

「Penn Medicine Collaborates with Regeneron to develop nasal spray to prevent COVID-19」

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Researchers from the University of Pennsylvania (USA) are working with the biotechnology company Regeneron to develop a nasal spray that protects against Covid-19. Regeneron's antibody cocktail (casirivimab and imdevimab administered together) is being studied in clinical trials for the treatment and prevention of COVID-19 and was recently granted an Emergency Use Authorization by the U.S. FDA. This nasal spray will deliver Regeneron's antibody cocktail intranasally via Adeno-Associated Virus (AAV) vectors and could serve as an adjunct to future vaccines. [1]

The project is led by gene therapy pioneer James Wilson, MD, PhD, professor of Medicine and director of the Gene Therapy Program and the Orphan Disease Center at Penn's Perelman School of Medicine. He and his team will work with Regeneron to study the safety and effectiveness of using AAV vectors to introduce the sequence of the cocktail's virus-neutralizing antibodies directly to nasal epithelial cells. To date, AAV vectors has been shown to be a particularly durable method of introducing antibodies into the body, because the AAV genome that codes for the therapeutic antibody remains stable in the nucleus of transduced cells. This new collaboration will introduce the application of AAV vectors to fight against the novel coronavirus virus that has infected more than 50 million people across the globe and taken the lives of 1.25 million to date. [2]

"The advantage of AAV in this application is that can achieve sustained expression of the antibodies in the nasal mucosa, which is the site of infection, following a single administration," James Wilson said. "In contrast to traditional vaccines, AAV delivery of antibodies provides a rapid onset of response and no reliance on the need for the recipient to mount an immune system response over time. This latter feature may be particularly attractive in people with weakened immune systems, like the elderly, or people who need rapid protection, like frontline healthcare workers." [2]

"Regeneron scientists specifically selected casirivimab and imdevimab to block infectivity of SARS-CoV-2, the virus that causes COVID-19, and we have been encouraged by the promising clinical data thus far," said Christos Kyratsous, PhD, Vice President of Research, Infectious Diseases and Viral Vector Technologies at Regeneron. "In the quest to use cutting-edge science to help end this disruptive and often very devastating disease, we are excited to explore alternate delivery mechanisms such as AAV that may extend the potential benefits of this investigational therapy to even more people around the world." [2]

The collaboration between Prof. Wilson and Regeneron will have two phases. The first phase will include the validation of the effectiveness of the antibodies delivered via AAV in a large animal model challenge

study, where animals will be given the antibody cocktail via AAV and exposed to the novel coronavirus. If that study is successful, the research team will complete studies to support filing of an investigational new drug (IND) application with the FDA, which is a necessary step before clinical trials in humans can begin.

[3]

Reference:

- 1. Mccadmin, 2 Dec 2020. "A nasal spray against the virus under investigation" The Courier news
- 2. 1 Dec 2020. "Penn Medicine Collaborates with Regeneron to Investigate Delivery of COVID-19 Antibody Cocktail via Gene Therapy Platform" *Penn Medicine News Release*.
- 3. 2 Dec 2020. "U.S. scientists developing nasal spray to prevent COVID-19" The Japan Times press.

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