

BARYCELA inj. was demonstrated to have a seroconversion rate non-inferior to that of the control vaccine in a multinational phase III clinical trial.

Seroconversion rate (SCR) at 42 days after vaccination

Conversion criteria		MG1111 <sup>1</sup> N= 239	Control <sup>2</sup> N = 239	Difference	P-value
SCR (%)	FAMA titer ≥1:4	97.91 (95.19, 99.32) <sup>3</sup>	99.16 (97.01, 99.90) <sup>3</sup>	-1.3 (-4.03, 1.22) <sup>4</sup>	0.2533
	Sub-analysis Subjects aged 12 M to ≤23 M	97.96 (94.86, 99.44) <sup>3</sup>	100.00 (98.11, 100.00) <sup>3</sup>	-2.0 (-5.13, 0.27) <sup>4</sup>	-
	Sub-analysis Subjects aged 24 M to ≤12 Y	97.67 (87.71, 99.94) <sup>3</sup>	95.65 (85.16, 99.47) <sup>3</sup>	2.0 (-8.21, 12.38) <sup>4</sup>	-
	FAMA titer ≥1:16	95.65 (93.51, 98.54) <sup>3</sup>	98.33 (95.77, 99.54) <sup>3</sup>	-1.7 (-4.95, 1.36) <sup>4</sup>	-

1. Development name of BARYCELA inj. 2. Varivax 3. Two-sided 95% confidence interval (CI) is calculated using exact binomial method.  
4. 95% confidence interval for rate difference is calculated using Newcombe-Wilson score method.



BARYCELA inj. showed a similar safety profile to that of the control vaccine.

Safety Assessments

	MG1111 <sup>1</sup> (N=258)		Control <sup>2</sup> (N=257)		P-value
	N(%)	event	N(%)	event	
Total AEs	202(78.3)	1109	192(74.7)	1071	0.337
Solicited local AEs	122(47.3)	462	132(51.4)	535	0.355
Solicited systemic AEs	93(36.0)	450	83(32.3)	379	0.370
Treatment-related AEs	160(62.0)	838	162(63.0)	902	0.811
Treatment-related solicited AEs	153(59.3)	789	154(59.9)	864	0.886
Treatment-related unsolicited AEs	41(15.9)	49	27(10.5)	38	0.071
SAEs	29(11.2)	39	21(8.2)	33	0.240
Treatment-related SAEs	3(1.2)	5	4(1.6)	7	0.724

1. Development name of BARYCELA inj. 2. Varivax  
AE, adverse event; SAE, serious adverse event

Prepare with BARYCELA inj.  
for effective varicella prevention.



Upgraded  
varicella vaccine  
through accumulated  
technology



The world's first  
antibiotic-free  
varicella vaccine



Vaccine  
Stability



Improved safety  
risk through the  
aseptic processing  
and single-use systems



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#VARICELLA  
#VACCINE  
#BARYCELA inj.

#MAV/06 #World 1st Antibiotic-free varicella vaccine #Prevent household infections



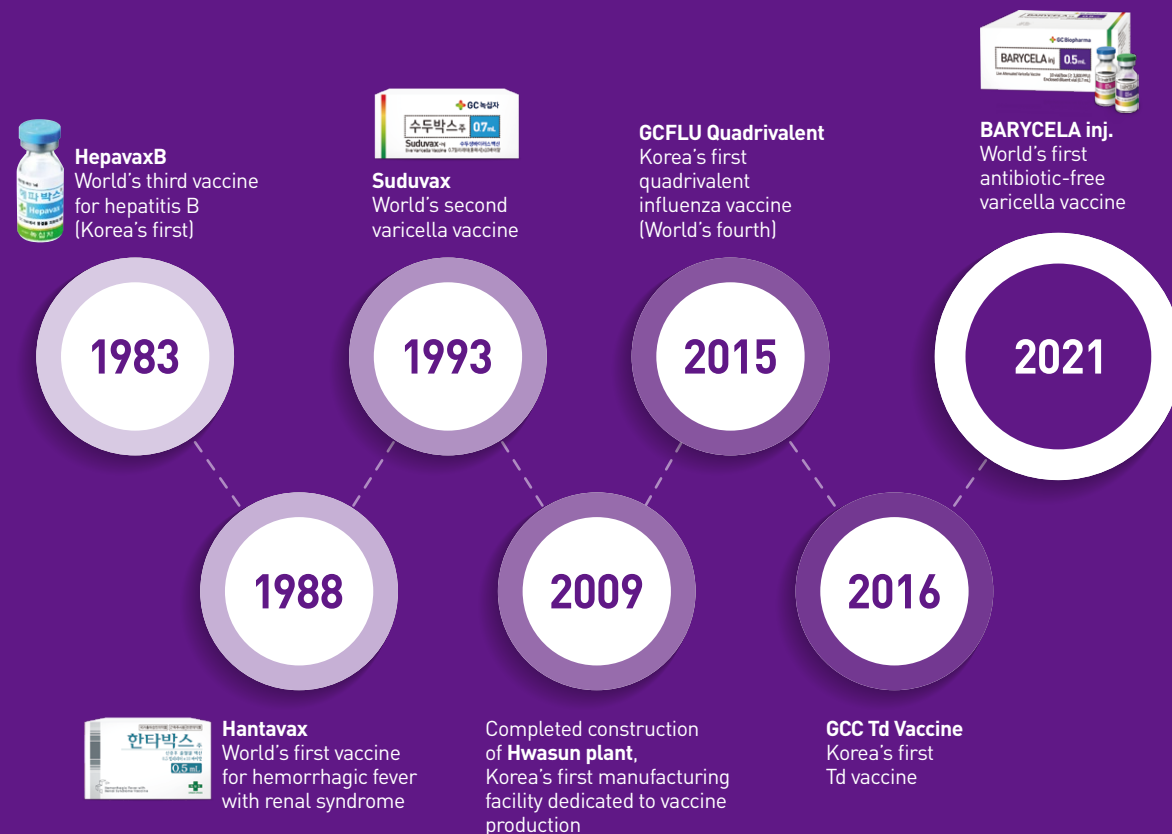


# GC Biopharma

The world's first antibiotic-free varicella vaccine

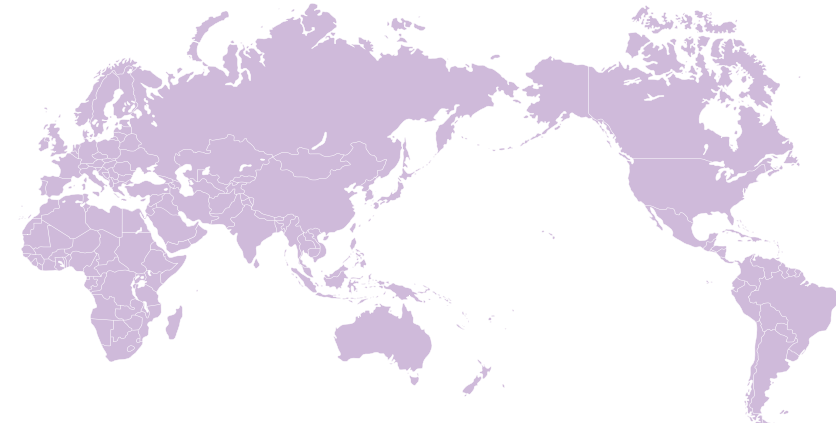


**History** GC Biopharma, the leader of Korea's vaccine development



## Over the past 28 years, more than 28 million doses of GC Biopharma's varicella vaccine

have been used worldwide and based on our accumulated R&D know-how, an upgraded varicella vaccine, BARYCELA inj. has recently been developed.



**28**  
years



**28**  
million



Over the past 28 years, 28 million doses of Varicella Vaccine-GCC inj. were used in more than 30 countries including Republic of Korea, Brazil, Turkey, Argentina, Saudi Arabia, Vietnam and so on.

## BARYCELA inj. has not only increased virus content, but also significantly improved stability.

Brand name	SUDUVAX inj. (Varicella vaccine-GCC inj.) <small>(First approval date: 05 June 1993)</small>	BARYCELA inj. <small>(First approval date: 02 March 2020)</small>
Virus Strain	MAV/06 <small>(isolated from a Korean patient and attenuated)</small>	MAV/06 <small>(isolated from a Korean patient and attenuated)</small>
Virus content	≥1,400 PFU	≥3,800 PFU
Manufacturing Process	<ul style="list-style-type: none"><li>Manual process</li><li>Multi-use system <small>(Open process, Class 100)</small></li><li>Antibiotics contained</li></ul>	<ul style="list-style-type: none"><li>Automated process <small>(Purification, Fill &amp; Finish)</small></li><li>Single-use system <small>(Closed process, Class 100,000)</small></li><li>Antibiotic free</li><li>Improved formulation for stability</li></ul>



UPGRADE

BARYCELA inj. is the world's only **antibiotic-free varicella vaccine.**

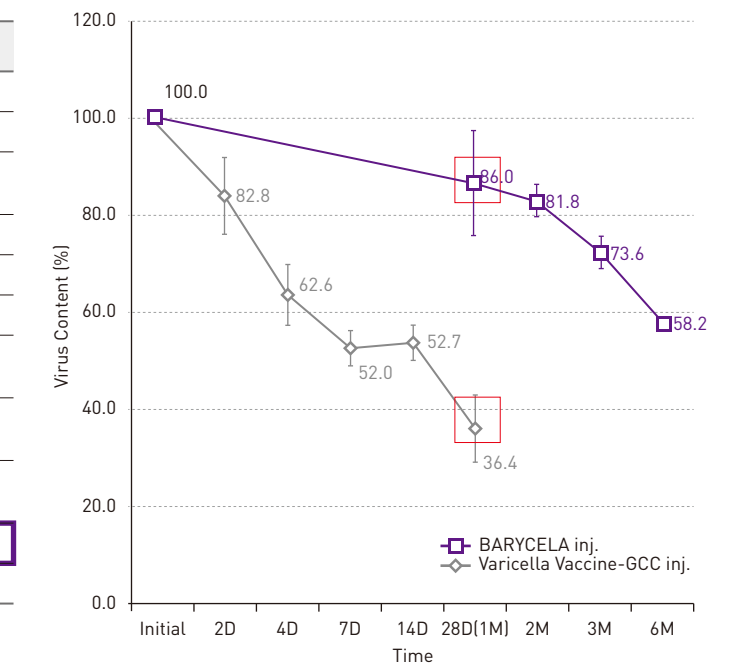
**ANTIBIOTIC-FREE**

## Improved product stability by addition of urea

Accelerated stability test (25.0 ± 2.0 °C/60.0 ± 5.0% RH\*)  
Varicella Vaccine-GCC inj. vs BARYCELA inj. (1 month) = 36.4% : 86.0%

Formula (product)	SUDUVAX inj. (Varicella vaccine-GCC inj.)	BARYCELA inj.
Sucrose	25 mg	18.21 mg
Glycine	2.5 mg	1.82 mg
Sodium L-glutamate hydrate	0.55 mg	0.40 mg
Gelatin	12.5 mg	8.74 mg
L-Cysteine	0.25 mg	0.18 mg
EDTA or its hydrate	0.25 mg	0.18 mg
Na <sub>2</sub> HPO <sub>4</sub> · 12H <sub>2</sub> O(buffer)	Appropriate amount	1.14 mg
NaH <sub>2</sub> PO <sub>4</sub> · 2H <sub>2</sub> O(buffer)	Appropriate amount	
Potassium phosphate monobasic(buffer)		0.06 mg
<b>Urea</b>		<b>0.87 mg</b>
Volume per dose (mL)	0.5 mL	0.5 mL

\*RH, relative humidity



BARYCELA inj. has improved product safety risk through the introduction of aseptic processing, automated systems, and single-use systems.

