LYMEnrix
Lyme Disease Vaccine (Recombinant OspA)

Post-licensure safety assessment

Bernard J. Hoet

Head of Clinical Safety and Pharmacovigilance
GSK Biologicals
LYMErix
Post-licensure safety assessment

- Post-licensure commitments
- Passive postmarketing surveillance
- Additional clinical trials
Post-Licensure Commitments

- **Study report on cellular immunity**
  - No evidence of association between vaccination and incidence of inflammatory arthropathy
- **Reproductive toxicity study in rats**
  - No maternal or fetal toxicity detected
- **Pregnancy registry**
  - No unexpected findings
- **Safety assessment cohort study**
  - Presentation by R. Platt, M.D., MSc, Professor at Harvard Medical School