

# ENVIRONMENTAL SCAN: CURRENT STATUS OF NEW HPV VACCINE DEVELOPMENT

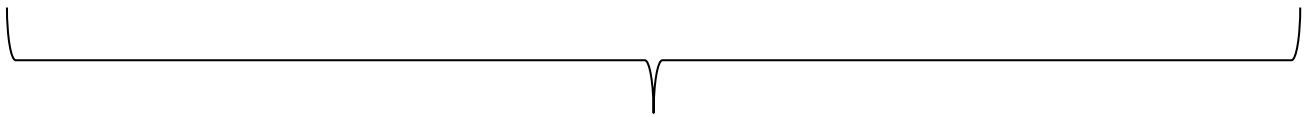
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Integrated Clinical Vaccine Development,  
Bill & Melinda Gates Foundation

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12 November 2020  
HPV Prevention and Control Board's Online Technical Meeting

# ENVIRONMENTAL SCAN OF HPV FOR DISCUSSION TODAY

Evidence for Single Dose	HPV Introductions in Gavi 73	Low-Cost HPV Supply	Cervical Cancer Elimination
Generate evidence for the safety and efficacy of single-dose HPV vaccination	For Gavi and Gavi-graduating countries, maximize uptake by enabling accelerated introductions with equitable coverage and reduced WAP	Enable reliable, sustainable, sufficient and appropriate supply of cost-effective HPV vaccines	WHO's Cervical Cancer Elimination Campaign



## Current BMGF Focus Areas


# RELIABLE, SUSTAINABLE AND COST-EFFECTIVE SUPPLY OF HPV VACCINES

- Support Developing Country Vaccine Manufacturers (DCVMs) toward lower-cost L1 VLP vaccines
- Financial and technical support in exchange for global access agreements for Gavi markets
- Support directed toward achieving and maintaining WHO pre-qualification status targeting 2020-3
- Three DCVMs in advanced clinical development
- Innovax/YST. Xiamen, China (HPV2 types 16, 18) expressed in E.coli. Est. WHO PQ 2021. GSK collaboration on 9V+AS04
- Zerun/Walvax. Shanghai/Yuxi, China (HPV2 types 16, 18) expressed in Pichia pastoris. Est. WHO PQ 2022
- Serum Institute of India. Pune, India (HPV4 types 6, 11, 16, 18) expressed in Hansenula yeast. Est. WHO PQ 2023
- Others
  - Butantan, Brazil (HPV4 types 6, 11, 16, 18) / Saccromyces
  - SK Chemical, Korea (HPV4 types 6, 11, 16, 18) / Baculovirus



# HPV VACCINES IN DEVELOPMENT – CHINA (APRIL 2019)

Company	Vaccine	Expression system	IND	P I	P II	P III	BLA	MKT
1	GSK	HPV-2 (16, 18)	<i>Insect cell</i>					
2	Merck	HPV-4 (6,11,16,18)	<i>Yeast (S. cerevisiae)</i>					
3	Merck	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (S. cerevisiae)</i>					
4	Innovax	HPV-2 (16,18)	<i>E.coli</i>					
5	Zerun	HPV-2 (16,18)	<i>Yeast (P. pastoris)</i>					
6	CNBG/CDIBP	HPV-4 (6,11,16,18)	<i>Yeast (H. polymorpha)</i>					
7	Innovax	HPV-2 (6,11)	<i>E.coli</i>					
8	Kangleweishi	HPV-3 (16,18,58)	<i>E.coli</i>					
9	Bovax	HPV-4 (6,11,16,18)	<i>Yeast (H. polymorpha)</i>					
10	Bovax	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (H. polymorpha)</i>					
11	Zerun	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (P. pastoris)</i>					
12	Innovax	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>E.coli</i>					
13	CNBG/SIBP	HPV-4 (6,18,52,58)	<i>Yeast (P. pastoris)</i>					
14	Kangleweishi	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>E.coli</i>					
15	Jiangsu Ruike	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (H. polymorpha)</i>					
16	CNBG/CDIBP	HPV-11 (6,11,16,18,31,33,45,52,58,59,62)	<i>Yeast (H. polymorpha)</i>					
17	Nuoning	HPV-14 (6,11,16,18,31,33,35,39,45,51,52,56,58,59)	<i>Insect cell</i>					

 Early stage
  Late stage

Data source: NMPA data; clinicaltrial.gov. updated in April, 2019

# HPV VACCINES IN DEVELOPMENT – CHINA (OCTOBER 2020)

Company	Vaccine	Expression system	IND	P I	P II	P III	BLA	MKT
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18 Yidao	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (P. pastoris)</i>						

- Walvax HPV2 Phase 3 efficacy met pre-defined success criteria Q1
- BLA submitted to China NMPA (NRA) in Q2
- Anticipate licensure in 2022 and WHO PQ in 2023

 Early stage
  Late stage

# HPV VACCINES IN DEVELOPMENT – CHINA (OCTOBER 2020)

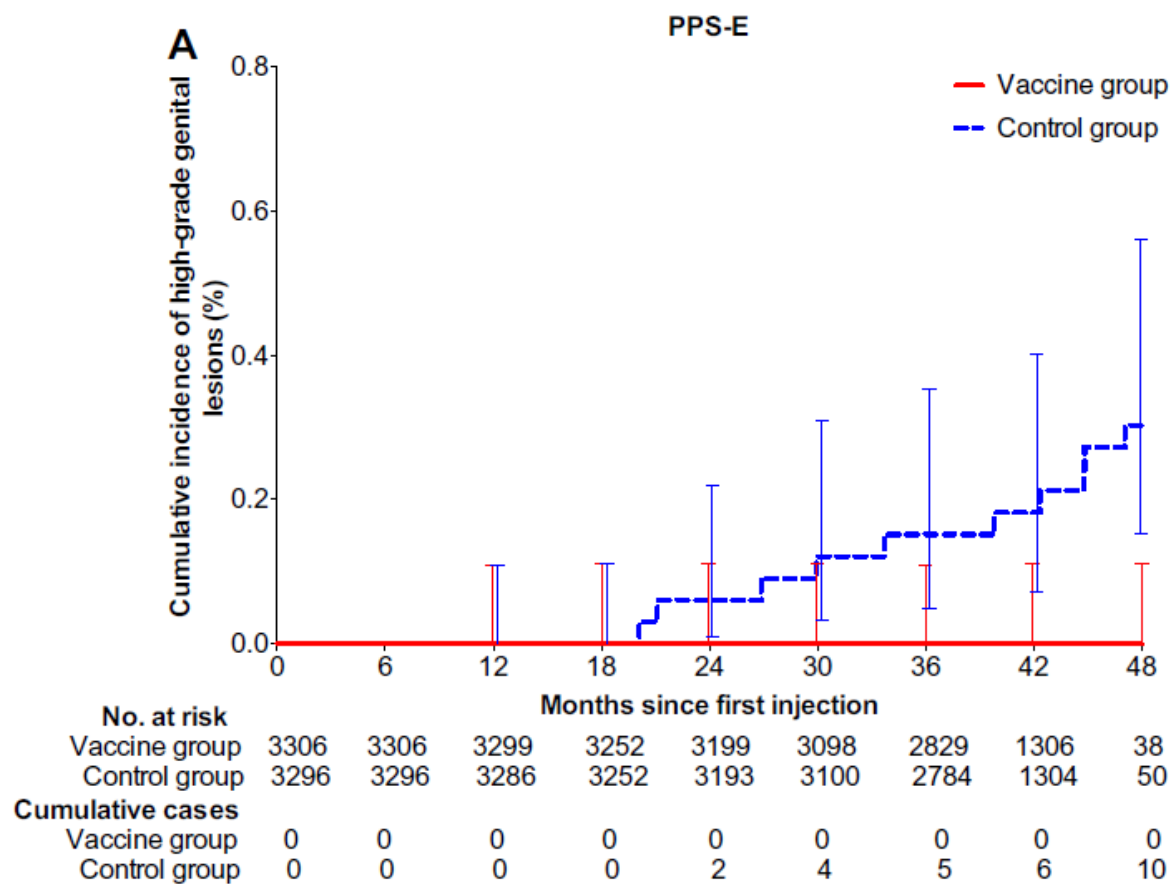
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- Innovax HPV2 licensed in China in December 2019
- WHO PQ application submitted Q1 with ongoing review
- WHO PQ in first half of 2021 (Covid-dependent)

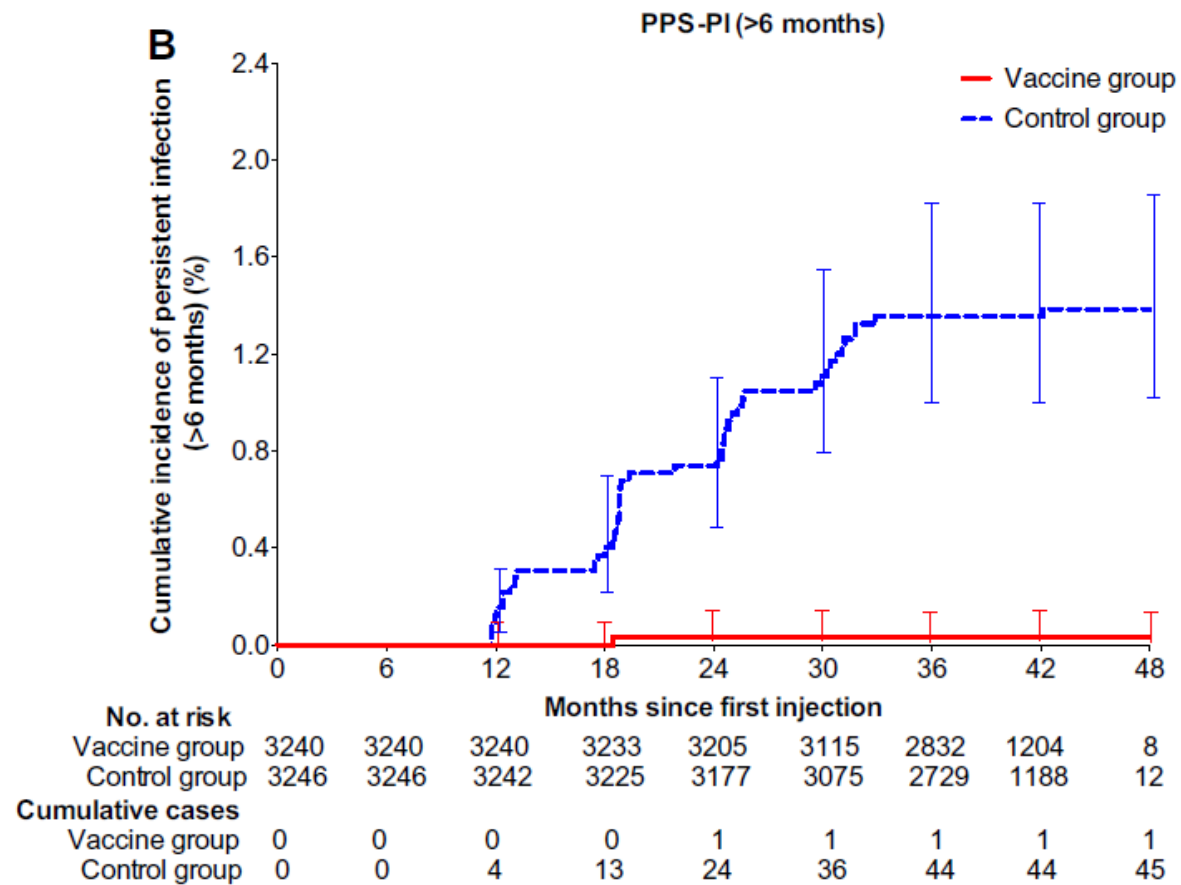
 Early stage
  Late stage

# INNOVAX ---- RESULTS FROM PHASE 3 EFFICACY STUDY

## HIGH EFFICACY IN ADULT WOMEN



Efficacy vs. CIN2+: 100% (95% CI: 55.6 – 100%)



Efficacy vs. 6M-PI: 97.8% (95% CI: 87.1 – 99.9%)