Summary of Results for Laypersons

What was the Study Called?

A Phase 1, Randomized, 2-period Crossover Study to Assess Bioequivalence of a Tablet Formulation versus a Capsule Formulation of ASP8273 in Subjects With Non-small Cell Lung Cancer Harboring Epidermal Growth Factor Receptor Mutations

Why was this Study Needed?

Some non-small cell lung cancer cells have a mutation, or change, in the gene for a protein (epidermal growth factor receptor or "EGFR") on the cell surface. The mutated EGRF helps the non-small cell lung cancer cells grow faster. ASP8273 (also known as naquotinib) is a medicine taken by mouth that blocks mutated EGFR. That way, ASP8273 may stop or slow down the growth of the non-small cell lung cancer. This study was conducted in patients who had non-small cell lung cancer with an EGFR mutation.

This study compared ASP8273 capsule and tablet formulations. The main questions this study was meant to answer were whether ASP8273 tablets are absorbed into the body as well as ASP8273 capsules; and whether ASP8273 from the tablets stays in the body as long as does ASP8273 from the capsules. The absorption of the ASP8273 tablets and capsules into the body was measured by the amount of ASP8273 in the blood. It was also important to find out what unwanted effects patients had from the study medicines.

This study took place at 2 clinics in the US. The study started in March 2017. At the same time, another study of ASP8273 in patients who had non-small cell lung cancer with an EGFR mutation was going on. In that study, the anticancer effects of ASP8273 did not outweigh its unwanted effects. The sponsor (Astellas) decided to stop the ASP8273 treatment for patients who had other treatment options. Astellas continued ASP8273 treatment for patients who had no other treatment options. These were patients with a certain EGFR mutation ("exon 20 insertion"). Astellas decided not to start any new studies of ASP8273.

Astellas stopped this study in June 2017. When the study was stopped, 3 patients had taken study medicine. 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. What this means is that all patients knew which study medicine they took (ASP8273 tablets or ASP8273 capsules).

Men and women aged 18 years or older could take part in the study if:

- Their doctor had determined that they had advanced non-small cell lung cancer with an EGFR mutation. Their cancer was too far gone and was very difficult to cure.
- They were ambulatory and able to take care of themselves. They were up and about more than half of the time that they were awake.

- They were expected to live for at least 3 months.

Patients could not take part in this study if:

- They had at least moderate intolerant effects that were caused by earlier anticancer treatment. (The exception was baldness.)
- They had taken an experimental drug within a certain period before their first dose of study drug. The period was specified in the study protocol. The length of the period depended on the experimental drug.
- Within 2 weeks before their first dose of study drug, they had taken anticancer treatment. Or within 6 days before their first dose of study drug, they had taken a medicine that blocks EGFR.
- Within 2 weeks before their first dose of study drug, they had major surgery; a blood transfusion; treatment that stimulated growth of certain blood cells; or they had an infection for which they needed to take medicine by mouth or via a vein. Or they planned to have major surgery during the study.

During the study, the study doctor did a check-up of the patients at several study visits. At visit 1, patients were checked to see if they could be in the study. Patients who could be in the study took study medicine on the first day of two 5-day periods. Patients were assigned by chance to 1 of the 2 following study treatments:

- Study treatment 1: Patients took a single dose of ASP8273 tablets (300 mg) on day 1 of period 1. They took no study medicine on days 2 through 4 of period 1. They took a single dose of ASP8273 capsules (300 mg) on day 1 of period 2. They took no study medicine on days 2 through 4 of period 2.
- Study treatment 2: Patients took a single dose of ASP8273 capsules (300 mg) on day 1 of period 1. They took no study medicine on days 2 through 4 of period 1. They took a single dose of ASP8273 tablets (300 mg) on day 1 of period 2. They took no study medicine on days 2 through 4 of period 2.

The intention was that at the end of period 2, patients would take ASP8273 capsules (300 mg) once a day for 4 weeks.

Blood samples were collected before and at several time points after the patients took the study medicines.

When this study was stopped, 3 patients were in the study.

- All 3 patients took at least 1 dose of ASP8273 capsules (300 mg).
- 2 of the 3 patients took at least 1 dose of ASP8273 tablets (300 mg).

	Number of Patients
Age Group	
Aged less than 65 years	2
Aged 75 years or older	1
Sex	
Men	0
Women	3
Clinic Location	
The US	3

What Were the Study Results?

The main questions this study was meant to answer were whether ASP8273 tablets are absorbed into the body as well as ASP8273 capsules; and whether ASP8273 from the tablets stays in the body as long as does ASP8273 from the capsules. When this study was stopped, 3 patients had taken study medicine. It was decided not to analyze the blood samples from the 3 patients. Those blood samples were not enough to answer the study's main questions.

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.

One of the 3 patients in the study (33.3%) had adverse reactions (diarrhea and fatigue or tiredness). The patient had taken 1 dose of ASP8273 capsules (300 mg).

A "serious adverse reaction" is any adverse event that is possibly caused by a medicine or treatment used in the study (as judged by the study doctor) and is life-threatening, causes lasting problems or needs hospital care.

None of the patients experienced a serious adverse reaction.

One patient (ASP8273 capsules 300 mg) died. The patient did not die because of the study medicine.

Where Can I Learn More About This Study?

The information in this document reflects the information available as of June 2017.

This summary of the clinical study results is available online at http://www.astellasclinicalstudy results.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 ASP8273, please discuss these with your doctor.

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