Future Vaccines Research & Development Meeting

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Activirosomes develops effective, safe and affordable vaccines and virotherapies, to solve urgent and global health needs.

Our vision:

To bring affordable, accessible, modern medicine to mass markets, globally.
7 billion people are at risk of infection and death from viral diseases, globally.

- Viruses change quickly:
  - Can suddenly re-emerge causing life and economy-threatening diseases;

- No one is “safe”:
  - Spread quickly and efficiently via global travel;
  - And through communities due to traditions and lifestyles;

- Vaccines aren’t always fit for use in the areas they are needed;

- Vaccination “programmes” leave many unprotected:
  - As they don’t fit people’s lifestyles.

- Medicine development is expensive, risky and takes a long time.

**Chikungunya – 7.1 billion at risk**
- 95% of the global population is at risk.
- 2013 epidemic ongoing, began in the Americas for first time.

**Zika – 7.1 billion at risk**
- 95% of the global population is at risk
- 2016 epidemic ongoing, 4M cases projected, mainly across the Americas and Asia pacific

**Ebola – 24M at risk**
- 24M people at risk in Guinea, Sierra Leone and Liberia alone
- 2014-2017 epidemic – 30,000 cases, 11,315 deaths

**Dengue – 7.1 billion at risk**
- 95% of world population is at risk
- 390M cases per year, globally.
Active virosomes technology platform uses the effectiveness of the measles virus without the risks.

- Virosomes display Target Antigens & also carry a genome coding for Target Antigens.
- Virosomes infect human cells & deliver genes coding for "Target antigens" into the cell. These genes are expressed & the "Target antigens" are displayed on cell surface.
- SBPL technology incorporates ONLY vaccine relevant genes
  - Inherently safe, easy and cheap to produce;
  - very efficient at delivery into human cells.
- Cannot cause disease because virosome does NOT contain:
  - target virus polymerase & cis-acting Regulatory regions essential for Target virus replication.
  - the MV genes essential for MV replication.
AVs have advantages over other vaccines technologies that addresses the problems of development time, cost and risk.

- Development of new vaccines and production can be completed within 3-4 months;
- the cost of development of an active virosome therapy candidate is <$1M
- Potent stimulators of cellular & humoral immunity;
- No need to grow the virus;
- Cassette construction gives us capability for production of multivalent vaccines;
- Low cost of production.
A simple 2-plasmid production and manufacture system

1. Prepare Cloning & Helper Plasmids
2. Co-transfect into Packaging Cells
3. Double Selection Methotrexate + Geneticin
4. Stably transfected cell lines
5. Filtered through 100 kd filter

Packaging cell line
- VeroM
- VeroMFH
Proof of concept studies completed on 5 vaccine candidates.

- Objectives – evaluation of vaccine candidates efficacy and vaccine platform scale up:
  - Produce Active Virosome Agents potentially useful as vaccine agents for prevention of Chikungunya, Ebola and Zika virus diseases.
  - Evaluate the immunogenicity of these Active Virosome Agents in lab animals & determine whether they produce protective immune response.
  - Determine the efficacy of these Active Virosome Agents.
  - Determine whether “Divalent Active Virosome formulations can be produced and are useful as vaccine agents.

- Funded by SBRI contract from the UK’s Department of Health, £0.45M
Findings

- Monovalent AV agents displaying antigens from Chikungunya, Zika and Ebola viruses were produced.

- Divalent antigens were prepared and displayed antigens from
  - Chikungunya and Zika antigens.
  - Sudan Ebola virus and Zaire Ebola virus antigens.

- All antigens induced, measured by:
  - Cellular Immune responses.
  - PRNT antibodies.

- Animal protection studies:
  - Marginal, short lasting protection was observed in case of AV-Zika vaccine agent.
  - No protection was observed using Ebola virosomes.
  - Viral load was found to be reduced in mice immunized with Chikungunya antigens. This may indicate protective efficacy of Chikungunya virus AV agents.
Summary

- Activirosomes develops effective, safe and affordable vaccines and virotherapies, to solve urgent and global health needs.
- Flexible, robust and proven platform technology.
- Inherently safe and stable.
- Economical and simple to develop and manufacture.
- Proof of concept of multiple and multivalent vaccines.