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NEWS RELEASE

STATEMENT FROM WYETH VACCINES ON CHMP POSITIVE OPINION FOR 10-VALENT PCV IN EUROPE

Taplow, UK – 23rd January 2009 – Wyeth is aware that the GSK 10-valent pneumococcal conjugate vaccine (PHiDDT-CV) has received a positive opinion from the CHMP in Europe.

Wyeth is unable to specifically comment on GSK's vaccine. However, Wyeth's 7-valent pneumococcal conjugate vaccine, Prevenar* (PCV-7) has been part of the UK childhood immunisation schedule since September 2006 and has become the standard in pneumococcal disease prevention in infants and young children as a result of its established immunogenicity and efficacy. Earlier this year the Department of Health announced that following the introduction of Prevenar onto the schedule in the UK, they estimate that up to 470 children have avoided serious illnesses like meningitis, septicaemia and severe pneumonia and up to 28 deaths have been avoided.¹

Due to the significant burden of pneumococcal disease and demonstrated vaccine efficacy, the World Health Organization (WHO) recommends the priority inclusion of Prevenar (PCV-7) in national childhood immunisation programmes worldwide.² Wyeth has recently reached an agreement with GAVI (the Global Alliance for Vaccines and Immunization) to provide a donation of more than three million doses of Prevenar to immunise African children in GAVI-eligible countries. The vaccine programme will begin in Rwanda and Gambia, in the first half of 2009. Furthermore, in December 2008 Wyeth filed for approval for a 13-valent pneumococcal conjugate vaccine (PCV-13).

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Notes for Editors

The 13-valent pneumococcal conjugate vaccine (PCV-13) for which Wyeth is seeking approval includes the 13 most prevalent disease-causing pneumococcal serotypes worldwide. Seven of these (4, 6B, 9V, 14, 18C, 19F and 23F) are included in Prevenar with six additional serotypes being 1, 3, 5, 6A, 7F and 19A.

Wyeth is seeking an indication for the prevention of pneumococcal disease (PD) caused by the 13 serotypes included in the pneumococcal conjugate vaccine in children aged two months to five years of age. The review of the Marketing Authorisation Application will be coordinated by the European Medicines Agency (EMA) for all 27 countries in the European Union, as well as Norway, Iceland, and Liechtenstein.

Data from four Phase 3 studies show that Wyeth's investigational 13-valent pneumococcal conjugate candidate vaccine (PCV-13) may broaden protection against pneumococcal disease in infants and young children.^{3,4,5,6}

The results suggest that PCV-13 may be as effective as PCV-7 in helping to prevent pneumococcal disease caused by the seven serotypes shared by the vaccines, and that PCV-13 may provide expanded coverage in helping to prevent PD caused by the six additional serotypes.

The results also indicated that the safety and tolerability of PCV-13 and PCV-7 were comparable and that PCV-13 did not interfere with the immune responses to concomitantly administered paediatric vaccines. The data were first presented in October 2008 at the joint annual meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Disease Society of America (IDSA) in Washington, D.C.

The 13-valent pneumococcal conjugate vaccine is also being studied in global Phase 3 clinical trials in adults, with regulatory filings expected in 2010.

References

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