

News digest 17 Q2, 2008

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 <a href="mailto:info@meningvax.org">info@meningvax.org</a> 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**

- Clinical material for the Phase 2/3 infant study (dose-range study) has been released by the National Control Laboratory in India. This is an important step toward the launch of this clinical trial that will start shortly at the Navrongo Health Research Center (NHRC) in Ghana.
- The preparation of the consistency lots for the Phase 3 clinical trials is in progress at Serum Institute of India Limited, India.

## **Clinical Activities**

- Phase 2 and Phase 2/3 studies in three African sites and one Indian site continue with excellent results to date. The studies look at safety and immunogenicity of the meningococcal A (MenA) conjugate vaccine in the age groups targeted by the mass vaccination campaigns.
- On April 29 the Data Safety Management Board met in Ferney-Voltaire, France, to review the safety data at week 4 (a) postbooster immunization in the Phase 2 study in Africa and (b) postimmunization in the Phase 2/3 study in India. There are no safety concerns related to the vaccine.
- The investigators' meeting for the infant study in Ghana was held June 17–18 in Navrongo in preparation for the start of the upcoming clinical study. On June 19 Dr. Elisa Marchetti, MVP clinical operations manager, led a training on good clinical practice for approximately 75 enthusiastic NHRC staff. The University of Siena laboratory team visited the NHRC on June 19–21 to prepare for the capacity-building activities for the serology testing to be conducted on site.

## **Surveillance and Epidemic Preparedness Activities**

- The World Health Organization (WHO) Multi-Disease Surveillance Centre (MDSC) team in Ouagadougou, Burkina Faso, monitors the epidemiological situation of bacterial meningitis in 13 countries of the belt: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Côte d'Ivoire, Democratic Republic of the Congo (DRC), Ethiopia, Ghana, Mali, Niger, Nigeria, and Togo. For the past three years Burkina Faso has been the most severely-hit country in terms of meningitis epidemics. Between January 1 and June 22, 2008, out of a total of 28,946 suspected cases of cerebrospinal meningitis, this country reported 9,578 cases followed by Nigeria (6,605 cases), DRC (4,680 cases), Niger (3,182 cases), and Mali (1,392 cases). Neisseria meningitidis A has been the main causal pathogen reported in the epidemic districts this year, accounting for 78 percent of the confirmed cases. High case-fatality rates (11 percent to 28 percent) were recorded in Benin, Central African Republic, Chad, Côte d'Ivoire, DRC, and Togo.
- Mass immunization campaigns using bivalent AC vaccines took place in Burkina Faso, Central African Republic, DRC, Mali, Niger, and Nigeria. Reports from Burkina Faso show high vaccine coverage rates to almost 100 percent.

- In preparation for the introduction of the MenA conjugate vaccine guidelines are developed for case-based surveillance of bacterial meningitis in the African meningitis belt. Under the current system suspected cases are reported. In the future confirmed cases with complete descriptions of epidemiological and laboratory characteristics will be reported. This will enable better control and understanding of bacterial meningitis and epidemic patterns in Africa. The change in reporting procedures was developed by the MDSC, the International Science and Technology Institute, and the Centers for Disease Control and Prevention. A first draft of the new guidelines will be available by the end of August 2008.
- The surveillance and laboratory performance in the control of the 2008 meningococcal disease epidemic in Nigeria, in Jigawa and Kebbi states, was reviewed on May 10–20.
- MDSC staff organized a training workshop on enhanced meningitis surveillance in Moundou, Chad, on May 21–28. Some 70 surveillance and laboratory officers from 19 districts and 5 regions of Chad attended the workshop.

## **Vaccine Introduction Strategy and Communication**

- Science published a six-page feature story on meningitis and the development of a meningococcal A conjugate vaccine for Africa. The article is written by Leslie Roberts, an award-winning news editor and reporter. She traveled to Africa and Europe to research the epidemiology of meningitis and the science of vaccine development, as well as the devastating effect of the disease on adults, children, and families. The article is accessible from: http://www.meningvax.org/index.htm.
- MVP held its annual meeting with the MVP Expert Panel to review clinical trial results to date and study plans for the future. The Expert Panel congratulated the team on its outstanding performance and study results.
- Preparations are well underway for the 16<sup>th</sup> International Pathogenic Neisseria Conference that will take place in Rotterdam, The Netherlands, September 7–12. For additional information on the conference, click here.
- Agence de Médecine Préventive (AMP) completed an extensive study on the socioeconomic burden of meningitis in Burkina Faso. The study, funded by MVP and WHO, outlines the burden of epidemics on the health service at all levels and shows that direct and indirect costs induced by a single case of meningitis can throw a family into a spiral of poverty. The study was conducted by AMP staff in Ouagadougou, under the direction of health economist Anaïs Colombini.
- The seventh meeting of the MVP Project Advisory Group (PAG) took place in Accra, Ghana, on May 8–9. Warmly welcomed by Dr. Joachim Saweka, Ghana WHO representative, and Dr. Gladys Ashitey, Ghana deputy minister of health, participants were then updated on meningitis surveillance, vaccine development, and clinical trials. Special attention was paid to the challenges associated with the first introduction of the MenA conjugate vaccine in Africa. PAG members emphasized WHO AFRO's pivotal role in the introduction of the MenA conjugate vaccine in Africa. This role will be increasingly important as the transition from vaccine development to mass vaccination campaigns in Africa will be made.
- The GAVI Alliance Board approved the introduction strategy outlined in the meningitis
  investment case. Funds (US\$55 million) for the immediate creation of a meningococcal A
  vaccine emergency stockpile have been approved. The GAVI secretariat has been authorized to
  release funds to implement other components of the strategy (up to an envelope of US\$371
  million).

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 <a href="http://www.meningvax.org">http://www.meningvax.org</a>.