Emergent BioSolutions Announces Granting of Marketing Authorization in Five EU Countries for Its Oral Typhoid Vaccine; Expands Availability Across Europe

May 20, 2019

GAITHERSBURG, Md., May 20, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) announced today that it has successfully obtained marketing authorization for its oral typhoid vaccine Vivotif® (Typhoid Vaccine Live Oral Ty21a) in five additional European Union Member States, including France, Portugal, Poland, Czech Republic and Slovakia as well as approval of harmonized prescribing information in the EU also known as the Summary of Product Characteristics or SmPC.

Abbey Jenkins, SVP and vaccines and anti-infectives business unit head, stated, “We are excited about the expanded approval of our oral typhoid vaccine in Europe enabling more patients to access this important product. We recently conducted a survey of travelers in the UK, which showed that many travelers would prefer an oral vaccine to an injection. The results of the online survey of 2,007 participants indicated that 48% of participants would opt for oral, while 43% would choose an injection. The results also indicated that 79% of participants expected to be given a choice of travel prevention options by their nurse or pharmacist.”[1]

In the U.S. and Europe, the vaccine is marketed under the name Vivotif® and in Germany under the name Typhoral® L. The vaccine is indicated for active oral immunization against typhoid fever, caused by *Salmonella enterica* serovar Typhi, (*S.* Typhi), in adults and children aged five years and older. The harmonized SmPC aligned the age indication and expanded the revaccination interval from one to three years following the most recent vaccination.

Typhoid fever is a potentially severe and life-threatening infection caused by the bacterium *Salmonella enterica* serovar Typhi (*Salmonella* Typhi). Typhoid Vaccine Live Oral Ty21a is an oral vaccine that stimulates an immune response against *Salmonella* Typhi. In the EU, it is taken as a three-capsule regimen with a single capsule being taken on days 1, 3, and 5.

More than 150 million doses of Typhoid Vaccine Live Oral Ty21a have been marketed worldwide,[2] with post-marketing surveillance showing that adverse reactions to the vaccine are generally infrequent and mild.[2] Typhoid Vaccine Live Oral Ty21a is licensed for sale in 26 countries.

For further information about the oral Typhoid Vaccine, please visit https://www.medicines.org.uk/emc/product/1912

About Typhoid Fever
Typhoid fever is a systemic, febrile disease contracted by ingesting contaminated food or water. It is unique to humans and commonly found where sanitation is deficient. Millions of people are affected by typhoid fever annually, especially people living in low- and middle-income countries and international travelers. Typhoid fever is caused by infection with the bacteria *Salmonella enterica* serovar Typhi. *S.* Typhi is spread from infected to susceptible people via the fecal-oral transmission route. Important risk factors for infection with *S.* Typhi include lack of access to improved sanitation and clean drinking water. A small proportion of infected individuals (2-5%) may develop chronic infection and serve as asymptomatic reservoirs of *S.* Typhi, potentially infecting contacts for years.[3]

About Oral Typhoid Vaccine
Typhoid Vaccine Live Oral Ty21a is a live attenuated typhoid fever vaccine for oral administration. It is the only oral vaccine indicated for use against *Salmonella* Typhi. A recent analysis from the Global Burden of Disease Study estimated 10.9 million cases of typhoid fever in 2017.[4] If untreated, serious complications such as intestinal perforation and haemorrhage may occur several weeks after onset.[3]

Not all recipients of Typhoid Vaccine Live Oral Ty21a will be fully protected against typhoid fever. Vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms. The most common adverse events reported from clinical trials include: abdominal pain, nausea, diarrhoea, vomiting, fever, influenza-like illness, headache, and rash. Reported symptoms resolved spontaneously within a few days. Similar results have also been obtained in post-marketing surveillance. For full prescribing information, visit this link.

This information is for BUSINESS JOURNALISTS only.

---

[1] Data on file (PaxVax) ‘Research and Analysis. PaxVax Vivotif. April 2018’

[2] Vivotif (Typhoid Vaccine Live Oral Ty21a) [US package insert]. Thörishaus, Switzerland: PaxVax Berna GmbH; 2015.

[3] Levine, M. M., & Hone, D. M. (1991). Typhoid Fever. In S. Cryz (Ed.), *Vaccines and Immunotherapy* (pp. 59-72). New York, NY: Pergamon Press

[4] *GBD 2017 Typhoid and Paratyphoid Collaborators*. The global burden of typhoid and paratyphoid fevers: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet Infect Dis* 2019; 19: 369–81

Investor Contact:
Robert G. Burrows
Vice President, Investor Relations
240-631-3280

BurrowsR@ebsi.com

Media Contact:
Lynn Kieffer
Vice President, Corporate Communications
240-631-3391
KiefferL@ebsi.com

Emergent BioSolutions