National Institutes of Health
Turning Discovery Into Health

Weekly Pill Formulation Could Help Treat Schizophrenia, HIV, Malaria and more

June 10, 2020

The human digestive system was made to flush out food—and pills—from the body. To compensate for this, oral drugs usually have to be taken daily to keep a steady level of medication in the patient's system.change the medicine not the patient

"There's a huge body of literature that shows that most people don't take their medication on a daily basis," says Jen McGovern, senior vice president of business planning at Lyndra Therapeutics. "And there's a lot of side effects, hospitalizations, and preventable deaths that can occur as a result of not taking medicine, at a cost between $100 billion and $289 billion each year. We intend to change those outcomes for patients and the healthcare system."

Lyndra Therapeutics, in Watertown, Massachusetts, has developed a new form of capsule that can release medication not over the course of a day, but over a week or longer. The company is using the platform to develop ultra-long-acting medications that could enable patients to replace their daily drug regimens with taking a single pill once a week, once every other week, or even once a month. Thanks to Small Business Innovation Research (SBIR) grants from the National Institute of Allergy and Infectious Diseases (NIAID) and the National Center for Advancing Translational Sciences, Lyndra is working on applying their technology to HIV and organ transplants, and malaria. Other applications include ultra-long-acting oral medications for schizophrenia, Alzheimer's disease, diabetes and hypertension, opioid use disorder, and contraceptives.

> **"It's allowing us to accelerate our programs so we can bring these treatments to patients, which is a core part of our public health mission."**

"We are transforming the way patients take medicine," McGovern says.

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Lyndra
65 Grove St
Watertown, MA, 02472-2826

State-District
MA - 5

Technology
Drug

Primary Institute
Translational Sciences (NCATS)

Secondary Institute
Allergy and Infectious Diseases (NIAID)

Project Details from NIH RePORTER
Lyndra

Contact
Jessica Ballinger
Jballinger@Lyndra.com

https://www.lyndra.com/

The unique capsule was originally developed in the lab of Dr. Robert Langer at the Massachusetts Institute of Technology. Folded inside the capsule is a dosage form with six arms. Once in the stomach, the outer capsule dissolves, allowing the dosage form to unfold into a star-like formation. Lyndra capsulThis structure is too big to exit the stomach, so it stays there and continues to release medication over the course of a week or longer. The dosage form is designed to break down and leave the stomach after a determined period of time.

Lyndra received an SBIR grant from NIAID to develop a consistent and effective manufacturing process for the capsules, which enabled them to test the capsules in people. Those clinical trials have been successful, demonstrating that the capsule delivers a consistent level of medication over the course of seven days—more consistent, in fact, than the medication level of someone taking a daily pill. In addition, no unusual side effects have been reported in any of the 80 patients tested, and patients cannot feel the larger, star-like structure of the dosage form after they take it.

For McGovern, supporting Lyndra's mission is personal.

"One of the reasons I joined Lyndra was that my mom died of Alzheimer's disease," she says. "Getting her to take medication and stay on her medication became a huge, huge effort from a caregiver perspective: she didn't want to do it, she didn't remember to do it. So I saw joining Lyndra as an amazing opportunity to help not only patients, but also families and caregivers."

"Working with the NIH Small Business Program has really been transformative for us," McGovern says. "It's allowing us to accelerate our programs so we can bring these treatments to patients, which is a core part of our public health mission."