Sementis AGM November 2017

Disclaimer

We believe that the information in this presentation is correct and any opinions and conclusions are reasonably held or made, based on the information available at the time of its compilation, but no representation or warranty, either expressed or implied, is made or provided as to accuracy, reliability or completeness of any statement made in this presentation.

Sementis does not accept any liability for any loss or damage arising out of the use of all or any part of this presentation.
This presentation has been prepared without taking into account the objectives, financial situation or needs of any particular individual.

The distribution of this presentation outside Australia may be restricted by law, and any person who resides out of Australia and who obtains a copy of this document should seek advice on, and observe, any such restriction.

This document does not constitute an offer or invitation in any place where, or to any person to whom, it would not be lawful to make such an offer or invitation and no action has been taken that may be necessary to permit an investment in Sementis in any jurisdiction outside Australia.

FORWARD LOOKING STATEMENTS

This presentation may include predictions, estimates or other information that might be considered forward-looking. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from what is suggested here.

No representation is made that any forward-looking statement will in fact occur. You are cautioned not to place undue reliance on these forward-looking statements when evaluating this presentation, which reflect our opinions only as of the date of this presentation.

Sementis does not undertake any obligation to publicly update forward-looking statements to reflect subsequent events or circumstances.

There are many risks for Sementis, many of which involve factors that cannot be controlled by board of Sementis. Sementis cannot provide any assurance that any known or unknown risks will not adversely affect its business or financial position in the future.

2017 Achievements

SCV Technology

- Firmly established
- Vector technology proof-of-concept Published in Peer Review Journal: *Eldi etal (2017) Production of a Chikungunya Vaccine Using a CHO Cell and Attenuated Viral-Based Platform Technology. Mol. Ther.; 25 (10): 2332-2344*

SCV-chikungunya vaccine

- Preclinical proof-of-concept studies completed
- Results published in Peer Review Journal: *Eldi etal (2017) Production of a Chikungunya Vaccine Using a CHO Cell and Attenuated Viral-Based Platform Technology. Mol. Ther.; 25 (10): 2332-2344*

SCV-dual chikungunya/Zika virus vaccine

- Preclinical proof-of-concept studies completed
- Results submitted for publication – in peer review process

Peanut Hypoallergy Vaccine

- Preclinical proof-of-concept studies near completion – few more experiments to be publication ready

Cat Hypoallergy Vaccine

- Preclinical proof-of-concept studies in progress

Process Development

- Construction of manufacturing grade production cell substrate for SCV vaccine production completed
- Design of down-stream manufacturing process (vaccine purification process) in progress

Recent Progress

SCV-dual Chikungunya/Zika virus vaccine preclinical proof-of-concept:

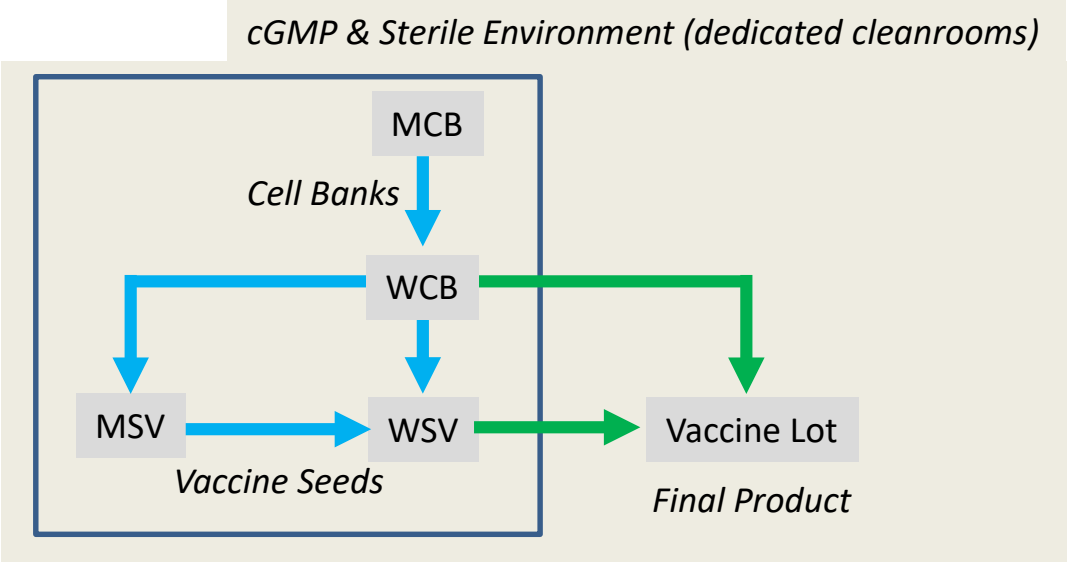
- Vaccine protects against chikungunya infection
- Vaccine protects against Ross River virus infection (relative to chikungunya)
- Vaccine protects against Zika virus infection
- Vaccine prevents Zika virus persistence in testis (blocks sexual transmission of Zika virus)
- Vaccination of female mice prevents subsequent infection of unborn mice during pregnancy (prevents CZS)

Peanut Hypoallergy vaccine preclinical proof-of-concept:

- **Human Ex vivo studies (test-tube vaccination studies) using blood donated by peanut allergic individuals:**
  - Vaccination of Antigen Presenting Cells followed by mixing with total T-cell population (Th2 biased population) and then exposing to peanut protein stimulation the production of peanut-specific Th1 T-cells and the reduction of peanut-specific Th2 T-cells
    - Vaccination of Antigen Presenting Cells obtained from peanut allergic individual “flicks the switch” form peanut-specific Th2 to peanut-specific Th1 immune environment
      - The essential ingredient for initiating desensitization against peanut allergy
- **Mice vaccination and peanut sensitization studies:**
  - Vaccinated mice stimulate a strong robust Th1 immune response as measure by peanut-specific T-cells and peanut-specific IgG antibodies. No production of peanut-specific IgE antibodies!
  - Serial sensitizations of vaccinated mice to peanut protein **does not** change the Th1 bias to peanut protein or stimulation sensitizing levels of IgE
  - Blood from vaccinated/sensitized challenged mice when mix with Mast Cells followed by treatment with peanut protein **do not** degranulate to release mediators of allergy

Business Opportunities

Manufacturing Overview



National Institute of Allergies and Infectious Diseases (NIAID) – Vaccine Production

- Manufacture and biosafety test Sementis' MCB free of charge ($500K worth of work)

CSIRO-Manufacturing, Clayton Victoria

- Develop and GMP validate manufacturing process and manufacturing biopharmaceutical grade vaccine batches

Intellectual Property

The Company has filed the following:

Peanut Allergy vaccine antigen design

PCT filing March 2014
International Application Number: PCT/AU2014/000286
International Publication Number: WO 2014/138824A1
National phase examinations: AU, US, EU, RU, ZA, CN, KR, IL, MY, JP, CA, HK,
Granted: NZ, SG

SCV Production Cell Line

PCT filing November 2014
International Application Number: PCT/AU2014/050330
International Publication Number: WO 2015/061858
National phase examinations: AU, NZ, US, EU, RU, CN, KR, IL, MY, JP, CA, HK, IN
Granted: SG, ZA

Chikungunya & Zika virus multivalent Vaccine

PCT filing August 2017
International Application Number: PCT/AU2017/050879

SCV1002: Outlook for 2018 and beyond

Preparation Work in 2018:

- Produce a GLP batch of SCV-CHIK/ZIKA (SCV1002) vaccine at CSIRO-Manufacturing Melbourne
- Biosafety testing at BioReliance in UK
- Toxicology Study at Charles River Laboratories (UK/USA)
- Write Technical Document that includes CMC, Toxicology, Investigator Brochure and Clinical Trial Protocol
- File CTX application for licence to do clinical trial in Australia (TGA)
- Perform clinical Trial at Q-Pharm, QLD

Possible NGO non-dilution funding to support SCV-CHIK/ZIKA vaccine development

SCV1002: Outlook for 2018 and beyond

To Test the Safety and Immunogenicity of the SCV system in Human

- Small Open label Phase Clinical Trial using SCV-CHIK/ZIKA vaccine
  - Objectives:
    - In 10 healthy volunteers:
      - Single shot vaccination with “MVA dose”
      - Safety (site reaction and blood chemistry and organ functions)
      - Immunogenicity using pre-vaccination status as bench mark:
        - Antibody and T-cell responses to:
          - Chikungunya
          - Zika Virus
          - Ross River Virus
      - Passive Protection against challenge (passively transfer human serum into mice and then challenge with Chikungunya/Zika virus/Ross River Virus)

SCV-PHAV: Laboratories and Collaborations

Preparation Work in 2018:

- Produce a GLP batch of SCV-Peanut Hypoallergy vaccine at CSIRO-Manufacturing Melbourne
- Biosafety testing at BioReliance in UK
- Toxicology Study at Charles River Laboratories (UK/USA)
- Write Technical Document that includes CMC, Toxicology, Investigator Brochure and Clinical Trial Protocol
- File CTX application for licence to do clinical trial in Australia (TGA)
- Perform clinical Trial at C-MAX, SA (or InFlamax, USA (IND filing with FDA))

Investor/commercial partner funded?

SCV-PHAV: Outlook for 2018 and beyond

Double Blinded Placebo Controlled Phase 1/2a Peanut Hypoallergy vaccination study in Peanut allergic individuals

- Objective:
  - Vaccinate peanut allergic volunteers
  - Monitor immune status with respect to peanut-specific Th1 immune response (akin to previous Ex Vivo studies)
  - Challenge with escalating doses of peanut (akin to Mini Tang's Probiotic clinical trial – determination of tolerating levels prior to therapeutic treatment)
- Trial Design:
  - Treatments groups:
    - Vaccine
    - Placebo (SCV vector only)
  - Treatment group size: 30 volunteers (total 60 volunteers)
  - Follow up period: 12 months

Laboratories and collaborations

University of South Australia (UniSA)
Scientific work carried out in the Experimental Therapeutic Laboratories (ETL) headed and run by Assoc. Prof. John Hayball

Lab staff:
- 3 PhD scientists (Salaries: 50% Sementis/50% Grants)
- Laboratory consumables and animal housing and maintenance costs in UniSA animal house
- Overheads (30%)

UniSA/ETL ensures:
- Laboratory facilities to accommodate scientist and access to service facilities, eg, animal house, sequencing, pathology
- OH&S compliant (Assoc. Prof. Hayball's responsibility)
- HR management of staff (employment contracts, monthly salary payments etc)
- OGTR compliant (Assoc. Prof. Hayball's responsibility)

Note:
- Staff are official employees of UniSA but contracted to work on Sementis projects only
- Sementis manages and directs the scientific work through Paul Howley (UniSA Adjunct Senior Research Fellow)

Laboratories and staff at University of South Australia (UniSA)

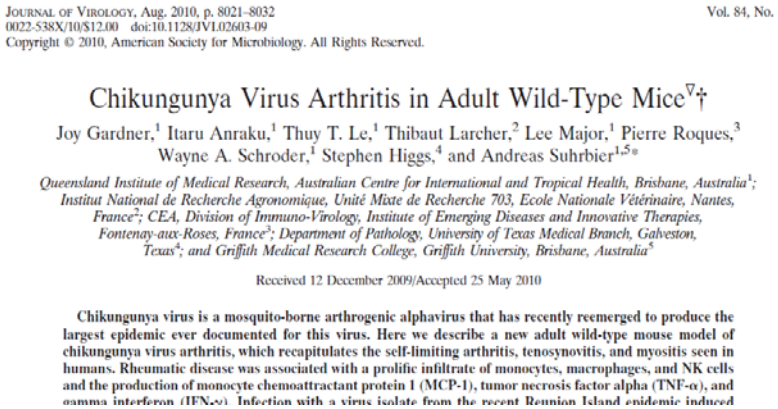
Collaborations

Queensland Institute of Medical Research Berghofer (QIMR-B):
Prof Andreas Suhrbier

- 1 PhD scientist (salary: Queensland Government; Consumables: Sementis)

Zika virus and chikungunya vaccination studies in mice

- Biosafety Level 3 laboratories (Chikungunya is a BSL3 organism)
- Stocks of multiple strains of Chikungunya
- Stocks of multiple Zika virus strains
- Inventors of the chikungunya and CZS animal models – accepted world wide for testing vaccines and antivirals



JOURNAL OF VIROLOGY, Aug. 2010, p. 8021–8032 Vol. 84, No.
0022-538X/10/$12.00 doi:10.1128/JVI.02603-09
Copyright © 2010, American Society for Microbiology. All Rights Reserved.

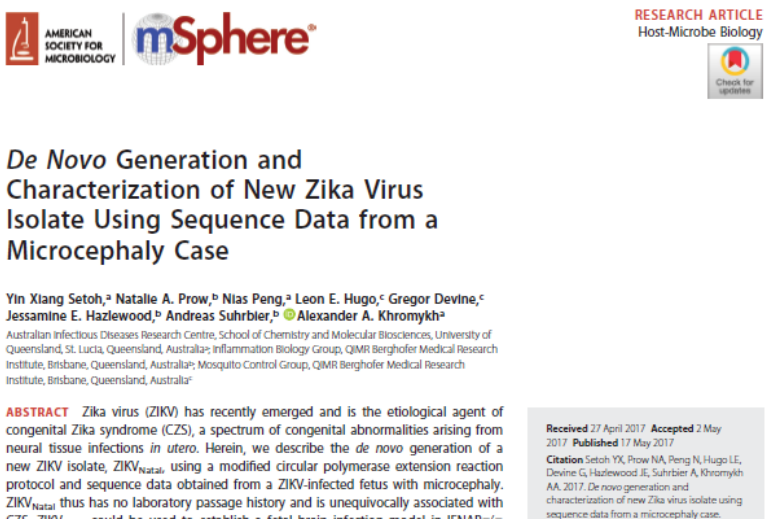
Chikungunya Virus Arthritis in Adult Wild-Type Mice[▽]†

Joy Gardner,[1] Itaru Anraku,[1] Thuy T. Le,[1] Thibaut Larcher,[2] Lee Major,[1] Pierre Roques,[3] Wayne A. Schroder,[1] Stephen Higgs,[4] and Andreas Suhrbier[1,5]*

Queensland Institute of Medical Research, Australian Centre for International and Tropical Health, Brisbane, Australia[1]; Institut National de Recherche Agronomique, Unité Mixte de Recherche 703, Ecole Nationale Vétérinaire, Nantes, France[2]; CEA, Division of Immuno-Virology, Institute of Emerging Diseases and Innovative Therapies, Fontenay-aux-Roses, France[3]; Department of Pathology, University of Texas Medical Branch, Galveston, Texas[4]; and Griffith Medical Research College, Griffith University, Brisbane, Australia[5]

Received 12 December 2009/Accepted 25 May 2010

Chikungunya virus is a mosquito-borne arthrogenic alphavirus that has recently reemerged to produce the largest epidemic ever documented for this virus. Here we describe a new adult wild-type mouse model of chikungunya virus arthritis, which recapitulates the self-limiting arthritis, tenosynovitis, and myositis seen in humans. Rheumatic disease was associated with a prolific infiltrate of monocytes, macrophages, and NK cells and the production of monocyte chemoattractant protein 1 (MCP-1), tumor necrosis factor alpha (TNF-α), and gamma interferon (IFN-γ). Infection with a virus isolate from the recent Reunion Island epidemic induced



AMERICAN SOCIETY FOR MICROBIOLOGY | mSphere®

RESEARCH ARTICLE
Host-Microbe Biology

Check for updates

De Novo Generation and Characterization of New Zika Virus Isolate Using Sequence Data from a Microcephaly Case

Yin Xiang Setoh,[a] Natalie A. Prow,[b] Nias Peng,[a] Leon E. Hugo,[c] Gregor Devine,[c] Jessamine E. Hazlewood,[b] Andreas Suhrbier,[b] Alexander A. Khromykh[a]

Australian Infectious Diseases Research Centre, School of Chemistry and Molecular Biosciences, University of Queensland, St. Lucia, Queensland, Australia[a]; Inflammation Biology Group, QIMR Berghofer Medical Research Institute, Brisbane, Queensland, Australia[b]; Mosquito Control Group, QIMR Berghofer Medical Research Institute, Brisbane, Queensland, Australia[c]

ABSTRACT Zika virus (ZIKV) has recently emerged and is the etiological agent of congenital Zika syndrome (CZS), a spectrum of congenital abnormalities arising from neural tissue infections *in utero*. Herein, we describe the *de novo* generation of a new ZIKV isolate, $ZIKV_{Natal}$, using a modified circular polymerase extension reaction protocol and sequence data obtained from a ZIKV-infected fetus with microcephaly. $ZIKV_{Natal}$ thus has no laboratory passage history and is unequivocally associated with

Received 27 April 2017 **Accepted** 2 May 2017 **Published** 17 May 2017

Citation Setoh YX, Prow NA, Peng N, Hugo LE, Devine G, Hazlewood JE, Suhrbier A, Khromykh AA. 2017. *De novo* generation and characterization of new Zika virus isolate using sequence data from a microcephaly case.

Downloaded from http://msphere

Sementis Board

Dr Tom Quirk

Retired from the board of directors July 2017

Peter Wulff (Ex CEO of Bavarian Nordic) engaged as new board director

Peter has gained over 30 years' experience in the biotech and pharma industry, especially vaccines and patents. He was a co-founder of NeuroSearch, a Danish corporation listed on the Copenhagen Stock Exchange developing drugs acting on the central nervous system. Peter was the Director of Patents and Licensing and Corporate Management member until 1997. Peter co-founded Bavarian Nordic, a biotechnology company listed on the Copenhagen Stock Exchange developing vaccines for infectious diseases and cancer, where he served as president and CEO from 1994 until the company had secured a large supply contract with the U.S. government for its MVA smallpox vaccine, Immvamune, in 2007. At NeuroSearch and Bavarian Nordic, Peter participated in several private placements, two IPOs, and a number of follow-on offerings. He also has extensive experience with investor relations and government relations in Europe, Asia, and North America. Peter later co-founded Sentinext Therapeutics (Malaysia) in 2009 to develop vaccines against EV71 and dengue, as well as other infectious diseases. He is currently an Independent Consultant to the Biotech industry, sits on the Advisory Board of the Veterinary Institute at the Danish Technical University and serves as advisor and/or board member of a number of companies in Malaysia, US, Germany, France, Denmark and Sweden. Peter holds a Master of Science in Organic Chemistry from the University of Copenhagen and qualified as a European Patent Attorney. Peter was the 2007 winner of the Biotechbuilders Association Hall of Fame.

Management Team

Maurice O'Shannassy: ***Non-executive Chairman***
25yrs experience in the financial services industry. Currently holds a number of Directorships in a variety of industries and not for profit organizations.

Dr Paul Howley: ***Co-founder, Inventor of SCV technology, CEO and Chief Scientific Officer***
Scientific background in the field of molecular virology & vaccinology. Inventor of the SCV vaccine delivery technology and of a number of vaccines in development.

Peter Wulff: ***Non-executive Director***
Ex CEO of Bavarian Nordic, brings to Sementis business development experience and expertise in the Biotech and vaccine industry.

Mei Cockerall: ***Financial Controller***
CPA. Previous experience in Biotech: Virax Holdings Ltd.