

## Mankind Pharma Seeks Regulatory Nod for Trials of Novel Anti-Diabetic Molecule

Mankind Pharma recently submitted its first Investigational New Drug (IND) application for approval to the Indian Drug Regulatory Authority, Central Drugs Standard Control Organization (CDSCO) for MKP10241, a patented first in Class Novel Anti Diabetic Molecule.

The company has worked relentlessly in developing this new class of anti-diabetic molecules- designed and developed at the Mankind Research Centre. MKP10241 is a potent and orally administered small molecule, GPR119 agonist. GPR 119 is highly expressed in pancreatic beta cells and intestinal enteroendocrine cells.



GPR119 elevates intracellular secondary messengers such as cAMP inside the cells and promotes postprandial insulin and incretin secretion (GLP-1) in a glucose-dependent manner. This dual mechanism by GPR119 in mediating glucose-dependent insulin secretion is distinct from the currently available therapeutic options for Type 2 diabetes and thus becomes a promising new approach for the treatment of type 2 diabetes and related metabolic disorders.

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## Converting Available Infrastructure into a Vaccination Facility

When the Cooper Hospital needed to host the vaccination centre, an abandoned building (old canteen area) was renovated and refurbished in record time and all the required facilities were made.

Following which, the HBTMC Cooper Vaccination Centre was divided into 3 zones which included the waiting area/registration area, vaccination area and observation area.

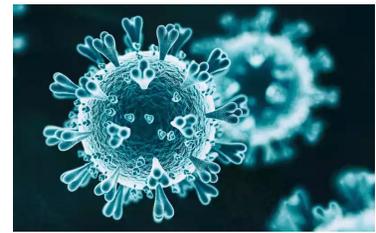
There were separate entry and exit points to avoid crisscross movement of beneficiaries at the session site.



As of 31<sup>st</sup> March 2021, 37,247 vaccine doses have been administered at HBTMC Cooper Vaccination Centre alone.

## Diarrhoea, Body Aches: More Frequent in the Second Wave

Covid symptoms have been milder and undergone subtle changes during the second wave along with a much higher transmission rate, often making it difficult to identify the virus, according to doctors in Kolkata.



While cough, cold and fever had been the most common symptoms during the first wave, weakness, body ache and mild diarrhoea have been more frequent this time.

The reason could be that more younger people with stronger immunity have been affected resulting in non-lung symptoms, they said.

“While the virus is more transmissible this time with a lower mortality rate, there has been a paradigm shift in the mean age of the affected population, from 59-60 last time to less than 45 now. Being more mobile, the younger population has been affected but due to their stronger immunity, the virus is often not being able to penetrate the lungs. So, the non-lung portions are being affected, resulting in symptoms like tiredness, fatigue, lethargy and body ache. Cold and fever have been absent in 10%-15% of cases, which makes it a challenge to diagnose. Non-specific symptoms like diarrhoea, vomiting and even stomach ache have been widespread this time,” said Raja Dhar, director of pulmonology at CMRI Hospital.

## WHO Global Compact to Expedite Action to Tackle Diabetes

The World Health Organization (WHO), has launched the Global Diabetes Compact, which aims to boost efforts to prevent diabetes and bring treatment to all who need it 100 years after the discovery of insulin.

The Compact was launched at the Global Diabetes Summit, which is co-hosted by WHO and the government of Canada, with the support of the University of Toronto. The development comes as the risk of early death from diabetes is increasing, underscoring why countries must tackle the disease and bring treatment to all who need it, 100 years after the discovery of insulin.

“The need to take urgent action on diabetes is clearer than ever”, WHO Director-General Tedros Adhanom Ghebreyesus said. “The number of people with diabetes has quadrupled in the last 40 years. It is the only major non-communicable disease for which the risk of dying early is going up, rather than down. And a high proportion of people who are severely ill



in hospital with COVID-19 have diabetes.” More than 420 million people worldwide live with diabetes, a group of chronic diseases characterized by elevated blood sugar, which can cause damage to the heart, blood vessels, eyes, kidneys and nerves.

The pre-qualification process ensures that medicines meet global standards for quality, safety and efficacy.

## Zydus's Covid-19 Vaccine to Cover Children Too

Cadila Healthcare (also known as Zydus Cadila), which plans to roll out its much-awaited ZyCoV-D vaccine in the second half of May or in June, will also be administered to children if all goes as planned, said company officials.

For the third generation DNA-based vaccine against Covid-19, Zydus has set up a production facility with a capacity of 120-150 million doses. It has plans to double it soon after the launch given the worsening situation in the country, according to the officials.

While there are no vaccines available in the country for children right now, Zydus Cadila is to commence clinical trials for this age group too.



In the United States, Johnson & Johnson has carried out clinical trials on children of this age group, the results of which are awaited.

## Dr Reddy's Cuts Remdesivir Price

Amid a surge in Covid-19 cases and a serious shortage of remdesivir, Hyderabad-based pharmaceutical giant Dr Reddy's Laboratories not only increases drug production but also maximizes retail prices for the benefit of patients. I decided to cut it in half.

The company also plans to roll out a liquid variant of the Remde-



sivir brand Redyx, which will be faster to manufacture and supply.

“We are making every effort to ensure that Dr Reddy's Remdesivir, sold under the brand name Redyx, reaches as many patients as possible in India. We are increasing production and more manufacturing and supply. We are also launching fast liquid products on

the market, "the company said.

"We also reduced MRP by 50% so that prices are not a barrier to access, allowing for more patients to access MRP," it added.

To fully understand whether patients and healthcare professionals have access to the drug, the company has set up a dedicated website that updates in real-time,

making Redyx and Favipiravir available at various stockers and hospitals across the country. Gender is shown for each city.

### Health ministry Issues Regulatory Pathways for Foreign-produced Covid Vax

The Central government recently issued the regulatory pathway in India for Covid-19 vaccines approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL), said the Union health ministry.

The Central Drugs Standards Control Organisation (CDSCO) headed by the Drugs Controller General of India (DCGI) has explained that it has prepared detailed guidelines specifying regulatory pathway for approval of foreign approved Covid vaccines based on NEGVAC recommendations.



"These guidelines have since been prepared and posted by CDSCO on its website. CDSCO will take steps to widely disseminate these guidelines to the concerned stakeholders," the ministry said.

It said that the applicants for grant of approval for Restricted Use in the Emergency situation may be submitted to CDSCO and the application can be made by the foreign manufacturer through its Indian subsidiary or through its authorized agent in India (in case it does not have an Indian subsidiary).

The CDSCO will process such applications and decide within three working days from the date of submission of the complete application by the applicant. DCGI will issue permission for Restricted Use in Emergency situation if the vaccine will be used as per the guidelines prescribed under the national Covid-19 Vaccination Programme.

The first 100 beneficiaries of such vaccines shall be assessed for seven days for safety outcomes before it is rolled out for further Vaccination programme. "Applicant shall initiate conduct of post-approval bridging clinical trials within 30 days of such approval," it said.

### Gennova Starts Enrolment for Phase 1/2 Human Clinical Trials

Gennova has initiated the enrolment of volunteers for Phase 1/2 clinical trials for its mRNA vaccine candidate HGCO19, the Department of Biotechnology, which has provided seed funding for its development, said recently.



The DBT said it has approved additional funding towards clinical studies of India's first of its kind mRNA-based COVID-19 vaccine, HGCO19, developed by Pune-based biotechnology company Gennova Biopharmaceuticals Ltd.

The funding has been provided under the DBT's 'Mission COVID Suraksha - The Indian COVID-19 Vaccine Development Mission'. It is being implemented by DBT's public sector undertaking Biotechnology Industry Research Assistance Council (BIRAC).

The move augurs well for India as it could give the country, which has been witnessing a massive surge in coronavirus cases combined with concerns of a shortage of vaccines from states, another option to battle the pandemic.

## Newborns Won't Get COVID Through Infected Mom's Breast Milk

A new study offers more reassurance that mothers infected with SARS-CoV-2 can safely breastfeed their babies.

Researchers said that the findings support existing advice from public health authorities. Last year, the World Health Organization (WHO) said that moms with suspected or confirmed COVID-19 can continue breastfeeding.

The U.S. Centers for Disease Control and Prevention has said that breast milk is "not a likely source" of SARS-CoV-2 transmission, and that infected moms can breastfeed as long as they take



some precautions.

"If you wash your hands and wear a mask, there's no reason you can't breastfeed," said Dr Marcel Yotebieng, an associate professor at Albert Einstein College of Medicine in New York City, US. Yotebieng co-wrote an editorial

published with the new study in the journal Pediatrics. He said that while breastfeeding recommendations already exist, studies need to keep tracking whether infant infections related to breast milk do occur.

These latest findings do not rule out that possibility, said lead researcher Dr Noa Ofek Shlomai, who heads the neonatal unit at Hadassah and Hebrew University Medical Center in Jerusalem. "But transmission by breast milk is most probably unlikely," Shlomai said.

## Stealthy Virus Beating RT-PCR Tests

The novel coronavirus variant that is causing the current wave of Covid-19 is not just highly infectious but also stealthy.

City hospitals say there are getting cases where a patient has typical symptoms of the disease but tests negative for the viral infection, sometimes twice or thrice even through RT-PCR, considered the gold standard for Covid testing.

The mutated variants of the novel coronavirus contagion that are now circulating in the second wave continue to throw more challenges to the treating doctors in treating the afflicted patients. It is now observed that whether deadly or not, these variants are not just highly virulent but also seem to be operating in a stealth mode. Doctors are finding that RTPCR tests run on several patients are showing up as false negatives as the evasive virus escapes detection.



## Covid Vaccination Centre Resumes at Nair Hospital

It was very challenging to find a separate space for vaccination in the hospital as all available space was already being used by other departments for patient care especially since Nair was designated as a COVID Hospital too.

Finally, a suitable location which used to be a tutorial room near the Nursing quarters was selected and repurposed.

A canopy was set up outside the entrance to the building, along with barricades to allow the smooth unidirectional flow of beneficiaries.

Banners were prepared to prominently display the centre and proper signage had to be made to facilitate client movement.



## Lancet Reports Solutions to Control the Spread of the Virus in India

With India in the grip of a second Covid-19 wave, the country may see 1,750 coronavirus related deaths per day, rising to approximately 2,320 by the first week of June, a report of the Lancet Covid-19 Commission by India Task Force members said.

The report, titled "Managing India's second Covid-19 wave: Urgent steps", highlights the key points of the second wave of pandemic. The report also recommends steps that should be taken now to help slow down the spread of infection.

The report proposed following solutions to control the spread of the virus in India:

- **VACCINATE: COVER YOUNGER POPULATION BASED ON SUPPLIES:** The report recommended including all adults, including those below 45, with severe co-morbidities into the priority group.
- **MORE VACCINES NEEDED:** Currently, India uses two vaccines- Covishield and Covaxin. As of April 13, 2021, the government has given nod for emergency approval of other vaccines that have met safety and efficacy standards and received regulatory green signal in other markets. These include Johnson and Johnson, Pfizer-BioNTech, Moderna.
- **RAMP UP VACCINE MANUFACTURING:** The report states, "Today Indian manufacturers are producing approximately 70-80 million doses of vaccines per month (Covishield and Covaxin). Even if 100% of this supply was for domestic use, at a target of 5 million doses a day, the monthly supplies would fall short by half."
- **ADDRESS VACCINE HESITANCY:** Despite high rates of vaccinations, surveys show that even though acceptance is increasing, only 57% respondents said they are now ready to take the shot.
- **NO BLANKET LOCKDOWNS:** The report does not recommend a blanket national or state lockdown. Pointing out that economic closures are most disruptive to the poorest sections of society,



the report recommends a middle ground approach in India, including localised, phased restrictions or closures.

- **INCREASE GENOME SEQUENCING:** The report urges an expansion of genome sequencing of the coronavirus to understand if mutants or variants are responsible for the current surge, and if so, the nature and type of such variants.
- **TRAVEL:** The report recommends a mandatory seven-day institutional quarantine for all visitors arriving from other countries, with an RT-PCR test conducted on Day 8, and the option of completing another week in home isolation if the test is negative.
- **BAN ON GATHERING OF GROUPS OF MORE THAN 10:** A temporary ban on gatherings of groups larger than 10 for the next two months has been recommended to control the spread of infection.
- **INFORM IF THOSE TESTING FOR COVID WERE VACCINATED OR NOT:** The report recommends that the Covid-19 test registration form be immediately amended to include information on whether the individual getting tested has received one or both doses of the vaccine (with details of the type of vaccine). This information can help track the spread of post vaccination infections, and the spread of potential variants.

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