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FDA Approves Remdesivir, the First COVID-19 Treatment

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:

Welcome to the Drug Report, with special focus on the COVID-19 pandemic. The Food and Drug Administration announced on October 22, 2020 Remdesivir as the first treatment for COVID-19 to gain their approval. Today on the Drug Report we highlight a few studies that have helped to shed light on the benefits and limitations of this antiviral agent.

We begin with a follow up to an earlier Drug Report on the World Health Organization's Solidarity Therapeutics Trial which looked at remdesevir, among other potential COVID-19 treatments. The WHO reported on October 15, 2020, "In just six months, the world's largest randomized control trial on COVID-19 therapeutics has generated conclusive evidence on the effectiveness of repurposed drugs for the treatment of COVID-19." The study spanned more than 30 countries and 405 hospitals as trial sites. Over 11,000 adults were randomized to four treatment groups and one that received no drug. The researchers looked at the effects of these treatments on overall mortality, initiation of ventilation, and duration of hospital stay in hospitalized patients. The results of the trials are currently under review for publication in a medical journal and are available in a preprint format. The preliminary data indicate that Remdesivir, Hydroxychloroquine, Lopinavir (fixed-dose combination with Ritonavir) and Interferon-β1a (mainly subcutaneous; initially with Lopinavir, later not) regimens appeared to have little or no effect on hospitalized COVID-19, as indicated by overall 28-day mortality, initiation of ventilation and duration of hospital stay. Other uses of the drugs, such as for treatment of patients in the community setting or for prevention, are to be studied with different trials. Newer antiviral drugs, immunomodulators and anti-SARS COV-2 monoclonal antibodies are also now being considered for evaluation.

More encouraging findings for remdesivir were reported in the New England Journal of Medicine, October 8, 2020 issue. In an article entitled, "Remdesivir for the Treatment of Covid-19 – Final Report", Dr. John H. Biegel and associates reported on their double-blind, randomized, placebo-controlled trial known as ACTT-1, that studied intravenous remdesivir in adults who were hospitalized with Covid-19 and had evidence of lower respiratory tract infection. Patients were randomly assigned to receive either remdesivir (200 mg loading dose on day 1, followed by 100 mg daily for up to 9 additional days) or placebo for up to 10 days. The primary outcome was the time to recovery, defined by either discharge from the hospital or hospitalization for infection-control purposes only. A total of 1,062 patients at sixty trial sites were randomly assigned to receive either remdesivir or placebo. Patients who received remdesivir had a median recovery time of 10 days as compared with 15 days among patients who received placebo. Further analysis revealed that the patients who received remdesivir were found to be more likely than those who received placebo to have clinical improvement at day 15 after adjustment for actual disease severity. The Kaplan–Meier estimates for mortality were 6.7% with remdesivir and 11.9% with placebo by day 15 and 11.4% with remdesivir and 15.2% with placebo by day 29. Serious adverse events were reported in approximately 25% of remdesivir patients vs. 32% of patients who received placebo. The authors concluded that remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with Covid-19 and had evidence of lower respiratory tract infection. They also noted that, "However, given high mortality despite the use of remdesivir, it is clear that treatment with an antiviral drug alone is not likely to be sufficient for all patients. Current strategies are evaluating remdesivir in combination with modifiers of the immune response (e.g., the Janus kinase [JAK] inhibitor baricitinib in ACTT-2, and interferon beta-1a in ACTT-3 [trials]). A variety of therapeutic approaches including novel antivirals, modifiers of the immune response or other intrinsic pathways, and combination approaches are needed to continue to improve outcomes in patients with Covid-19." This study was funded by the National Institute of Allergy and Infectious Diseases and others.

Two additional randomized, open-label multi-center clinical trials of hospitalized adult subjects also supported the recent approval of remdesivir (Veklury). The antiviral is approved for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of Covid-19 requiring hospitalization. The drug should only be given in a hospital or in a healthcare setting capable of providing acute care equivalent to inpatient hospital care. Use of Veklury for treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or those less than 12 years of age weighing at least 3.5 kg is still authorized under an Emergency Use Authorization (EUA) originally issued on May 1, 2020 and is not included in the FDA approval at this time. Clinical trials studying safety and efficacy of Veklury in this pediatric population are in process.

For The Drug Report, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
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