



News digest 20
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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

- On March 30–April 3, MVP convened a meeting in the PATH office in Ferney-Voltaire, France, to perform a formal review of the nonclinical part of the regulatory file before it is submitted to the Drugs Controller General of India (DCGI) for Indian licensure. Participants included pharmaceutical and regulatory teams from Serum Institute of India Ltd. (SIIL) and MVP as well as MVP scientific advisers. Participants felt that the dossier was very strong, and the meeting ended with a trip to Le Col de la Faucille in the snow-covered mountains of the French Jura, where participants enthusiastically engaged in snowball fights and snowman building—a winter time team-building activity that was much appreciated by the Indian colleagues.
- It is expected that SIIL can submit the nonclinical part of the regulatory dossier to DCGI within a month. The clinical file will follow suit by June at the latest. The regulatory dossier can be submitted to the World Health Organization (WHO) for prequalification as soon as the DCGI has granted its market authorization.
- Although the timetable for licensure and prequalification is uncertain, the MVP partnership hopes to be able to introduce the vaccine in Burkina Faso at the end of this year.

Clinical Activities

- The PsA-TT-001 clinical study in India has officially ended. The official report on this Phase 1 study, which will be part of the regulatory file, has been completed.
- The PsA-TT-002 clinical study in Mali and The Gambia is near closeout. The last visit of the last subject took place at the end of March. The clinical study report is in an advanced stage of drafting and will be part of the clinical regulatory dossier to be submitted to DCGI. This two-year-long pivotal Phase 2 study looks at safety and immunogenicity of the meningococcal A (MenA) conjugate vaccine in 600 12- to 23-month-olds (the younger age group targeted by the mass vaccination campaigns).
- The MVP clinical team is working on closeout activities for the PsA-TT-003 clinical study in Mali, Senegal, and The Gambia. Closeout of the PsA-TT-003a clinical study in India is also on track and imminent. Both these phase 2/3 studies look at safety and immunogenicity of the MenA conjugate vaccine in the age groups targeted by the mass vaccination campaigns (2–29 years).
- The PsA-TT-004 clinical study at the Navrongo Health Research Centre, Ghana, is going well. So far over 420 infants have been enrolled and immunized. Screening and enrollment will proceed until a total of 1,200 subjects have been recruited. This Phase 2 study evaluates the safety and immunogenicity of three different schedules using the MenA conjugate vaccine in healthy infants.
- Preparations for PsA-TT-005 in India are almost complete. This Phase 3 study will evaluate the safety and consistency of consecutive lots of the MenA conjugate vaccine administered as a

single dose to healthy children ages 5 to 10 years. The MVP clinical team awaits the final approval from all relevant ethical review boards. The study is expected to start by the end of May.

- The MVP clinical team is drafting the protocol for PsA-TT-006, a large Phase 3 safety study that will take place in Africa. PsA-TT-006 is scheduled to start later this year.

Surveillance and Epidemic Preparedness Activities

- Our last newsletter of January 2009 reported that the WHO Multi-Disease Surveillance Centre (MDSC) team in Ouagadougou, Burkina Faso, was investigating rumors of meningococcal meningitis cases in Nigeria (state of Sokoto). These rumors turned out to be true as northern Nigeria and neighboring Niger are experiencing one of the worst meningitis epidemics in recent years, with 43,547 suspected cases (35,255 in Nigeria and 8,292 in Niger) and 2,028 deaths reported between January 1 and April 5. Cerebrospinal fluid specimens have confirmed the large predominance of group A *Neisseria meningitidis* in both countries.
- The urgency of the situation propelled the MDSC team to make four field visits to Nigeria during the first quarter of 2009. In addition to training local staff on standard operating procedures for enhanced meningitis surveillance, data management and mapping, laboratory confirmation, and epidemic investigation and response, the MDSC team also held sensitization meetings with ministries of health from 26 states of northern Nigeria, and they helped epidemic management committees fill application forms so that they could access the emergency stockpile of polysaccharide vaccines that is being managed by the International Coordinating Group (ICG) on vaccine provision for meningitis epidemic control.
- Emergency mass vaccination campaigns using the ICG vaccines have been or are currently being implemented with the support of WHO and partners, including the European Commission's Humanitarian Aid Department—which recently allocated €4.7 million to support efforts to contain the epidemic and treat those affected—and Médecins sans Frontières (MSF). By March 31, MSF had dispatched 77 emergency vaccination teams in Nigeria alone where, with the support of the Ministry of Health, UNICEF, and WHO, they have already vaccinated 700,000 people in the hardest-hit states of Jigawa, Katsina, and Sokoto. Vaccination campaigns are scheduled in the coming weeks in at least 7 other states. A total of 2 million people should also be vaccinated in Niger. In all, MSF plans to vaccinate 4 to 5 million people in West Africa this year.
- Most of the 9 million doses of ICG vaccines that are currently available have been or are being shipped to Nigeria and Niger, and ICG fears that the stockpile will be exhausted before the epidemic season ends in sub-Saharan Africa. WHO has therefore made recommendations to standardize vaccine strategy and the rational use of vaccine. The organization is also developing contingency plans and considering the use of fractional doses as a means to compensate for the global shortage of polysaccharide vaccine.
- Also responding to the crisis, the Global Alliance for Vaccines and Immunization (GAVI) is fast tracking a US\$55 million contribution to replenish the current stockpile of vaccine until the new meningococcal A conjugate vaccine becomes available.

Vaccine Introduction Strategy and Communication

- MVP and partners are working with the Ministry of Health from Burkina Faso to draw up detailed plans for vaccine introduction for the end of 2009.
- The second round of the carriage study in Burkina Faso has been completed. Study results will enable MVP to monitor the impact of the vaccination campaign.
- The Advanced Immunization Management (AIM) e-Learning module on group A meningococcal conjugate vaccine has been launched and is accessible on CD-ROMs and at <http://aim.path.org/en/vaccines/mening/index.html>. The module is aimed at all professionals involved or interested in immunization.

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>.