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Maxwell's CLAROMER™ Biotechnology Platform

Maxwell Biosciences technology has been shown to functionally mimic the most effective molecules of the human innate immune system - cathelicidin antimicrobial peptides - the front line of defense against almost all types of pathogens. [Source] Longitudinal human pulmonary studies have correlated low levels of plasma cathelicidin to increased vulnerability to serious pulmonary disease. [Source 1 | Source 2] Compared to these powerful innate immune molecules, the CLAROMER biomimetic technology demonstrates accurate biomimicry with enhanced potency, safety, and biostability in animal studies as published in peer-reviewed, high impact journals (see below).

Maxwell's synthetic biology approach is highly disruptive to the traditional drug discovery industry, and was founded with the mission to prove the biomimetic CLAROMER™ biotechnology platform as effective and safe in humans against otherwise untreatable, life threatening disease. Maxwell's novel and patented compounds have been shown by multiple independent labs (including Stanford, New York University, NIAID and others) to rapidly and safely inactivate life-threatening viral, bacterial, fungal and oncological targets as shown in preclinical animal models. The company is raising money to fund large animal research and FDA Phase I clinical trials.

Financial Overview

The company leverages over $30MM in non-dilutive government grants, awards and support. The company has raised $5MM on convertible instruments from biotech CEOs, clinicians and venture capitalists. An IPO/SPAC exit opportunity is planned for 2023 to fund clinical trials and expand the platform into development for multiple large, serious, and otherwise untreatable medical needs.

Business Overview

Maxwell is developing a family of related antimicrobial agents as tailored therapeutics for treatment of viral, bacterial and fungal pathogens in the context of infectious disease and wound care. The first target indication of the platform is Chronic Refractory Sinusitis ("CRS") which is an otherwise untreatable, serious condition resistant ("refractory") to existing antiviral, antifungal, antibacterial drugs. This polymicrobial condition is difficult to treat with existing drugs due to the refractory characteristics of polymicrobial ecosystems. [Source] Invasive forms of the condition

are life threatening and are comorbid with diabetes, cancer, chemotherapy, and other immunosuppressed conditions. Characteristic inflammatory responses can become resistant to steroidal treatment, and repetitive use of steroids can potentially create severe side effects. [Source] Chronic sinusitis is one the most common chronic conditions in the developed world, affecting approximately 5% to 15% of the general population, is often resistant to current treatments and causes $15B - $20B in direct medical and indirect economic costs. [Source 1 | Source 2] As demonstrated in preclinical animal studies, the broad spectrum anti-infective capabilities of CLAROMER lead product candidates makes CRS a uniquely suitable clinical indication.

The company has shown promising results in mice treated intranasally with Maxwell's lead product candidates against refractory, polymicrobial airway infections. Large animal studies are planned for Q1 2022, and an FDA Investigational New Drug filing is planned for 4Q23. Follow-on oncological, viral, fungal and bacterial infectious disease targets are planned through licensing/partnering.

Science

The CLAROMER technology platform can mimic a broad range of bioactive peptides - providing a family of fully synthetic, abiotic "peptoid" oligomers with enhanced biostability, activity and tissue compatibility. The first class of product candidates - also referred to as "peptoids" - are N-substituted glycine oligomers shown to be structural and functional analogs of helical, cationic, amphipathic, cathelicidin antimicrobial peptides. Maxwell's CLAROMERS offer broad-spectrum virucidal, bactericidal, fungicidal and anti-cancer activities with enhanced pharmacological properties relative to peptides, as demonstrated in preclinical animal models.

Key Published Studies

Virucidal

Diamond, Gill, et al. "**Potent antiviral activity against HSV-1 and SARS-CoV-2 by antimicrobial peptoids.**" *Pharmaceuticals* 14.4 (2021): 304.
https://www.mdpi.com/1424-8247/14/4/304

Partial Abstract

> Our results demonstrate that several peptoids exhibit potent in vitro antiviral activity against both HSV-1 and SARS-CoV-2 when incubated prior to infection. In other words, they have a direct effect on the viral structure, which appears to render the viral particles non-infective. Visualization by cryo-EM shows viral envelope disruption similar to what has been observed with [antimicrobial peptide] activity against other viruses.

Furthermore, we observed no cytotoxicity against primary cultures of oral epithelial cells. These results suggest a common or biomimetic mechanism, possibly due to the differences between the phospholipid head group makeup of viral envelopes and host cell membranes, thus underscoring the potential of this class of molecules as safe and effective broad-spectrum antiviral agents.

Bactericidal

Chongsiriwatana, Nathaniel P., et al. "**Intracellular biomass flocculation as a key mechanism of rapid bacterial killing by cationic, amphipathic antimicrobial peptides and peptoids.**" *Scientific Reports* 7.1 (2017): 1-15.
https://www.nature.com/articles/s41598-017-16180-0

Partial Abstract

Here, we show through quantitative studies of membrane permeabilization, electron microscopy, and soft X-ray tomography that both AMPs and ampetoids trigger extensive and rapid non-specific aggregation of intracellular biomacromolecules that correlates with microbial death. We present data demonstrating that ampetoids are “fast killers”, which rapidly aggregate bacterial ribosomes in vitro and in vivo. We suggest intracellular biomass flocculation is a key mechanism of killing for cationic, amphipathic AMPs, which may explain why most AMPs require micromolar concentrations for activity, show significant selectivity for killing bacteria over mammalian cells, and finally, why development of resistance to AMPs is less prevalent than developed resistance to conventional antibiotics.

Anticancer

Huang, Wei, et al. "**Learning from host-defense peptides: cationic, amphipathic peptoids with potent anticancer activity.**" *PloS One* 9.2 (2014): e90397.
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0090397

Partial Abstract

Herein, we present a library of anti-proliferative peptoids that mimics the cationic, amphipathic structural feature of the host defense peptides and explore the relationships between the structure, anticancer activity and selectivity of these peptoids. Several peptoids are found to be potent against a broad range of cancer cell lines at low-micromolar concentrations including cancer cells with multidrug resistance (MDR), causing cytotoxicity in a concentration-dependent manner. They can penetrate into cells, but their cytotoxicity primarily involves plasma membrane perturbations. Furthermore, peptoid 1, the most potent peptoid synthesized, significantly inhibited tumor growth in a human breast cancer xenotransplantation model without any noticeable acute adverse effects in mice.

Fungicidal

Uchida, Maho, et al. "**Soft X-ray tomography of phenotypic switching and the cellular response to antifungal peptoids in Candida albicans.**" *Proceedings of the National Academy of Sciences* 106.46 (2009): 19375-19380.
https://www.pnas.org/content/106/46/19375.short

Partial Abstract

> In this work we used soft X-ray tomography to image the subcellular changes that occur as a consequence of both phenotypic switching and of treating C. albicans with antifungal peptoids, a class of candidate therapeutics unaffected by drug resistance mechanisms. Peptoid treatment suppressed formation of the pathogenic hyphal phenotype and resulted in striking changes in cell and organelle morphology, most dramatically in the nucleus and nucleolus, and in the number, size, and location of lipidic bodies. In particular, peptoid treatment was seen to cause the inclusion of lipidic bodies into the nucleus.

Preclinical Therapeutic Index

Preclinical animal models of airway, lung and skin consistently support a favorable therapeutic index. *S*afety data derived from human tissue and animal models (confirmed in collaboration with universities and independent labs) show that CLAROMER lead product candidates are well tolerated *in vivo* at micromolar concentrations; whereas, preclinical virucidal efficacy studies conducted in partnership with NIAID indicate activity at nanomolar concentrations.

Manufacturing at Scale

Manufacturing is fully synthetic, using state-of-the-art manufacturing equipment commonly used in large scale, solid phase peptide synthesis facilities. Maxwell Biosciences has contracted with a US-based, FDA-inspected contract manufacturing organization with cGMP capability for synthesis of our candidate compounds in multi-kilogram quantities. Maxwell has successfully manufactured multiple product candidates for preclinical studies at 50g scale with purities exceeding 95%. The company is well prepared for manufacturing product candidates at a higher scale, and will soon commence manufacturing toxicology batches for GLP large animal studies.

Management Qualifications

Joshua McClure, MBA, CEO, has a successful 18 year track record as a technology chief executive with almost a third of that in biotech. He is the company founder and a co-inventor of Maxwell's technology.

Annelise Barron, PhD, the W.M. Keck Professor of Bioengineering at Stanford University, is a scientific co-founder and co-inventor, leads our global network of scientific collaborators and is a director on the board of directors.

Stephen Pearse, MSM, Board Chair, is an oncology therapeutics pioneer and has led several technology companies to multi-billion dollar exits.

Mark Pomeroy, MSM, COO, is a former Johnson & Johnson VP of R&D with a background in therapeutic peptide delivery systems.

Kent Kirshenbaum, PhD, CSO, is a scientific co-founder and co-inventor of antimicrobial peptoid technology “on loan” to Maxwell while also a tenured professor of chemistry at NYU.

Sheetal Vali, PhD, Director of Drug Development, is a pharmaceutical executive with experience in early to late stage drug development and experience in regulatory strategy & preparing regulatory documents.
Meagan Stone, MSF, Director of Operations, is a molecular biologist with experience in project management and lab management.

Competitive Advantage & Intellectual Property

Maxwell owns a broad, granted patent portfolio with full control of IP for antimicrobial and antiviral compounds in this class. All known IP has been purchased outright or in-licensed. All relevant key inventors in the field are stakeholders of the company.