BioClonetics Immunotherapeutics

"Science Improving Health"

Clone 3 Human Monoclonal Antibody Neutralizing Effect on HIV

2017

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The BioClonetics Team

CORPORATE OFFICERS

Charles S. Cotropia
JD, BS Aerospace Engineering
CEO and Co-founder

Joseph P. Cotropia
MD, MS Physiological Chemistry BS
CFO and Founder

Gaurav Chandra
MD, FAGE, MBA
Executive Vice President of Research and Development

Paul D. Fellegy
BA
Chief Financial Officer

ADVISORY BOARD

- **Ellen S. Vitetta, Ph.D.,** Professor at the University of Texas Southwestern Medical Center at Dallas, The Scheryle Simmons Patigian Distinguished Chair in Cancer.
- **Yvonne J. Bryson, M.D.,** Professor of Pediatrics and Chief, Division of Pediatric Infectious Diseases, David Geffen School of Medicine at UCLA.
- **Dalila B. Corry, M.D.,** Professor of Clinical Medicine, Chief, Division of Nephrology, David Geffen School of Medicine at UCLA.

Source: BioClonetics Immunotherapeutics

What We Have

BioClonetics Immunotherapeutics is a biotechnology company with a proprietary methodology and expertise for creating cell lines that produce fully human IgG1 monoclonal antibodies for the treatment of HIV/AIDS and other infectious diseases.

From this technology, we have created proprietary cell lines that produce a fully human monoclonal antibody (called Clone 3) that targets and neutralizes HIV. The company has also produced monoclonal antibodies that can be used to treat influenza, tetanus, rabies and diphtheria.

Find more information and invest at www.wefunder.com/bioclonetics.

The Problem

The Problem:

- 36.9 million individuals have HIV worldwide.
- Over 2 million people are newly infected each year and 1.2 million die each year.
- Approximately 700 new infections occur daily through maternal to child transmission (MTCT).
- In North America, 1.4 million individuals are infected with HIV annually and over 87,000 are newly infected each year.
- Those infected by HIV are primarily treated with anti-retroviral (ARV) chemotherapy drugs that only suppress the symptoms of the virus and can cause severe injury to critical body organs.

* UNAIDS Statistics on HIV/AIDS Infection rates

The Solution

The Solution:

- The Company's Clone 3 monoclonal antibody is effective against:
  - All HIV strains of the virus found around the world, including North America, Europe, Asia, Africa, South American and Australia
  - Including those strain identified as drug-resistant to antiretrovirals (ARVs)
- The antibody is non-toxic, provides an immunotherapeutic and safe treatment option and is more affordable than ARVs.
- The cell line that produced Clone 3 is proprietary and intellectual property is owned by the company.

How Clone 3 Antibody Was Discovered

At the outset of the AIDS epidemic in the early to mid 1980's, the founder of BioClonetics, Dr. Joseph Cotropia, M.D., treated numerous HIV positive patients in his medical practice. In treating these patients, he recognized that some, while having the virus, did not progress to frank AIDS but rather were able to naturally fend off the virus.

Dr. Cotropia theorized and later confirmed that these patients were a small subset of HIV patients (today called "long-term nonprogressors") who naturally carry antibodies that controll the virus. Using what is now a company proprietary technique invented by Dr. Cotropia, he cloned the repertoire of B cells of these patients and isolated several clones that were producing antibodies that would bind to the virus.

How Clone 3 Antibody Works

These antibodies were then tested against HIV isolates (strains of the virus) and one antibody was found to remarkably neutralize 41 of 43 strains of the virus against which it was tested. Dr. Cotropia also identified the location on the virus to which the antibody binds and found that that location is immutable (never changing) in over 98% of all 4,000 different global strains of HIV. This means that Dr. Cotropia had found an antibody that binds to and thus neutralizes the virus by binding to a stable portion (called the gp41 epitope binding site). The binding of the antibody to the virus at this location results in the virus not being able to bind to and infect the human CD4+ cells.

The immutability of the target site on the virus provides the basis on which a vaccine can be produced for HIV prevention.

PROOF Of Efficacy

Clone 3 has been tested against 43 strains of the virus at these 5 independent research institutions :

1. University of California, San Francisco, CA, USA (Jay Levy, MD)
2. University of South Florida, Tampa, FL, USA (Kenneth Ugen, PhD)
3. University of Vienna, Polymun Scientific, GmbH, Vienna, AUSTRIA, (Hermann Katinger, PhD)
4. Duke University, Durham, NC, USA (David Montefiori, PhD)
5. Harvard University, Dana Farber Cancer Institute, Boston, MA, USA, (Ruth Ruprecht, MD, PhD)

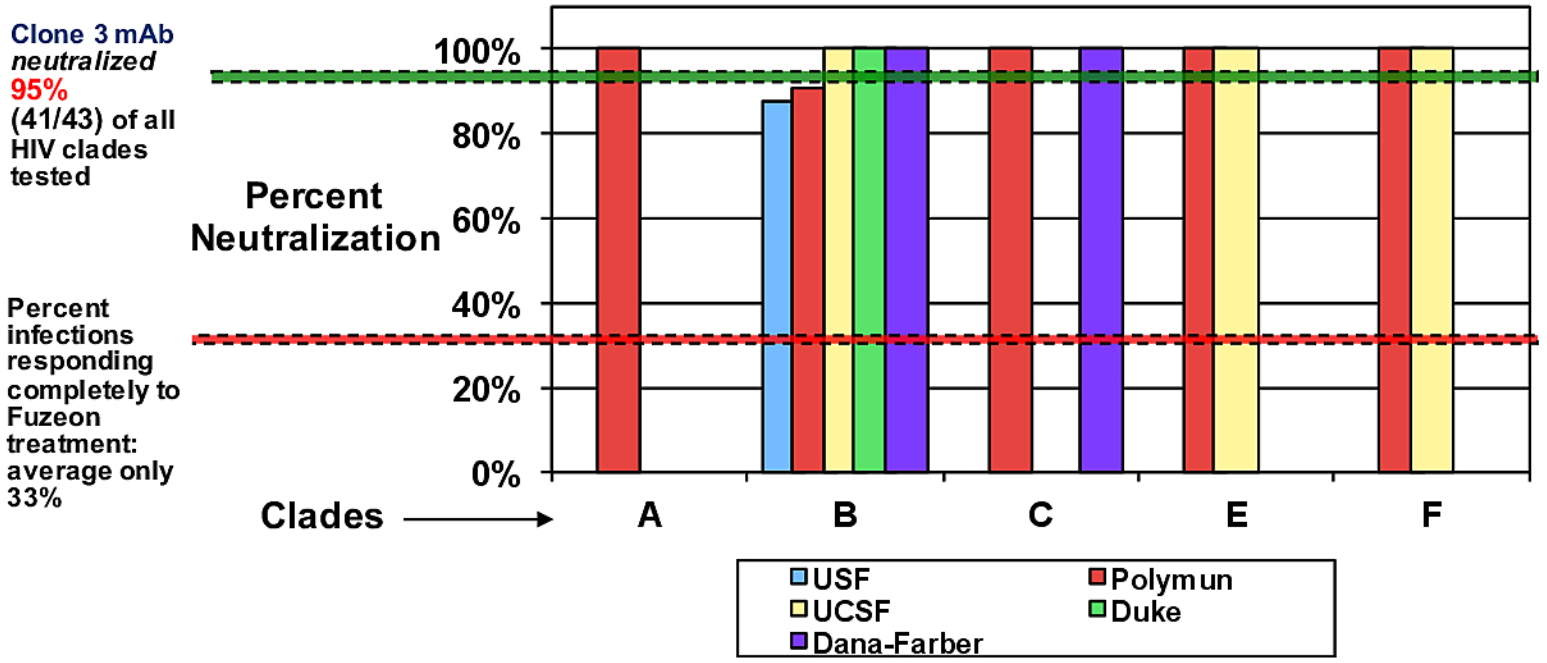
Results of these *in-vitro* neutralization tests of Clone 3 show over 95% of the HIV viruses tested to be neutralized.

The Clone 3 fully human antibody neutralized HIV in all clades and groups found around the world.

Proof of EFFICACY – 3rd Party Evidence

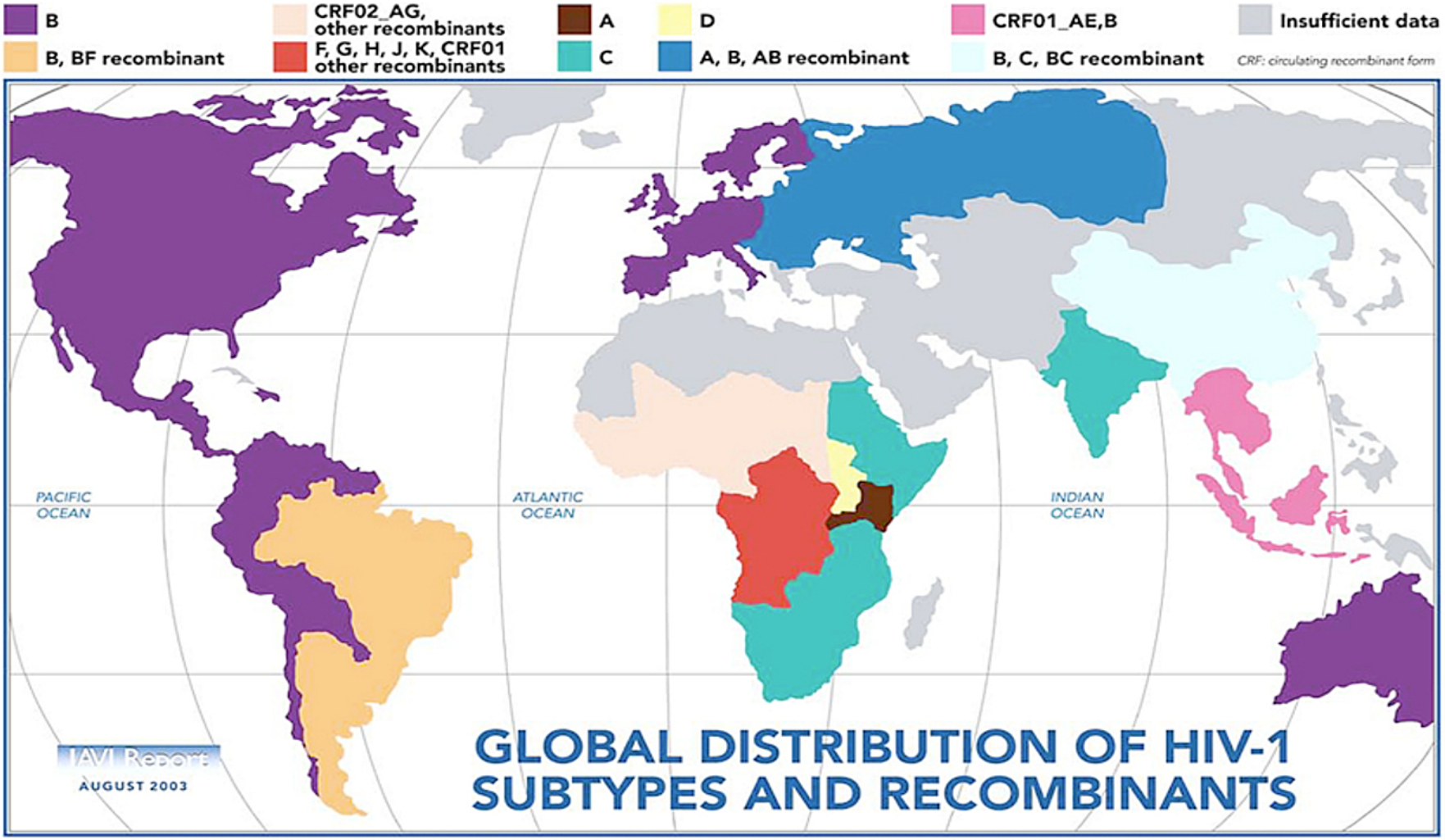
Independent Laboratory Test Results

- Test in five (5) international research institutes have shown that Clone 3 antibody ***neutralizes*** **(at IC90*) 41 of 43 (95%) of primary HIV isolates tested, from clades A, B, C, E, and F from around the globe.**



* IC90 - Inhibitory Concentration of Clone 3 mAb (<30 microgram/ml) that *neutralizes* 95% of all HIV virions tested

Clone 3 Antibody has GLOBAL application by neutralizing HIV clades A, B, C, E, and F that exit around the world.



Source: Francine E. McCutchan, Henry M. Jackson Foundation (Rockville, Maryland). McCutchan and colleagues are indebted to the many international collaborators who helped develop the data used to generate this map.

Completed Steps

Completed Work

- Isolating and cloning of B cells of HIV patients to create monoclonal antibodies.
- Screening of antibodies to identify Clone 3.
- *In vitro* testing of Clone 3 against HIV strains to confirm neutralizing capability.
- Identification of the binding site of Clone 3 on the HIV virus.
- Fully sequenced the light chain protein and heavy chain protein that programs for the full Clone 3 mAb molecule.

Next Steps

Next Steps

- Pharmaceutically produce Clone 3 in a form (called the "recombinant" antibody) that will ultimately be used in the treatment of patients – this is accomplished using a known procedure through isolation of corresponding DNA from the parent cell line genomic blueprint which encodes to produce the existing monoclonal antibody and inserting the genetic code into a fast producing and FDA approved CHO cell line.

- Testing the recombinant antibody against a full panel of HIV isolates and then in animal trials and human trials -- leading to patient application.

Management Team

Executives

- Charles S. Cotropia, JD, Co-Founder and CEO
- Joseph Cotropia, MD, MS, Founder and CSO
- Gaurav, Chandra MD, FAGE, MBA, MRCS, VP Research and Development
- Tomasz H. Zastawny, DSc, PhD, Chief Operations Officer
- Paul D. Fellegy, Co-Founder and CFO

Advisors

- Ellen S. Vitetta, PhD
- Yvonne J. Bryson, MD
- Dalila B. Corry, MD

Intellectual Property

- Patent application covering two of several commercial applications to treat HIV based on the Clone 3 antibody. This patent covers the use of small molecules derived from the structure of the Clone 3 antibody for interrupting and preventing binding between the HIV virus and the CD4+ cell using blocking peptides and/or competitive peptides.

- Patent application covering the recombinant form of the Clone 3 antibody, the commercial form of the antibody for patient therapy.

- Clone 3 Cell Line that produces the fully human antibody that specifically targets and neutralizes the HIV virus is proprietary. This specific cell line is necessary to create the clinical anti-HIV passive immunotherapy and potential anti-HIV vaccine.

- The Company proprietary mAb methodologies & immunotherapeutic technologies platform will be used to create monoclonal antibodies for treatment of viral infectious diseases against numerous infectious diseases.

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