Protocol Plain Language Summary

A clinical study of the V116 vaccine for children and teenagers (V116-013)

Protocol title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Children and Adolescents With Increased Risk of Pneumococcal Disease

Why is this study needed?

Researchers are looking for new vaccines to prevent and provide longer protection than current standard vaccines against **invasive pneumococcal disease** (**IPD**). IPD is a group of severe infections like pneumonia, meningitis and sepsis caused by pneumococcal bacteria. There are many different types of pneumococcal bacteria, called **serotypes**. Pneumococcal vaccines contain small parts of certain serotypes. These parts will not cause an infection but will help the body make **antibodies** (proteins) to fight the serotypes.

Children and teenagers with certain health conditions may have a higher risk (chance) of getting IPD. **PPSV23** is a standard vaccine given to children and teenagers with certain health conditions who have previously received another vaccine, usually during early childhood, to prevent IPD. The PPSV23 vaccine prevents IPD caused by 23 different serotypes of pneumococcal bacteria. **V116** is a **study vaccine** designed to prevent IPD caused by 21 different serotypes. V116 includes 12 of the same serotypes as PPSV23 and 9 different serotypes that are not in PPSV23.

Researchers want to know if V116 is safe and learn how well the body's immune system responds by making antibodies to fight IPD after receiving V116 compared to PPSV23.

Who will take part in this study?

About 820 people will be in this study. They will be between 2 years and less than 18 years of age and:

- Have been treated for more than 3 months for certain long-term health conditions, such as diabetes, liver, lung, heart, or kidney disease
- Have previously received another vaccine to prevent IPD during early childhood
- Not have had IPD in the past 3 years

What treatments are being given during this study?

People will receive either:

- **V116**, the study vaccine
- **PPSV23**, a standard vaccine

V116 or PPSV23 will be given as an injection (shot) into a muscle.

How is this study designed?

Neither the people in the study nor the researchers will know which vaccine a person gets (**double-blind study**). During the study, people will give blood samples, have physical

examinations, a mouth swab, and answer questions. People may have a urine test. Each person will be in the study for about 6 months.

What are the goals of this study and how will they be measured?

Main goals	How they will be measured

To learn if V116 is **safe** and how well people **tolerate** it	• The number of people who have certain **adverse events (AE)** up to 5 days after getting the vaccine – an AE is a health problem that first happens or worsens during a study. These AEs include:
	  ○ Problems in the area where people got the injection, including pain, redness, or swelling
	  ○ Problems anywhere in the body, including muscle aches, headache, tiredness, hives or welts, fussiness, joint pain, increased sleep, and feeling unwell
	• The number of people who have **serious adverse events (SAE)** that researchers think may be related to the study vaccine about 6 months after getting the vaccine – an SAE is a serious health problem that first happens or worsens during the study

To learn if the **immune system responds** to V116 the same or better than PPSV23	People will have a blood test 30 days after getting V116 or PPSV23. Researchers will measure how well people's antibodies can fight: • The 12 serotypes that are the same in both vaccines • The 9 serotypes that are only in V116
Other goals	**How they will be measured**
To compare the **levels (amount) of antibodies** in people who receive V116 to people who receive PPSV23	People will have a blood test 30 days after getting V116 or PPSV23. Researchers will measure the average level of antibodies for each serotype.

To learn about the **change in the level of antibodies** and **how well the immune system responds** to each serotype	People will have blood tests before treatment and 30 days after getting V116 or PPSV23. Researchers will measure:
	• The change in:
	  ○ The average level of antibody for each serotype
	  ○ How well people's antibodies can fight each serotype
	• The number of people who have at least 4 times higher:
	  ○ Levels of antibody for each serotype
	  ○ Ability of antibodies to fight each serotype

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study. This study has an external group of experts that will oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe or does not show benefit, the study can be stopped.

More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.