

News digest 29 Q2, 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 <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 introduction and communication activities

- Preparations continue to advance smoothly both for the last introduction phase of MenAfriVacTM in Mali and Niger and for the first introduction phase in Cameroon, Chad, and Nigeria. Multipartner teleconferences conducted by the World Health Organization (WHO) Intercountry Support Team (IST) in Ouagadougou, Burkina Faso, prepare the way for vaccine introduction by addressing a variety of issues relevant to MenAfriVacTM rollout in these countries this coming fall, including coordination and planning of the mass campaigns, social mobilization and advocacy, logistics, cold chain and waste disposal management, pharmacovigilance, training and supervision of health workers, and resource mobilization.
- The funding gap for vaccine rollout in Mali and Niger has been reduced from US\$3.1 million at the time of our last update to US\$2.2 million. Once the remaining gap is closed, Mali and Niger will be able to fully implement the last phase of their vaccination campaigns and immunize the rest of their 1- to 29-year-old population against group A meningococcal meningitis (some 6 million people in Mali and some 8 million people in Niger).
- WHO HQ in Geneva and the IST team continue to support Cameroon, Chad, and Nigeria in their resource mobilization efforts to cover their share of the operational costs (some US\$22 million) for MenAfriVac[™] introduction next fall.
- The first of a series of communication workshops took place in N'Djamena, Chad, on June 13–18. Jointly organized by the UNICEF West and Central African office in Dakar and WHO IST, the workshop informed communication and health professionals on MenAfriVac[™] introduction in the country. Similar briefings are being planned for Cameroon, Mali, Niger, and Nigeria, along with workshops focusing on the development of country-specific communication plans and messages.
- Representatives from WHO HQ and WHO IST made country visits to Benin, Ghana, and Senegal to meet with the national introduction committee in each country. The main purpose of the visits was to support vaccine introduction activities and to help national authorities in mobilizing resources for the cofinancing of MenAfriVacTM campaigns.
- The *New England Journal of Medicine* published an MVP-authored paper titled "Immunogenicity and Safety of a Meningococcal A Conjugate Vaccine in Africans." This paper, which is the scientific reference for the clinical trials PsA-TT-002 and PsA-TT-003, is freely available via the <u>homepage</u> of our website.
- The June issue of *Health Affairs* published an article authored by Drs. LaForce (PATH) and Okwo-Bele (WHO) titled "Eliminating Epidemic Group A Meningococcal Meningitis In Africa Through A New Vaccine." The article summarizes the MVP approach to developing an affordable vaccine and the plans for MenAfriVac[™] rollout in the coming years. Read the <u>abstract</u>.
- The same issue of *Health Affairs* published an analysis of the business development decisions that led to the creation of MenAfriVac[™]. The paper is entitled "Product Development Partnerships Hit Their Stride: Lessons From Developing A Meningitis Vaccine For Africa." The article is authored by faculty from the Bloomberg School of Public Health and the Carey Business School at Johns Hopkins University. Read the <u>abstract</u>.
- An MVP press release was issued on June 9 to report on the dramatic fall in the number of meningitis cases where the vaccine has been introduced and draw attention to obstacles to achieving vaccine rollout over the coming years. Read the <u>press release</u>.

Surveillance and epidemic preparedness activities

- The 2010–2011 meningitis epidemic season is now over in Burkina Faso, and the country reports no meningococcal A meningitis cases in the 11,075,996 Burkinabè nationals who received one dose of MenAfriVacTM during the December 2010 nationwide vaccination campaign. *Streptococcus pneumoniae* is now by far the leading cause of meningitis in the country.
- Chad pays the heaviest toll this year, with 5,796 suspected cases of meningitis reported at week 24. The predominance of *Neisseria meningitidis* A has been confirmed. Group A meningococci have also been reported in northern Cameroon during 2011.
- The IST made country visits to Cameroon, the Central African Republic, the Democratic Republic of the Congo, Mali, Niger, and Nigeria. The main purpose of the visits was to provide training on standard operating procedures for enhanced surveillance of meningitis, data management, and laboratory confirmation work.
- The MenAfriCar consortium's third meeting took place in Dakar, Sénégal, May 11–13. A short meeting summary is available on the MenAfriCar website.

Clinical activities

- The following five 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 <u>PsA-TT-002</u> study in Mali and the Gambia.
 - Phase 2/3 <u>PsA-TT-003</u> study in Mali, Senegal, and the Gambia.
 - Phase 2/3 <u>PsA-TT-003a</u> study in India.
 - Phase 2/3 <u>PsA-TT-005</u> study in India.
- The Phase 2 PsA-TT-004 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, but preliminary data are already being collected to help design PsA-TT-007, a newly-funded MVP study that will further investigate an indication for use of MenAfriVacTM in infancy. As the dry "meningitis" season ends and the rainy "malaria" season begins in Africa, a bednet distribution campaign was organized for the Navrongo health district where PsA-TT-004 is conducted. This campaign aims to protect families from malaria and hence reduce the number of malaria cases in the district. For reasons of equity, bednets were made available to all children below the age of 3 years in the district, not only children enrolled in the study. More than 10,000 MVP-purchased bednets were distributed, reaching more than 95% of the target population. The campaign took two weeks to complete and was planned and executed by the health district in partnership with the MVP study staff. The district health staff and study staff have instituted follow-up programs that will ensure that the bednets are properly installed and used.
- The Phase 3 <u>PsA-TT-006</u> study conducted at the Center for Vaccine Development-Mali in Bamako has been completed. The study looked at potential rare adverse reactions following the administration of a single dose of the meningococcal A conjugate vaccine in healthy subjects aged between 1 and 29 years. The clinical study report will be submitted to regulatory authorities later this year.
- The Independent Data Safety and Monitoring Board has reviewed the second safety report from PsA-TT-004 and the final safety report for PsA-TT-006. The board concluded that there are no safety concerns to date.
- A persistence study is in advanced stages of planning. This study aims to retrace individuals who participated in the PsA-TT-002 and PsA-TT003 clinical trials in Mali, Senegal, and The Gambia and to measure immunogenicity up to 5 years after receiving MenAfriVacTM. Study results will be particularly useful for the timing of future national immunization campaigns with MenAfriVacTM.

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

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.