

HPV global vaccine status, supply and procurement challenges: where are we now?

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Regulatory Summary: Initial Licensure of HPV Vaccine in Males (2009)

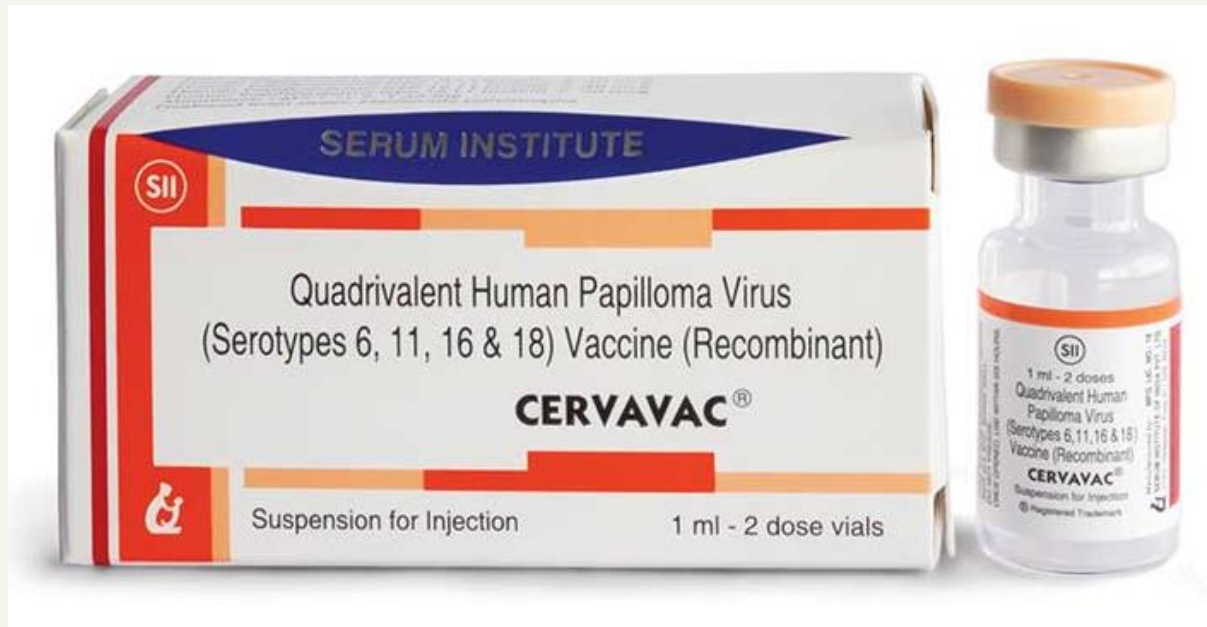
Quadrivalent HPV (6/11/16/18) Vaccine, Gardasil (Merck)

- Indication: Prevention of external genital warts in males aged 9–26 years
- Pivotal Efficacy Trial:
 - Population: Males 16–26 years, HPV-naïve at baseline
 - Design: Randomized, double-blind, placebo-controlled, ~4000 subject enrolled
 - Endpoint: Genital warts due to HPV types 6 and 11
 - Result: Vaccine efficacy = 89.4% (95% CI: 65.5%, 97.9%)
 - Success criteria: Lower bound of 95% CI > 0% (met)
- Safety Profile:
 - Acceptable reactogenicity and safety profile consistent with female population
- Indication: Prevention of AIN 2/3 and Anal cancer granted “given the biological plausibility and strong epi linkages between AIN and cancer”.

Regulatory Expansion: Immunobridging to Younger Males (Ages 9–15)

- Study Design:
 - Open-label, multicenter immunogenicity trials
 - Compared anti-HPV GMTs in 9–15-year-old males vs. 16–26-year-old males
 - Also compared to immunogenicity in females with established efficacy
- Immunobridging Criteria:
 - GMT ratio (younger vs. older): Lower bound of 95% CI ≥ 0.5
 - Seroconversion rates: $\geq 99\%$ across all HPV types
 - Immunogenicity deemed non-inferior
- Regulatory Outcome:
 - Supported licensure without additional efficacy trials
 - FDA approved expanded indication to males aged 9–15 years

HPV vaccine in India – Licensed in 2022 with male indication



- Licensure based on immunobridging to Gardasil
- Only available on private market vaccine in India.
- Has not received WHO Pre-qualification
- Public comment from Adar Poonawalla states SIIPL will “reach 100 million doses annually”
- Single dose study conducted by ICMR among girls aged 9-14 years

INDICATION

CERVAVAC® is indicated in girls and women 9 through 26 years of age for the prevention of the following diseases caused by Human Papillomavirus (HPV) types, included in the vaccine:

- Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16 and 18.
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11.

CERVAVAC® is indicated in boys and men 9 through 26 years of age for the prevention of the following diseases caused by HPV types included in the vaccine:

- Anal cancer caused by HPV types 16 and 18.
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11.

HPV R&D PIPELINE IN CHINA: 10 HPV9V+ IN CLINIC WITH 1 IN BLA AND 6 IN PHASE 3

	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) (male in Ph3)	<i>Yeast (S. cerevisiae)</i>						
4	Innovax	HPV-2 (16,18)	<i>E.coli</i>						
5	Zerun/Walvax	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-9 (6,11,16,18,31,33,45,52,58) (Preparing for male in ph3)	<i>E.coli</i>						
8	Health Guard	HPV-3 (16,18,58)	<i>E.coli</i>						
9	Bovax	HPV-9 (6,11,16,18,31,33,45,52,58) (male in ph3)	<i>Yeast (H. polymorpha)</i>						
10	Health Guard	HPV-9 (6,11,16,18,31,33,45,52,58) (male in ph3)	<i>E.coli</i>						
11	RecBio	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (H. polymorpha)</i>						
12	CNBG/CDIBP	HPV-11 (6,11,16,18,31,33,45,52,58,59,68)	<i>Yeast (H. polymorpha)</i>						
13	SCT	HPV-14 (6,11,16,18,31,33,35,39,45,51,52,56,58,59)	<i>Insect cell</i>						
14	Zerun/Walvax	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (P. pastoris)</i>						
15	CNBG/SIBP	HPV-4 (16,18,52,58)	<i>Yeast (P. pastoris)</i>						
16	Immune Path	HPV-9 (6,11,16,18,31,33,45,52,58)	<i>Yeast (P. pastoris)</i>						
17	Bovax	HPV-15 (6,11,16,18,31,33,35,39,45,51,52,56,58,59,68)	<i>Yeast (H. polymorpha)</i>						
18	Chengda (Health Guard)	HPV-15 (6,11,16,18,31,33,35,39,45,51,52,56,58,59,68)	<i>Ecoli</i>						

China HPV vaccine clinical trials among males

Sponsor	Valent	Phase	Target Population	Sample Size	Vaccination Schedule (Month)	Enrollment Start Date	CDE Code
Innovax	2-valent	Phase I	18-55 Male & Female	144	0,1,6	2015-03-26	CTR20140713
		Phase II	18-55 Male & Female	640	0,1,6	Not available	CTR20140712
	9-valent	Phase I	18-45 Male & Female	24	0,1,6	2019-01-03	CTR20190027
		Phase III	9-17 Male & Female	1,300	0,1,6 0,6 (9-14)	2021-09-19	CTR20212272
		Phase III	18-45 Male	9,300	0,1,6	2025-04-11	CTR20250669
Beijing Health Guard	9-valent	Phase I	9-45 Male	50	0,2,6	2021-08-06	CTR20211491
		Phase III	18-45 Male	9,000	0,2,6	2022-12-18	CTR20223306
Recbio	2-valent	Phase I	18-45 Male	60	0,2,6	2021-05-20	CTR20210109
CDIBP	4-valent	Phase I	9-30 Female & 9-17 Male	135	0,2,6	2016-09-18	CTR20160668
Bovax	9-valent	Phase I	9-45 Male	90	0,2,6	2022-09-23	CTR20222155
		Phase III	9-45 Male	9,000	0,2,6	2024-07-11	CTR20242197
	15-valent	Phase I	9-45 Male & Female	72	0,2,6	2024-08-03	CTR20242006
		Phase II	9-45 Male & Female	330	0,2,6	2025-01-15	CTR20244986
	9-valent	Phase III	9-14 Male 9-19 Male	1,590	0,2,6 (9-14) 0,6 (9-19)	2022-05-07	CTR20220441
MSD		Phase III	20-45 Male	8,100	0,2,6	2022-02-18	CTR20212488

Data source: <http://www.chinadrugtrials.org.cn/>