Summary of Results for Laypersons

What was the Study Called?

The title of the study was: An Open-Label Study to Characterize the Pharmacokinetic Parameters of Erlotinib (Tarceva®, OSI-774) in Cancer Patients with Advanced Solid Tumors with Adequate and Moderately Impaired Hepatic Function

Why was this Study Needed?

Erlotinib (also known as OSI-774 and Tarceva®) is a medicine that blocks a molecule called the epidermal growth factor receptor (EGFR) which is found on the surface of certain cancer cells. This molecule helps cancer cells grow. EGFR is present on solid cancer tumor cells. Since erlotinib is a medicine that blocks EGFR it could be effective in preventing the growth of solid cancer tumor cells.

The main question this study helped answer was how erlotinib goes through the body in cancer patients with advanced solid tumors. Cancer patients with advanced solid tumors were very sick. Some of the patients in this study had a liver that did not work as well as it should (moderate liver dysfunction). Also, it was important to find out what unwanted effects might occur.

This study for erlotinib took place at 5 clinics (4 in the US and 1 in the UK). The study took place between August 2005 and April 2007. When the study ended, the sponsor (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 study was done to see if erlotinib given to cancer patients with moderate liver dysfunction goes through the body the same way as cancer patients given the same dose with normal liver function. If there was a difference, the dose of erlotinib would have to be changed for patients with moderate liver dysfunction.

The patients were given 150 mg of erlotinib on Day 1 followed by blood tests over 96 hours. Men and women were allowed to volunteer for this study. They were all over 18 years old. They all had cancer and advanced solid tumors. Patients were required to have normal liver function or moderate liver dysfunction.

The study lasted up to 5 days, including:

- 1 day to receive the one dose of erlotinib (150 mg)
- 96 hours during which blood samples were obtained
- On day 5, the patient decided if they wanted to continue taking erlotinib to treat their cancer

Patients stayed at the clinic during the study. On Day 5 the patients were able to leave the clinic. Blood samples were taken from patients until all of the erlotinib was out of their body.

From the 39 patients who were enrolled into the study 36 patients received erlotinib. Fifteen patients with moderate liver dysfunction and 21 patients will normal liver function received erlotinib. All patients completed the study. The patients with moderate liver dysfunction were sicker than the patients with normal liver function.

	Number of Patients		
	Moderate Liver Dysfunction (out of 18 patients)	**Normal Liver Function (out of 21patients)**	**Total (out of 39)**
Age Group Aged 18 years and older	18	21	39
Women Men	3 15	9 12	12 27
EU Countries Outside EU	2 16	0 21	2 37

What Were the Study Results?

The study suggests that erlotinib goes through the body in a similar way for patients with moderate liver dysfunction and normal liver function. The safety of erlotinib is similar for patients with moderate liver dysfunction and normal liver function. The dose of erlotinib does not need to be changed for cancer patients with moderate liver dysfunction.

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.

The chart below shows the most common adverse reactions experienced by patients while taking part in this study.

Adverse Reactions	Moderate Liver Dysfunction (out of 15 patients)	Normal Liver Function (out of 21 patients)	Total (out of 36 patients)
Acne	4	5	9
Diarrhea	4	10	14
Vomiting	3	3	6
Nausea or urge to vomit	2	10	12
Feeling tired	3	9	12
Loss of appetite	1	7	8
Rash	3	6	9

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. One patient with moderate liver dysfunction had serious adverse reactions. None of the patients with normal liver function had serious adverse reactions.

Nine patients died during the study or within 30 days of the study. None of the deaths were related to study medication.

Where Can I Learn More About This Study?

Astellas may perform additional studies to better understand erlotinib.

This summary of the clinical study results is available 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. If you have questions about erlotinib, please discuss these with your doctor.

Sponsor Contact Details:

Astellas Pharma Global Development, Inc. (formerly OSI Pharmaceuticals, Inc.)

1 Astellas Way

Northbrook, IL 60062

USA