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**Editorial**

Scientists are working hard for developing medicines and vaccines to combat COVID-19 round the world. They are either trying to develop new drug or vaccine for this purpose or some of them are trying to repositioning old drugs to combat COVID. As per the reports several groups are working on different type of drugs like-anti virals, antimalarials, Cardiovascular drugs, H2 receptors, anti psoriasis drugs etc. Already USFDA has given permission of use of Hydroxychloroquine and Chloroquine for emergency purpose and it is in use in full swing. Last Friday USEDA has cautioned against use of these drugs outside hospital and for clinical trial because of its serious adverse reaction i.e. QT prolongation. Indian people are eagerly waiting for the reaction of ICMR and CDSCO regarding use of Hydroxychloroquine and Chloroquine in this back drop.

Yesterday USFDA extended EUA approval to Remdesivir for COVID treatment, which was tried earlier for several purposes without much positive result.

Several scientific groups are working for developing vaccines for COVID and their results are at different stages like- pre clinical, Phase I, Phase II and Phase III etc, but as per the report the Oxford University developed vaccine is much ahead and are expecting to market within a very short time. One of the Indian company is also partnering with them in manufacturing of this vaccine.

However whole world has to wait for vaccine against COVID and curative drug of COVID patient.

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**Dr. Subhash C. Mandal**

Editor

E mail: subhash.mandaldr@gmail.com
Mob. 9830136291
USFDA issue an Emergency Use Authorization (EUA) for emergency use of Remdesivir for the treatment of hospitalized 2019 coronavirus disease (COVID-19) patients (a part of the authorization letter is reproduced as available)

Remdesivir is a nucleoside ribonucleic acid (RNA) polymerase inhibitor. Remdesivir for injection, 100 mg, is a sterile, preservative-free lyophilized solid that is to be reconstituted with 19mL of sterile water for injection and diluted into 0.9% saline prior to intravenous (IV) administration. Following reconstitution, each single-dose, clear glass vial contains a 5 mg/mL remdesivir concentrated solution with sufficient volume to allow withdrawal of 20 mL. Remdesivir Injection, 5 mg/mL, is a sterile, preservative-free, clear, solution that is to be diluted into 0.9% saline prior to intravenous (IV) administration. The authorized remdesivir vial label and/or the carton labeling is clearly marked for “emergency use authorization” or for “investigational use.”

Remdesivir for injection, 100 mg, vials should be stored below 30 °C until time of use. Remdesivir injection, 5 mg/mL vials should be stored at refrigerated temperatures (2 °C to 8 °C) until time of use. Following dilution with 0.9% saline, the solution can be stored for up to 4 hours at room temperature (20 °C to 25 °C) or 24 hours at refrigerated temperatures (2 °C to 8 °C).

Remdesivir is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to healthcare providers and patients respectively: • Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734) • Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Remdesivir for Coronavirus Disease 2019 (COVID-19) I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of remdesivir when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks. I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that remdesivir may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act. Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that remdesivir (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS’s corresponding declaration under Section 564(b)(1), remdesivir is authorized for the treatment of suspected or laboratory confirmed COVID-19 in adults and children who are hospitalized with severe disease as described in the Scope of Authorization (section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

For details: https://www.fda.gov/media/137564/download

WHO accidentally posts remdesivir trial data from China
The World Health Organization accidentally posted on its website a synopsis of results of Gilead Sciences’ remdesivir trial in China that indicated the antiviral medication did not help improve outcomes of COVID-19 patients, nor did it prevent mortality. "A draft manuscript was provided by the authors to WHO and inadvertently posted on the website and taken down as soon as the mistake was noticed. The
manuscript is now undergoing peer review and we are waiting for a final version before WHO comments on it," said WHO spokesperson Daniela Bagozzi.

Full Story: BioPharma Dive

Oxford Group leaps ahead in developing Coronavirus vaccine

In the worldwide race for a vaccine to stop Covid-19, the laboratory sprinting fastest is at Oxford University. Most other teams have had to start with small clinical trials of a few hundred participants to demonstrate safety. But scientists at the university’s Jenner Institute had a head start on a vaccine, having proved in previous trials that similar inoculations — including one last year against an earlier coronavirus — were harmless to humans.

That has enabled them to leap ahead and schedule tests of their new coronavirus vaccine involving more than 6,000 people by the end of next month, hoping to show not only that it is safe, but also that it works. The Oxford scientists now say that with an emergency approval from regulators, the first few million doses of their vaccine could be available by September — at least several months ahead of any of the other announced efforts — if it proves to be effective. The Oxford scientists now say that with an emergency approval from regulators, the first few million doses of their vaccine could be available by September — at least several months ahead of any of the other announced efforts — if it proves to be effective. Now, they have received promising news suggesting that it might.

Ref. New York Times

DCGI extends CoPP validity expiring between March & August 2020 by Six Months

In a bid to maintain the continuity of export by the pharmaceutical companies amid coronavirus pandemic, the Drugs Controller General of India (DCGI) has extended validity of World Health Organization good manufacturing practices (WHO GMP) certificate of pharmaceutical product (CoPP) expiring from March to August 2020 by six months.

The validity of CoPP will be extended by six months from the date of expiry of the certificate as per WHO GMP certification guidelines, said DCGI in a circular.

The DCGI has written to drugs controllers in states and Union Territories in this regard.

The six-month extension was granted by the DCGI following representations from stakeholders seeking extension of validity of WHO GMP certificate/CoPP whose validities are expiring between now and August 2020 in the wake of COVID-19 outbreak.

CoPP is issued under the WHO GMP certification scheme for registration of products in foreign countries. It is required by the importing country when the product in question is intended for registration (licensing, authorization) or renewal of registration, with the scope of commercialization in that country.

CoPP is aimed at minimizing the risks inherent in drug manufacturing. The certificate helps the drug regulator ensure that drugs are consistently produced and are quality controlled before they leave the country.

Earlier the validity of CoPP was extended from two years to three years by DCGI through a circular on May 8, 2018. The move aimed at boosting drug export and promoting ease of doing business.

Drug exporters hailed the DCGI’s decision to extend validity of CoPP expiring in next four months.

Said Nipun Jain, chairman of SME panel, Pharmaceuticals Export Promotion Council of India, “The DCGI has taken a welcome step. The six months extension of validity of CoPP expiring till August will provide respite to exporters facing hardship in renewing the certificate since lockdown.”

Source: Pharmabiz

The Food and Drug Administration on Friday cautioned against prescribing Hydroxychloroquine to COVID-19 patients outside of hospital settings or clinical trials

The drug, an antimalarial, was repeatedly touted by President Donald Trump as a possible treatment for the coronavirus.

"The FDA is aware of reports of serious heart rhythm problems in patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with azithromycin," the FDA wrote on its website.
"We are also aware of increased use of these medicines through outpatient prescriptions. Therefore, we would like to remind health care professionals and patients of the known risks associated with both hydroxychloroquine and chloroquine," the FDA said.

The agency said hydroxychloroquine can still be used in hospital settings or in clinical trials, but it was not immediately clear whether some planned trials would be stopped. Cardiologists have been sounding the alarm about hydroxychloroquine’s heart risks for weeks, saying the drug could be deadly in a small number of patients who are susceptible to heart conditions.

Hydroxychloroquine, and a related compound called chloroquine, is a medication that's been around for decades. It's used to treat malaria, as well as certain autoimmune diseases, including lupus and rheumatoid arthritis. Enthusiasm for its potential as a treatment for the coronavirus began to build in March, when a French study suggested hydroxychloroquine plus azithromycin (the antibiotic known as a Z-Pak) might benefit COVID-19 patients. The journal that published the French study, however, later said that the article did not meet its expected standard.

A week later, the FDA issued an emergency use authorization for hydroxychloroquine, allowing health care providers to use the medicine for COVID-19 in hospitalized patients with severe disease, even though the drug had not been approved as a specific treatment for the illness, and was known to increase the risk for irregular heartbeat.

But the previous fervor for hydroxychloroquine has diminished. In one case, a New York woman with coronavirus symptoms died after her family said a doctor prescribed her a combination of hydroxychloroquine and azithromycin without confirming she had COVID-19 or testing her for heart problems ahead of time. The exact cause of death for the woman has not yet been determined.

The Centers for Disease Control and Prevention has also pulled back on its guidance for using hydroxychloroquine for COVID-19 and no longer offers recommendations for dosage. And earlier this week, a National Institutes of Health panel of experts said doctors should not use hydroxychloroquine and azithromycin to treat the illness, citing lack of evidence.

Ref.: NBC News