

# 海外の臨床試験データについて

資料 3

## H7N9臨床試験データ：Novartis H7N9 アジュバントワクチン

(2013.11.14)



Novartis International AG  
Novartis Global Communications  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTELUNG

### **Novartis announces positive clinical trial results for novel H7N9 vaccine**

- *85% of subjects immunologically protected after receiving second dose of investigational cell culture vaccine when combined with proven MF59<sup>®</sup> adjuvant*
- *Vaccine now in large scale production highlighting rapid response capability of novel FDA licensed cell culture technology*
- *135 confirmed cases and 45 deaths from H7N9 virus since emergence in March according to the World Health Organization<sup>1</sup>*

# H7N9 臨床試験データ : NOVAVAX H7N9 VLPワクチン (1/2)

(2013.11.13)



## **New England Journal of Medicine Publishes Positive Data From Clinical Trial of Novavax' Vaccine Against H7N9 Avian Flu**

- *Data are industry's first from clinical trial of vaccine against A(H7N9) strain of influenza*
- *81% of 5ug adjuvanted vaccine recipients had protective HAI levels*
- *97% of 5ug adjuvanted vaccine recipients had anti-neuraminidase antibody responses*
- *Protective levels achieved from vaccinations within 116 days of the announced outbreak of novel lethal H7N9 virus*
- *Dose-sparing formulation shows significant potential utility in the event of a pandemic*
- *Vaccine safety consistent with previously tested adjuvanted pandemic vaccines*

# H7N9 臨床試験データ : NOVAVAX H7N9 VLP ワクチン (2/2)

- The New England Journal of Medicine (Downloaded from nejm.org on Nov 14, 2013)

**Table 1. Summary of A/Anhui/1/11 Antibody Responses in the Per-Protocol Population.\***

Variable	Vaccine with No Adjuvant			Vaccine with Adjuvant			
	Placebo	15 µg	45 µg	30 ISCO-LH-01	15 µg	5 µg	15 µg
<b>Study treatment</b>							
Antigen dose	Placebo	15 µg	45 µg	15 µg	15 µg	5 µg	15 µg
No. of participants	18	35	32	17	34	16	14
<b>HA1 reciprocal titer</b>							
<b>Baseline†</b>							
Geometric mean titer (95% CI)	5.1 (4.9–5.3)	1.1 (4.9–5.3)	0	1	1.1 (4.9–5.3)	1.2 (4.9–5.3)	2
Participants with titer of ≥40 — %	0	0	0	0	0	0	0
<b>Day 21: 3 wk after dose 1</b>							
Geometric mean titer (95% CI)	5.1 (4.9–5.3)	1.4 (4.5–8.6)	1.7 (4.7–4.8)	1.4 (4.9–5.3)	1.8 (5.0–8.7)	6.7 (5.9–7.7)	1.4 (4.9–5.0)
Participants with seroconversion — % (95% CI)‡	0	2.9 (0.3–14.9)	1.1 (0.3–16.2)	0	2.6 (0.3–13.4)	0	0
<b>Day 28: 2 wk after dose 2</b>							
Geometric mean titer (95% CI)	5.1 (4.9–5.3)	8.8 (1.2–5.9)	8.0 (6.2–13.0)	17.1 (27.9–49.4)	21.7 (18.1–33.7)	84.3 (48.3–85.3)	17.1 (28.4–45.3)
Participants with seroconversion — % (95% CI)‡	0	1.7 (0.3–19.2)	13.8 (1.3–32.8)	64.9 (47.5–79.8)	38.8 (21.8–54.0)	88.8 (84.0–91.8)	84.7 (46.3–92.3)
<b>NA1 reciprocal titer</b>							
<b>Baseline</b>							
Geometric mean titer (95% CI)	225 (183–288)	218 (175–280)	367 (240–199)	136 (137–241)	189 (135–238)	197 (155–250)	158 (119–199)
<b>Day 21: 3 wk after dose 1</b>							
Geometric mean titer (95% CI)	224 (183–275)	316 (21–110)	110 (230–401)	111 (270–406)	405 (305–136)	425 (105–159)	120 (245–418)
Participants with seroconversion — % (95% CI)‡	1.7 (0.3–19.7)	8.8 (1.8–23.1)	21.9 (8.3–30.0)	21.8 (8.8–31.2)	44.7 (28.6–61.7)	38.1 (28.8–53.8)	33.3 (19.8–51.3)
<b>Day 28: 2 wk after dose 2</b>							
Geometric mean titer (95% CI)	220 (183–262)	372 (286–483)	468 (318–648)	880 (579–1142)	871 (840–1178)	1471 (1093–1905)	838 (713–1284)
Participants with seroconversion — % (95% CI)‡	1.9 (0.3–14.8)	57.1 (39.4–73.7)	71.9 (53.3–85.3)	81.9 (78.1–88.2)	92.1 (78.6–98.1)	87.2 (85.5–88.9)	87.1 (84.7–89.9)