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?

A Multi-center, Open-label, Non-comparative Study to Evaluate the Efficacy and Safety of Micafungin for the Treatment of Invasive Candidiasis or Candidemia

Why was this Study Needed?

Micafungin (also known as FK463 and Mycamine®) is a prescription medicine used to treat patients when a fungal infection has spread throughout their body (called an "invasive" infection). Invasive fungal infections can be caused by yeast called *Candida* (invasive candidiasis or infections in the blood called candidemia). Patients who are at increased risk of yeast infections are those who have long hospital stays, have central venous catheters (a central venous catheter is a tube inserted in a large vein that returns blood to the heart) and patients who have been on antibiotics, steroids and parenteral hyperalimentation (parenteral hyperalimentation is when a person is fed through a vein, bypassing the usual process of eating and digestion).

This study was conducted in China in patients who had been diagnosed with invasive fungal infection caused by *Candida*. In this study all patients were given the same study drug, micafungin. The main question this study helped answer was how well micafungin works in Asian patients with diagnosed invasive candidiasis (infection throughout the body caused by *Candida*) or candidemia (infection of the blood caused by *Candida*). The study looked at the number of patients who survived and if the symptoms of their disease were gone (complete response) and/or who survived and showed improvement in the symptoms of their disease (partial response). It was also important to find out what unwanted effects these patients had from micafungin.

The study started in March 2013 and ended in September 2015. The study was stopped earlier than planned because not enough patients joined the study. When the study ended, 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 patients and study doctors knew the patients took micafungin.

This study included adult women and men who were thought to have invasive candidiasis or candidemia. They had not taken any medications for their fungal infection within 1 month before the study started. Before study start, they did not have human immunodeficiency virus (HIV), an organ transplant or a severe reduction in their number of white blood cells which makes infections more likely.

Micafungin was given to the patient through a vein in the arm once a day. The dose was 50 to 300 mg, as needed and patients were treated for 2 to 4 weeks or up to 8 weeks if necessary.

This study took place at 30 clinics throughout China. 68 patients were in the study and 67 patients received at least 1 dose of micafungin. Out of these 67 patients, 57 had been diagnosed with invasive candidiasis or candidemia and could be evaluated for how well micafungin worked.

	Number of Patients
Age Group	
65 years or younger	40
Older than 65 years	17
Sex	
Men	33
Women	24

What Were the Study Results?

This study in Asian patients with invasive candidiasis or candidemia evaluated how well micafungin treatment worked. The study looked at the number of patients who survived and if the symptoms of their disease were gone (complete response) and/or who survived and showed improvement in the symptoms of their disease (partial response). Because this study stopped early, we do not fully know the answer to the question that was studied. This is a summary of what we learned while the study was open. In 41 patients out of the 57 patients who had been diagnosed with invasive candidiasis or candidemia (41/57, approximately 72%) micafungin worked well. This result was similar to the results reported from micafungin studies conducted in other countries.

What Adverse Reactions 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. 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.

Seven patients out of 67 who were given at least 1 dose of micafungin had 11 adverse reactions. The adverse reactions the patients had included: liver worked poorly, skin rash, diarrhea, liver damage, increased blood level of a liver enzyme called alanine aminotransferase, increased blood level of a liver enzyme called aspartate aminotransferase, increase in number of a type of blood cell that helps to clot blood (platelet) and increased blood level of a liver or bone enzyme (alkaline phosphatase).

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

None of the patients experienced serious adverse reactions related to micafungin.

12 patients died during the study. None of the patients died because of micafungin.

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 June 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 reactions they might cause. This summary only shows the results of this 1 study. If you have questions about micafungin, please discuss these with your doctor.

Sponsor contact details:

Astellas Pharma China, Inc.
27th Floor, International Finance Center
No. 8 Jianguomenwai Street
Chaoyang District
Beijing
China