Emergent BioSolutions Receives Positive CHMP Opinion for Vaxchora; Anticipates Near-Term Approval by European Medicines Agency

January 31, 2020

GAITHERSBURG, Md., Jan. 31, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for the approval of the company's single-dose oral cholera vaccine, Vaxchora® (Cholera Vaccine, Live, Oral). A marketing authorization decision from the European Commission is anticipated within three months from positive opinion. If approved, Vaxchora will be the only single-dose oral vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1 in adults and children from 6 years of age. The marketing authorization will be valid in all 28 member states of the European Union (EU).

Abbey Jenkins, senior vice president and vaccines business unit head at Emergent BioSolutions, stated, "It is estimated that cholera is endemic in almost 70 countries worldwide making travelers to these destinations vulnerable to cholera infection. Millions of Europeans travel to cholera-endemic regions each year. In addition to taking safe precautions with food, water, and hygiene, vaccination is recommended to help protect against this virulent disease. Emergent is pleased with receiving CHMP positive opinion, which brings us a step closer to providing a single-dose vaccine to address this travel health threat. As a company whose mission is to protect and enhance life, we seek to bring peace of mind to patients and healthcare professionals by offering a consistent supply of a new option for cholera prevention."

Dr. Rogelio López-Vélez, head of the National Referral Unit for Tropical Diseases of the Ramón y Cajal University Hospital in Madrid, Spain, said, "The positive opinion of the CHMP for the approval of this single-dose oral cholera vaccine is excellent news for all those who are dedicated to the practice of Travel Medicine. In this global world that we live in today, this new vaccine represents an advanced tool to help in the protection of European travelers against immuno-preventable diseases when traveling abroad to cholera-affected areas."

The positive CHMP opinion is based on data from five randomized, double-blind, placebo-controlled clinical trials, including a Phase 1 safety and immunogenicity study,[i] a Phase 3 challenge study, where Vaxchora demonstrated 90.3% efficacy at 10 days and 79.5% efficacy at 3 months,[ii] a Phase 3 safety and immunogenicity study that examined lot-to-lot consistency,[iii] a Phase 3 study that demonstrated a similar immune response in older adults compared with younger adults,[iv] and a Phase 4 study in children that demonstrated a similar immune response in children compared to younger adults.[v]

About Vaxchora
Approved in the U.S. in June 2016, the vaccine is marketed as Vaxchora® and is the only vaccine licensed by the U.S. Food and Drug Administration for active immunization against cholera caused by *Vibrio cholerae* serogroup O1. In May 2017, the Centers for Disease Control and Prevention published its recommendation for the use of Vaxchora in adults 18-64 years traveling from the U.S. to areas of active cholera transmission.[vi]

About Cholera
Cholera, transmitted by ingestion of food and water contaminated with *Vibrio cholerae,* may present with a broad range of symptoms. Cholera commonly presents as watery diarrhea, but may also be asymptomatic or, in severe cases, characterized by profuse watery diarrhea.[vii] If untreated, these severe cases may lead to dehydration, hypovolemic shock and death within hours.[vii] With limited surveillance capacities, as well as social, economic and political disincentives, cholera is an underreported disease. The World Health Organization (WHO) estimates that only 5-10% of cases occurring annually are officially reported.[viii,ix] Non-vaccine interventions to prevent cholera infection include the avoidance of contaminated water and food and frequent handwashing.[vii]

Important Facts About VAXCHORA® (vaks-CORE-ah). It is also known as Cholera Vaccine, Live, Oral.

What is VAXCHORA used for?
VAXCHORA is a prescription vaccine used in adults for a disease called cholera. You take VAXCHORA by mouth to help protect you against the type of cholera caused by the bacteria *Vibrio cholerae* serogroup O1.

VAXCHORA should only be used by certain people. You should only take VAXCHORA if you are between 18 and 64 years old and plan to travel to places where there is cholera.

VAXCHORA may not work for:

- People who live in places where there is cholera
- People who have pre-existing protection from cholera or have had a cholera vaccine
- Cholera caused by bacteria not covered by the vaccine

It is not known if VAXCHORA is safe and effective in children.

Who should not take VAXCHORA?
Do not use VAXCHORA if you are allergic to any ingredient of VAXCHORA or have had an allergic reaction to any cholera vaccine.

Warnings
Can I take VAXCHORA if I have a weakened immune system?
It is important to tell your healthcare provider (HCP) if:

- You have any medical condition that may lower your ability to fight infections
- You are taking any medications that may lower your ability to fight infections
- You have a weakened immune system

VAXCHORA was not studied in people with a weakened immune system. The vaccine may not protect these people.

What are important things to speak with my HCP about?

- It is important to tell your HCP if you are in close contact with anyone that has a weakened immune system
- For at least a week after you take the vaccine, it is possible to spread the bacteria in the cholera vaccine while using the bathroom

Can I take VAXCHORA if I take other medications?
Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VAXCHORA and certain other medicines may affect how VAXCHORA works and may cause side effects.

What are the most common side effects of VAXCHORA?
After you take VAXCHORA, you may feel tired or lose your appetite, or you may experience headache, stomach pain, nausea, vomiting, or diarrhea. These are not all the possible side effects of VAXCHORA. Talk to your HCP about any side effects that you may experience.
You can report side effects to the FDA at 1-800-822-7967 or vaers.hhs.gov.

Learn More
This summary provides basic information about VAXCHORA, but it does not include all information known about this vaccine. Talk to your HCP or pharmacist about this information.
Your HCP is the best person to help you decide if VAXCHORA is right for you.

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Please see full U.S. Prescribing Information for VAXCHORA.

About Emergent BioSolutions
As a global life sciences company whose mission is to protect and enhance life, we provide solutions that target public health threats. Through our specialty products and services as well as our social responsibility efforts, we aspire to build healthier, safer communities and deliver peace of mind to our patients and customers so they can focus on what's most important in their lives. For more information visit www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

Safe Harbor Statement
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements related to receipt of a marketing authorization decision from the European Commission within the anticipated time frame, our ability to provide a single-dose vaccine for prevention of cholera infection, our ability to offer a consistent supply of a new option for cholera prevention and expansion of customer base and market area, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including our ability to obtain and maintain regulatory approvals; and our commercialization, marketing and manufacturing capabilities. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

[i] Chen WH, Greenberg RN, Pasetti MF, et al. Safety and immunogenicity of single-dose live oral cholera vaccine strain CVD 103-HgR, prepared from new master and working cell banks. *Clin Vaccine Immunol*. 2014;21(1):66-73. https://clinicaltrials.gov/ct2/show/NCT01585181?term=PXVX0200&draw=2&rank=3

[ii] Chen WH, Cohen MB, Kirkpatrick BD, et al. Single-dose Live Oral Cholera Vaccine CVD 103-HgR Protects Against Human Experimental Infection With Vibrio cholerae O1 El Tor. *Clin Infect Dis*. 2016; 62(11):1329-35. https://clinicaltrials.gov/ct2/show/NCT01895855?term=PXVX0200&draw=2&rank=2

[iii] McCarty JM et al, Safety and immunogenicity of single-dose live oral cholera vaccine strain CVD 103-HgR in healthy adults age 18-45. Vaccine. 2018 Feb 1;36(6):833-840. doi: 10.1016/j.vaccine.2017.12.062. Epub 2018 Jan 6. https://clinicaltrials.gov/ct2/show/results/NCT02094586?term=CVD103-HgR&cond=Cholera&draw=2&rank=6

[iv] McCarty JM et al. Age-related immunogenicity and reactogenicity of live oral cholera vaccine CVD 103-HgR in a randomized, controlled clinical trial. Vaccine. 2019 Mar 7;37(11):1389-1397. doi: 10.1016/j.vaccine.2019.01.077. Epub 2019 Feb 13 https://clinicaltrials.gov/ct2/show/results/NCT02100631?term=CVD103-HgR&cond=Cholera&draw=2&rank=5

[v] *McCarty JM et al. Safety and Immunogenicity of Live Oral Cholera Vaccine CVD 103-HgR in Children and Adolescents Aged 6–17 Years. Am. J. Trop. Med. Hyg. 102(1), 2020, pp. 48–57.* https://clinicaltrials.gov/ct2/show/NCT03220737?term=vaxchora&draw=2&rank=1

[vi] *Wong KK et al. Recommendations of the advisory committee on immunization practices for use of cholera vaccine. MMWR. 2017; 66 (18): 482-485.*

[vii] Wong KK, Burdette E, and Mintz ED. Cholera. Centers for Disease Control and Prevention website. https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/cholera. Updated May 31, 2017. Accessed May 2019.

[viii] *Ali M et al.* Updated Global Burden of Cholera in Endemic Countries. 2015; PLoS Negl Trop Dis. 2015 Jun 4;9(6):e0003832. doi: 10.1371/journal.pntd.0003832. eCollection 2015.

[ix] WHO (2016) Cholera surveillance and number of cases. Geneva: World Health Organization. https://www.who.int/gho/epidemic_diseases/cholera/cases_text/en/. Accessed May 2019.

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