May 2013

Additional Media Statements

"It gives me great pleasure to note that the international rotavirus symposium is scheduled to take place on 14-15 May 2013 at Hotel Oberoi, New Delhi. The licensed vaccines are doing quite well in the market. However, the 116E rotavirus vaccine has also performed amicably in the clinical trials. There were initial apprehensions with the differential performance of licensed vaccine in developed and developing countries such as the trials carried out in South Africa and Malawi respectively, with lower vaccine efficacy in the developing countries. However, these apprehensions have taken a backstage as the 116E vaccine has proved itself to be highly efficacious in the Indian population. I take this opportunity to wish the international rotavirus symposium a grand success."

Prof. N.K. Ganguly, President, Jawaharlal Institute of Post Graduate Medical Education and Research; former Director General of the Indian Council of Medical Research

"I had a great privilege to be associated with the rotavirus vaccine development project since 1989-90 and had a great opportunity to coordinate this project from DBT under the Indo-US Vaccine Action Programme by involving eminent scientists like: Dr. M.K. Bhan; Dr. Roger Glass, CDC, Atlanta; Dr. Harry Greenberg, Stanford University; Dr. Durga Rao, IISc., Bangalore; and Dr. George Curlin and Dr. Carole Heilman, NIAID/NIH. Subsequently, Dr. John Boslego from PATH, Dr. Krishna Ella from BBIL (an industrial partner), Dr. Nita Bhandari from SAS, New Delhi, Dr. Gagandeep Kang from CMC, Vellore, and Dr. Ashish Bavdekar from KEM, Pune and their teams conducting the Phase III clinical trials of rotaviral diarrhoea vaccine in infants. I consider it an excellent model of a vaccine development project under a successful public-private partnership with unique features. I am personally very happy to see the long journey of 23 years where the research outcome has been transformed as ROTAVAC®, a rotaviral diarrhoea vaccine developed first time indigenously from R&D to manufacturing under cGMP and clinical trial in human subjects."

Dr. T.S. Rao, Adviser, Department of Biotechnology, Ministry of Science & Technology, Government of India

"As someone who has conducted several Phase III trials as well as serving on several Data Safety Monitoring Boards, I am very impressed with the quality of the 116E Phase III trial. This trial meets the highest standards for ethics and patient care and has been conducted in compliance with international standards for Good Clinical Practices. The trial design included a strong safety net to identify and treat illnesses, especially gastroenteritis, among study infants as quickly as possible. All of the infants enrolled in the trial have received high-quality medical and emergency care, and the surveillance system for collecting cases of diarrhea is meticulous."

Dr. Mathuram Santosham, Professor, Departments of International Health and Pediatrics, Johns Hopkins University; Acting Chair of the Data Safety Monitoring Board for the ROTAVAC® Phase III efficacy trial

"We are deeply gratified to have played a role in establishing the safety and efficacy of the ROTAVAC® vaccine. No infant or child should die as the result of rotavirus-induced severe diarrhea. NIAID is proud to be among the scientific partners who have worked over the past decades to potentially make that affliction a thing of the past for the children of India."

Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health

"We are delighted with the demonstration that this vaccine, developed over a 25-year period of Indo-US collaboration, has proven to be not only safe and effective but affordable for immunization programs in India. This vaccine is perhaps the first totally new vaccine developed in India in many years, derived from an unusual Indian strain of rotavirus, researched by Indian investigators, manufactured by an Indian company and supported by investments from the Government of India

and other partners. Now, we cannot feel content until this vaccine reaches all Indian children and achieves a measureable impact to reduce the 100,000 deaths and millions of cases of rotavirus diarrhea that occur in India each year."

Dr. Roger I. Glass, Director of the Fogarty International Center, U.S. National Institutes of Health

"For me, the most remarkable part of this study, other than, of course, the very exciting results, is the fact that the development of the 116E vaccine represents the highly collaborative efforts of very many groups, representing multiple different constituencies and fields of expertise, all working together for the shared goal of developing a safe, effective and financially sustainable vaccine for rotavirus in India for Indian babies. This has been a wonderful example of team science at its best."

Dr. Harry Greenberg, Joseph D. Grant Professor of Medicine and Microbiology and Immunology, Senior Associate Dean for Research, Stanford University School of Medicine

"The clinical study results showing *ROTAVAC®* to be safe and efficacious are tremendously exciting. This unique social innovation partnership, which brought together a consortium of scientists and experts from a range of agencies and sectors in India and the United States, provides a great collaborative model for meeting a public heath need: a more affordable rotavirus vaccine. Rotavirus is the most severe and lethal cause of diarrhea, taking the lives of approximately 100,000 young children each year in India alone. PATH is pleased and honored to have played a role in reaching this incredible milestone, and we congratulate all of the partners involved on these positive clinical trial results."

Steve Davis, President and CEO, PATH

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This document is available online: http://www.defeatdd.org/rotavac-clinical-trial-results

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