

News digest 30 Q3, 2011

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 introduction and communication activities

- The funding gap for MenAfriVacTM rollout in Mali has been filled with the help of the World Health Organization (WHO), the Canadian International Development Agency, and UNICEF. The national organizing committee can now fully focus its attention on the organization of the last introduction phase of MenAfriVacTM in the country, which is currently scheduled for November 10–20, 2011. Médecins sans Frontières has offered the use of its cold chain so that Mali's remaining target population (6 million people aged 1–29 years) can be vaccinated over 11 days. If all goes according to plan, Mali will become the second meningitis belt country to have introduced MenAfriVacTM, the meningococcal A conjugate vaccine developed through the Meningitis Vaccine Project, nationwide.
- The funding gap for MenAfriVacTM rollout in Niger has been reduced to US\$1.2 million thanks to the Korean International Cooperation Agency, WHO, and UNICEF. The national organizing committee continues to actively plan the last MenAfriVacTM introduction phase in the country's 31 remaining districts for late November–early December, 2011. The Niger 2011 campaign, which targets some 8 million people aged 1–29 years, will bring the total number of MenAfriVacTM recipients to about 33 million in the African meningitis belt. The country hopes to complete the campaign by December 5, one day prior to the first anniversary of the official launch of MenAfriVacTM on the continent.
- Preparations for the first introduction of MenAfriVacTM in Cameroon, Chad, and Nigeria are advancing. Some 30 million doses have been made available to the three countries which are all planning to launch their first vaccination campaigns in December. Cameroon and Chad have mobilized their share of the operational costs for vaccine introduction, while resource mobilization efforts are ongoing in Nigeria.
- The WHO Intercountry Support Team (IST) in Ouagadougou, Burkina Faso, continues to play a key role in planning vaccine introduction activities in Cameroon, Chad, Mali, Niger, and Nigeria—not a small task considering that the biweekly planning meetings via teleconference are attended by no fewer than 20–30 partner staff across three continents.
- The IST and consultants conducted missions in Cameroon, Chad, and Nigeria to help countries select the regions for the first MenAfriVacTM introduction phase in 2011. Given the size of the target population and the diversity of the epidemiologic risk in the countries, priority must indeed be set regarding the regions that might (not) be vaccinated and the order in which the vaccination campaigns might be phased and completed.

Surveillance and epidemic preparedness activities

• Not a single case of group A meningococcal meningitis has been reported in the 19.5 million people in Burkina Faso, Mali, and Niger who received one dose of MenAfriVacTM last year.

Clinical activities

- The following six clinical trials related to licensing and prequalification of MenAfriVacTM for use in 1- to 29-year olds have been successfully completed:
 - Phase 1 <u>PsA-TT-001</u> study in India.
 - Phase 2 PsA-TT-002 study in Mali and the Gambia.
 - Phase 2/3 PsA-TT-003 study in Mali, Senegal, and the Gambia.

- Phase 2/3 PsA-TT-003a study in India.
- Phase 2/3 PsA-TT-005 study in India.
- Phase 3 <u>PsA-TT-006</u> study in Mali.
- The Phase 2 <u>PsA-TT-004</u> study is on schedule. A total of 1,200 infants are enrolled in the study that investigates the safety and immunogenicity of different dosages and schedules of MenAfriVacTM when administered concomitantly with EPI vaccines. Conducted at the Navrongo Health Research Centre in Ghana, the study is scheduled for completion in early 2013.
- The clinical team is finalizing the PsA-TT-006 study report to be submitted to regulatory authorities later this year.
- A persistence study is about to start in Mali, Senegal, and The Gambia. This study will retrace
 individuals who participated in the PsA-TT-002 and PsA-TT003 clinical trials to measure
 immunogenicity up to 5 years after receiving MenAfriVacTM. Study results will be used to plan the
 timing of future national immunization campaigns with MenAfriVacTM.
- Scientific meetings were held in Mali and Senegal to inform local partners, ministries of health, and ethics committees about clinical development results. These meetings were followed by investigator meetings to prepare study site staff for the upcoming persistence study, and by community meetings to share local study results and vaccine introduction data. The community meetings drew large crowds of people both in Mali (photo) and Sénégal and provided MVP, sponsors, and the sites an opportunity to thank study participants and other community members for their continued support. Similar meetings will be held in The Gambia in October.
- A new Phase 3 clinical study is being planned with an expected study start in December. The
 clinical team is finalizing the protocol and other study documents for ethical approvals. This study
 will evaluate the immunogenicity and safety of different schedules and formulations of the
 meningococcal A conjugate vaccine administered concomitantly with local EPI vaccines in healthy
 infants and toddlers.



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.