All You Need To Know About Merck's Covid Pill Molnupiravir

October 2, 2021

Molnupiravir was developed for the treatment of Influenza. According to whistleblower complaint Molnupiravir has mutagenic properties and may change your DNA. Now, Molnupiravir has been repurposed for COVID-19. Merck has entered into agreements with Indian manufacturers and has also announced $5 million of donations to enter into Indian market. Here is all you need to know about Merck's Covid pill Molnupiravir.

Contents [hide]

Molnupiravir was developed for Influenza

Molnupiravir (development codes MK-4482 and EIDD-2801) is an experimental antiviral drug which is orally active and was developed for the treatment of influenza.

It is a prodrug of the synthetic nucleoside derivative N4-hydroxycytidine, and exerts its antiviral action through introduction of copying errors during viral RNA replication.

The drug was developed at Emory University by the university's drug innovation company, Drug Innovation Ventures at Emory (DRIVE).

It was then acquired by Miami-based company Ridgeback Biotherapeutics, who later partnered with Merck & Co. to develop the drug further.

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Molnupiravir may change your DNA

In April 2020, Rick Bright, who was removed as head of the Biomedical Advanced Research and Development Authority (BARDA) before the approval of the drug, submitted a whistleblower complaint asserting that Ridgeback pressured BARDA to provide funding to manufacture EIDD-2801 despite Bright's concerns that similar drugs in its class have mutagenic properties.

A previous company, Pharmasset, that had investigated the Molnupiravir's active ingredient had abandoned it over similar concerns.

In genetics, a mutagen is a physical or chemical agent that permanently changes genetic material, usually DNA, in an organism and thus increases the frequency of mutations above the natural background level.

As many mutations can cause cancer, such mutagens are therefore carcinogens, although not all necessarily are. All mutagens have characteristic mutational signatures with some chemicals becoming mutagenic through cellular processes.

These claims were denied by George Painter, CEO of DRIVE, noting that toxicity studies on Molnupiravir had been carried out and data provided to regulators in the US and UK, who permitted safety studies in humans to move forward in the spring of 2020.

At that time, DRIVE and Ridgeback Biotherapeutics stated they planned future safety studies in animals.

Merck's Covid Pill Molnupiravir

In late July 2020 Merck, which had been partnering with Ridgeback Biotherapeutics on developing the drug, announced its intention to move Molnupiravir to late stage trials beginning in September 2020.

On October 19, 2020, Merck began a one year Stage 2/3 trial that focused on hospitalized patients.

In June 2021, the U.S. Department of Health and Human Services committed to buy US$1.2 billion worth of molnupiravir (approximately 1.7 million courses) from Merck if it received an emergency use authorization (EUA) or approval from the U.S. Food and Drug Administration (FDA).

On 1 October 2021, Merck stated that an independent advisory board that had been monitoring the COVID-19 clinical trial recommended that recruitment into the study be stopped early because of convincing evidence of the drug's benefits, reducing the risk of hospitalization or death by 48%.

Merck announced plans to seek an EUA from the FDA, and to submit marketing applications to other global drug regulators. The company announced plans to

Merck has announced that the company has entered into non-exclusive voluntary licensing agreements for Molnupiravir with five established Indian generics manufacturers.

Merck has entered into these agreements to accelerate availability of molnupiravir in India and in other low- and middle-income countries (LMICs) following approvals or emergency authorization by local regulatory agencies.

"The scale of human suffering in India at this moment is devastating, and it is clear that more must be done to help alleviate it. These agreements, toward which we have been working as we have been studying molnupiravir, will help to accelerate access to molnupiravir in India and around the world," said Kenneth C. Frazier, chairman and CEO, Merck.

"We remain committed to aiding in the global response that will bring relief to the people of India and, ultimately, bring an end to the pandemic."

The agreements have been signed with Cipla Limited, Dr. Reddy's Laboratories Limited, Emcure Pharmaceuticals Limited, Hetero Labs Limited and Sun Pharmaceutical Industries Limited – five generics manufacturers with World Health Organization (WHO) Pre-Qualified Manufacturing facilities and experience as major suppliers to global and key LMIC procurers.

Under the agreements, Merck will provide licenses to these manufacturers to supply molnupiravir to India and more than 100 LMICs. Merck is also in discussions with the

Separately, Merck will also donate more than $5 million worth of oxygen-production equipment, masks, hand sanitizer and financial aid to support relief efforts in India.

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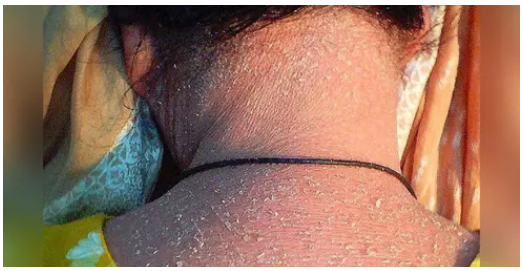

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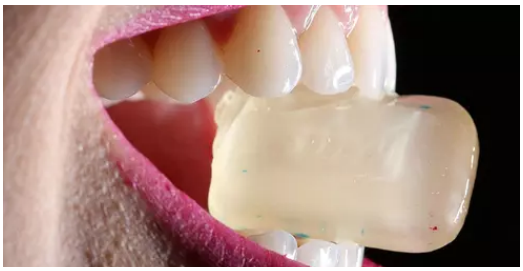

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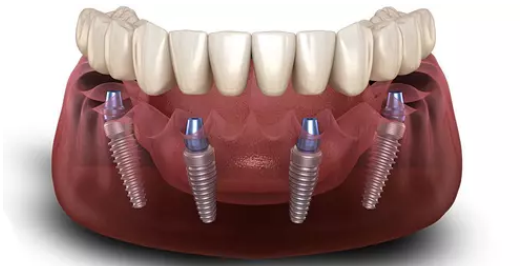

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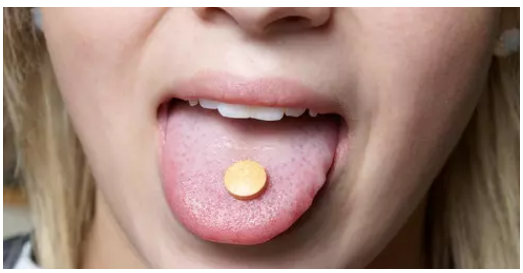

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