patients were supposed to come to the study center 9 times for visits. Of the 418 patients who joined the study and received study treatment, 314 patients finished the study. 104 patients did not finish the study by their own choice, because they had a medical problem, or because a doctor decided it was best for a patient to stop the study.

The figure on the following page shows what happened during the study.

When the study ended in July 2016, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

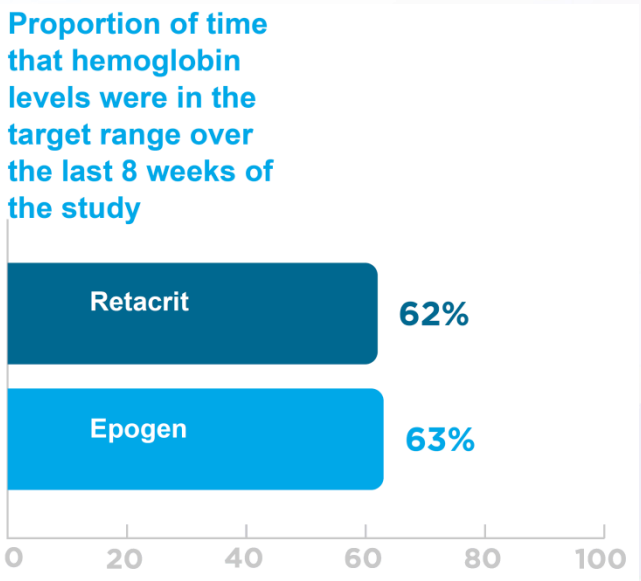
WHAT WERE THE RESULTS OF THE STUDY?

Over the last 8 weeks of the study, what proportion of time were hemoglobin levels in the target range, for patients who took Retacrit compared to those who took Epogen?

To answer this question, researchers looked at patients' hemoglobin levels over the last 8 weeks of the study. They looked for a target range of 9 to 11 g/dL.

The proportion of time that patients' hemoglobin levels were in the target range was 62% in the Retacrit group. The proportion of time that patients' hemoglobin levels were in the target range was 63% for the Epogen group. Based on these results, the researchers concluded that Retacrit was not less effective than Epogen.

The graph on this page shows the results of the study.



This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the website listed at the end of this summary.

WHAT MEDICAL PROBLEMS DID PATIENTS HAVE DURING THE STUDY?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could have been caused by a study treatment, or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what the side effects of an experimental drug might be.

A total of 31 out of 418 patients (7%) in this study had at least 1 of the most common non-serious medical problems (that means a medical problem that is not life-threatening, does not cause lasting problems, or needs hospital care). A total of 22 patients (5%) left the study because of medical problems. The most common non-serious medical problems reported by participants in this study are listed below.

Most Common Non-Serious Medical Problems (Reported by at Least 5% of Patients)

Medical Problem	Retacrit (212 Patients)	Epogen (206 Patients)
Nausea	3 (1%)	13 (6%)
Trouble breathing	7 (3%)	11 (5%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care.

A total of 130 out of 418 patients (31%) had serious medical problems. There were 66 patients in the Retacrit group and 64 patients in the Epogen group who had serious medical problems. The table below shows the most common serious medical problems that happened during the study.

Most Common Serious Medical Problems (Reported by at Least 2% of Patients)

Medical Problem	Retacrit (212 Patients)	Epogen (206 Patients)
Heart stopped beating	2 (1%)	6 (3%)
Lung infection	7 (3%)	1 (1)
Too much fluid in the body	4 (2%)	3 (2%)
Worsening of a medical problem	4 (2%)	3 (2%)
High level of potassium in the blood	5 (2%)	1 (1%)

There were 12 out of 212 patients (6%) in the Retacrit group who passed away during the study. There were 12 out of 206 patients (6%) in the Epogen group who passed away during the study.

No unexpected medical problems were seen in this study. Medical problems were similar between those patients who took Retacrit and those who took Epogen.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

If you have questions about the results of this study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.clinicaltrials.gov Use the study identifier **NCT02504294**

Please remember that researchers look at the results of many studies to find out which treatments work best and are safest for patients.

Again, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!