GSK Proposal for a Biopreparedness Organization (BPO)

WHO 2nd Technical Workshop on ideas for potential platforms to support development and production of health technologies for priority infectious diseases

21 July 2016
Our motivation at GlaxoSmithKline

- Commitment to global health (Malaria Vaccine, DDW R&D center, Vaccines tiered pricing…): Patient focus
- Commitment to Public health (H1N1 Flu Pandemic, SARS, H5 Flu, H9 Flu, Ebola): Patient focus
- Commitment to doing the right thing (Transparency, new commercial model…): Social Responsibility
- Requirement to be a sustainable/profitable/predictable business: Shareholders responsibility
GSK Biopreparedness Organization (BPO)

- Lessons learned
  - Most biothreat agents have “no or very limited market incentive”
  - Industry is a necessary participant for vaccine preparedness
  - Reactive approach unsustainable: disruption, direct and opportunity costs, too late!
  - Partnership with all stakeholders is key (regulatory, supranational, legal…)
  - Waning interest post-crisis is a real risk
- **Proactive** approach is necessary to meet preparedness needs
  - **Permanent** dedicated R&D and pilot production facilities and organization(s)
  - **Predictable** long-term committed financial support
  - Validated **Platforms** to develop/stockpile vaccines up to Phase 2 and process scale up
    - Research, develop and stockpile priority vaccines on ongoing basis
    - Respond rapidly to future global health emergencies when needed
    - Tech transfer for very large scale manufacturing and supply
  - Network of multiple BPOs under common global governance and oversight
GSK Biopreparedness Organization (BPO)

• **Organization**
  - Fully integrated end to end R&D
  - GSK subsidiary co-localised with active Vaccines R&D (stay current)
  - Access validated GSK Vaccines platforms, expertise, know how and experience
  - GSK IP, but open access to pathogen specific IP (supply)
  - Sized to develop two new vaccines against “no incentive” pathogens in parallel
  - Co-ordinate collaborative efforts for insert designs, assays, and field trials
  - No loss or profit to GSK: external funders to cover 100% running costs,

• **Governance**
  - An international governance board external to GSK
  - Programmatic oversight/guidance through external Scientific Advisory Committee
Platform Technologies

- Adjuvant plus recombinant proteins (AS01, AS03, AS04, new)
  - Rapid, broad and durable immune responses
  - Can store adjuvant apart from antigen
- Live-attenuated viral vectors (ChAd)
  - Mimics natural infection including CD8+ T cell responses
  - Being used for Ebola, HCV, RSV, Malaria
- Self-amplifying mRNA (SAM)
  - No immune response to a vector
  - SAM H7N9 produced in 8 days following publication of sequence
- Chemical conjugation
  - Targets bacterial pathogens
  - GSK has mastered glycoconjugate vaccines production
- Bioconjugation
  - Targets bacterial pathogens
  - One-step chemistry-free production in E. coli
BPO Facility and Laboratory Capabilities

• R&D Laboratories (B)
  • Support platform selection, antigen design, technical development and technology transfer
  • Multi platform capable but equipment for chimpanzee adenovirus (ChAd) and self-amplifying mRNA (SAM) vaccine platforms initially

• Two Pilot Plants (C)
  • Drug substance production, BSL 2 capable, flexible/portable/disposable design
  • Initial equipment for ChAd and SAM platforms

• GMP Testing (C)
  • Raw material
  • Lot release
  • Stability

• Clinical Immunology Laboratories (C)

• Administration (throughout)
  • Space for 150-200 people to support all functions within the BPO
Key Discussion points: *(CEPI may help address)*

- **Governance** – independent oversight and scientific advise
- **Priority Pathogens** – WHO 8+3 list: what platform and what order?
- **IP** – appropriate protection (broad platform versus pathogen-specific)
- **Regulatory plan** – establish strategy for rapid approval (outside normal pathways)
- **Production** – stockpile, tech transfer for additional supply, and surge capacity
- **Access** – driven by science and optimal outbreak control
- **Indemnification** – need an established legal frameworks
- **Funding Model** – GSK not to make a profit and not to incur a loss