

## Our Vision

Zalgen's vision is to serve all people—regardless of ethnicity, income status, or nationality.

To create a world where every person lives free without fearing deadly infectious diseases.

To anticipate and respond effectively to the impact of likely, imminent, or current hazards, events, or conditions.

Who We Are

Programs

Commercialization

Future Programs



# Who We Are

- A highly focused global leader in the commercialization of medical countermeasures addressing easily transmissible viral hemorrhagic fevers (VHF)
- Privately-held company with well-established strategic alliances, a sustainable customer base, progressively increasing revenue streams, a positive bottom line, and no debt.
- Developer and distributor of commercial immunodiagnostic platforms for Lassa fever (LF)
- Arevirumab-3, the company's flagship product, is a pre-IND stage drug specifically developed for the treatment of multi-lineage LF infections

# Why, How We Are Needed

- Lassa virus (LASV) is a top priority, highly lethal viral pathogen without adequate preventative and therapeutic solutions
- A robust therapeutic solution will benefit millions of people in West Africa while greatly enhancing global preparedness
- Unique consortium of experts in VHF research, portfolio of diagnostic and novel therapeutic platforms, are well positioned to lead development of next-generation solutions
- Diagnostics and reagents critically support current global LF vaccine development programs

## Leadership



Dr. Luis Branco
Managing Director and Co-Founder
PhD (Tulane University)
BS (University of Massachusetts at Amherst)



Dr. Robert F. Garry, Jr
Co-Founder and Chairman, Scientific Advisory Board
Tulane University
Professor of Microbiology and Immunology
PhD (University of Texas)
BS (Indiana State University)

## Facilities



#### Headquarters and Biotechnology Operations Frederick, MD







Clinical and Research Testing Site Kenema, Sierra Leone

## Milestones

- First-in-class immunotherapeutic specifically designed to treat acute Lassa infections ready for Phase I clinical study
- First rapid diagnostic test for Ebola to receive both FDA Emergency Use Authorization (EUA) and WHO Emergency Listing Approval
- First (and only) rapid diagnostic test for Lassa to be CE Marked
- Extensive unique line of immunodiagnostics for the detection of acute
  - Pan-Lassa infections and for characterization of the post-acute humoral immune response
- E-commerce platform for commercialization of VHF reagents and diagnostic kits
- Peer-reviewed publications in high-impact scientific journals

# Vertically Integrated

- Cutting-edge immunotherapeutic technology
- Patented recombinant processes
- Expanding global commercialization & distribution
- Well-established infrastructure
- Scientific and industry collaboration
- Partnering capabilities
- Most extensive line of VHF diagnostics

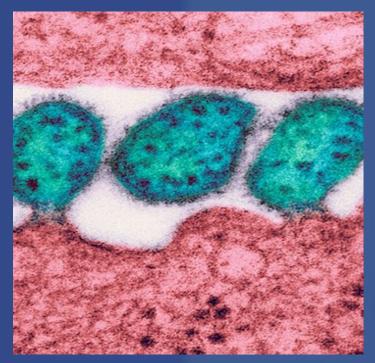
#### **FDA EUA for ReEBOV Rapid Test for Ebola NIAID** award **NIAID** award **Launch of Pan Preclinical evaluation Antibody Immuno-**WHO EUAL of LASV GP/NP of LF immunotherapeutics for **ReEBOV Rapid** IgM/IgG ELISA therapeutic biodefense against **Test for Ebola** product line **LASV NIAID** award **CEPI** award **Launch of Ebola NIAID** award **Structure based CEPI ENABLE Arevirumab-3** diagnostic Launch of IVD. design of novel Structure-guided **NIAID** award pre-IND products in West **RUO SARS CoV-2** Serology Zalgen History reviewed by **Africa Ebola LASV GP for vaccine Ebola rapid** design of LASV **ELISA product** studies Filed patent on outbreak **Arevirumab-3** development **Bispecific Abs** diagnostics line **US FDA** 2013 2015 2016 2018 2017 2019 2020 2021 2023 **Launch of ReLASV** Zalgen -**NIAID** award Colorado **CEPI** award **Arevirumab-3 CEPI** award **Rapid Test – first** Maryland Multilineage **Diagnostics Patent awarded** LASV antigens LASV huMAb diagnostic test for diagnostics for **Development HQ** initiates supply to CEPI supply to Lassa to be CE **Center opens** LF **operations LASV** vaccine **CEPI LASV** Marked vaccine developers **Transfer of** developers diagnostic product **NIAID** award technology **CETR forLassa/Ebola Immunotherapeutics Transfer of FDA** development **EUA for ReEBOV**

## Affiliations

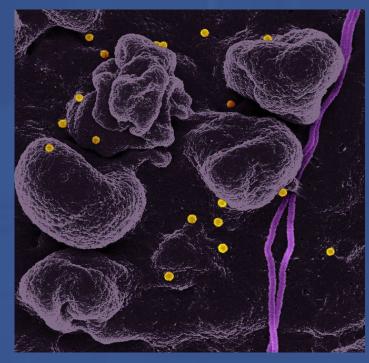


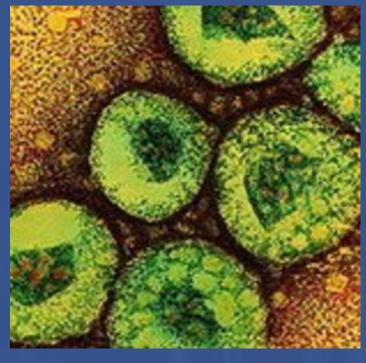
Viral Hemorrhagic Fever Immunotherapeutic Consortium

# Zalgen Virus Group Programs









#### **ARENAVIRUSES**

- Lassa virus all lineages
- LymphocyticChoriomeningitis virus

#### **FILOVIRUSES**

- Ebolavirus
- Marburg virus

#### **NAIROVIRUSES**

Crimean-CongoHemorrhagic Fever

#### **CORONAVIRUSES**

- SARS CoV-2
- MERS CoV
- 229 CoV
- NL-63 CoV
- HKU-1 CoV

### Immunotherapeutics

- File an IND and initiate Phase I studies of Arevirumab-3, our first-in-class fully human monoclonal antibody cocktail specifically designed for the prevention and treatment of acute Lassa fever infections
- Advance to preclinical testing additional human monoclonal antibodies in our existing portfolio directed against Lassa and Ebola viruses

# Strategic Priorities

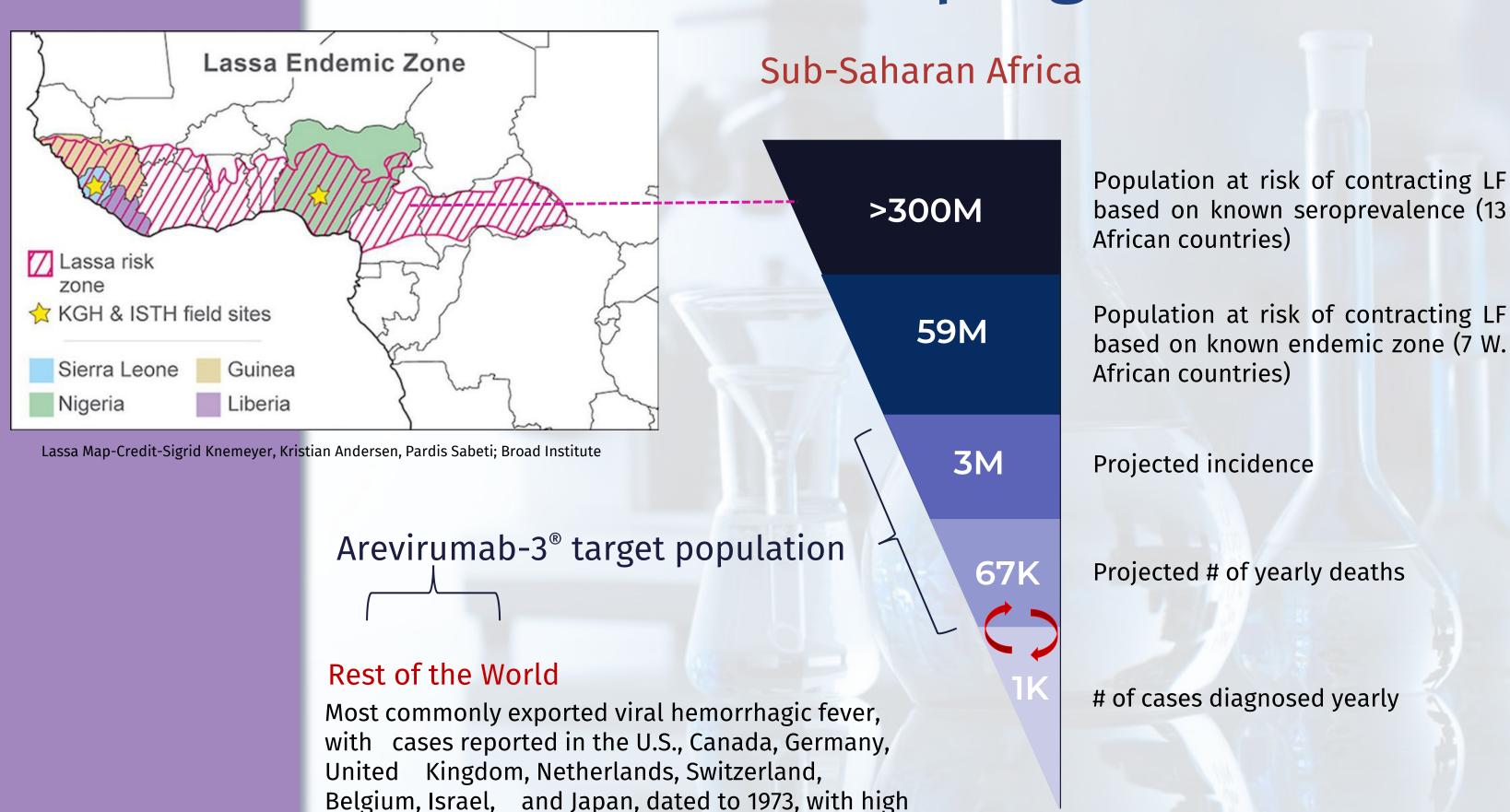
#### Vaccines

• Advance selected LASV GPC constructs from our proprietary library through validation and scale-up to assess immunogenicity and vaccine efficacy in two animal models; down-select prime vaccine candidates for pre-clinical evaluation as a first-in-class multivalent vaccine for all circulating lineages of Lassa and Ebola viruses

## Diagnostics

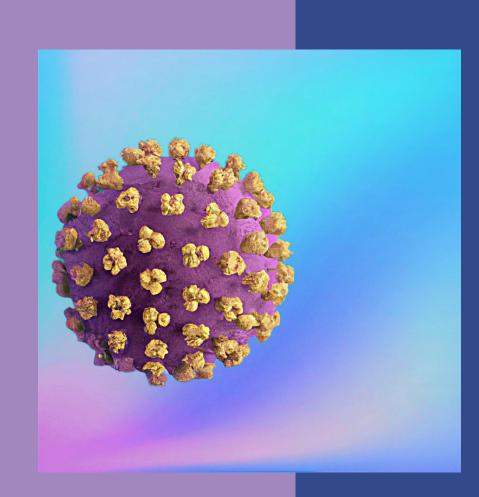
- Enhance our position as global leader for hemorrhagic fever immunodiagnostic tests by securing additional regulatory approvals and building market presence
- Expand our diagnostic product portfolio with additional products for detection of acute viremias (circulating antigens) and human convalescent immune responses (IgM/IgG) to support immunotherapeutic and vaccine research

## Lassa Fever Incidence – Shaping the Market



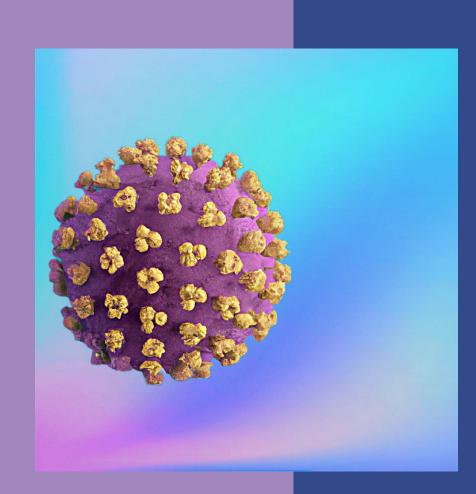
fatality rates

## Commercialization

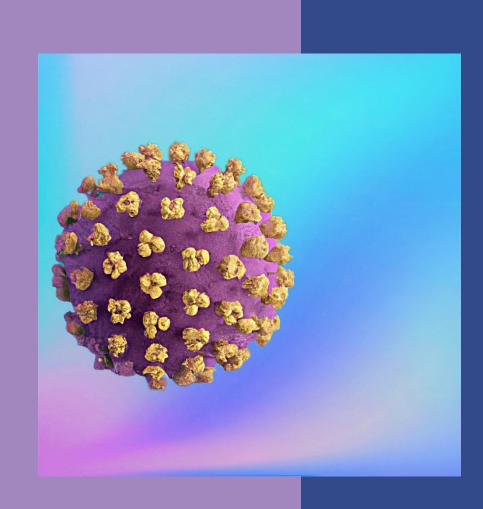


- 3 Ebola testing platforms: Antigen RDT, Antigen ELISA, Serology tests IgM/IgG
- 6 Lassa testing platforms: Lineage IV Antigen RDT, Pan Lassa RDT, Pan Lassa Antigen ELISA, Pan Lassa and single lineage (II, III and IB) IgM/IgG
- Portfolio of human monoclonal antibodies specific to LASV GPC or subunits (GP1 and GP2), with defined research applications
- Portfolio of recombinant proteins of Ebola, Lassa, Marburg,
   Coronavirus and other hemorrhagic fever viruses
- 3 virus-like particles (VLP), from lineages II, III (Nigeria), IV (SLE, GIN, LBR)

## Future Programs



- Zalgen and its partners have derived superior human monoclonal antibodies with therapeutic potential for Lassa fever and Ebola; future immunotherapeutic programs may focus on employing the same technology to identify and characterize antibodies to additional, highly relevant and high value infectious agents
- Our extensive experience in developing highly sensitive, specific, and clinically relevant immunodiagnostics maybe applied in future development programs to address unmet needs in the infectious agents arena



## Contact Us

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