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ANKYRBIO

AnkyrBio: *Life-Changing Eye Therapeutics*

ID: 3935

Featured Innovators: Jes Klarlund, PhD and Robert Shanks, PhD

Treatment options for eye conditions such as dry eyes are severely limited because drugs that are applied to the eye are washed away in 1-2 minutes by tear flow and blinking. Dry eye disease (DED) is a ubiquitous, complex, and multifactorial condition, and its effect on patients ranges from intermittent and annoying discomfort to a serious and chronic vision-threatening disorder. Nearly 30 million adults in the U.S. experience dry eye symptoms, and its economic burden on the U.S. healthcare system is about $3.8 billion per year. DED represents a large, commercially attractive market that is currently underserved. Given the pervasiveness of the condition, the demand for dry eye treatments continues to increase, with the global dry eye treatments market to grow at a compounded annual growth rate of 5.5 percent, reaching $4.5 billion in 2021.

The AnkyrBio platform technology solves the drug washout problem and allows drugs to locally adhere in wet environments, thereby delivering optimum therapeutic benefit targeted to the affected tissue while minimizing side-effects, patient discomfort, and healthcare costs. This technology provides a fundamentally new approach to treat several other eye indications such as corneal haze, uveitis, keratitis, etc., and can help unlock the true therapeutic and commercial potential of a wide array of existing and new drugs.

Technology Description

The AnkyrBio technology enables therapeutics to be administered in eye drops and remain active on the surface of the eye for up to 3-5 days. This unique technology localizes the therapeutics to the site of the application, extends the drug duration of action, reduces dosing requirements and, minimizes systemic toxicity. The technology can be used with many currently marketed and future protein based therapies, including but not limited to drugs that inhibit inflammation, formation of haze, and unwanted growth of blood vessels. The procedure can be used with any antibody. AnkyrBio creates new uses for established drugs and new therapeutics in environments where they normally would be washed away.

Advantages

Key advantages of the anchor technology over other solutions include, but are not limited to:

- Delivery of optimum therapeutic benefit
- Substantial reduction in drug dosage
- Prevention of systemic toxicity due to localization of therapeutics

Applications

In addition to treating several eye conditions, this technology can be extended to drug delivery to other wet environments in the body including the oral cavity, joints, and the gastrointestinal tract, which also suffer from similar drug washout problems.

Stage of Development

The anchoring technology has been successfully verified in tissue culture and on rabbit and human eyes (*ex vivo*), wherein it has been observed that the protein biological drugs remain anchored while maintaining biological activity. Applied proteins have been shown to remain on the surface of the eye in two different animal disease models for 1-5 days. A reduction in dry eye symptoms was observed in mice after less than 2 weeks of drops, applied once a day.

IP Status

WO 2018/057522 *'Harnessing protein-based drugs for use on the ocular surface and other fluid-covered tissues' (nationalized in the US, EU, Japan and Australia)*

Provisional Application, *'Delivering Biological Drugs to Tissues'. Filed 3/11/19.*

Notable Mentions

Research grants and competitions generated over $100K in funds including:

- Clinical and Translational Science Institute (CTSI) – Pittsburgh
- Sjogren's Syndrome Foundation
- Lion's Fund Grant Recipient
- Pitt Innovation Challenge (PInCh)
- Chancellor's Innovation First Place Award Winner

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Innovators

Jes K. Klarlund, PhD

Retired Associate Professor Departments of Ophthalmology and Microbiology and Molecular Genetics
University of Pittsburgh School of Medicine

Dr. Klarlund has 40+ years of experience in biochemistry and cell biology. He initially worked in cancer research and was the first to demonstrate that genes that cause cancer need to be continuously active for tumors to grow and discovered a crucial role of a class of enzymes in conversion of normal cells to cancer cells.

He subsequently moved to the US to work in diabetes research, making several important contributions, including identifying a new protein in cells that is part of the mechanism of how insulin works. He turned to studying wound healing which is compromised in diabetes.

Dr. Klarlund primarily worked with understanding how the outer layer of the eye, the epithelium, moves to cover wounds. He determined that movement occurs by two profoundly different mechanisms and identified the initial stimulus that induces the epithelium to initiate migration.

Education

PhD at the Institute of Molecular Biology, University of Copenhagen, Copenhagen, Denmark
Post-doc Program in Molecular Medicine, University of Massachusetts, Worcester, MA, U.S.

Publications

40 peer reviewed papers in leading scientific journals:

- Klarlund, JK. Transformation of Cells by an Inhibitor of Phosphatases Acting on Phosphotyrosine in Proteins. Cell 1985
- Klarlund, JK, Guilherme, A, Holik, J, Virbasius, JV, Chawla, A, Czech, MP. Signaling by Phosphoinositide (3,4,5) trisphosphate through Proteins Containing Pleckstrin and Sec7 Homology Domains. Science 1997
- Block, ER, Tolino, MA, Lozano, JS, Lathrop, KL, Sullenberger, RS, Mazie AP and Klarlund, JK. Free Edges in Epithelial Cell Sheets Stimulate Epidermal Growth Factor Receptor Signaling. Molecular Biology of the Cell 2010
- Klarlund, JK. Dual Modes of Motility at the Leading Edge of Migrating Epithelial Cell Sheets. Proc. Natl. Acad. Sci. USA 2012

Robert M.Q. Shanks, PhD

Associate Professor Departments of Ophthalmology and Microbiology and Molecular Genetics; Basic Science Director of the Charles T. Campbell Laboratory of Ophthalmic Microbiology
University of Pittsburgh School of Medicine

Dr. Shanks has 20+ years of experience in molecular biology. He has developed a large set of molecular tools to facilitate the design and expression of synthetic proteins and the genetic manipulation of bacteria that will be used to rapidly generate AnkyrBio anchors and therapeutics.

Dr. Shanks' research group studies ways to combat bacterial antibiotic resistance and microbial pathogenesis for which he currently has grants from the NIH National Eye Institute, DARPA, and industry partners.

Dr. Shanks is a director of the Charles T. Campbell Laboratory that is a world leader in ophthalmic drug testing and regularly works with major ophthalmic pharmaceutical companies including Alcon, Allergan, Shire, and TRB.

Education

PhD at Tufts Sackler School of Biomedical Sciences Microbiology and Molecular Biology Department
Post-doc Dartmouth Medical School Department of Microbiology and Immunology

Publications

Over 75 primary peer reviewed papers in major ophthalmic and microbiology journals.

- Romanowski, EG, Shanks, RM. Predatory bacteria are nontoxic to the rabbit ocular surface. Scientific Reports 2016
- Brothers, KM…Klarlund JK, Shanks, RM. Putting on the breaks: bacterial impediment of wound healing. Scientific Reports 2015
- Brothers KM…Shanks RM. EepR mediates secreted-protein production, desiccation survival, and proliferation in a corneal infection model. Infection and Immunity 2015
- Shanks RM…O'Toole. *Saccharomyces cerevisiae*-based molecular tool kit for manipulation of genes from gram-negative bacteria. Applied and Environmental Microbiology 2006.

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