



News digest 9
Q1, 2006

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 info@meningvax.org 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

- The meningococcal A conjugate (MenA conjugate) vaccine that Serum Institute of India Limited (SIIL) prepared for Phase II clinical trials is undergoing quality-control testing at SIIL.
- Ongoing stability studies on Phase I material show that the MenA conjugate vaccine remains stable after 18 months at temperatures between +2°C and +8°C.

Clinical Activities

- Phase I week 4 results show that the MenA conjugate vaccine is safe and immunogenic. These encouraging results open the prospect to start the pivotal Phase II clinical study in The Gambia and Mali later this year. To view the full press release, click this link <http://www.meningvax.org/files/press-0603-improved.htm>.
- The Agence Africaine de Recherche en Santé Humaine (AARSH), a contract research organization (CRO) based in Dakar, Senegal, was selected to monitor the upcoming Phase II clinical trial in Africa and to support trial sites on operational activities linked to the trial. The agency is headed by Dr. Véronique Mazarin Diop who has extensive experience both as a vaccine scientist and as a vaccine trial monitor.
- On March 16–17, MVP convened a serology meeting at the PATH office in Ferney-Voltaire, France. The objectives of the meeting were to review and discuss Phase I serological results and, in light of these results and other emerging information, to refine the MVP serological plan for future trials and licensure of the MenA conjugate vaccine. Participants included SIIL, MVP, and MVP partners and advisers including scientific experts from Sierra Leone, the United Kingdom (Health Protection Agency), the United States (Centers for Disease Control and Prevention, Food and Drug Administration), and Norway (World Health Organization [WHO] Collaborating Centre for Reference and Research on Meningococci at the Norwegian Institute of Public Health).
- The MVP clinical team and Dr. Mazarin Diop (AARSH) made a site visit to the Medical Research Council Laboratories in The Gambia, one of the two sites selected for the Phase II clinical study. Dr. Aissatou Touré-Baldé participated in the field visit as a member of the MVP Project Advisory Group (PAG). Meetings were held with the secretary general of health services at the ministry of health, the management team of the Expanded Programme on Immunization, and regulatory authorities. The MVP team also met with colleagues at the WHO country office who emphasized their strong commitment towards the success of the project and ensured that they would provide support and advice as necessary for all aspects of the project.
- The MVP clinical team and Dr. Mazarin Diop conducted a follow-up site visit to the Center for Vaccine Development-Mali (CVD-Mali) in Bamako. CVD-Mali is the second site selected

for the Phase II clinical study. The purpose of the visit was to strengthen relationships between MVP and the site and to discuss in great detail study organization and timelines.

- The MVP clinical team finalized the dossier in support of the Phase II clinical study in Mali and The Gambia and submitted the documents to PATH's institutional review board, thereby completing the first step in the clearance process for the Phase II study.

Surveillance Activities

- The WHO Multi-Disease Surveillance Center (MDSC) team in Ouagadougou, Burkina Faso, made country visits to Chad and the Central African Republic to assess their preparedness and provide training for the epidemic season as needed.
- The MDSC is implementing a laboratory quality control program and monitoring meningococci resistance to antibiotics, which started with a visit to Niger. Other countries will follow.
- With 8,186 suspected cases of meningitis and 784 deaths reported between January 2 and March 26, Burkina Faso is the hardest-hit country in the meningitis belt of Africa so far this year. Of the country's 55 sanitary districts, 22 have crossed the epidemic threshold and 13 have crossed the alert threshold. Virtually all meningococcal isolates are serogroup A.
- During the first 10 weeks of the 2006 meningitis season, meningococcal outbreaks have occurred in six other countries—Côte d'Ivoire, Kenya, Mali, Niger, Sudan, and Uganda.
- Emergency mass vaccination campaigns with polysaccharide vaccines have been or are currently being implemented in the affected districts with the support of WHO and partners, including the European Commission Humanitarian Aid Department (ECHO), Médecins sans Frontières, and UNICEF.

Vaccine Introduction Strategy and Communication

- His Excellency Blaise Compaoré, President of Burkina Faso, has agreed to act as official patron of the new initiative “Stop meningitis epidemics in Africa.” He will advocate for the initiative among meningitis belt countries' heads of state and financing agencies to mobilize Africa-based funds.
- The draft French and English versions of the vaccine introduction strategic plan for the MenA conjugate vaccine were finalized and distributed to PAG members for comments.
- The fifth meeting of the MVP PAG took place at the WHO Regional Office for Africa in Brazzaville, Congo, on March 3–4. The MVP team presented an update of the clinical development plan, the Phase II study protocol, reports of clinical site visits in Africa, and Phase I week 4 results. Agreement was reached on the updated overall clinical development plan for the Men A conjugate vaccine, on the Phase II pivotal study protocol, and on the proposed selection of sites for the next studies. The involvement of PAG members in initial site visits was found to be very positive and will be pursued for future site preparation visits. Dr. Luis G. Sambo, the new regional director of the WHO regional office in Africa, attended the meeting and assured MVP of his full support to the project.
- The MVP press release promoting Phase I clinical study results received good media coverage on five continents (Africa, Asia, Europe, North America, and South America). Major news agencies and print and online outlets covered the announcement, and BBC World Service, Radio France Internationale, and Voice of America broadcast stories after requesting interviews from MVP and WHO staff members.

That's all for now from the MVP team. Stay tuned for our next news digest (July 2006). 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>.