**INTRODUCTION**

The introduction of pneumococcal conjugate vaccines (PCVs) has led to substantial reductions in the burden of pneumococcal diseases in infants.

Currently, two high-valency PCVs are in use or routine infant vaccination in many countries: the 13-valent PCV (PCV13) and the pneumococcal non-typeable Haemophilus influenzae protein D conjugate vaccine (PHiD-CV). The latter is not licensed in the USA.

Both vaccines have shown to be highly effective in protecting young children against vaccine type pneumococcal diseases.2

Limited data are available on the interchangeability between PCV13 and PHiD-CV.4,5 Data on the immunogenicity of PHiD-CV after 1 or more primary or booster vaccination doses are incomplete.6

### Study design and participants

In this phase II, partially blind (observers blind in the primary phase and open in the booster phase), multicenter study (ClinicalTrials.gov: NCT01641133), 457 infants were randomized to receive 2-dose primary vaccination, followed by a booster dose with either PCV13 (SSS control group), or PCV13 and PHiD-CV in primary and booster phase (PPS group) or PCV13 followed by PHiD-CV and PHiD-CV in booster (PPS group) (Figure 1).

Immune responses to pneumococcal serotypes

**Antibody geometric mean concentrations (GMCs) and percentages of infants reaching the 0.2 µg/mL threshold** were in similar ranges across the 3 vaccination schedules (Table 2).

**Immune responses to protein D carrier**

**A 2+1 series with 2 PCV13 primary doses followed by a PHiD-CV booster or 1 PCV13 dose followed by a PHiD-CV primary and booster dose** was associated with lower antibody GMCS for some serotypes.

**The clinical relevance of this trend is unknown**, pending onaphosphorycactivity data from this study may shed further light on this question.

**Boostability was observed for both the PSS and the PPS groups, for the 10 common vaccine serotypes as well as for serotypes 19A and 6A.**

### Results

#### Demographic characteristics

Enrolled infants were 16–24 months old at diagnosis, 74.4% were males, 56.2% were born in the country, and 43.8% were born outside of the country. 12.0 ± 0.2% of the infants were born at a gestation age of <32 weeks. 12.1 ± 0.5% of the infants were preterm, and 28.4 ± 0.8% of the infants were considered low birth weight (<2500 g).

#### Immunogenicity assessment

Blood samples were collected at 4 time points (pre- and post-primary, pre- and post-booster), as illustrated in Figure 1. The concentration of antibodies against protein D was quantified by ELISA. Blood samples were collected at 4 time points (pre- and post-primary, pre- and post-booster), as illustrated in Figure 1. The concentration of antibodies against protein D was quantified by ELISA.

**Table 2. Immunogenicity of PCV13 and PHiD-CV following primary vaccination with either 2 doses of PCV13 or 1 dose each of PCV13 and PHiD-CV.

<table>
<thead>
<tr>
<th>Group</th>
<th>Age at dose 1 (weeks), mean ± SD</th>
<th>Age at booster (months), mean ± SD</th>
<th>% of children with pneumococcal antibody concentrations ≥0.2 µg/mL pre- and 1 month post-primary (A) or pre- and 1 month post-booster (B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary phase</td>
<td>12.0 ± 0.2</td>
<td>9.0 ± 1.1</td>
<td>100 (11.5–36.0)</td>
</tr>
<tr>
<td>PPS (1+1)</td>
<td>12.0 ± 0.3</td>
<td>12.1 ± 0.5</td>
<td>100 (9.0–25.0)</td>
</tr>
<tr>
<td>PSS (2+1)</td>
<td>12.1 ± 0.5</td>
<td>9.0 ± 1.1</td>
<td>100 (20.0–30.0)</td>
</tr>
</tbody>
</table>

#### CONCLUSIONS

A 2+1 series with 2 PCV13 primary doses followed by a PHiD-CV booster or 1 PCV13 dose followed by a PHiD-CV primary and booster dose was associated with lower antibody GMCS for some serotypes.

The clinical relevance of this trend is unknown, pending onaphosphorycactivity data from this study may shed further light on this question.

Boostability was observed for both the PSS and the PPS groups, for the 10 common vaccine serotypes as well as for serotypes 19A and 6A.

### Acknowledgements

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### References

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5. Mascarenas de Los Santos et al. SLIPE-16 2015