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Presented By

North Carolina Biotechnology Center

Title Sponsor

BDO

Venue Host

Sands Capital ventures
High Value Opportunities at NIH Infectious, allergic, and immunologic areas
NIAID Intramural Program

Clinical Center, NIH
Bethesda

Dale and Betty Bumpers
Vaccine Research Center
“The VRC”

Rock Mountain Laboratories
Hamilton, Montana “RML”

Integrated Research Facility
Frederick, MD “IRF”

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Collaborative Agreements
- Research collaboration agreement (RCA)
- Clinical trial agreement (CTA)
- Collaborative research and development agreement (CRADA)

License
- Research material, patented technology, software
- Internal use, evaluation, commercialization

Vaccines

SmithKline Beecham
Vaccine against Hepatitis A

Serum Institute of India
Heat stable rotavirus vaccine, protecting against five most common rotavirus serotypes

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MedImmune
Immunoprophylaxis to reduce respiratory syncytial virus (RSV) related hospitalizations in high-risk infants and children

Biological material commercial license

PATH
Biplex test for combined surveillance of Onchocerciasis (river blindness) and Lymphatic filariasis (elephantiasis)
Commercialization Story of Success

Treating Atopic Dermatitis with Live Biotherapeutic (Roseomonas)
YouTube

Transplantation of human skin microbiota in models of atopic dermatitis

Ian A. Myles, Kelli W. Williams, Jensen D. Rackhow, Momodou L. Jammeh, Nathan B. Pincus, Inka Sastalia, Daniel Saleem, Kelly D. Stone, and Sandip K. Datta

First-in-human topical microbiome transplantation with Roseomonas mucosa for atopic dermatitis.

Myles IA, Earland NJ, Anderson ED, Moore IN, Kieh MD, Williams KW, Saleem A, Fontecilla NW, Welch PA, Darnell DA, Ramhart LA, Sun AA, Uzel G, Datta SK

Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information

Guidance for Industry

This guidance is for immediate implementation

NIH National Institute of Allergy and Infectious Diseases
**Commercialization Story of Success**

**Time Line**

Pre-2016 Atopic Dermatitis (AD) models in mice and human cells (microbiome hypothesis)

Investigators NIAID Sandip Datta and Ian Myles

2016 Provisional Patent Application: Bacterial Tx of AD

2016 Publication of results from model systems: Ian Myles et. al.

2016 Federal Register Notice: Availability for Licensing

2017 Phase 1 clinical trial (clinical improvement and safety)

2017 PCT Patent Filing

2017 BIO 2017 David Yang, PhD seeking partners

2017 Federal Register: Intent to Grant

2017 License to Forte Biosciences

2018 Publication first in human: Ian Myles et. al.

Future large controlled clinical trials phase 2/3 AND Licensing as first Live Biotherapeutic Product for AD

**Benefit to NIH:** Validation of Live Biotherapeutic and license for commercial development

**Benefit to Patients:** see video
Becton, Dickinson, and Company (BD)
Protecting healthcare workers by detecting contamination from hazardous antineoplastic drugs
BD HD Check System

AP&G Co., Inc.
A low cost mosquito trap that requires neither power nor pesticide
Catchmaster Mosquito Trap

CDC contact at NIAID: Tara Kirby, PhD, tara.kirby@nih.gov

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ONE-ON-ONE WITH THE NIH

BIO & HEALTH

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