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 vaccine 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.

Vaccine(s) Studied: Meningococcal Polysaccharide Groups A, C, W-135, and Y Tetanus Toxoid Conjugate Vaccine (MenACWY-TT), Marketed as Nimenrix®, Compound Number: PF-06866681

Protocol Number: MENACWY-TT-099/116725/C0921002

Dates of Trial: 29 April 2014 to 10 August 2018

Title of this Trial: Final Report: A Phase IIIb, Open, Multi-Center Study to Evaluate the Long-Term Antibody Persistence at 6, 7, 8, 9 and 10 Years After the Administration of One Dose of Meningococcal Conjugate Vaccine MenACWY-TT Versus 1 Dose of Meningococcal Polysaccharide Vaccine Mencevax® ACWY, and to Evaluate the Safety and Immunogenicity of a Booster Dose of MenACWY-TT Vaccine Administered 10 Years After Primary Vaccination of 11-55 Year Old Subjects With MenACWY-TT or Mencevax® ACWY

Date of this Report: 14 August 2019

– Thank You –

Pfizer, the Sponsor, would like to thank you for your participation 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?

Invasive meningococcal disease is an illness which may cause a serious infection in the blood, as well as swelling around the brain and spinal cord. People who get this illness are at risk for disabilities such as hearing loss and loss of limbs, and even death. However, invasive meningococcal disease may be prevented with a vaccine. A vaccine is a type of medicine 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 A disease is caused by the meningococcus A germ. MenACWY-TT (Nimenrix) is a vaccine approved in Europe for the prevention of meningococcal disease. This vaccine targets 4 common types of meningococcus germ: types A, C, Y, and W-135. It is given by injection into the muscle.

The main purpose of this study was to learn more about the long-term effects of Nimenrix in healthy participants, compared to another vaccine against meningococcal disease, called Mencevax® ACWY. Mencevax is also aimed at preventing meningococcal diseases caused by the meningococcus A, C, Y, and W-135 germs. Researchers wanted to know:

- **Would participants who received Nimenrix still have antibodies against meningococcus germs at 6, 7, 8, 9, and 10 years after vaccination, compared to participants who received Mencevax?**

To answer this question, researchers collected blood samples from the participants. The researchers looked for antibodies in the blood against the 4 different types of meningococcus germ. 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 meningococcus germs.

WHAT HAPPENED DURING THE STUDY?

This study compared 2 groups of participants to learn more about the long-term effects of MenACWY-TT.

The sponsor asked participants who participated in a previous study on Nimenrix to join this study. All the participants were healthy and had received vaccination with Nimenrix or Mencevax during the previous study.

The participants were placed in 2 groups (the same groups as the previous study):

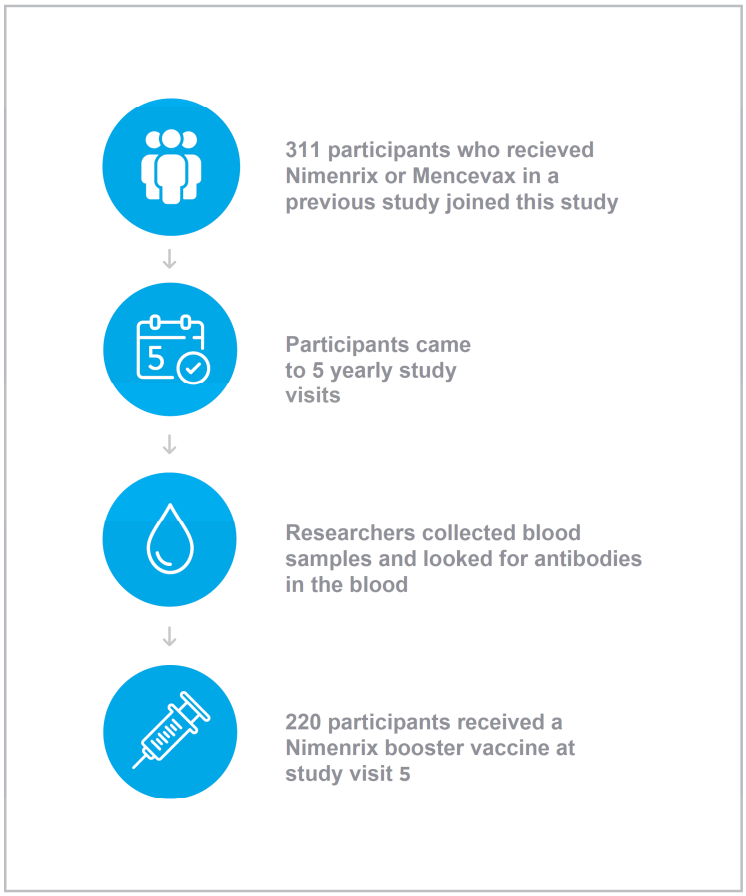
- Group 1: Participants who received Nimenrix in the previous study (235 participants)
- Group 2: Participants who received Mencevax in the previous study (76 participants)

The participants were asked to come to up to 5 visits, each a year apart, at the study center. This was known as the "persistence phase" of the study. During these visits, the researchers collected blood samples from the participants. The researchers looked for antibodies in the blood against the 4 different types of meningococcus germ.

164 participants from the Nimenrix group and 56 participants from the Mencevax group received a booster dose of Nimenrix at study visit 5. This was known as the "booster phase" of the study.

This was an "open label" study, which means that the participants and the researchers knew which vaccine the participants received.

The figure on the following page shows what happened during this study.



Participants were in this study for up to 4 years, and the entire study took a little more than 4 years to complete. Participants joined the study at 1 of 2 locations in the Philippines. The first participant joined the study on 29 April 2014 and the last participant finished the study on 10 August 2018. A total of 163 men (52%) and 148 women (48%) joined the study. All participants were between 18 and 60 years old.

Participants were supposed to come to up to 5 visits, each a year apart, at the study center. Of the 311 participants who started the study, 203 (65%) completed all visits. A total of 80 participants did not finish the study by their choice or because a doctor decided it was best for a participant to stop the study.

When the study ended in August 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?

Did participants who received Nimenrix still have antibodies against meningococcus germs at 6, 7, 8, 9, and 10 years after vaccination, compared to participants who received Mencevax?

In general, participants from the Nimenrix and Mencevax groups still had antibodies against meningococcus germs at each of the study visits. The amount of antibodies in the blood was similar at each study visit.

The charts below show the percentage of participants in each group who still had a certain level of antibodies against meningococcus germs at 7, 8,9, and 10 years after vaccination. The year 6 visit was not completed in this study. Therefore, there is no data for this visit.

Percentage of Participants in Nimenrix Group With Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 7	88%	83%	61%	80%
Year 8	76%	86%	66%	76%
Year 9	83%	90%	56%	90%
Year 10	77%	91%	70%	87%

Percentage of Participants in Mencevax Group with Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 7	68%	77%	23%	46%
Year 8	57%	81%	24%	40%
Year 9	66%	90%	10%	57%
Year 10	70%	89%	24%	65%

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 medical problems the participants had during 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 vaccine, 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.

During the booster phase, the researchers recorded medical problems that occurred within 31 days of receiving the booster vaccine. Out of 164 participants in the Nimenrix group, 15 participants (9%) had a medical problem during this time. Out of 56 participants in the Mencevax group, 2 participants (4%) had a medical problem during this time.

The medical problems during the booster phase are listed on the following page.

Medical Problem	Nimenrix Group (164 Participants)	Mencevax Group (56 Participants)
Common cold	3 (2%)	0 (0%)
Respiratory tract infection	3 (2%)	0 (0%)
Flu-like illness	2 (1%)	0 (0%)
Stomach Inflammation	1 (1%)	0 (0%)
Toothache	1 (1%)	0 (0%)
Wound infection	1 (1%)	0 (0%)
Back pain	1 (1%)	0 (0%)
Dizziness	1 (1%)	0 (0%)
Headache	1 (1%)	0 (0%)
Decreased sense of touch	1 (1%)	0 (0%)
Menstrual pain	1 (1%)	0 (0%)
Throat pain	1 (1%)	0 (0%)
Dandruff	1 (1%)	0 (0%)
Inflammation of the tonsils	0 (0%)	1 (2%)
Infection after medical procedure	0 (0%)	1 (2%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

No participants in this study had a serious medical problem. No participants died during this 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 **NCT01934140**

Please remember that researchers look at the results of many studies to find out which vaccines work best and are safest for patients. Additional studies with Nimenrix are ongoing.

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