

News digest 16 Q1, 2008

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 <u>info@meningvax.org</u> 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**

- MVP held its semiannual project management committee meeting in Geneva, Switzerland, on January 9 with discussions focused on vaccine development and introduction activities and timelines.
- Vaccine lyophilization trials were performed at the Serum Institute of India Limited, India, and at Aérial, France, to study vaccine formulation.

## **Clinical Activities**

- One-year follow-up visits for the pivotal Phase 2 clinical study at Center for Vaccine Development-Mali (CVD-Mali) and the Medical Research Council (MRC) in Basse, The Gambia, have been successfully completed, and sera have been shipped to the contract laboratories for testing. The Phase 2 clinical study looks at safety and immunogenicity in 600 12- to 23-month-olds (the younger age group targeted by the mass vaccination campaigns).
- 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 meningococcal A (Men A) conjugate vaccine have been reported for 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). Clinical audits for the study have been carried out at the sites in India and Senegal with no critical findings. Clinical audits at the sites in Mali and The Gambia were conducted previously.
- Preparations for the upcoming infant study are being finalized. The study could start as early as June 2008 in Africa.
- MVP study investigators from Mali, The Gambia, Senegal, and Ghana convened in Dakar, Senegal, on March 3–4 for a follow-up certified training on good clinical practices (GCP). The GCP training was conducted by Rita Walt Consulting, an independent clinical auditor based in Schaffhausen, Switzerland.
- On March 24–25 the MVP clinical team and MVP partner contract research organizations from Africa and India held a meeting in Mumbai, India, to discuss operational issues and lessons learned from previous studies and to better plan for the upcoming Phase 2/3 infant study in Africa and the Phase 3 clinical studies (a lot-to-lot consistency study in India and a large safety study in India).

## **Surveillance and Epidemic Preparedness Activities**

- The World Health Organization (WHO) Multi-Disease Surveillance Centre (MDSC) team in Ouagadougou, Burkina Faso, reports that during the first quarter of 2008 Burkina Faso was severely affected by meningitis epidemics. During week 12, there were 8 epidemic districts and 12 districts on alert. A total of 6,594 suspected cases and 650 deaths have been reported between January 1 and March 30, 2008, and more than 90 percent of isolates were serogroup A *Neisseria meningitidis*.
- A cross-border meeting took place on February 20 in Bouna, Ivory Coast, with delegations from Burkina Faso and Ivory Coast. The meeting focused on finding a joint solution to the epidemics ravaging both countries. The MVP advocacy and social mobilization officer and the MVP epidemiologist were present. Both countries committed to improving cross-border communications and to enhancing technical collaboration and surveillance to more effectively manage meningitis epidemics. To read the full press release, published by IRIN (United Nations Office for the Coordination of Humanitarian Affairs), please click <u>here</u>. A second meeting is planned for the end of the year to assess the enhanced cooperative measures.
- Vaccine introduction specialists convened in Ouagadougou on February 12–19 to discuss preparations of the meningococcal carriage study that will be implemented in Burkina Faso. The meeting was chaired by the department of Vaccine Preventable Diseases from the WHO regional office in Africa. A carriage study workshop to train laboratory personnel was concurrently organized by the Norwegian Institute of Public Health with support from an MVP consultant.
- During the first quarter of 2008 experts from the Centers for Disease Control and Prevention, based in Atlanta, were invited to the MDSC to participate in a collaborative exercise to upgrade the existing epidemiology database in preparation for Men A conjugate vaccine introduction. The experts also looked at ways to improve studies designed to measure vaccine efficacy and impact.

## **Vaccine Introduction Strategy and Communication**

- The draft communication/social advocacy plan that will be used for introduction of the new Men A conjugate vaccine in Burkina Faso has been submitted to the United Nations in Burkina Faso and to the Burkina Faso Ministry of Health.
- Expert reviews of the Advanced Immunization Management (AIM) e-Learning module on meningococcal meningitis have been completed, and an expanded cost-effectiveness analysis section has been added to the module. AIM e-Learning modules are educational tools designed to help national immunization managers and other decision/policy makers in developing countries make well-informed management and implementation decisions on introduction of new vaccines.
- MVP partners, MVP consultants, and the whole MVP team are preparing for the 16<sup>th</sup> International Pathogenic Neisseria Conference that will take place in Rotterdam, The Netherlands, September 7–12. For additional information on the conference, click <u>here</u>.

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 info@meningvax.org.

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 http://www.meningvax.org.