

www.eubiologics.com

Euvichol[®]

Easy-to-use, oral vaccine to prevent Cholera



eubiologics 

EuBiologics Co., Ltd.

EuBiologics Co., Ltd. is a privately-held Korean biopharmaceutical company providing contract research and manufacturing services to domestic and international clients, in addition to building a portfolio of vaccines designed to improve global public health. The company was established with the objective of becoming a preferred strategic partner providing solutions for the development and manufacturing of biopharmaceutical products.

The company is capable of manufacturing a variety of mammalian cell and microbe-derived, protein based therapeutics and antibodies. It provides customized services for various stages of product development, including cell banking, GMP production, validation and regulatory support.

The company has licensed the manufacturing technology necessary to produce an oral cholera vaccine from the International Vaccine Institute and worked on development of a safe and effective oral cholera vaccine for global public market.

Our mission is "For health that lasts a lifetime" and a 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® Oral Cholera Vaccine

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-us-7-5m-investment-into-eubiologics/>)

Finally, Euvichol® received prequalification from the World Health Organization (WHO) in December 2015.

Appearance	1.5ml yellow to yellowish suspension consists of inactivated <i>Vibrio cholerae</i>	
Composition	V. Cholerae O1 and O139 bivalent inactivated vaccine	
	V. Cholerae O1 Inaba Cairo 48 (H)	300 L.E.U.*
	V. Cholerae O1 Inaba Phil 6973 El Tor (F)	600 L.E.U.
	V. Cholerae O1 Ogawa Cairo 50 (F)	300 L.E.U.
	V. Cholerae O1 Ogawa Cairo 50(H)	300 L.E.U.
	V. Cholerae O139 4260B (F)	600 L.E.U.
	Phosphate buffered saline (pH7.3)	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	
Characteristics	1) Easy to store, deliver and handle 2) Easy to be administered	

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

Euvichol® Development Status

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.

WHO Prequalification

2016 Apr.

Execution of a Long-Term Arrangement until 2018 with UNICEF



The Certificate of a Pharmaceutical Product from MFDS

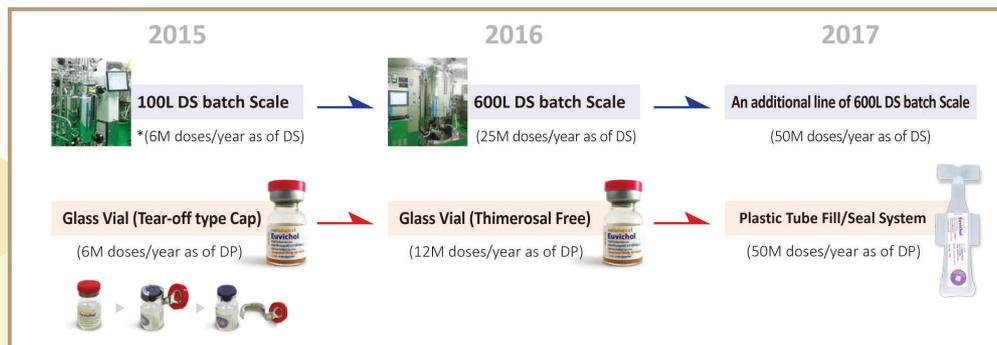


WHO PQ Letter

* MFDS: Ministry of Food and Drug Safety, Korea

Euvichol® Future Plan

EuBiologics is able to produce at 100L production scale, enabling annual production of 6 million doses of Euvichol. However, EuBiologics has already begun to scale up from 100L to 600L, which will expand production capacity to 25 million of doses Euvichol per year. In addition, EuBiologics has purchased a fill-seal (FS) system to migrate from glass vials to a plastic tube presentation as it offers a number of benefits over the current glass vial presentation, such as: lower overall production costs, ease storage, transportation and administration.



*(Capacity Plan)

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.



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