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Euvichol[®] Euvichol-Plus[®]

Easy-to-use, oral vaccine to prevent Cholera



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EuBiologics Co., Ltd.

EuBiologics Co., Ltd. is a publicly traded Korean biopharmaceutical company mainly focusing on research & development of vaccine product. EuBiologics has made the best effort to build a portfolio of vaccines to improve global public health, the company was established with the objective of becoming a preferred strategic partner providing solutions for the global epidemic disease.

EuBiologics is providing contract research and manufacturing services to domestic and international clients. The company is capable of manufacturing a variety of mammalian cell and microbe-derived, protein based therapeutics and antibodies. It provides customized services to various stages of product development, including cell banking, GMP production, validation and regulatory support.

Our mission is "For health that lasts a lifetime" and the vision is "To be a global biopharmaceutical company providing safety, health and lively future" For additional information about the company, please visit <http://www.eubiologics.com/ENG/>.

Euvichol-Plus® Development History

EuBiologics was selected as the 2nd manufacturer of Oral Cholera Vaccine (OCV) through the Cholera Vaccine Initiative (CHOVI) program financially supported by the Bill and Melinda Gates Foundation (BMGF), and got transfer for the manufacturing technology of OCV from the International Vaccine Institute (IVI) in September 2010.

On August 2014, EuBiologics has entered into a Global Access Agreement with IVI to ensure that the cholera vaccine will be made available and accessible at an affordable price for the public sector. Furthermore, Global Health Investment Fund (GHIF), a new \$108 million USD fund developed by the Bill & Melinda Gates Foundation, Lion's Head Global Partners and JPMorgan Chase & Co., has committed 2.5 million USD of equity capital and made a 2.5 million USD loan to support EuBiologics in the development and production of the OCV. (<http://www.lhgp.com/ghif-leads-us7-5m-investment-into-eubiologics/>)

Finally, Euvichol® was accredited by obtaining World Health Organization (WHO) prequalification in 2015 and began to be supplied to all over the world by signing LTA with UNICEF from 2016. Recently, Euvichol-plus®, the world's first plastic tube presentation OCV, also received prequalification from WHO.

2011 Apr.

Non-clinical Trial for OCV in Korea
(<http://dx.doi.org/10.5487/TR.2012.28.4.225>)

2012 Oct.

Phase I Clinical Trial in Korea
(<http://synapse.koreamed.org/DOIx.phpid=10.3346/jkms.2014.29.4.494>)

2014 Aug.

A Randomized, Non-inferiority Trial Comparing Two Bivalent Killed, Whole Cell, Oral Cholera Vaccine (Euvichol vs Shanchol) in the Philippines
(<http://www.ncbi.nlm.nih.gov/pubmed/26348402>)

2015 Dec.

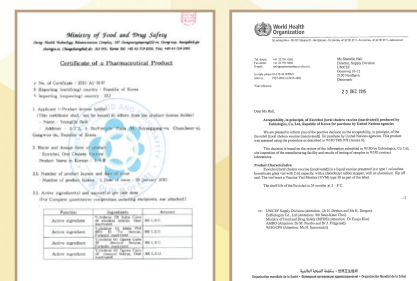
Obtaining WHO prequalification for Euvichol®

2016 May.

Euvichol® (Thimerosal Free) Approval (MFDS)

2017 Aug.

Obtaining WHO prequalification for Euvichol-Plus®



The Certificate of a Pharmaceutical Product from MFDS

WHO PQ Letter

*MFDS: Ministry of Food and Drug Safety, Korea

Euvichol-Plus® / Euvichol®



Plastic tube presentation
(Durable, light plastic tube / No buffer required)



Glass vial presentation
(Tear-off type Cap / No buffer required)

- * Easy to store, deliver and handle
- * Easy to administered

Composition

Appearance	1.5ml yellow to yellowish suspension consists of inactivated <i>Vibrio cholerae</i> <i>V. cholerae</i> O1 and O139 bivalent inactivated vaccine	
Composition	<i>V. cholerae</i> O1 Inaba Cairo 48 (H)	300 L.E.U.*
	<i>V. cholerae</i> O1 Inaba Phil 6973 El Tor (F)	600 L.E.U.
	<i>V. cholerae</i> O1 Ogawa Cairo 50 (F)	300 L.E.U.
	<i>V. cholerae</i> O1 Ogawa Cairo 50(H)	300 L.E.U.
	<i>V. cholerae</i> O139 4260B (F)	600 L.E.U.
	Phosphate buffered saline	20 mM
Recommended age	1 year and older	
Doses	2 given \geq 2 weeks apart	
Buffer solution	Not required	
Storage temperature	2 to 8 °C	
Shelf life	24 months	

L.E.U.*: Lipopolysaccharide ELISA Units (H): Heat inactivated (F): Formalin inactivated

Every year, about 3 million people suffer from cholera, and up to 100,000 people die because of cholera. Half of the case occurs in children less than 5 years.

Cholera is a rapidly dehydrating diarrheal disease caused by the ingestion of toxigenic serogroups of *Vibrio cholerae*. Humans are the only known natural host for *Vibrio cholerae*, and the disease is spread mainly by faecal contamination of water and food. Cholera occurs endemically in South and South-East Asia and in Africa, but may also cause in major outbreaks. Throughout the history, devastating outbreaks of cholera have resulted in millions of traumatic cases with uncountable deaths of mankind.