This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to compare how Anthrax Vaccine Adsorbed works when given with or without raxibacumab.

Full Scientific Title: A Randomized, Open-label Study to Evaluate the Immunogenicity of Anthrax Vaccine Adsorbed Alone or Concomitantly with Raxibacumab (GSK3068483).

Study Number: 201436

Who sponsored this study?

GlaxoSmithKline (GSK)
GSK Clinical Support Help Desk
Website: www.clinicalsupporthd.gsk.com
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When and where was this study done?

The study started in February 2015 and ended in June 2017. Study sites were in the United States of America.

What were the reasons for conducting this study?

Anthrax of the lungs (inhalation anthrax) is a rare type of anthrax. It can develop if a person breathes in anthrax spores. Anthrax spores are inactive forms of anthrax bacteria. Once spores become active, anthrax bacteria can cause serious flu-like symptoms. If inhalation anthrax is not diagnosed and treated quickly, anthrax bacteria can grow and spread throughout the body. Untreated, inhalation anthrax can be deadly.

When diagnosed early, medicines that fight bacteria, such as antibiotics, are effective treatments. Other medicines are also used to help prevent and treat inhalation anthrax. Anthrax Vaccine Adsorbed (AVA) can be used to protect against anthrax. This vaccine may be particularly useful for people with a high risk of coming in contact with

anthrax spores. Anthrax bacteria makes a substance called the protective antigen (PA). AVA helps the body make anti-PA antibodies, which defend against anthrax bacteria.

Raxibacumab is a medicine which binds to PA and reduces the ability of the bacteria to make a person ill. Raxibacumab is approved in the United States of America for the treatment of inhalation anthrax in combination with antibiotics. It can also be used to prevent inhalation anthrax when other therapies are not available or suitable. In some circumstances, we may want to give people preventative treatment with both AVA and raxibacumab at the same time, but this has not been studied in the past.

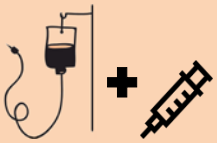
In this study, researchers wanted to learn if raxibacumab, when given with AVA, affected the ability of AVA to protect against anthrax bacteria. The study also tested the safety of AVA when given with raxibacumab.

Which medicines were tested in this study?

There were two treatment groups in this study (who were not infected with anthrax):

- AVA
- AVA and raxibacumab

Both AVA and raxibacumab were given as injections. AVA was injected just below the skin of the upper arm. Raxibacumab was given through a vein in the arm as an infusion. Below are the details of the treatment schedule for both treatment groups.

Treatment Schedule			
	Day 1 (First Day)	Day 15 (Week 2)	Day 29 (Week 4)
AVA			
AVA and raxibacumab			

 = raxibacumab

 = AVA

Which volunteers took part in this study?

A total of 573 healthy volunteers took part in this study. They were put into one of the two treatment groups by chance (randomisation).

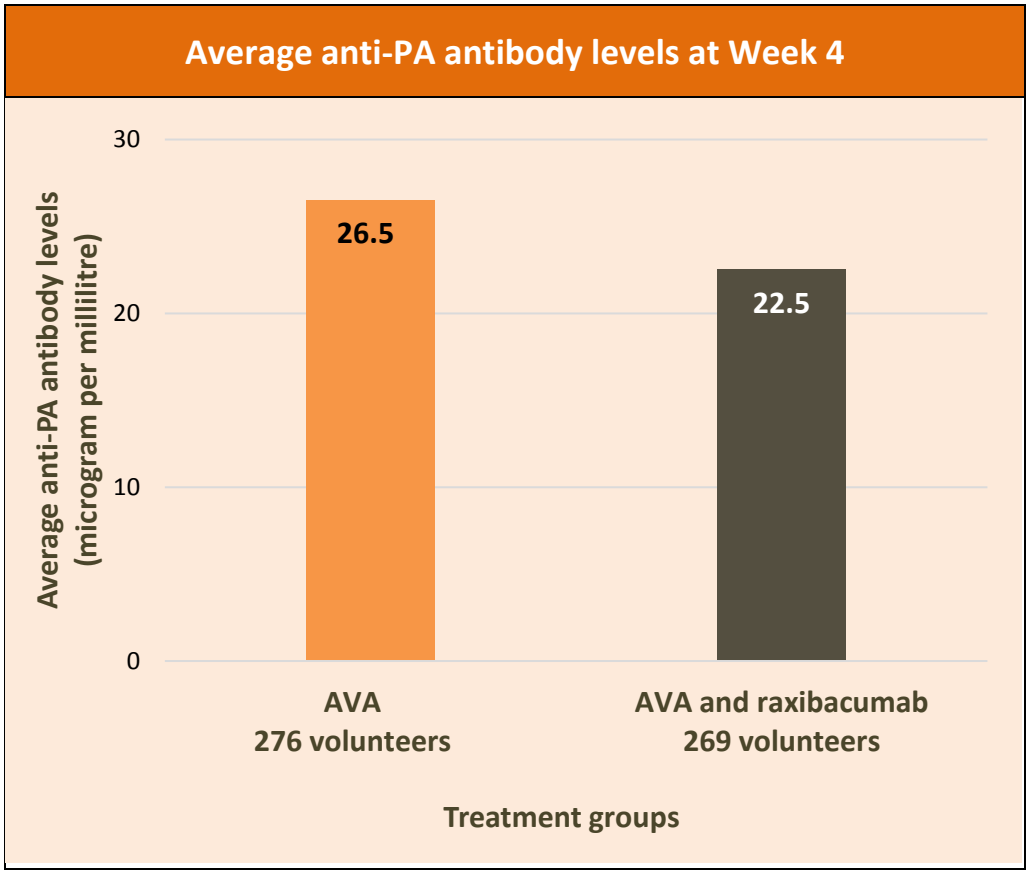
The table below presents the gender and age of these healthy volunteers.

Volunteers included in the study		
	AVA **287 volunteers**	**AVA and raxibacumab** **286 volunteers**
Gender - Number of volunteers (Percent)		
Female	150 (52%)	142 (50%)
Male	137 (48%)	144 (50%)
Age - In Years		
Range	18 to 66	18 to 63
Average	36	36

For more detailed information about the volunteers included in this study, see the scientific summary on the ClinicalTrials.gov website (see link provided at the end of this document).

What were the overall results of the study?

This study measured the level of anti-PA antibodies in the blood four weeks after the first dose of treatment with AVA alone or AVA and raxibacumab. Higher anti-PA antibody levels may mean better protection against anthrax bacteria. The anti-PA antibody levels were not measured for 28 volunteers, as they did not stay in the study to have their antibody measurement.



At four weeks, the amount of anti-PA antibodies in the two treatment groups was close enough that researchers concluded that AVA protection was similar even when given with raxibacumab.

For more detailed information on the overall results of this study, see the scientific summary on the ClinicalTrials.gov website (see link provided at the end of this document).

What were the side effects?

Study doctors collect information about the safety of study medicines. Any medical events including symptoms reported by volunteers in the clinical study are called adverse events. These adverse events can be found in the scientific summary (see link provided at the end of this document).

The study doctors record if they think any of these events may be caused by the medicine. If the study doctor believes that the event was caused by the medicine, they record this adverse event as a possible side effect. In a clinical study these are called **adverse reactions**. A **serious adverse reaction** is an adverse reaction that is life threatening, requires hospitalisation, or results in death or permanent damage.

This plain language summary describes those side effects (adverse reactions including serious adverse reactions) recorded by study doctors.

The details of adverse reactions were collected from volunteers who received at least one dose of the study medicine. Seven volunteers did not receive AVA during this study and safety information was not collected.

No serious adverse reactions were reported in this study.

The table below shows the non-serious adverse reactions reported by six or more volunteers (2% or more) in either of the treatment groups.

Non-serious adverse reactions reported by six or more volunteers		
	AVA 286 volunteers	**AVA and raxibacumab 280 volunteers**
Injection site reaction	18 of 286 (6%)	18 of 280 (6%)
Redness where the injection was given	11 of 286 (4%)	12 of 280 (4%)
Pain where the injection was given	6 of 286 (2%)	8 of 280 (3%)
Headache	2 of 286 (less than 1%)	6 of 280 (2%)

For further information about safety, including details about the adverse events that study doctors did not think were related to the study medicine, please see the scientific summary using the link at the end of this document.

How has this study helped patients and researchers?

Information from this study may help researchers to gain a better understanding of how well AVA and raxibacumab work when given together for the treatment of inhalation anthrax. The study also helps researchers know how well AVA and raxibacumab are tolerated when given in combination.

Are there plans for further studies?

No studies with this combination of medicines are planned or ongoing at this time.

Where can I find more information about this study?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study numbers associated with this study are shown below with an internet link to scientific summary and other information.

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02339155

For readers of this document in printed form, the website that goes with the internet link above is

https://clinicaltrials.gov/ct2/show/results/NCT02339155

Your doctor can help you understand more about this study and the results.

We would like to thank the volunteers who contributed to this study. The results of this study will help answer scientific questions about treating inhalation anthrax.

The content for this document was finalised by GSK on 21st October 2018. The information in this summary does not include additional information available after this date.