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: C0921004

Dates of Trial: 09 October 2013 to 11 June 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 the Meningococcal Conjugate Vaccine MenACWY-TT Versus One Dose of Meningitec® Vaccine or One Dose of the 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 1-10 Year Old Subjects With MenACWY-TT, Meningitec, or Mencevax ACWY.

Date of this Report: 2 July 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.

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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. Meningococcal disease is more common in children than adults. Children who get this illness are at risk for hearing loss and other disabilities. 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 children, compared to 2 other vaccines against meningococcal disease, called Meningitec® and Mencevax® ACWY. Meningitec is aimed at preventing meningococcal diseases caused by the meningococcus C germ. Mencevax is aimed at preventing meningococcal diseases caused by the menigococcus A, C, Y, and W-135 germs. Researchers wanted to know:

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

To answer this question, researchers collected blood samples from the children. 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 children from getting sick if they ever do come into contact with meningococcus germs.

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WHAT HAPPENED DURING THE STUDY?

This study compared 4 groups of children to learn more about the long-term effects of MenACWY-TT.

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

The children were placed in 4 groups (the same groups as the previous study):

- Group 1: Children who received Nimenrix when they were between 1 and 2 years old (76 children)
- Group 2: Children who received Meningitec when they were between 1 and 2 years old (23 children)
- Group 3: Children who received Nimenrix when they were 2 to 10 years old (115 children)
- Group 4: Children who received Mencevax when they were 2 to 10 years old (29 children)

The children 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 children. The researchers looked for antibodies in the blood against the 4 different types of meningococcus germ.

181 children 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 children, their parents/guardians, and the researchers knew which vaccine the children received.

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

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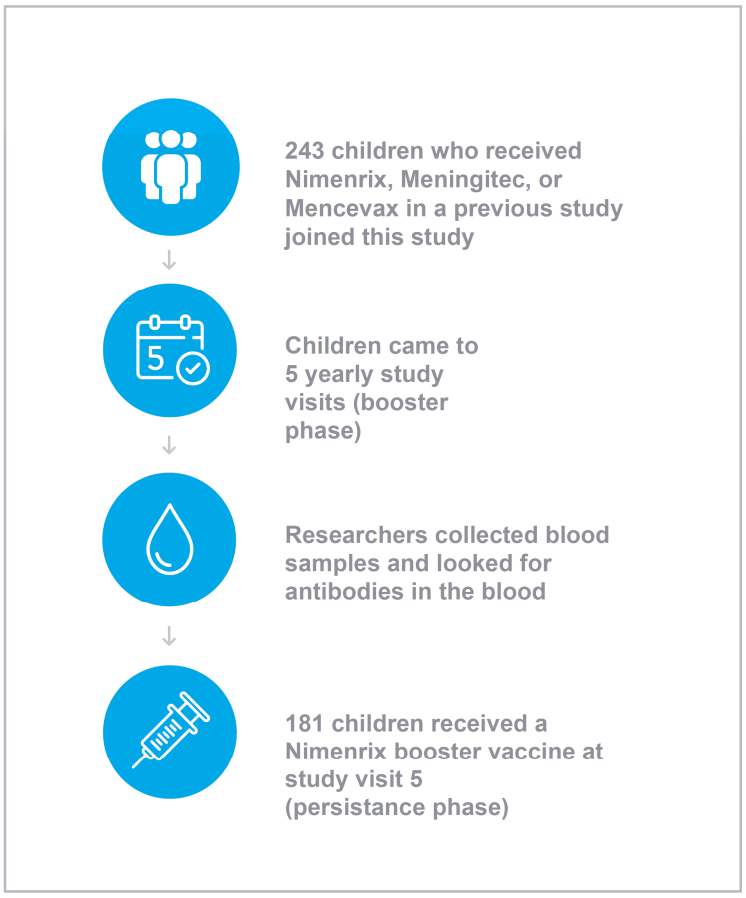

Children were in this study for up to 4 years, but the entire study took almost 5 years to complete. Children joined the study at 1 of 9 locations in Finland. The first child joined the study on 09 October 2013 and the last child finished the study on 11 June 2018. A total of 122 girls and 121 boys joined the study. The children were between 7 and 18 years old when they began the study.

Children were supposed to come to up to 5 visits, each a year apart, at the study center. Of the 243 children who joined the study, 191 (79%) completed it. A total of 52 children (21%) left before the study was over by their parent/guardian's choice or a doctor decided it was best for a patient to stop the study.

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

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WHAT WERE THE RESULTS OF THE STUDY?

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

In general, children from the Nimenrix, Meningitec, 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. However, there were fewer children in the Meningitec and Mencevax groups than the Nimenrix groups, so the results for each group can not be directly compared.

The charts below show the the percentage of children in each group who still had a certain level of antibodies against meningococcus germs at 6,7,8,9, and 10 years after vaccination. Recall that Meningitec is aimed at preventing meningococcal diseases caused by the meningococcus C germ only, while Mencevax and Nimenrix are aimed at preventing meningococcal diseases caused by the menigococcus A, C, Y, and W-135 germs.

Percentage of Children in Nimenrix Group (Younger Than 2 Years Old) with Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 6	52%	78%	33%	39%
Year 7	58%	78%	27%	35%
Year 8	48%	79%	29%	40%
Year 9	67%	81%	33%	42%
Year 10	66%	83%	31%	44%

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Percentage of Children in Nimenrix Group (2 to 10 Years Old) with Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 6	80%	83%	74%	71%
Year 7	74%	84%	74%	76%
Year 8	70%	85%	76%	79%
Year 9	80%	86%	76%	67%
Year 10	89%	84%	67%	66%

Percentage of Children in Meningitec Group with Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 6	19%	75%	13%	38%
Year 7	10%	71%	10%	29%
Year 8	5%	77%	14%	41%
Year 9	5%	86%	10%	48%
Year 10	18%	88%	0%	35%

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Percentage of Children in Mencevax Group with Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 6	13%	79%	13%	21%
Year 7	19%	82%	11%	15%
Year 8	24%	88%	20%	24%
Year 9	24%	84%	16%	20%
Year 10	29%	81%	24%	24%

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 CHILDREN HAVE DURING THE STUDY?

The researchers recorded medical problems the children had during the study. Children 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.

Out of 243 children who participated in the persistence phase, 2 children (less than 1%) left the study because of medical problem. The study doctors determined that these medical problems were not related to the study vaccines.

During the booster phase, the researchers recorded medical problems that occurred within 31 days of receiving the booster vaccine. Out of 181 children who participated in this phase, 59 children (33%) had a medical problem that the study doctors determined was related to the vaccine. This included 16 children (24%) in Group 1,

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5 children (31%) in Group 2, 27 children (35%) in Group 3, and 11 children (52%) in Group 4.

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

Most Common Medical Problems During Booster Phase (Reported in More Than 5% of Children)

Medical Problem	Group 1 (67 Children treated)	Group 2 (16 Children treated)	Group 3 (77 Children treated)	Group 4 (21 Children treated)
Fever	0 (0%)	2 (13%)	0 (0%)	0 (0%)
Upper Respiratory Tract Infection (Viral infection of the nose, throat, and airways)	0 (0%)	0 (0%)	7 (9%)	2 (10%)
Headache	0 (0%)	0 (0%)	6 (4%)	0 (0%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

1 child in this study had a serious medical problem, which the study doctors determined was not related to the study vaccine. This medical problem was

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considered serious because the child was hospitalized, but the medical problem was not life-threatening. No children passed away during the study.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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

For more details on this study protocol, please visit:

www.clinicaltrials.gov	Use the study identifier **NCT01962207**
www.clinicaltrialsregister.eu	Use the study identifier **2013-001549-15**

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!

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