Trump’s treatments primer: Regeneron antibodies and Gilead’s Remdesivir

[After Trump’s COVID diagnosis,] his treatment began with a leading drug candidate, Regeneron Pharmaceuticals’ two-antibody combination or “cocktail,” REGN-COV2. Within days, his medical team announced that the antiviral remdesivir, from Gilead Sciences, was added to the interventions given to the president. The treatment regimen, which incorporated dexamethasone on Sunday [October 4] —a steroid typically reserved for serious or more advanced COVID-19 cases—has been rolled out both aggressively and quickly.

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Whether these treatments will diminish the president’s battle with COVID-19 remains unknown and a source of unending speculation.

Despite the questions that remain regarding this situation, these two treatments have been making their way through the required safety and regulatory hurdles.

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Neither drug is [FDA] approved. Remdesivir received emergency use authorization (EUA) from the FDA on May 1.

REGN-COV2 has not received EUA. The FDA allows “expanded access” (also called “compassionate use”) allowing patients with an “immediately life-threatening condition or serious disease or condition” to access investigational drugs, biologics, or medical devices for use outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Regeneron said it gave Trump REGN-COV2 under a compassionate use: “All we can say is that they asked to be able to use it, and we were happy to oblige,” Regeneron founder, president, and CEO Leonard S. Schleifer, MD, PhD, told The New York Times.

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