Immunogenicity and Safety Results of Walvax 13-Valent Pneumococcal Conjugate Vaccine for 3-month and 3~71-month Infants in Pivotal Phase III Clinical Study

Yuxi Walvax Biotechnology Co., Ltd.
October 31, 2018

DCVMN AGM 2018
Kunming, China

Randomized, double blinded and controlled study(PCV13-TT-002)

—— Study design

Age group	Arms	Number of Subjects	Schedule (months of age)	Booster dose (months of age)
2 m (3+1)	Study	520	3-dose (2, 4, 6)	12-15
3 m (3 + 1)	Study	520	3-dose (3, 4, 5)	12-15
	Control	520	3-dose (3, 4, 5)	
7 - 11 m (2 + 1)	Study	200	2-dose (0, 2)	12-15*
	Control	200	2-dose (0, 2)	
12 - 23 m (2 + 0)	Study	200	2-dose (0, 2)	/
	Control	200	2-dose (0, 2)	
24 – 71m (1 + 0)	Study	200	1-dose	/
	Control	200	1-dose	

Note*:at least 2 months apart from the 2nd dose

No. of subjects: 2760 in total.

Age range: 2 months (initiate as young as 6 weeks) to 71 Months.

Comparator vaccine: Prevnar 7® (Pfizer) conjugated with diphtheria CRM_{197} protein.

Distribution of subjects : 1640 to receive PCV13-TT, 1120 to receive Prevnar7®.

Randomized, double blinded and controlled study(PCV13-TT-002)

—— Evaluation criteria

- **Immunogenicity Evaluation Criteria:**

IgG antibody positive rate (percentage of subjects with IgG concentration ≥ 0.35μg/ml) and IgG antibody GMC after primary doses and booster dose.

- **Safety Evaluation Criteria:**

Incidence of AEs and ARs 0-7 days post each dose; SAEs from day 0 to 6 months after the last dose of vaccination.

Evaluation for common serotypes:

Non-inferiority to the actual result of Prevnar7 ® .

Evaluation for additional serotypes:

Non-inferiority to the lowest serotype in Prevnar7 ® .

Randomized, double blinded and controlled study(PCV13-TT-002)

—— Non-inferiority evaluating summary of 3-month age group and 3~71-month population

Types	3-month group		3~71-month group
	Primary dose	Booster dose	Primary and or full doses
Common types			
4	√	√	√
6B	X	√	√
9V	√	√	√
14	√	√	√
18C	√	√	√
19F	√	√	√
23F	√	√	√
Add. types			
1	√	√	√
3	√	√	√
5	√	√	√
6A	√	√	√
7F	√	√	√
19A	√	√	√

√: pass non-inferiority test; X: fail non –inferiority test

- **For 3-month age group, after 3 primary doses of PCV13, 12 serotypes except serotype 6B passe non-inferiority test; while after booster dose, all 13 serotypes achieve non-inferiority to Prevnar7 ® .**
- **For 3~71-month population, all 13 serotypes are non-inferiority to Prevnar7 ® after full immunization .**

Conclusion

Immunogenicity: Both of pivotal 3-month age group and whole populations were demonstrated non-inferiority to Prevnar7® after full doses of immunization.

Safety: Similar profile between PCV13 and Prevnar7® in whole population.

In pivotal phase III clinical study, Walvax PCV13-TT show a good immunogenicity and safety, both of which are comparable to Prevnar7.

With success of pivotal phase III clinical study, Walvax PCV13-TT has submit BLA in Feb. 2018, and will hopefully be licensed by Q1 2019.

WALVAX 沃森生物

THANKS !