CLINICAL TRIAL RESULTS

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer, Inc.

Medicine(s) Studied: PF-05212366 (*Neisseria meningitidis* Serogroup B Bivalent Recombinant Lipoprotein 2086 Vaccine [Bivalent rLP2086])

Protocol Number: B1971033

Dates of Trial: 07 September 2012 to 05 January 2018

Title of this Trial: Final Report: A Phase 3 Study to Assess the Persistence of hSBA Response up to 48 Months After Completion of a Primary Series of Bivalent rLP2086, and the Safety, Tolerability, and Immunogenicity of a Booster Dose of Bivalent rLP2086

Date of this Report: 2 July 2019

– Thank You –

Pfizer, the Sponsor, would like to thank you for participating in this clinical trial, and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

WHY WAS THIS STUDY DONE?

"Meningococcal disease" is an infection that can cause swelling around the brain and spinal cord. The risk of meningococcal disease is increased in adolescents and young adults. People who get meningococcal disease are at risk for hearing loss and other disabilities. However, meningococcal disease may be prevented with a vaccine. A vaccine is a medication that helps people fight off germs.

Meningococcal disease is caused by the meningococcus germ. There are different types of this germ. For example, meningococcal type B disease is caused by the meningococcus B germ. Since vaccines were available to help fight off other types of meningococcus germ, but not type B, researchers were interested in finding a vaccine that can protect against meningococcal type B disease.

rLP2086 is a vaccine for meningococcal type B disease. It is approved for use in adolescents and young adults in Europe and the United States. It is given by injection into the arm. The purpose of this study was to learn more about how the rLP2086 vaccine works. Researchers wanted to know:

- How many participants would have antibodies against meningococcus B at 6, 12, 18, 24, 36, and 48 months after receiving their last dose of vaccine?
- How many participants would have antibodies against meningococcus B 1 month after receiving their last dose of vaccine, before receiving a booster vaccine, and at 1, 12, and 26 months after receiving the booster vaccine?

To answer these questions, researchers collected blood samples from the participants. The researchers looked for antibodies in the blood against 4 different strains of meningococcus B. Antibodies are special proteins that can recognize and help kill germs. These antibodies can protect people from getting sick if they ever do come into contact with the meningococcus B germ.

Researchers were also interested in learning more about the safety of the vaccine. They monitored for any medical problems the participants had after receiving the vaccine.

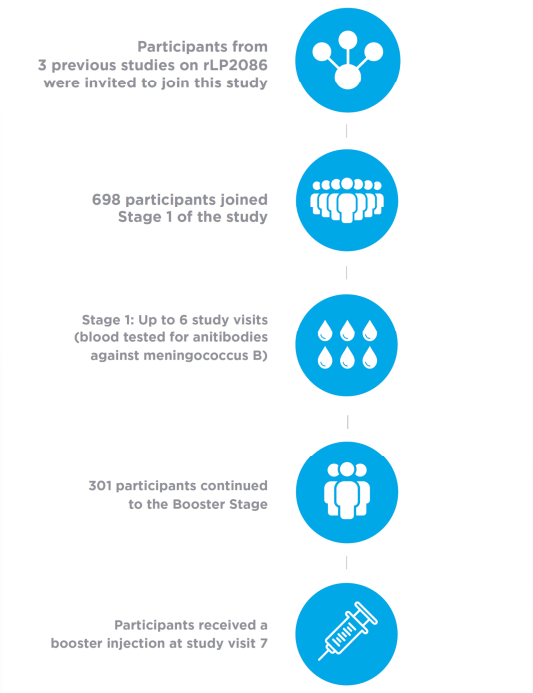
WHAT HAPPENED DURING THE STUDY?

Adolescents who participated in 3 previous studies with rLP2086 were invited to join this study. In this study, the participants were monitored to find out if they would have antibodies against the meningococcus B germ.

The study was divided into 2 stages. Stage 1 lasted from month 6 to month 48 after the last vaccine was given. Participants came to visits at the study center up to 6 times to have blood samples collected. No vaccines were given during this stage.

The booster stage was optional, so only some of the adolescents participated in this stage. A single booster dose of rLP2086 was given at study visit 7. This stage of the study lasted up to 26 months after the booster dose was given.

The figure below shows what happened during the study.



The entire study took about 5 ½ years to complete, although participants may have completed the study sooner. Participants joined the study at 1 of 50 locations in the Czech Republic, Denmark, Germany, Sweden, Finland, and the United States. It began 07 September 2012 and ended 05 January 2018. For stage 1, a total of 360 girls

(52%) and 336 boys (48%) participated. For the booster stage, a total of 165 girls (55%) and 136 boys (45%) participated. All participants were between the ages of 11 and 20 when this study began.

Participants were supposed to come to the study center up to 11 times for visits, and some of the participants may have received a single dose of booster vaccine. Of the 698 participants who participated in stage 1, 623 (89%) completed it. 75 participants (11%) did not finish stage 1 by their choice or because a doctor decided it was best for a participant to stop the study.

When the study ended in January 2018, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

How many participants had antibodies against meningococcus B at 6, 12, 18, 24, 36, and 48 months after receiving their last dose of vaccine?

For stage 1, the number of participants with antibodies against meningococcus B decreased during the first 12 months after the last dose of vaccine, then stayed about the same through month 48:

- At month 1, the percentage of participants with antibodies against meningococcus B ranged from 74% to 100%, depending on which strain was tested.
- At month 12, the percentage of participants with antibodies against meningococcus B ranged from 17% to 76%, depending on which strain was tested.
- At month 48, the percentage of participants with antibodies against meningococcus B ranged from 18% to 61%, depending on which strain was tested.

How many participants had antibodies against meningococcus B at 1 month after receiving their last dose of vaccine, before receiving a booster vaccine, and at 1, 12, and 26 months after receiving the booster vaccine?

- At month 1 after receiving the booster vaccine, the percentage of participants with antibodies against meningococcus B ranged from 93% to 100%, depending on which strain was tested.
- At month 12 after receiving the booster vaccine, the percentage of participants with antibodies against meningococcus B ranged from 59% to 100%, depending on which strain was tested.
- At month 26 after receiving the booster vaccine, the percentage of participants with antibodies against meningococcus B ranged from 58% to 83%, depending on which strain was tested.

This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

WHAT MEDICAL PROBLEMS DID PARTICIPANTS HAVE DURING THE STUDY?

The researchers recorded any medical problems the participants had during the booster stage of the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment, or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what the side effects of an experimental drug might be.

292 out of 301 participants (97%) in the booster stage had at least 1 medical problem. No participants (0%) left the study because of medical problems. The most common medical problems during the booster stage are listed below.

Most Common Medical Problems During Booster Stage (Reported by More Than 5% of Participants)	
Medical Problem	**rLP2086 (301 Children)**
Tenderness at injection site	**272 (90%)**
Feeling tired	**182 (60%)**
Headache	**148 (49%)**
Chills	**75 (25%)**
Muscle pain	**70 (23%)**
Redness at injection site	**61 (20%)**
Swelling at injection site	**52 (17%)**
Joint pain	**48 (16%)**
Diarrhea	**30 (10%)**

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

5 out of 301 participants (2%) in the booster stage had at least 1 serious medical problem, which were not considered related to the vaccine. No participants died during the study.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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

For more details on this study protocol, please visit:

www.clinicaltrials.gov	Use the study identifier **NCT01543087**
www.clinicaltrialsregister.eu	Use the study identifier **2011-005697-31**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you and your child helped us to do that!