Evaluate Vantage

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# The winds change again for Gilead and remdesivir

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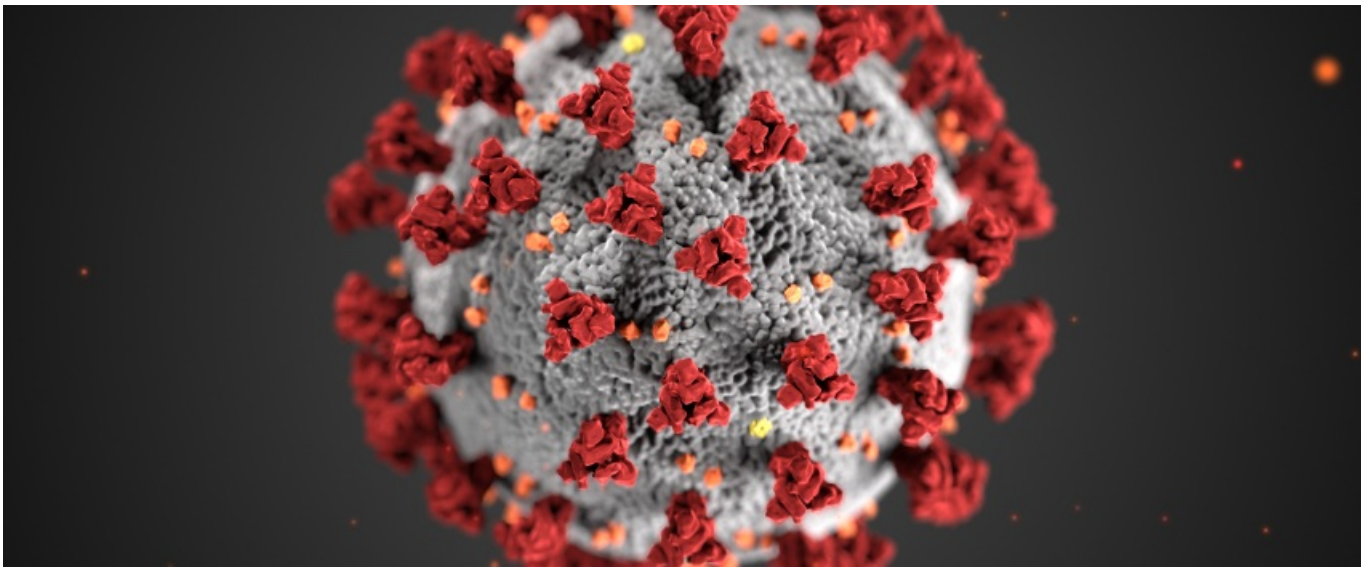

**A world desperate to know whether remdesivir will blunt Covid-19 received another hint today, and this time the news was more encouraging.**

Gilead's antiviral, remdesivir, has received more attention than any other potential treatment for sufferers of Covid-19, but hard data on its true utility is still being collected. Two releases today raise hopes, though the caveat that more evidence is needed remains.

First, the company said it "understands" that a huge trial being run by the National Institute of Allergy and Infectious Diseases' (NIAID) has met its primary endpoint. The NIAID will provide detailed information at an upcoming briefing, Gilead said; when that might be is not immediately clear though some have speculated that it could be made at the US government's daily coronavirus taskforce press briefing.

The study was seeking 800 patients and was a rigorous, double-blind, placebo-controlled test of remdesivir. The trial recruited subjects with a range of severities, although they needed to require supplemental oxygen or mechanical ventilation.

Patients went on to receive a 10-day course of the antiviral, and the primary endpoint measured time to recovery.

The study was not expected to report for weeks – however, according to the entry on clinicaltrials.gov, the design allowed for interim monitoring to introduce new arms and allow early stopping for futility, efficacy, or safety.

The actual effect size remains the crucial question here, as well as whether efficacy was only seen in a particular cohort of patients – more severe patients are most likely to see a benefit, analysts believe.

**Another glimmer**

The second statement from Gilead concerned one of the company's own phase III studies in severe patients. Over the past month this has been massively upsized, and is now seeking 6,000 patients, while the recruitment criteria were widened to allow subjects receiving mechanical ventilation.

The study was comparing five and 10-day courses of remdesivir and had no placebo arm, which limits the conclusions that can be drawn. This first cut concerned only 397 patients, and concluded that a five day course might be just as helpful as longer treatment.

In that five-day group, the mortality rate was 8%. The caveats of comparing across trials notwithstanding, this seems to be better than the 14% mortality rate seen in a placebo-controlled China-based study. That data, released by accident last week, knocked confidence in remdesivir, though the study was never completed because of poor enrolment. The Lancet released full data from that trial today.

The winds changed again today, with Gilead jumping almost 4% on the new information. A lot of data is still to come on remdesivir, while Evercore ISI analyst Umer Raffat summed up what many people are probably thinking right now. Remdesivir appears to be a real drug for Covid-19, although it is not a silver bullet, he said on a call to investors today.

| **Interim data from Gilead's Simple trial in severe Covid-19 ( NCT04292899)** | | | |
|---|---|---|---|
| | **5-day treatment course (N=200)** | **10-day treatment course (N=197)** | **Baseline adjusted p value** |
| Time to clinical improvement for 50% of patients | 10 days | 11 days | - |
| ***Clinical efficacy at day 14 (N, %)*** | | | |
| ≥ 2-point improvement in ordinal scale | 129 (65) | 107 (54) | 0.16 |
| Clinical recovery | 129 (65) | 106 (54) | 0.17 |
| Discharge | 120 (60) | 103 (52) | 0.44 |
| Death | 16 (8) | 21 (11) | 0.70 |
| ***Safety (N, %)*** | | | |
| Nausea | 20 (10) | 17 (8.7) | - |
| Acute respiratory failure | 12 (6) | 21 (10.7) | - |
| Any adverse event (AE) | 141 (71) | 145 (74) | 0.86 |
| Grade ≥3 study drug-related AE | 8 (4) | 10 (5) | 0.65 |
| Study drug-related serious AE | 3 (2) | 4 (2) | 0.73 |
| AE leading to discontinuation | 9 (5) | 20 (10) | 0.07 |
| *Note: p values adjusted for baseline clinical status. The p values compare the five-day course with the 10-day course; there was no control group in the study. Source: Gilead.* | | | |