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NEWS LETTER
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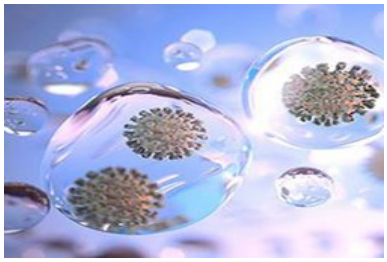
Molnupiravir Safe For Non-Pregnant, Unvaccinated People: Study



Found to be effective in preventing disease progression and hospitalisation Molnupiravir, an antiviral drug which recently got emergency use authorisation from the Drugs Controller General of India (DCGI) for mild to moderate cases, is safe for use in adults, a new study has revealed.

According to the study, a five-day course for adults who are non-pregnant and unvaccinated Covid-19 patients, is effective and safe and can prevent further disease progression and hospitalisation requirements.

The study was conceived by Dr Anoop Misra, Padma Shri, Executive Chairman and Director, Diabetes and Endocrinology, Fortis C-DOC and conducted jointly by G. D Hospital & Diabetes Institute, Jawaharlal Nehru Medical College & Hospital, Fortis C-DOC Hospital for Diabetes & Allied Sciences, National Diabetes, Obesity and Cholesterol Foundation and Diabetes Foundation, Fortis Healthcare said Monday in a release.

Published in the journal, Diabetes & Metabolic Syndrome: Clinical Research & Reviews, the final results of the study revealed that usage of the drug showed a significant reduction in composite risk of hospitalisation or death.

The study assessed the efficacy and safety of Molnupiravir by analysing published results of phase 3 randomised study in 1,433 non-hospitalised COVID-19 patients. Additional data available in the public domain between October 15, 2021 and January 5, 2022 and prescribing information of the drug and data presented at the US FDA AMDAC (Antimicrobial Drugs Advisory Committee) meeting held on November 30, 2021 was also accessed, according to the Fortis Healthcare release.

“The effectiveness of Molnupiravir is competitive to three monoclonal antibodies, remdesivir and nirmatrelvir-ritonavir, with a relatively lower cost. No scope of treatment with Molnupiravir was found in cases when treatment was initiated after hospitalisation due to COVID-19. Molnupiravir is not authorised for use in patients less than 18 years of age,” Fortis said.

“These findings are very important in the context of India as the drug can be used in outpatient settings and is also effective against the Omicron variant compared to other drugs. However, it is effective only when used within 5-days of onset of symptoms. Inappropriate use of the drug without assessing the risk may pose an unknown long-term risk of public concern,” Dr Misra said.

“This drug has to be used only by those who are at high risk. The problem with this drug is that the data which we have right now only relates to unvaccinated people. We have no idea whether it will work in those who are vaccinated. It is yet to be ascertained,” Misra told BusinessLine.

“It has to be used while taking all precautions. Men and women in the reproductive age group should also use contraception for the duration of treatment. And it should not be used by those who are above 18 years. These are the two major concerns in the usage of this drug.

It may be recalled that the drug got embroiled in a big controversy after the Indian Council of Medical Research (ICMR) raised concerns over its usage among those in the reproductive age group. On a Business Line query in a press conference, whether Molnupiravir is part of Covid treatment or not, Balram Bhragava, the Director General of ICMR had said, “WHO has not included it..

We are still concerned about issues of pregnancy, lactation, children, soft tissue injury, reproductive age group history of infection and vaccination. Whatever benefit was there in those 1,433 patients was on unvaccinated individuals and only three per cent from mild to moderate diseases.” (Source: Business Line)

Anti-Viral Molnupiravir Gets 'Conditional Recommendation' From WHO

Covid-19 treatment update also streamlines use of Regeneron-Roche's monoclonal antibody cocktail Even as some researchers raise safety concerns over molnupiravir, the anti-viral has received a "conditional recommendation" from the World Health Organisation.

The WHO updated its living guidelines on Covid-19 therapeutics to include a conditional recommendation on molnupiravir, the UN health agency said, making it the first oral antiviral drug to be included. "As this is a new medicine, there is little safety data. WHO recommends active monitoring for drug safety, along with other strategies to mitigate potential harms," it added. This is the ninth update of WHO's living or evolving guideline on therapeutics and included an update on Casirivimab-Imdevimab, a monoclonal antibody cocktail. "Based on evidence that this combination of drugs is ineffective against the Omicron variant of concern, WHO now recommends that it is only given when the infection is caused by another variant," it said.

The injectable antibody cocktail from Regeneron was, in fact, included in the WHO's guideline in September 2021. The product is produced and marketed globally by Swiss drugmaker Roche. In India, Roche sells the product through Cipla. And the one-dose treatment costs close to ₹60,000.

The drug had made global headlines when it was given to former US President Trump when he had tested positive for Covid-19. But in late January, the United States Food and Drug Administration, too, restricted its use against the Omicron variant of SARS-CoV-2. Data gaps on the pill On molnupiravir, taking note of the concerns and data gaps, WHO said it should be given "only to non-severe Covid-19 patients with the highest risk of hospitalisation.

These are typically people who have not received a Covid-19 vaccination, older people, people with immunodeficiencies and people living with chronic diseases." Children and pregnant and breastfeeding women should not be given the drug, it added. People who take molnupiravir should have a contraceptive plan, and health systems should ensure access to pregnancy testing and contraceptives at the point of care, the WHO explained.

The drug is approved in India, but the Indian Council of Medical Research had also sounded a similar caution on the oral drug. Merck Sharpe Dohme (MSD) (or Merck in the US and Canada) has voluntary licensing agreements with multiple Indian companies on Molnupiravir, including Dr Reddy's Laboratories, Cipla, Sun Pharma, Hetero, Emcure, Aurobind, Torrent etc.

Treatment schedule "Under the care of a healthcare provider, molnupiravir is given as four tablets (total 800 mg) twice daily for five days; within 5 days of the onset of symptoms. Used as early as possible after infection, it can help prevent hospitalisation," the WHO said. The latest recommendation comes on the back of new data from six randomised controlled trials involving 4,796 patients. This is the largest dataset on this drug so far, the WHO said. Access issues Molnupiravir is not widely available, but steps have been taken to increase access.

WHO said it has invited manufacturers to submit their products for prequalification, and a number of manufacturers of molnupiravir are going through assessment now, it added. The availability of more quality-assured manufacturers would mean that countries have a greater choice of products and more competitive prices, it pointed out. (Source: Business Line)

Pfizer Begins COVID Pill Study in High-Risk Children Aged 6-17

Pfizer said on Wednesday it has begun a mid-to-late-stage study of its antiviral COVID-19 pill for non-hospitalized children aged 6-17 years who are at high risk of developing severe illness.

Pfizer's Paxlovid pill is authorized for emergency use in the United States for kids 12 years or older and high-risk adults. But there are no oral antiviral treatments for COVID-19 authorized in the United States for younger children. The drugmaker plans to enroll 140 children in the study across two groups of 6- to 17-year-olds, with one group including those at least 40 kilograms in weight and the other weighing between 20 kgs and 40 kgs.

"Since the beginning of the pandemic, more than 11 million children under the age of 18 in the United States alone have tested positive for COVID-19, representing nearly 18% of reported cases and leading to more than 100,000 hospital admissions," said Pfizer Chief Scientific Officer Mikael Dolsten.

Pfizer said on Wednesday it was also working to develop an age-adjusted formulation of the drug for patients younger than 6 years and will start enrolling three groups of kids under 6 once the modified formulation becomes available. Data from a mid-to-late stage study in November showed Paxlovid was nearly 90% effective in preventing hospitalizations and deaths compared to placebo, in adults at high risk of severe illness. (Source: Reuters)

Moderna Plots Vaccines Against 15 Pathogens With Future Pandemic Potential

Moderna Inc (MRNA.O) said on Monday, March 7 it plans to develop and begin testing vaccines targeting 15 of the world's most worrisome pathogens by 2025 and will permanently wave its COVID-19 vaccine patents for shots intended for certain low- and middle-income countries.

The U.S. biotechnology company also said it will make its messenger RNA (mRNA) technology available to researchers working on new vaccines for emerging and neglected diseases through a program called mRNA Access.

Moderna announced its strategy ahead of the Global Pandemic Preparedness Summit sponsored by the UK government and the Coalition for Epidemic Preparedness Innovations (CEPI), an international coalition set up five years ago to prepare for future disease threats.

Moderna is already collaborating with partners on vaccines against some of the 15 pathogens, which include Chikungunya, Crimean-Congo hemorrhagic fever, Dengue, Ebola, Malaria, Marburg, Lassa fever, MERS and COVID-19.

Those collaborations include a Nipah virus vaccine with the U.S. National Institutes of Health and an HIV vaccine with the Gates Foundation and the International AIDS Vaccine Initiative, Moderna President Stephen Hoge said in an interview.

The company will either seek out new partners for the others or develop them internally, he said.

Moderna Chief Executive Stephane Bancel told a virtual press briefing on Monday that the 15 viruses are known threats that have not been addressed by many large drugmakers. The COVID-19 pandemic, which has killed six million people worldwide and sickened millions more, has made clear that needs to change, Bancel said.

"Too many lives were lost in the last few years," he said.
Early in the COVID pandemic, Moderna pledged not to enforce its vaccine patents during the emergency phase of the health crisis.

That has allowed for development of a vaccine manufacturing plant in Africa backed by the World Health Organization as part of a pilot project to give poor and middle-income countries the know-how to make COVID-19 vaccines.

Moderna said it will make that pledge permanent for the 92 low- and middle income countries that qualify for assistance under the COVAX Advance Market Commitment (AMC) led by the GAVI vaccine alliance.

A company spokesperson said Moderna will not enforce patents for COVID-19 vaccines developed in South Africa by WHO-backed Afrigen Biologics for AMC-92 low- and middle-income countries.

Although it will not enforce its patents in these countries, Hoge said Moderna does not intend to share its vaccine technology with the WHO-backed technology transfer hub in South Africa, in spite of lobbying efforts by the organization.

Earlier on Monday, the company said it will set up a manufacturing facility in Kenya, its first in Africa, to produce mRNA vaccines, including against COVID-19.

As part of its future pandemic plan, Moderna intends to make its technology available to academic research labs to test their own theories for vaccines to address emerging and neglected diseases. Hoge said some of these may eventually result in partnerships with Moderna to address the 15 priority pathogens.

"What we want to make sure happens is that scientists who have great ideas for how they could make vaccines will be able to access our standards and technology, almost as if they worked at Moderna," Hoge said.

Initially, the program will start with a few academic labs, but Hoge expects it to expand rapidly. He sees the program as a way to expand discovery of vaccines using mRNA technology.

"We want to make sure that we allow others to explore the space that frankly, we can't get to," he said. "And that's really what this is about." (Source: Business Line)

Natco Pharma Announces Launch of First Generic of Top Selling Cancer D

Natco Pharma along with its marketing partner Arrow International - an affiliate of Israeli-drug maler Teva Pharmaceutical Industries on Monday announced the launch of the first generic version of Celgene's (now acquired by Bristol Myers Squibb) top selling cancer drug Revlimid (lenalidomide capsules) in in the US market.

Revlimid had annual sales of $2.3 billion as of December 2021, according to IQVIA data. The generic version of Revlimid will be available in 5mg, 10mg, 15mg, and 25mg strengths

The announcement came after market hours. The Shares of Natco Pharma 2.98% to close at Rs 844.30 on BSE on Monday, the benchmark Sensex fell 2.74% to end at 52,842.75 points.

Natco is heavily banking on the Revlimid generic to push its sales and profits. Natco, along with its marketing partner Arrow International previously settled the Paragraph IV litigation related to the Revlimid with Celgene, now part of Bristol-Myers Squibb in 2015. Lenalidomide capsules are prescribed in adults for the treatment of multiple myeloma in combination with the medicine dexamethasone, certain myelodysplastic syndromes, and mantle cell lymphoma following specific prior treatment. (Source: Economic Times)

India-UAE Trade Pact Eet to Boost Pharma Exports

Indian drug-makers can look for significant gains in pharma exports to the United Arab Emirates, thanks to the new trade pact inked by India with the latter. Pharmaceuticals is one of the products that has been included in the vortex of Comprehensive Economic Partnership Agreement.

“There are many advantages that can hasten the product approvals and boost up demand for Indian pharmaceuticals in UAE,” R Uday Bhaskar, Director General Pharmaceutical Export Promotion Council (Pharmexcil), told BusinessLine. As of now, the process of approval for any dossier filed by Indian pharma companies in UAE may take up to 24 months.

“However, now those companies who have facilities approved by eight drug regulators including those of USFDA, EMA, UK-MHRA, TGA-Australia and Health Canada can get approval only in 90 days. This significantly hastens product approval period and thus augurs well for exports,’‘ Bhaskar said. UAE is also a gateway to exports to GCC and Africa regions and being a re-export country, it can expand the reach of Indian drugs further.

GCC market has been estimated at $15 billion out of which $4.6 billion is for generics which is an advantage for India. The presence of large number of USFDA (741)and 743 European GMP approved facilities in India will also be a positive factor for India. “The cost advantage our exporters offer coupled with a strong tradition of product quality and credibility help us to adually increase presence/consumption of Indian generics in UAE and GCC,’‘ the Pharmexcil DG said.

Generic sector India participates mostly in the generic sector of UAE. Though UAE pharma market size is of $3.5 billion, its generic market inclusive of vaccines is Just $ 718 million in 2021. Generic market is projected to grow at a CAGR of 7 per cent in the next five years. It may reach $1,000 million by 2026. ”It is to be noted that UAE is developing as a mini logistical centre which can help Indian pharma exporters,’‘ the official said.

India’s pharma exports to UAE during the last five years ending FY-21 grew at a CAGR of 24 per cent which is much faster than UAE’s local market. However, India’s pharmaceutical exports to UAE are also re-exported to other countries and the data pertaining to the actual consumption in UAE of India’s exports are not available.

It is to be noted that the export growth recorded in FY2020-21 was 58.4 per cent ($322 million) is inorganic growth owing to the pandemic and the CAGR observed during 2015-16 to 2019-20 was 16.7 per cent. “As their local formulation industry is also fast developing India’s exports may have a chance of increasing API’s much faster than now (only 5 per cent CAGR during the last five years).

Formulation exports, which have grown by a CAGR of 48 per cent during the last five years may register a smaller figure,’‘ Bhaskar said.

One of the directors of a Hyderabad-based listed pharma company said diversification of geographies should be a top priority for pharma exporters and the trade pact with UAE would act as a catalyst. (Source: Business Line)