

US-based HDT Bio's COVID-19 vaccine gets regulatory approval in India

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The vaccine uses self-amplifying RNA that could be a game changer



Indian regulators have issued an Emergency Use Approval for Gemcovac, a groundbreaking COVID-19 vaccine based on the technology of Seattle biotech HDT Bio Corp.

The vaccine uses self-amplifying RNA (saRNA), which replicates itself following administration and is thus effective at extremely low doses. In addition, it is stable at refrigerator temperatures unlike current mRNA vaccines, which require ultra-cold storage.

Gemcovac becomes the first saRNA vaccine ever approved for human use. HDT Bio's vaccine is currently undergoing clinical trials in the U.S., Brazil, and South Korea.

“Our saRNA vaccine is a game changer,” said HDT Bio CEO Steve Reed. “This technology can stimulate an immune response with a dose of up to 20 times lower than current vaccines, which enhances safety, lowers costs, and increases production speed. Also, the vaccine can be transported at refrigerator temperature, or even freeze-dried and shipped without temperature control. The combination of lower cost and higher stability will allow HDT Bio to take a truly global distribution approach.”