

News digest 27 Q4, 2010

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

- On December 6, Burkina Faso became the first country to introduce MenAfriVacTM, the new meningococcal A (MenA) conjugate vaccine developed through the Meningitis Vaccine Project, nationwide. Hosted by the government of Burkina Faso, the launch ceremony was attended by President Blaise Compaoré, the official patron of the "Stop Meningitis Epidemics in Africa" initiative, World Health Organization (WHO) Director General Margaret Chan, PATH President and CEO Christopher Elias, and high-level representatives from the Bill & Melinda Gates Foundation, vaccine manufacturer Serum Institute of India Ltd., the Global Alliance for Vaccines and Immunization, and UNICEF. Some 3,000 Burkinabè, including hundreds of schoolchildren, also attended the festive event that celebrated what could be the beginning of the end of one hundred years of meningitis epidemics in the country.
- Under the guidance of the Burkina Faso ministry of health, 2,710 vaccination teams of four staff each were deployed in the 274,200-sq-km country to immunize 11,075,996 Burkinabè, starting with schoolchildren, in only 10 days. The MenAfriVacTM campaign was monitored by 652 supervisors. Vaccine coverage and vaccine wastage rates reached 102.10% and .50% respectively.
- Four days after Burkina Faso, on December 10, the Prime Minister of Niger Mahamadou Danda launched a ten-day MenAfriVacTM vaccination campaign in 10 of the 42 health districts in Niger. A total of 2,816,474 people were immunized by some 5,000 staff, including volunteers from humanitarian organization Médecins sans Frontières (MSF), which also purchased some of the vaccine. Vaccine coverage and vaccine wastage rates reached 105.59% and .01% respectively. Provided the funding gap is met, Niger will vaccinate the rest of its 1- to 29-year-old population (some 8 million people) in 2011 after the annual meningitis season has ended.
- Six days after Niger, on December 16, President Amadou Toumani Touré launched a two-week mass vaccination campaign in 21 Malian health districts. By the end of the campaign, to which MSF also contributed, 4,575,446 young Malians had been vaccinated with MenAfriVac™. Vaccine coverage and vaccine wastage rates reached 101.44% and 1.63%, respectively. Provided the funding gap is met, Mali will vaccinate the rest of its 1- to 29-year-old population (some 6 million people) in 2011 after the annual meningitis season has ended.
- Taking into account the first round of vaccination campaigns in Burkina Faso, Mali, and Niger 19.5 million people have received MenAfriVacTM since September 2010. Pharmacovigilance activities conducted thus far in the three countries continue to indicate that MenAfriVacTM is a very safe vaccine. All safety data are reviewed by national expert committees, and summaries are presented to a WHO Global Advisory Committee on Vaccine Safety.
- In an effort to increase the awareness around vaccine launch, the PATH and WHO communication teams developed special MenAfriVacTM-related sections on their respective organization website.
 - View MenAfriVac[™]-related content on the PATH website.
 - View MenAfriVacTM-related content on the WHO website.
- Communication activities surrounding the launch of MenAfriVacTM succeeded in raising global awareness of the potential of the vaccine to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa. News of the launch was covered over several weeks and in more than eight languages by major news agencies and media around the globe, including *24 Hours*, *Al*

Eqtisadiah, Berliner Morgenpost, Daily Express, L'Express, Le Figaro, Financial Times, The Guardian, Daily Mirror, Jeune Afrique, Neue Zürcher Zeitung, New Scientist, The New York Times, El Pais, The Philadelphia Inquirer, Science, The Seattle Times, Sciences et Avenir, The Sydney Morning Herald, TIME, The Times of India, and Die Welt. Broadcast coverage included pieces on ABC's Good Morning America and Voice of America's In Focus and Special English Health Report, live interviews with MVP director Marc LaForce on Al-Jazeera and UK's Channel 4 news, and a 45-minute program on Radio France Internationale's Priorité Santé.

- MenAfriVac[™] had been the subject of news stories in the past, but coverage of the launch represented a sea change in the way journalists covered the vaccine as for the first time, media reported the new vaccine as a breakthrough—not just in combating meningitis epidemics—but in presenting an alternative model to development of vaccines and drugs, particularly for developing nations.
- The successful development and introduction of MenAfriVacTM in Africa has been recognized as
 one of the top health global success stories in 2010 by <u>WHO</u>, <u>MSF</u>, the <u>United Nations</u>, and <u>Faster</u>
 Times.

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 PsA-TT-001 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. The final report of this lot-consistency study was submitted to regulatory authorities in December. The consistency of the production process was successfully assessed: consecutive vaccine lots produced at commercial scale were shown to be equivalent in terms of immune response. Results of this clinical study confirm earlier findings from previous trials performed in India and Africa on the good safety and immunogenicity profile of MenAfriVac™. A study close-out visit took place in December at Vadu's Shirdi Sai Baba Rural Hospital, a rural division of the King Edward Memorial Hospital in Pune.
- Research to document an indication for MenAfriVacTM use in infancy (in under 1-year-olds) is progressing well and according to schedule. A database lock for <u>PsA-TT-004</u> was completed on December 21. PsA-TT-004 is a Phase 2 study that evaluates the safety and immunogenicity of different dosages and schedules of the MenA conjugate vaccine in 1,200 healthy infants when administered concomitantly with EPI vaccines. The study is conducted at the Navrongo Health Research Centre in Ghana and is scheduled for completion in early 2013.
- The Phase 3 <u>PsA-TT-006</u> study conducted at Center for Vaccine Development-Mali in Bamako is close to completion. The study looks at potential rare adverse reactions following the administration of a single dose of the MenA conjugate vaccine in healthy subjects aged between 1 and 29 years. The last visit is expected to be completed for all 6,000 subjects in January 2011. Like in all other MVP clinical studies conducted since 2005, no safety concerns have been identified thus far.

Surveillance and Epidemic Preparedness Activities

- A total of 28,421suspected cases of meningitis were reported between January 1 and November 28 in the 14 countries under enhanced meningitis surveillance. Burkina Faso is the hardest-hit country with 6,510 cases and 896 deaths (case-fatality rate: 13.8 %).
- Carriage studies are being planned in selected districts in Burkina Faso as part of a long-term study funded by the Norwegian Institute of Public Health and the Centers for Disease Control and Prevention in Atlanta to assess effect of MenAfriVacTM introduction on meningococcal carriage. The studies will start in January 2011.

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.