Fauci on remdesivir for COVID-19: 'This will be the standard of care'

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Anthony S. Fauci

National Institute of Allergy and Infectious Diseases Director **Anthony S. Fauci, MD,** said today that data from a multinational randomized control trial showed that Gilead's investigational antiviral remdesivir "has a clear-cut significant positive effect in diminishing time to recovery" for patients with COVID-19.

"This will be the standard of care," Fauci, a White House advisor on the pandemic, said during comments from the Oval Office. Fauci said the results, which have not yet been peer-reviewed, prove "that a drug can block this virus."

"We think it's opening the door to the fact that we now have the capability of treating" COVID-19, he said.

The trial, which began Feb. 21 this year, compared remdesivir with placebo in more than 1,000 patients. Remdesivir improved recovery from 15 days to 11 days, with a *P* value of 0.001, Fauci said.

He said the mortality rate trended toward being better in the remdesivir arm, 8% vs. 11%, but the result had not reached statistical significance.

"The reason why we're making the announcement now is something that I think people don't fully appreciate. Whenever you have clear cut evidence that you have a drug that works, you have an ethical obligation to immediately let the people in the placebo group know so that they can have access," Fauci said. "We would have normally waited several more days. The data may change, but the conclusion won't."

He said researchers would now start testing other investigational therapies in combination with remdesivir.

Elsewhere, a study published today in *The Lancet* showed no statistically significant benefit from remdesivir in 237 adult patients admitted to 10 hospitals in China for severe COVID-19. However, the study did show "a numerically faster time to clinical improvement" among participants who received remdesivir compared with those who received placebo among patients who experienced symptoms for 10 days or less. That finding "requires confirmation in larger studies," the researchers wrote.

Also today, Gilead announced in a news release that patients with severe COVID-19 infection who received a 10-day treatment course of remdesivir experienced similar improvement in clinical status as those who were treated with a 5-day course.

"The study demonstrates the potential for some patients to be treated with a 5-day regimen, which could significantly expand the number of patients who could be treated with our current supply of remdesivir," **Merdad Parsey, MD, PhD,** chief medical officer of Gilead Sciences, said in the release. "This is particularly important in the setting of a pandemic, to help hospitals and health care workers treat more patients in urgent need of care."

Peter Chin-Hong

In the phase 3 SIMPLE trial, researchers aimed to determine whether a 5-day course of remdesivir could provide similar efficacy as a 10-day treatment regimen.

Eligible patients had evidence of pneumonia and reduced oxygen levels that did not require mechanical ventilation at the time of study entry. Clinical improvement was defined as an improvement of 2 or more points from baseline on a seven-point scale that ranged from hospital discharge to increasing levels of oxygen support to death. Clinical recovery was defined as no longer requiring oxygen support and medical care or being discharged from the hospital.

"Infectious disease doctors continue to be hopeful that an antiviral will actually work for patients with COVID-19 — and not an anti-malarial drug, or a rheumatology drug, or a worm drug, or any of the things that have been held up as promising initially," *Infectious Disease News* Editorial Board Member **Peter Chin-Hong, MD,** professor of medicine and director of the transplant infectious disease program at the University of California, San Francisco, told Healio.

Time to clinical improvement for 50% of patients was 10 days in the 5-day treatment group and 11 days in the 10-day treatment group. More than 50% of patients in both groups were discharged from the hospital by day 14, including 60% of patients in the 5-day group and 52% in the 10-day group. Improvement in clinical status was similar in both groups (OR = 0.75; 95% CI, 0.51-1.12 at day 14).

Gilead said it plans to release data at the end of May regarding 5- and 10-day dosing regimens with remdesivir for patients with moderate cases of COVID-19. Gilead revised access to remdesivir last month due to a surge in demand from physicians hoping to repurpose the drug to treat patients with COVID-19.

Aruna Subramanian, MD, clinical professor of medicine and chief of immunocompromised host infectious diseases at Stanford University School of Medicine and one of the lead investigators of the Gilead study, noted that the research from Gilead may contribute to further optimization of remdesivir for COVID-19.

“While additional data are still needed, these results help to bring a clearer understanding of how treatment with remdesivir may be optimized, if proven safe and effective,” she said.

The results from Gilead may also have implications for supply issues related to remdesivir, according to Chin-Hong.

“This means that we can potentially treat double the number of patients with the same stash of drugs,” Chin-Hong said. “It’s an interesting finding that might have immediate relevance to people participating in the extended access program.” – *by Eamon Dreisbach, Gerard Gallagher and Caitlyn Stulpin*

Disclosures: Chin-Hong and Fauci report no relevant financial disclosures. Parsey is an employee of Gilead Sciences.

Reference:

Yang W, et al. *Lancet*. 2020;doi:10.1016/S0140-6736(20)31022-9.

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The NIAID and SIMPLE news, while not presenting detailed data, offer hope that remdesivir may help at least some COVID-19 patients. Wang and colleagues, in the first placebo-controlled, randomized remdesivir clinical trial, did not show conclusive benefit of the drug against severe COVID-19, despite a trend toward faster clinical improvement for treatment within 10 days of symptom onset. Taken together, today's news suggests that remdesivir may speed recovery of patients with non-severe COVID-19, if given early after disease onset. We need to analyze NIAID and SIMPLE data beside the Wang data, before we can draw definitive conclusions about how and where remdesivir fits within treatment approaches. My concern is that media reports and public perception may run with remdesivir as "standard of care" before data are fully vetted, or strengths and limitations of the drug are defined. To make best use of any COVID-19 treatment, testing needs to be more widespread nationally.

Reference:

Wang Y, et al. Lancet. 2020; doi:10.1016/S0140-6736(20)31022-9.

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