



News digest 5
Q1, 2005

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

- INTOX Pvt. Ltd. completed teratogenic and perinatal tests on the meningococcal A conjugate (MenA conjugate) vaccine that will be used in the Phase I clinical study, and the tests showed that the vaccine had no deleterious effects in animals. Teratogenic and perinatal tests provide information on the potential effect of a drug or vaccine in developing embryos, and results from these studies complete the preclinical toxicology package necessary for the initiation of the Phase I human clinical study in India.
- SynCo Bio Partners, B.V. in Amsterdam, Netherlands, produced industrial batches of polysaccharide A, one of the two main components of the MenA conjugate vaccine. The batches will be utilized to prepare the test vaccine used in the Phase II and III clinical studies. The other main vaccine component, tetanus toxoid, is produced by Serum Institute of India Ltd. (SIIL).

Clinical Activities

- Phase I clinical documents are under review by the ethics committees.
- Phase I clinical lots have been released by the Indian Central Drugs Laboratory.
- Phase I documents have been submitted to the Drugs Controller General of India, and MVP and SIIL are waiting for Indian regulatory clearance to start Phase I in India.
- The two laboratories responsible for antibody testing (Health Protection Agency in the United Kingdom and Centers for Disease Control and Prevention in the United States) are completing their harmonization process.

Surveillance Activities

- The World Health Organization (WHO) Multi-Disease Surveillance Center (MDSC) team made country visits to Benin, Burkina Faso, Mali, Niger, and Nigeria. During these visits, the team revised the national work plan for meningitis activities and provided technical support to ministry of health surveillance units.
- During a special visit to Sudan in February, the MDSC team trained national surveillance staff on data management, epidemiological mapping, and laboratory techniques. As a result of this training, Sudanese staff are now able to develop weekly meningitis surveillance reports including maps and graphs.
- Surveillance data compiled at the MDSC in Ouagadougou, Burkina Faso, between January 3 and March 27, 2005, show a relatively "quiet" season, with 6,981 confirmed cases of

meningitis and 1,156 deaths in countries of the sub-Saharan meningitis belt that are under enhanced meningitis surveillance.

Vaccine Introduction Strategy and Communication

- An information package related to the Phase I clinical study was developed and shared with MVP partners and principal collaborators.
- The communication and vaccine introduction team started collaboration with PATH Children Vaccine Program and Stanford University's School of Medicine to develop an Advanced Immunization Management (AIM) e-Learning module on meningococcal meningitis. AIM e-Learning modules are educational tools designed to help national immunization managers and other decision-makers in developing countries make well-informed management and implementation decisions.
- In addition, MVP participated in or made presentations at the following meetings:
 - Workshop on Strengthening National Regulatory Authorities (NRAs), Addis Ababa, Ethiopia, January 24–26.** Six countries (Ethiopia, Ghana, Nigeria, Gambia, Kenya, and Uganda) participated in the workshop whose objectives were to update participants on authorization and monitoring of clinical trials, vaccine regulation issues, regulatory systems capacities, marketing authorization and licensure activities, and postmarketing surveillance. The next NRA workshop is scheduled to take place in Ouagadougou in May 2005 and will address the issue of meningococcal vaccine introduction in core meningitis belt countries.
 - Workshop on Vaccine Pressure and *Neisseria meningitidis*, Annecy, France, March 9–11.** Drs. Mamoudou Djingarey and Marie-Pierre Préziosi, MVP's epidemiologist and medical officer, teamed up with Dr. Sylvestre Tiendrebeogo from the ministry of health in Burkina Faso and Dr. Kandioura Touré from the ministry of health in Mali to talk about vaccination strategies and meningococcal disease in Africa in recent years, with a focus on the experience of Burkina Faso, Mali, and Niger.
 - Advanced WHO Refresher Course on Immunology, Vaccinology, and Biotechnology Applied to Infectious Disease, Niamey, Niger, March 14–19.** Dr. Kader Konde, MVP's vaccine introduction manager, made presentations on MVP and vaccine development.
 - WHO Consultation on Ethical Considerations Related to the Provision of Care and Treatment in Vaccine Trials, Zomba, Malawi, March 15–16.** The workshop provided an opportunity for Dr. Marie-Pierre Préziosi and Colleen Ottoson (MVP's legal counsel) to present MVP, learn about the current situation in the provision of care and treatment in vaccine trials in Africa, and explore new approaches that could be used to guide decisions regarding care to trial participants.

Recent Hires

- Dr. Simonetta Viviani assumed leadership of the MVP vaccine development arm on March 1. For a short biography of Dr. Viviani, please visit <http://www.meningvax.org/team.htm#major>.
- Zerthum Alemubelay joined MVP in March to provide administrative assistance to the MVP/WHO team. For a short biography of Ms. Alemubelay, please visit <http://www.meningvax.org/team.htm#major>.

That's all for now from the MVP team. Stay tuned for our next news digest (July 2005). 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>.