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

Protocol Number: C0921001

Dates of Trial: 16 July 2013 to 08 November 2017

Title of this Trial: Final Report: A Phase III, Open, Multicentre, Controlled Study to Evaluate the Long-Term Antibody Persistence at 2, 3, 4, 5, and 6 Years After a Booster Dose of Meningococcal Serogroup A, C, W-135, and Y Tetanus Toxoid Conjugate Vaccine (MenACWY-TT) or Meningitec® Administered in Healthy 5-Year-Old Children in Study MenACWY-TT-048 EXT: 039 Y2, 3, 4, 5 (112036), Who Were Primed With the Same Vaccine in Study MenACWY-TT-039 (109670) at 12 Through 23 Months of Age

Date of this Report: 14 December 2018

– Thank You –

Pfizer, the Sponsor, would like to thank you and your child 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 child's 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. 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 another vaccine called Meningitec®. Meningitec is aimed at preventing only meningococcal diseases caused by the meningococcus C germ. Researchers wanted to know:

- **Would children still have antibodies against meningococcus germs at 2, 3, 4, 5, and 6 years after receiving a booster injection of either Nimenrix or Meningitec?**

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.

WHAT HAPPENED DURING THE STUDY?

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

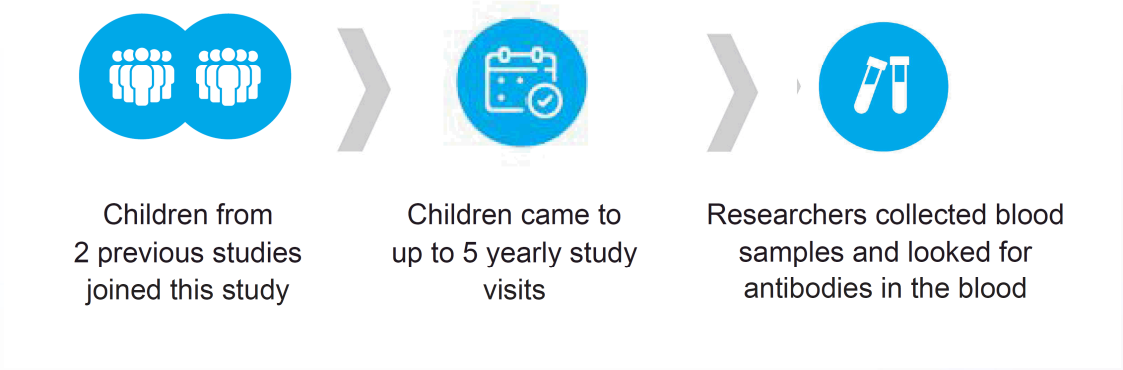
The sponsor asked children who participated in 2 previous studies on Nimenrix to

join this study. All the children were healthy and had received 2 injections (primary injection plus booster injection) of Nimenrix or Meningitec during the previous studies.

The children did not receive any study vaccinations or other medicines during this study, since they had already received either Nimenrix or Meningitec during the previous studies. Instead, the children were asked to come to up to 5 visits, each a year apart, at the study center. 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.

This was an "open label" study, which means that the children, their parents/guardians, and the researchers knew which vaccine the children received during the previous studies.

The figure below shows what happened during this study.



Children were in this study for up to 4 years, and the entire study took a little more than 4 years to complete. Children joined the study at 1 of 9 locations in Finland. The first child joined the study on 16 July 2013 and the last child finished the study on 08 November 2017. A total of 84 girls and 100 boys joined the study. The children were between 7 and 10 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 184 children who joined the study, 174 (95%) completed it. A total of 10 children (5%) did not finish the study by their parent/guardian's choice.

When the study ended in November 2017, 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 children still have antibodies against meningococcus germs at 2, 3, 4, 5, and 6 years after receiving a booster injection of either Nimenrix or Meningitec?

At each of the study visits, the majority of children from the Meningitec group still had antibodies against the meningococcus C germ. At each of the study visits, the majority of children from the Nimenrix group still had antibodies against each of the 4 types of meningococcus germ.

The 2 charts below show the percentage of children in each group who still had a certain level of antibodies against meningococcus germs at 2, 3, 4, 5, and 6 years after receiving a booster vaccination. Recall that the Meningitec vaccine is aimed at preventing diseases caused by the meningococcus C germ only.

Percentage of Children in Nimenrix Group with Antibodies Against Meningococcus Germs

	Type A	Type C	Type W-135	Type Y
Year 2	98%	98%	97%	100%
Year 3	96%	88%	98%	95%
Year 4	95%	89%	87%	95%
Year 5	90%	80%	88%	93%
Year 6	93%	72%	86%	94%

Percentage of Children in Meningitec Group with Antibodies Against Meningococcus Germs				
	Type A	Type C	Type W-135	Type Y
Year 2	24%	100%	10%	33%
Year 3	18%	77%	9%	36%
Year 4	26%	100%	17%	44%
Year 5	0%	78%	13%	26%
Year 6	9%	65%	13%	13%

This does not mean that everyone in this study had these results, and individual results could be better or worse than the overall group. Other studies may find different results. 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 that were related to the vaccines given during the previous study, to study participation, or to meningococcal disease. 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 have been caused by a study treatment. 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 184 children in this study, 1 child (less than 1%) had a non-serious medical problem (that means a medical problem that is not life-threatening, does not cause lasting problems, or does not need hospital care). This child was in the Nimenrix group and had arthritis (swelling in the joints). The study doctors determined that this medical problem was not related to the Nimenrix vaccine that the child had received during the previous studies.

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

No children in this study had a serious medical problem. 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 **NCT01900899**
www.clinicaltrialsregister.eu	Use the study identifier **2012-005816-25**

Please remember that researchers look at the results of many studies to find out which medicines 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!