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Update on Remdesivir, Investigational Antiviral for COVID-19

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 this special focus on COVID-19 .

Here's an update on what is happening with Remdesivir, one of the many potential drug candidates under study for use in COVID-19.

Remdesivir is an intravenously administered, broadly targeted antiviral drug that is under investigation for its ability to inhibit viral replication through early termination of RNA transcription. It has in-vitro activity against SARS-CoV-2 and in-vitro and in-vivo activity against related betacoronaviruses.

There are currently three options through clinical trials for obtaining remdesivir for treatment of hospitalized patients with COVID-19 and pneumonia in the United States. Here's an overview, but be sure to check out the full trial details at clinicaltrials.gov:

- A National Institutes of Health (NIH)-sponsored adaptive double-blinded, placebo-controlled trial of remdesivir versus placebo in COVID-19 patients with pneumonia and hypoxia is enrolling non-pregnant persons aged 18 years and older with oxygen saturation of ≤94% on room air or requiring supplemental oxygen or mechanical ventilation.
- Additionally, two phase 3 randomized open-label trials of remdesivir (5-days versus 10-days versus standard of care) are open to enrollment in persons aged 18 years and older with COVID-19, radiographic evidence of pneumonia and oxygen saturation of ≤94% on room air (aka severe disease) or >94% on room air (aka moderate disease).
- Finally, there was a recent change in the ability of clinicians to obtain remdesivir for use in patients on an uncontrolled compassionate use basis. The manufacturer, Gilead, due to as they described, an exponential increase in compassionate use requests for emergency access to remdesivir related to the spread of the coronavirus in Europe and the United States, is currently transitioning to an expanded access program they state is under rapid development in conjunction with national regulatory authorities worldwide, and may vary by region based on local laws and regulations.
- The company says this new approach will both "accelerate access to remdesivir for severely ill patients and enable the collection of data from all participating patients." They are focused on processing previously approved requests and anticipate the expanded access program will in turn process requests at a similar pace once it begins. As an exception, compassionate use requests may still be made for pregnant women and children less than 18 years of age with confirmed COVID-19 and severe manifestations of disease.

In related news, Gilead has asked the FDA to rescind its newly granted orphan drug designation for remdesivir following a wave of criticism over the decision, including from presidential candidate Sen. Bernie Sanders of Vermont and others. Gilead stated that the drug was already under expedited review and they didn't need the FDA's tag. They had sought the designation in early March in part to waive its requirement to create a pediatric study arm prior to submitting an FDA application—a process that could delay review by up to 7 months. But opponents argued that drugs with FDA's orphan tag would receive seven-year market exclusivity, preventing generic challengers and by extension bottlenecking wider access to a critical treatment.

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

Announcer:

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