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IMPROVED MENINGITIS VACCINE FOR AFRICA MOVES FORWARD IN TESTING

The Meningitis Vaccine Project and Serum Institute of India Limited Report Successful Phase I Clinical Trial of New Vaccine

PUNE, INDIA; GENEVA, SWITZERLAND; SEATTLE, WASHINGTON (March 15, 2006) – The Meningitis Vaccine Project (MVP), a partnership between the World Health Organization (WHO) and Seattle-based nonprofit, PATH, and the Serum Institute of India Limited (SIIL) announced today the successful completion of their Phase I clinical trial of a new conjugate vaccine against serogroup A meningococcus, a bacterium that causes deadly meningitis epidemics and much human suffering in sub-Saharan Africa.

As a result of the successful Phase I clinical study, SIIL and MVP will proceed to test the vaccine in Africa where the new vaccine will become part of the public health arsenal in the fight against meningococcal epidemics that have been plaguing the continent for more than 100 years.

“We believe in health for all and in reaching out to the poorest countries in the remotest places of the globe,” said Dr. Cyrus Poonawalla, the chairman of the Serum Institute of India Limited. “We are pleased to have embarked on this adventure because this new conjugate vaccine could make a real difference for African countries, some of which are among the poorest in the world. In addition, since the vaccine will be licensed in India, it could also be used in this country, where small outbreaks of serogroup A meningococcal disease occur sporadically.”

The underlying technology for the new conjugate vaccine was developed by the Center for Biologics Evaluation and Research of the Food and Drug Administration in the United States. The new vaccine is expected to be more effective than the existing polysaccharide meningococcal vaccines because of its high immunogenicity in young children and its ability to prime immunologic memory, reduce carriage of the bacteria, and induce herd immunity (whereby transmission of the bacterium is blocked, thus extending protection to the unvaccinated).

“Our Phase I clinical results are extremely encouraging and open the prospect to start pivotal Phase II clinical studies in The Gambia and Mali later this year after approvals from all regulatory authorities,” said Dr. F. Marc LaForce, director of the Meningitis Vaccine Project. “If all continues to go well in testing, the new vaccine, which will be priced at about 40 cents per dose, could be introduced in Africa within the next three to four years.”

The Phase I study was designed to determine the safety and immunogenicity of the new “PsA-TT” conjugate vaccine in healthy volunteers enrolled at three clinical sites in India: B.Y.L. Nair Hospital (Mumbai), King Edward Memorial Hospital (Mumbai), and Nizam's Institute of Medical Sciences (Hyderabad). A total of 74 subjects participated in the double-blind, randomized study that compared the PsA-TT vaccine to a reference vaccine currently used to fight epidemic meningitis in sub-Saharan Africa and to a control vaccine that is commonly used against tetanus. The new conjugate vaccine proved to be safe and as immunogenic as the comparator polysaccharide (un-conjugated) vaccine.

“The teams at three study sites worked diligently and carefully, and the results show that the PsA-TT conjugate meningococcal vaccine can be safely administered to humans, and that the new vaccine is immunogenic,” said Dr. Nilima Kshirsagar, dean, professor, and head of the department of clinical pharmacology and principal investigator at Seth GS Medical College & KEM Hospital. “We are all proud to have been able to contribute to the development of a vaccine that is critically needed in Africa.”

iGATE Clinical Research International, a full service contract research organization in Mumbai, provided data management and clinical monitoring services for the study.

Meningitis is an infection of the meninges, the thin lining that surrounds the brain and spinal cord. It is one of the world's most dreaded infectious diseases. Even with antibiotic treatment, at least 10 percent of patients die, with up to 20 percent left with permanent problems, such as mental retardation, deafness, epilepsy, or necrosis leading to limb amputation.

The most prominent groups of meningococci are A, B, C, Y, and W135. While groups A, B, and C are responsible for the majority of cases worldwide, group A causes deadly explosive cyclic epidemics predominantly in what is known as the African “meningitis belt,” an area that stretches from Senegal and the Gambia in the West to Ethiopia in the East. The belt has an at-risk population of about 430 million. Every year, epidemics kill thousands of people.

In 1996–1997, Africa experienced the largest recorded outbreak of epidemic meningitis in history, with over 250 000 cases and 25 000 deaths reported to the World Health Organization. “Meningococcal epidemics hit the African belt in seasonal waves, every 8 to 12 years,” explained Dr. James Mwanzia, director of communicable disease prevention and control at the WHO regional office in Harare, Zimbabwe. “The largest epidemic wave ever recorded swept across the entire region 10 years ago. Even though sub-Saharan Africa has been relatively spared in recent years, we know from experience that it is just a matter of time for another large epidemic to hit the region again.” A sharp meningococcal A epidemic is currently occurring in western Burkina Faso, with some 3 000 cases reported.

“Because the disease occurs in children, adolescents, and young adults of working age, the disruption and chaos in the community are considerable,” said Dr. Kader Konde, WHO focal point for MVP. “The impact of the disease on individuals and their families is such

that an epidemic can quickly turn into a social, human, and economic disaster for the affected countries. Meningitis is one of the most feared diseases on the African continent, and the new conjugate vaccine brings real hope that huge epidemics like that of 1996 will be a thing of the past.”

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The Meningitis Vaccine Project (MVP - <http://www.meningvax.org>) is a partnership between the World Health Organization (WHO) and PATH. It was established in May 2001 through a US\$70 million seed grant from the Bill & Melinda Gates Foundation. The mission of MVP is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines.

The World Health Organization (WHO - <http://www.who.int>), the United Nations’ specialized agency for health, was established on 7 April 1948. WHO’s objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health, defined as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

PATH (<http://www.path.org>) is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act.

Created in 1967, **Serum Institute of India Limited** (SIIL - <http://www.seruminstitute.com>) has emerged as a top supplier of quality vaccines and the world’s largest manufacturer of measles vaccine and diphtheria-tetanus-pertussis (DTP) vaccines. Currently, SIIL products are being exported to 150 countries. At least one of two children born throughout the world is administered a measles or DTP vaccine manufactured by SIIL.

The **Center for Biologics Research and Evaluation** (CBER - <http://www.fda.gov/cber>) of the U.S. Food and Drug Administration is committed to advancing the public health through innovative regulations that ensure the safety, effectiveness, and timely delivery to patients of biological products. The mission of CBER is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, tissue, allergenics, and biological therapeutics.

Founded in 1926, the **King Edward Memorial (KEM) Hospital** (<http://www.kem.edu>) partners with the Seth Gordhandas Sunderdas Medical College to provide teaching and medical care in India. With about 360 staff physicians and 750 resident doctors, the 1800-bed hospital treats about 1.5 million outpatients and 88 000 inpatients annually and provides both basic care and advanced treatment facilities in all fields of medicine and surgery.

B.Y.L. Nair Hospital (<http://www.nair.edu>) partners with T.N. Medical College to offer both education and health services to the Mumbai community. With about 250 senior staff members and 400 resident doctors, the 1300-bed hospital takes care of more than 1 million patients every year through its outpatient departments, and the total number of admissions in a year exceeds 37 000.

Established as an autonomous institution by the Government of Andhra Pradesh in 1989, the **Nizam's Institute of Medical Science** (<http://www.nims.ap.nic.in>) offers medical education, medical research, and health care to the Hyderabad community. With about 160 faculty members and 800 beds, the institute has 26 departments and laboratories engaged in investigation in the field of medical care, relief, and public health.

iGATE Clinical Research International (iCRI - <http://www.igate.com/icri>) is a full service contract research organization with offices in India and the United States. iCRI offers clinical trial management services to global clients, including clinical operations and central laboratory services, data management and biostatistical services, pharmacovigilance, pharmacy services, regulatory support, and India-specific consultancy services.