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Media contacts: see below

Serum Institute's vaccine demonstrates significant efficacy against severe rotavirus gastroenteritis

Indian Government orders the vaccine for use in Universal Immunization Programme

Pune, India (26 September 2017) – Results from a Phase 3 efficacy study in India of the Serum Institute of India Pvt. Ltd.'s rotavirus vaccine BRV-PV (known as ROTASIIL®) were published in the journal [Vaccine](#). The study showed the vaccine to be safe, well tolerated, and to provide significant efficacy against severe rotavirus gastroenteritis. In 2013, an estimated 47,100 rotavirus deaths occurred in [India](#), 22 percent of all rotavirus deaths that occurred globally.

ROTASIIL reduced severe rotavirus diarrhea by more than a third – 39.5 percent over two years. Significantly, the vaccine efficacy was nearly 55 percent against the most severe and potentially life-threatening cases of rotavirus diarrhea, which represent the highest risk of dehydration, hospitalizations, and deaths. The results demonstrated by ROTASIIL in India appear generally [comparable](#) to the performance of RotaTeq® and Rotarix® in Bangladesh and in some African countries.

Dr. Rajeev Dhere, executive director of the Serum Institute, under whose leadership this vaccine has been developed, commented, “We are delighted with these results, which indicate that ROTASIIL could save the lives of tens of thousands of children each year in India and, potentially, around the world.”

The international nonprofit PATH partnered with Serum Institute on evaluating this vaccine in the Phase 3 efficacy study. Six study sites across India enrolled 7,500 infants in the trial. ROTASIIL is an oral vaccine administered to infants in a three-dose course at 6, 10, and 14 weeks of age, at the same time as routine vaccinations under India's Universal Immunization Programme.

The office of the Drugs Controller General of India, through its subject expert committee, reviewed the Phase 3 safety and efficacy results and subsequently inspected Serum Institute's manufacturing facilities leading to licensure of ROTASIIL in January 2017.

The Government of India has placed an order for 3.8 million doses of ROTASIIL to use in the Universal Immunization Programme, which serves 26 million children. Serum Institute has manufactured the vaccine doses and is awaiting instructions from the Ministry of Health and Family Welfare for their distribution. ROTASIIL will also be available for sale in India's private market later this year.

Serum Institute is pursuing World Health Organization (WHO) prequalification to make this vaccine available for global procurement. PATH and Serum Institute partnered to conduct a separate Phase 3

study in India to gather additional data required for WHO prequalification; results from that study will be submitted for publication this year.

“This is great news for India,” noted Dr. David Kaslow, PATH’s vice president for Essential Medicines and global head of the Center for Vaccine Innovation and Access. “The results and successful licensure of this rotavirus vaccine is an exciting and encouraging milestone toward the public health goal of improving the supply of affordable rotavirus vaccines, both in India and worldwide.”

Médecins Sans Frontières and Epicentre are also evaluating the efficacy and safety of ROTASIIL in a separate Phase 3 study in Niger. That study is still ongoing, but results from the primary analysis (one year of data) also showed the vaccine to be highly efficacious for the prevention of severe rotavirus diarrhea and to have an excellent safety profile. The efficacy of the vaccine against severe and very severe rotavirus diarrhea in the Niger study was 66.7 percent and 78.8 percent, respectively. These results were published in the [New England Journal of Medicine](#) in March 2017.

The ROTASIIL used in the Niger study was stored at less than 25°C and transported for vaccination at ambient temperature, thus bypassing the typically challenging and costly cold-chain requirements that apply to most other vaccines. The ROTASIIL used in the India study was from the same lots of vaccine used in the Niger study.

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Additional resources for media:

- Fact sheet on rotavirus disease burden in India.
- Fact sheet on efficacy and impact of rotavirus vaccines.
- Additional quotes and media statements from experts.

These materials are available online: <https://www.defeatdd.org/rotasiil>.

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About the vaccine/study:

The bovine-human reassortant rotavirus vaccine was developed by the US National Institutes of Health and licensed to several emerging-country manufacturers and one US company for further development. Serum Institute was one of the licensees and developed a pentavalent (five-strain) vaccine product (BRV-PV). The BRV-PV (ROTAIIL) contains bovine-human reassortant rotaviruses against the most common rotavirus serotypes (G1, G2, G3, G4, and G9).

The Phase 3 efficacy trial enrolled 7,500 infants across six sites in India: Mahatma Gandhi Institute of Medical Sciences in Sewagram, Wardha (Central India); Government Medical College in Jammu (North West India); KEM Hospital Research Centre in Pune (West India); National Institute of Cholera and

Enteric Diseases in Kolkata (East India); Kasturba Medical College in Manipal (South India); and Centre for Health Research and Development at the Society for Applied Studies in New Delhi (North India). Other organizations involved in the study included Christian Medical College, Vellore, DiagnoSearch Life Sciences, and Enterovirus Research Centre, Mumbai. Children were followed until two years of age by the study team to assess vaccine efficacy and safety.

About the study partners:

Serum Institute of India Pvt, Ltd. (SIPL) is the world's largest producer of measles and DTP (diphtheria, tetanus, and pertussis) vaccines. SIPL was founded in 1966 with the aim of manufacturing lifesaving immunobiologicals, which were in shortage in India and imported at high prices. SIPL was able to manufacture several lifesaving biologicals at more affordable prices and in larger quantities, with the result that the country became self-sufficient in supplying tetanus anti-toxin and anti-snake venom serum, followed by DTP vaccines and later MMR (measles, mumps, and rubella) vaccines. SIPL's products have helped bring down the prices of newer vaccines, such as hepatitis B vaccine, rabies vaccine, and the DTP combination vaccine, so that not only Indians, but also underprivileged children in more than 140 countries, are protected from birth onwards. For more information, visit: <http://www.seruminstitute.com>.

PATH is the leader in global health innovation. An international nonprofit organization, PATH saves lives and improves health, especially among women and children. PATH accelerates innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness its entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, PATH delivers measurable results that disrupt the cycle of poor health. For more information, visit: <http://www.path.org>.

About the journal article:

“A Randomized Phase III Clinical Trial to Assess the Efficacy of a Bovine-Human Reassortant Pentavalent Rotavirus Vaccine in Indian Infants” by Prasad S Kulkarni, Sajjad Desai, Tushar Tewari, Anand Kawade, Nidhi Goyal, Bishan Swarup Garg, Dinesh Kumar, Suman Kanungo, Veena Kamat, Gagandeep Kang, Sudhir Babji, Sanjay Juvekar, Byomkesh Manna, Shanta Dutta, Rama Angurana, Deepika Dewan, Abhijeet Dharmadhikari, Jagdish K. Zade, Rajeev M. Dhere, Alan Fix, Maureen Power, Vidyasagar Upreti, Varsha Parulekar, Iksung Cho, Tamsunaro R. Chandola, Vikash K. Kedia, Abhishek Raut, Ashish Bavdekar, SII BRV-PV author group, Jorge Flores. DOI: <http://dx.doi.org/10.1016/j.vaccine.2017.09.014>. It appears in *Vaccine* (article in press) published by Elsevier. Copies of this paper are available to credentialed journalists upon request; please contact Elsevier's Newsroom at newsroom@elsevier.com or +31 20 485 2492.

About Vaccine:

Vaccine is the pre-eminent journal for those interested in vaccines and vaccination. It is the official journal of The Edward Jenner Society and The Japanese Society for Vaccinology and is published by Elsevier. For more information, visit: www.elsevier.com/locate/vaccine.