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Title: Anti-C.Diff Pill

Author(s): Kumar, Anand

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Anti-C.Diff Pill

Replacing the Fecal Transplant Process

CONTACT

Anand Kumar
Phone: 505-667-4778
Email: akumar@lanl.gov

PREVIOUS FUNDING:

DOE: $1M
LANL: $250K

SEEKING CAPITAL:

$750K

USE OF FUNDS:

PACKAGING: 20%
TESTING: 40%
PRODUCT DEV: 25%
MARKET DEV: 15%

TEAM:

Anand Kumar, Grace Vuyisich, and Armand Dichosa

PRINCIPAL INVESTIGATOR:

Anand Kumar, DVM, PhD
Is a UC-LANL Postdoc Entrepreneurship Fellow and Director's Postdoc at Los Alamos National Laboratory. His former technical mentor at LANL, Momo Vuyisich, is CSO of startup Viome, Inc., a Los Alamos company that has recently raised $15M for mapping gut microbiome and finding customized solutions to health problems.

AWARDS:

Anand Kumar has received number of highly competitive awards and fellowships. He also holds two patents under his name.

IP:

Invention disclosure filed

SUMMARY

The anti- C.diff pill is being developed for patients who are at high risk for *Clostridium difficile*, a bacterium that causes diarrhea and serious intestinal conditions like colitis. C-diff is deadly, killing over 30,000 people a year in the United States and costing an average of $42,000 per treatment. The most common treatment is a fecal transplant (FT). The anti-C.diff replaces the invasive and messy FT practice with a pill.

PROBLEM

Over 500,000 cases of C.diff are diagnosed each year in the United States. Following unsuccessful antibiotic treatments, many are left with a FT as the only option. Widespread acceptance of FT practice is limited due to unpredictable side effects and risk of pathogen transfer. Costs and patient trauma of treatment are high and a patient dedicates an average of 14 days for treatment. In 2013, the CDC listed C.diff as an urgent threat.

SOLUTION

For C.diff patients, especially those at high risk for a recurrent infection, the Anti-C.diff pill provides a universal, safe, non-invasive treatment in the form of a pill. This is accomplished by utilizing a new platform developed at Los Alamos National Laboratory that characterizes those microbial interactions that suppress C.diff. Key cell-to-cell interactions are identified that rid the body of C.diff and will prevent it from reoccurring. A microbial cocktail is developed from this testing and transferred into pill form.

MARKET

In 2016, the US total market for treating C.diff was $1.5B and the total addressable market of $750M with those at high-risk for a reoccurrence after treatment. Our initial targeted segment within the TAM are patients who have had a reoccurrence, accounting for $250M per year.

COMPETITIVE LANDSCAPE

SOLUTION	PROS	CONS	COMPANIES
Fecal transplant	▪ 90% success rate ▪ Inexpensive compared to cost of antibiotics	▪ Invasive procedure ▪ High risk of pathogens & chronic disorders ▪ Limited hospitals treat	▪ Rebiotix ▪ OpenBiome ▪ Alere ▪ AdvancingBio
Antibiotic therapy	▪ Non-invasive ▪ Wide acceptance by doctors & hospitals	▪ 30 yr old clinical data ▪ Side effects ▪ Expensive	▪ Merck ▪ Optimer ▪ Actelion
Vaccines	▪ In R&D phase, but could be safer option than antibiotics	▪ Untested, new approach ▪ Sanofi Phase III failed	▪ Valneva ▪ Pfizer ▪ Synthetic Biologics
Software that predicts key microbes for FT	▪ Assist current FT reduce risks by adding specific microbes to FT	▪ New, untested ▪ Microbes identified in algorithm not FT	▪ Takeda & Finch ▪ Seres Therapeutics
ANTI C.DIFF PILL	▪ Non-invasive ▪ 3x less costly than FT ▪ 1 day treatment vs 14	▪ New, untested	▪ LANL

GO TO MARKET

The Platform is thoroughly validated, and we are now in the process of identifying microbial a cocktail(s) from healthy donor fecal sample(s) to create anti-C.diff pill. Thus, developed anti-C.diff pill will be tested on humanized animals. Following successful testing on pigs, a local medical school will run a small-scale test on human C. diff patients. These two tasks should be completed by the 4th quarter of 2018. Scale-up and packaging activities will follow in 2019 with the goal of running the first clinical trial in 2019 partnered with a sponsor or company.