New Treatment for Obstructive Sleep Apnea

Up to 20% of Americans suffer from repeated episodes of upper-airway obstruction while they sleep, known as Obstructive Sleep Apnea (OSA). OSA can raise the risk for serious health problems, and can contribute to sleep-related accidents and reduced productivity. The main treatment for OSA is a Continuous Positive Airway Pressure (CPAP) device, which keeps the upper airway open during sleep. However it is not always comfortable, and up to 50% of patients fail to use it regularly.

The Solution

University of Michigan faculty Tiffany Braley, M.D., M.S., and co-investigators Ronald Chervin, M.D., M.S., and Benjamin Segal, M.D., are evaluating a potential pharmacologic alternative to CPAP, using an immune response altering therapy to address the inflammatory changes that may, in part, drive OSA.

The team is focusing on Dimethyl Fumarate (DMF), an immune modulating compound that suppresses inflammation and may activate genes that protect cells from oxidative stress. This compound is already FDA-approved for multiple sclerosis (MS), an inflammatory disease of the central nervous system. This research could provide key insight into brand new immunological therapeutic targets for OSA, as well as pave the way for future studies of immune-based therapies to improve OSA treatment.

The project was funded by the Michigan Translational Research and Commercialization (MTRAC) for Life Sciences Innovation Hub. MTRAC works to “fast forward” projects that have a high potential for commercial success, with the ultimate goal of positively impacting human health. MTRAC has been made possible by the Michigan Economic Development Corporation, the Michigan Institute for Clinical and Health Research, and the generosity of friends of the University of Michigan.
**Significant Need**
First-line treatment for OSA is CPAP, but many patients find the discomfort of the mask to be intolerable, and up to 50% of patients do not maintain adequate compliance. This creates the need for a safe, convenient, orally-available pharmacologic alternative to CPAP.

**Compelling Science**
A therapeutic that addresses the inflammatory changes that may, in part, drive OSA. The focus is on Dimethyl Fumarate (DMF), an immune modulating compound that suppresses inflammation and may activate genes that protect cells from oxidative stress.

**Competitive Advantage**
Currently, no pharmacologic therapies exist for Obstructive Sleep Apnea, so patients use an uncomfortable CPAP machine to treat symptoms.

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**MTRAC Project Key Milestones**

- Completion of IND submission, IRB approval, and Material Transfer Agreement
- Clinical trial initiation (60 patients)
- Subject recruitment
- Data collection/study visits (5 visits over 4-month period)
- Licensing

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**Overall Commercialization**

- **Engage Investors**
  - Patent licensing interest from major biotechnology company. Possible NIH-funded translational studies.

- **Intellectual Property**
  - Provisional patent application filed in June 2012, and was converted to a Patent Cooperation Treaty (PCT) in June 2013. DMF “composition of matter” patent held by large multi-national pharmaceutical company.

- **Regulatory Pathway**
  - IND-exempt – new use for FDA-approved compound.

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**Oral drug provides new treatment for Obstructive Sleep Apnea and addresses root cause of disorder.**

Tiffany Braley, M.D., M.S.

MTRAC funding and support has been crucial to our efforts to identify a therapeutic for one of the most common and consequential medical conditions in the U.S.