

**Vaccine for Infectious Diseases and Immuno-Oncology
Development & Manufacturing**

OCV Production and Future Development



Company Profile

Establishment	10 March 2010
Business Place	HQ: Seoul Facility - 2 Manufacturing sites in Chuncheon - R&D Center in Chuncheon
No. of Employee	Over 250
Market Cap	USD 150M Listed in KOSDAQ since Jan 2017
Business Area	- Vaccine Development, Manufacturing & Supply - CRMO(Contract R&D and Manufacturing Organization)

CEO Profile



Dr. YEONGOK BAIK

- Bachelor, Master in Veterinary Medicine, Seoul National Univ.
- Ph.D. in Life Science, Korea Univ.
- QA General Manager, CJ Corporation
- Director, Korea Institute of Industrial Technology

CEO Profile



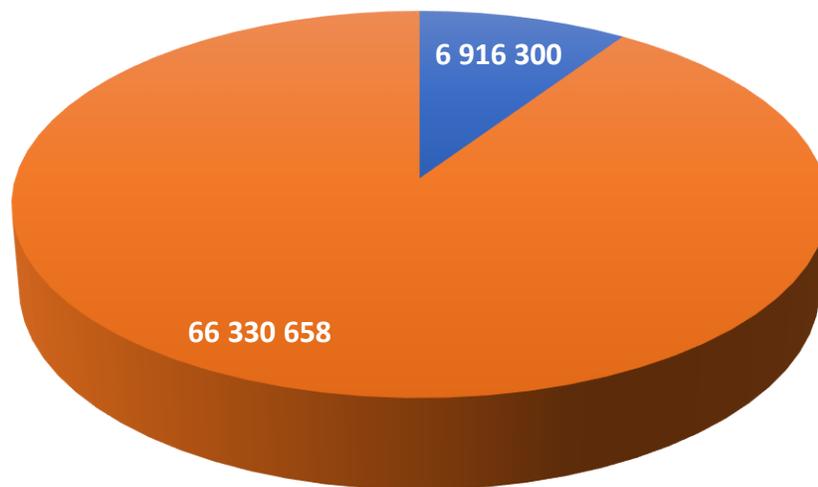
SEUKKEUN CHOI

- Bachelor in Microbiology, Seoul National Univ.
- Green Cross Corporation
- CJ Corporation
- General Manager, LG Life Sciences
- Director of Plant, Meditox

Euvichol-Plus Shipment History

EuBiologics has supplied about 73M doses of Euvichol and Euvichol-Plus to cholera endemic/outbreak countries through UNICEF. In 2021, EuBiologics has shipped 19.6M doses of Euvichol-Plus as of today.

of doses supplied



■ Euvichol ■ Euvichol-Plus

Month/2021	Country	Quantity	ICG vs GTFCC
Jan	Ethiopia	1,677,200	ICG
Mar	Ethiopia	1,195,300	ICG
	Uganda	1,037,190	GTFCC
Apr	DRC	2,755,980	GTFCC
May	Ethiopia	2,008,650	ICG
Jul	Ethiopia	1,195,300	ICG
	Nigeria	1,565,600	ICG
Aug	DRC	1,264,150	GTFCC
Sep	Bangladesh	1,327,700	ICG
	Yemen	790,000	GTFCC
TBD	Niger	1,986,200	ICG
Oct	Nigeria	1,783,320	ICG
Nov	Ethiopia	1,038,890	ICG
	Bangladesh	57,530	ICG
Total Quantity		19,683,010	

2022/23 Production Plan

The total quantity available for shipment in 2022 and 2023 is 31.1M and 36M doses, respectively.

Euvichol-Plus Availability in 2022													
Monthly availability	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
Ready for shipment	1,764,000	3,175,200	2,822,400	1,411,200	3,528,000	2,822,400	1,822,800	3,175,200	2,822,400	2,469,600	2,469,600	2,822,400	31,105,200
* Rolled over quantity from 2021 is not included													
* The cold storage capacity is up to 11M doses. If we reach 11M doses in our storage including both DS and DP, the production is suspended.													

Euvichol-Plus Availability in 2023														
Month	-	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	TOTAL
doses ready to ship	-	4,590,000	3,240,000	2,160,000	3,240,000	2,880,000	1,800,000	3,240,000	2,880,000	2,880,000	2,880,000	4,050,000	2,250,000	36,090,000

OCV Expansion

EuBiologics has been working on OCV facility expansion to double the production capacity, up to 50M doses. GMP production is expected in Oct 2023.



OCV Expansion Timeline (exp.)

No.	Process Breakdown	Start	Finish	Duration (Month)
1	Design	Nov '19	Dec '19	2M
2	Construction	Jul '20	Dec '20	6M
3	Equipment Purchase	Nov '19	Oct '21	24M
4	Qualification	Oct '21	Mar '22	6M
5	Process Validation	Apr '22	Jun '22	3M
6	Comparability Study	Jul '22	Sep '22	3M
7	Licensure by MFDS	Oct '22	Mar '23	6M
8	Variation Approval by WHO	Apr '23	Sep '23	6M
9	GMP Production	Oct '23		

OCV Reformulation (Euvichol-S)

- Simplified formulation (Euvichol-S) containing only two current components, O1 Inaba and O1 Ogawa, and inactivated by a single method (formalin), could be equally effective.
- Anticipate 20% reduction in costs and 38% increase in production capacity
- Clinical trial in Nepal started from Oct 2021 by International Vaccine Institute sponsored by BMGF
- Regulatory submission to WHO PQ expected in early 2023
- EuBiologics intends to switch from Euvichol-Plus Production to Euvichol-S after prequalification.

Registration Status of Euvichol-Plus

No.	Country	Registration approved (Y/N)	Approval date	Remarks
1	Republic of Korea	Y	Mar 2017	Export only
2	WHO PQ	Y	Aug 2017	-
3	Zambia	Y	Feb 2020	
4	Caribbean Regulatory System (CARPHA/CRS)	Y	Apr 2018	Haiti included in CRS
5	Nepal	Y	May 2018	
6	Nigeria	Y	Jul 2018	
7	Malaysia	Y	Dec 2019	
8	Pakistan	Y	Apr 2021	
9	Uganda	N		Site inspection expected
10	Mozambique	Y	Sep 2019	
11	Myanmar	Y	Mar 2020	
12	Philippines	N	-	
13	DRC	N		Dossier submitted in Feb '18