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Euvichol-Plus Update

12th Oct 2022

일생 동안 지속하는 인류의 건강에 기여

Health that lasts a lifetime!

I . Euvichol-Plus Availability

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- **As of today, we have 4,648,650 doses ready for shipment.**
- **By the year end, we expect to have 10,277,500 doses.**

Batch No.	Qty (vial)	Manufacturing date	Expiry date	Current Balance Shelf Life as of 07 Oct 2022	Production Step	Approval date
EP36-22034	97,000	19-May-2022	18-May-2024	**18 months**	Ready to ship	30-Jun-2022
EP36-22035	278,000	23-May-2022	22-May-2024	**18 months**	Ready to ship	11-Jul-2022
EP36-22035	79,350	23-May-2022	22-May-2024	**18 months**	Ready to ship	11-Jul-2022
EP36-22036	356,100	26-May-2022	25-May-2024	**18 months**	Ready to ship	12-Jul-2022
EP36-22037	354,800	30-May-2022	29-May-2024	**18 months**	Ready to ship	12-Jul-2022
EP36-22038	351,650	02-Jun-2022	01-Jun-2024	**19 months**	Ready to ship	20-Jul-2022
EP36-22039	353,150	06-Jun-2022	05-Jun-2024	**19 months**	Ready to ship	28-Jul-2022
EP36-22040	356,550	09-Jun-2022	08-Jun-2024	**19 months**	Ready to ship	28-Jul-2022
EP36-22041	355,250	13-Jun-2022	12-Jun-2024	**19 months**	Ready to ship	28-Jul-2022
EP36-22042	352,100	16-Jun-2022	15-Jun-2024	**19 months**	Ready to ship	16-Aug-2022
EP36-22043	348,750	11-Jul-2022	10-Jul-2024	**20 months**	Ready to ship	25-Aug-2022
EP36-22044	350,650	14-Jul-2022	13-Jul-2024	**20 months**	Ready to ship	25-Aug-2022
EP36-22045	346,250	18-Jul-2022	17-Jul-2024	**20 months**	Ready to ship	28-Aug-2022
EP36-22046	349,350	21-Jul-2022	20-Jul-2024	**20 months**	Ready to ship	13-Sep-2022
EP36-22047-R	341,450	27-Jul-2022	26-Jul-2024	**20 months**	Ready to ship	07-Oct-2022
EP36-22052	353,250	19-Aug-2022	18-Aug-2024	**21 months**	Ready to ship	07-Oct-2022
EP36-22053	347,450	22-Aug-2022	21-Aug-2024	**21 months**	National Lot Release Testing	19-Oct-2022
EP36-22054	349,400	25-Aug-2022	24-Aug-2024	**21 months**	National Lot Release Testing	24-Oct-2022
EP36-22055	345,600	29-Aug-2022	28-Aug-2024	**21 months**	National Lot Release Testing	28-Oct-2022
EP36-22056	213,750	01-Sep-2022	31-Aug-2024	**22 months**	National Lot Release Testing	10-Nov-2022
EP36-22057	352,800	22-Sep-2022	21-Sep-2024	**22 months**	Under Production	18-Nov-2022
EP36-22058	352,800	25-Sep-2022	24-Sep-2024	**22 months**	Under Production	21-Nov-2022
EP36-22059	352,800	28-Sep-2022	27-Sep-2024	**22 months**	Under Production	24-Nov-2022
EP36-22060	352,800	01-Oct-2022	30-Sep-2024	**23 months**	Under Production	27-Nov-2022
EP36-22061	352,800	04-Oct-2022	03-Oct-2024	**23 months**	Under Production	30-Nov-2022
Total	8,043,850					

Stage	No. of doses
Ready for shipment	4,648,650
National Lot Release Testing	1,256,200
Under Production	1,764,000
TOTAL	7,668,850

Month	Oct	Nov	Dec	Total
No. of doses available	5,691,100	1,764,000	2,822,400	10,277,500

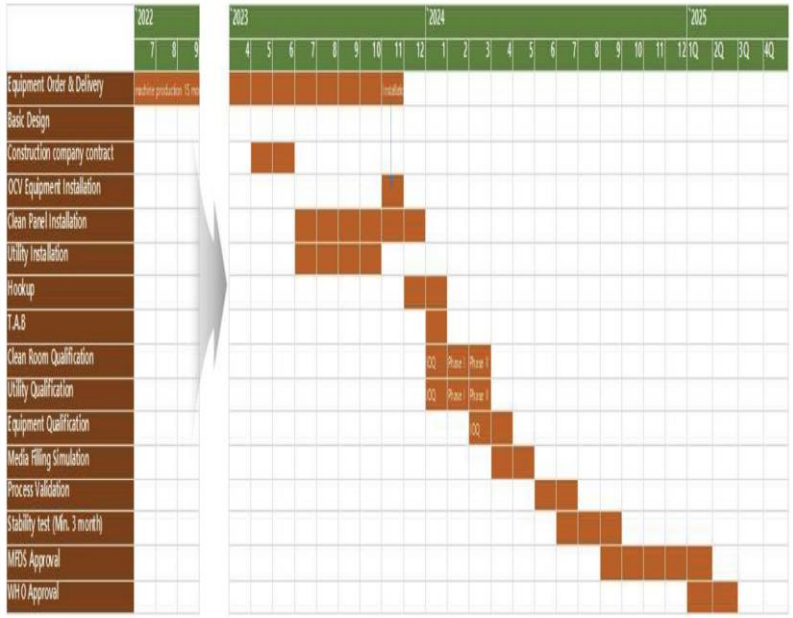
II. Future Production Capacity of Euvichol-Plus

- In 2023, the number of doses available for shipment is 36M doses.
- EuBiologics has been working on 2nd site to double the production capacity, 2nd site is expected to be prequalified in Mar 2024.
- EuBiologics expects to have an additional fill/finish facility in 2nd site to increase the capacity and as a contingency plan for 1st site, to be completed by June 30 2024

<Drug Substance>

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	Mar '22	29M
4	Qualification	Apr '22	Sep '22	6M
5	Process Validation	Oct '22	Dec '22	3M
6	Comparability Study	Jan '23	Mar '23	3M
7	License by MFDS	Apr '23	Sep '23	6M
8	Variation Approval by WHO	Oct '23	Mar '24	6M
9	GMP Production	Apr '24		

<Drug Product>



III. Euvichol-Simplified (Euvichol-S) Development

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- **Euvichol-Plus contains 5 distinct components. Euvichol-S contains only two current components, *O1 Inaba* (*Phil El Tor*) and *O1 Ogawa* (*classical Cairo 50*) and inactivated by a single method (formalin)**

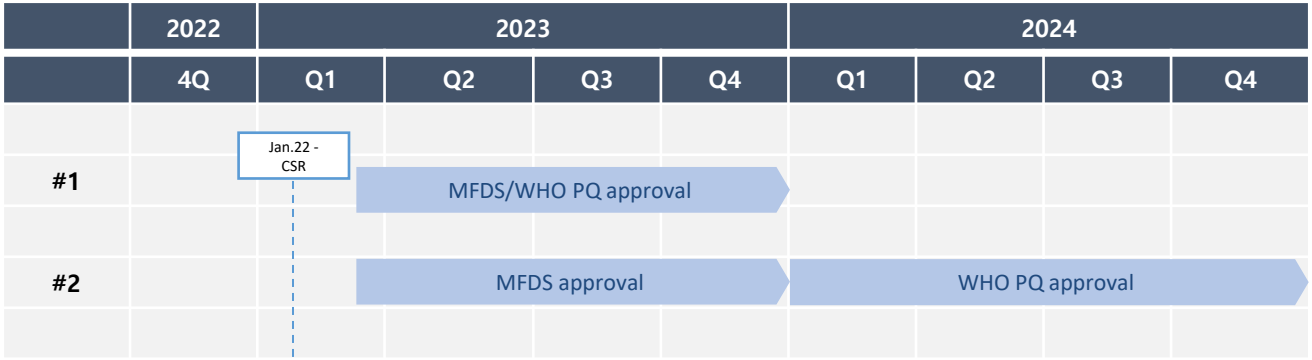
Arms	O1 Inaba Cairo 48 Heat	O1 Inaba Phil 6973 (El Tor) Formalin	O1 Ogawa Cairo 50 Heat	O1 Ogawa Cairo 50 (Classical) Formalin	O139 Formalin
Euvichol-P	300 LEU	600 LEU	300 LEU	300 LEU	600 LEU
Euvichol-S		900 LEU		600 LEU	

- **A Phase III, Multicenter, Observer-Blinded, Randomized, Active Controlled Trial to Evaluate Immune Non-Inferiority, Safety and Lot-to-Lot Consistency of Euvichol-S compared to Shanchol in 1 to 40 years old Healthy Nepalese Participants by IVI**
  - To demonstrate non-inferiority of Euvichol-S compared to Shanchol™ as measured by seroconversion rates of anti-*V. cholerae* O1 Inaba and anti-*V. cholerae* O1 Ogawa vibriocidal titer 2 weeks after second dose for all ages
  - 4 sites in Nepal
  - N=2,530 subjects (age 1-40 y)
  - Enrollment began 4 October

- **Key results expected in 1Q 2023**

IV. Euvichol-Simplified (Euvichol-S) Regulatory Timeline

- **Euvichol-S is expected to be prequalified by the end of 2023 given that concurrent review (both Ministry of Food and Drug Safety and WHO PQ) is feasible, at earliest.**
- **Concurrent review of Euvichol-S prequalification and CTC will go together.**
- **If concurrent review is not feasible, prequalification is expected by the end of 2024.**
- **EuBiologics has engaged with WHO PQ for feasibility of concurrent review.**



Scenario #1 – if concurrent review is feasible (both PQ and CTC with current data)
Mar 23 – MFDS/WHO PQ submission, Dec 23 – MFDS/WHO PQ approval
Scenario #2 – if concurrent review is not feasible (both PQ and CTC with current data)
Mar 23 – MFDS submission, Dec 23 – MFDS approval, Jan 24 – WHO PQ submission, Dec 24 – WHO PQ approval

V. Future Production Capacity

- **In order to maximize the availability, EuBiologics considers hire drug product CMO in 2024 and 2025 if there's demand.**

		2024	2025	Note
Euvichol-Plus	DS	58	65	Currently 33md, increasing 65md by April 2024 when 2nd site is online
	DP	41	70	Currently 41md capacity, increasing 91md by June 2025 when 2nd site is online
Euvichol-S	DS	80	80	Assuming a 38% increase in antigen availability following PQ of Euvichol-S in Sep 2023 earliest (based on concurrent review). However, we assume that we switch from Euvichol-P to Euvichol-S from 2024.
	DP	41	70	Currently 41md capacity, increasing 91md by June 2025 when 2nd site is online

<Max availability of OCV from EuBiologics>

(Unit: Mil)	2023	2024*	2025~
Euvichol-P	36	58	65
Euvichol-S	NA	80	80

*In 2024, EuBiologics can consider DP CMO for either glass vial or plastic tube if demand picks up.

**DS capacity: Assuming 33M in the 1st site and 25M in the 2nd site.