

**Research sponsor:** AstraZeneca AB

**Drug studied:** AZD8871

**Short study title:** A study to learn if AZD8871 is safe to take for Japanese patients with COPD

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## ***Thank you!***

Thank you for taking part in the clinical trial for the drug AZD8871. This drug is being developed to treat patients with chronic obstructive pulmonary disease, also known as COPD. The study started in June 2017 and ended in November 2017.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with you and the public. An independent nonprofit organization called CISCRP prepared this summary of the study results. We hope it helps you understand and feel proud of your important role in medical research.

If you participated in the study and have questions about the results, please speak with the doctor or staff at your study site.

## **Why was the research needed?**

Researchers are looking for a better way to treat a lung disease called COPD. COPD causes inflammation and narrowing of the airways, which can make it harder to breathe.

Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if the participants had any medical problems during the study. This information is important to know before other studies can be done that help find out if AZD8871 improves the health of people with COPD.

## What kind of study was this?

This was a “single-blind” study. This means the researchers knew what participants were taking, but the participants did not.

In this study, participants took different doses of AZD8871 or a placebo in an inhaler. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant took. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

## What happened during the study?

Before the study started, the doctors did a physical examination to make sure the participants could join the study. They also took blood and urine samples and checked the participants’ heart health using an electrocardiogram, also known as an ECG.

Throughout the study, the doctors continued checking the health of the participants and taking more blood and urine samples.

After this first visit, participants stayed at their study site for about 3 weeks. During this visit, participants took several doses of either AZD8871 or the placebo in an inhaler. Three different AZD8871 dose amounts were used in the study.

About 1 week after the participants went home, they visited their study site for a follow up examination. Then, they visited their study site again a few days later for a final follow-up examination.

## What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it also can be found on these websites.

Researchers wanted to find out if AZD8871 was safe to take for the Japanese participants in this study. So, they checked the health of participants several times throughout the study. In general, the researchers found that participants who took the different doses of AZD8871 had about the same number of medical problems as the participants who took the placebo. No participants had any medical problems that the researchers thought were serious.

## **What medical problems did participants have during the study?**

The medical problems participants have during clinical studies that the doctors think might be related to the study drug are called “adverse reactions.” An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The adverse reactions that happened in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

## **How has this study helped patients and researchers?**

This study helped researchers learn if AZD8871 was safe to take for the Japanese participants in this study.

The results presented here are for a single study. Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this 1 study. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

Further clinical studies with AZD8871 are planned.

## Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it also can be found there.

- [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type “**NCT03159442**” into the search box and click “**Search**”.
- [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu). Once you are on the website, click “**Home & Search**”, then type “**2017-000890-35**” in the search box and click “**Search**”.

**The full title of your study is:** A Phase I, Single Centre, Randomised, Single Blind, Placebo-Controlled Study to Investigate the Safety, Tolerability and Pharmacokinetics of Multiple Ascending Doses of Inhaled AZD8871 in Healthy Male Japanese Subjects

**The protocol number of your study is:** D6640C00005

AstraZeneca AB is the sponsor of this study and has its headquarters in Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

## Thank you

Clinical trial participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for participants.



The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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