

News digest 15 Q4, 2007

Dear partners, friends, and colleagues:

The following is a summary of recent, current, and upcoming activities at the Meningitis Vaccine Project (MVP). We welcome your comments and suggestions at <a href="mailto:info@meningvax.org">info@meningvax.org</a> and encourage you to forward this update to friends or colleagues who might be interested in learning about MVP's progress.

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## **Vaccine Development Activities**

• Serum Institute of India (SIIL) prepared the clinical lot of meningococcal A (Men A) conjugate vaccine that will be used for the upcoming infant study.

## **Clinical Activities**

- The Phase 2 clinical study is ongoing at two sites—Center for Vaccine Development-Mali (CVD-Mali) and the Medical Research Council (MRC) in Basse, The Gambia. The study, which looks at safety and immunogenicity in 600 12- to 23-month-olds (the younger age group targeted by the mass vaccination campaigns) is going well. New results including memory evaluation and antibody persistence will be available during the first quarter of 2008.
- The Phase 2/3 clinical study is ongoing at four sites—CVD-Mali, MRC, Institut de Recherche pour le Développement in Senegal, and Shirdi Sai Baba Rural Hospital in India. No safety issues with the new Men A conjugate vaccine have been reported in the study that looks at safety and immunogenicity in 1,240 2- to 29-year-olds (the older age group targeted by the mass vaccination campaigns).
- The study protocol for the upcoming infant study has entered the ethical and regulatory submission process. The study could start as early as June 2008 in Africa.
- Extensive testing of Phase 1 sera by the U.S. Food and Drug Administration (Dr. Margaret Bash) and by the U.K. Health Protection Agency (Dr. Ray Borrow) confirmed the higher immunogenicity in adults of the Men A conjugate vaccine with respect to the polysaccharide vaccine. View the <a href="https://linear.complement.poster">https://linear.complement.poster</a> presented by Dr. Bash at the annual meeting of the Infectious Diseases Society of America. Testing of Phase 2 sera is ongoing.

## **Surveillance and Epidemic Preparedness Activities**

- The World Health Organization (WHO) Multi-Disease Surveillance Centre (MDSC) team in Ouagadougou, Burkina Faso, reports that the situation remains calm during the fourth quarter of 2007 despite some alerts in the districts of Sapouy (Burkina Faso) and Kauguna (Jigawa State/Nigeria), and in two subdistricts of Niger (Birni Konni and Mayahi). A little more than 250 suspected cases of meningitis were reported between October 1 and December 31. Serogroup A *Neisseria meningitidis* was isolated in Niger, and the two subdistricts were vaccinated with polysaccharide AC vaccine.
- Meningitis partners and the international community are making preparations for what they
  fear could be the worst meningitis epidemics in a decade. Read a <u>press release</u> from The
  International Federation of Red Cross and Red Crescent Societies.

- The polysaccharide bivalent AC vaccine developed by Bio-Manguinhos and Carlos Finlay was prequalified by WHO in December 2007. A total of 3.6 million doses will be produced and available by January 2008 for epidemic response in Africa.
- A consultative meeting on meningitis environmental risk took place on September 26–27 in Geneva. The purpose of the meeting was to find a common platform between relevant communities to discuss issues of meningitis epidemics in Africa and perceived environmental, biological, economic, and demographic influences; to gain a better understanding of current knowledge and research projects surrounding these issues; and to communicate information requirements from a public health perspective to help focus research efforts towards the effective enhancement of epidemic meningitis control strategies in Africa. The meeting was organized by the Group on Earth Observations (GEO) and WHO, in collaboration with the World Meteorological Organization, the Health and Climate Foundation, and the International Research Institute for Climate and Society.
- On October 8–11 meningitis experts, vaccine manufacturers, and several partners, including MVP, convened in Ouagadougou to participate in three meetings—the sixth annual review and planning meeting for meningitis surveillance and response in Africa, a meeting on the introduction of the new Men A conjugate vaccine, and a meeting on advocacy for resource mobilization given the high risk of major epidemics in 2008.
- On December 10–15, the MDSC team conducted training on standard operating procedures for enhanced meningitis surveillance in Juba, Southern Sudan. A total of 47 participants from ten states attended the meeting.
- With funding from MVP, the WHO office in Geneva sent more than 3,000 lumbar puncture kits containing material for sampling, transport, and analysis of cerebrospinal fluid (CSF) specimens to 12 countries as part of the preparedness activities for the 2008 epidemic season.
- The MDSC microbiology laboratory produced 3,000 Trans-Isolate bottles (transport media for CSF) for the coming meningitis epidemic season.
- The Norwegian Research Council has granted US\$2 million to the Norwegian Institute of Public Health (NIPH) to support the meningococcal carriage studies in Burkina Faso for the next 2.5 years. The study will be linked to the first introduction of the Men A conjugate vaccine. This project is a collaboration between the NIPH, MVP, MDSC, the U.S. Centers for Disease Control and Prevention, the Ministry of Health and national laboratories in Burkina Faso, and the Centre for Global Infections at the University of Oslo, Norway.
- The United States Agency for International Development has committed financial support to safety follow-up to the Men A conjugate vaccine introduction in Burkina Faso. Safety follow-up will be conducted through surveillance of adverse events following immunization to ensure that the new conjugate vaccine is safe when used in large numbers of recipients.

## **Vaccine Introduction Strategy and Communication**

- The communication team finalized the draft communication/social advocacy plan that will be used for introduction of the new Men A conjugate vaccine in Burkina Faso.
- MVP's annual workshop took place in Thoiry, France, on October 17–18. Work sessions focused on how to plan towards the first introduction of the Men A conjugate vaccine.
- The GAVI Board Alliance reaffirmed its prior decision (taken in 2002) to prioritize
  meningococcal A containing conjugate vaccine. An investment case to support introduction of
  meningococcal A containing conjugate vaccine as well as a stockpile of polysaccharide
  vaccine will be considered by the Board at its June 2008 meeting.

That's all for now from the MVP team. Stay tuned for our next news digest in three months' time.

We look forward to receiving your comments at <a href="mailto:info@meningvax.org">info@meningvax.org</a>.

Created in 2001, the Meningitis Vaccine Project is a partnership between WHO and PATH. 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.

For more information on MVP, please visit our website at <a href="http://www.meningvax.org">http://www.meningvax.org</a>.