Johnson & Johnson files for EU vaccine approval

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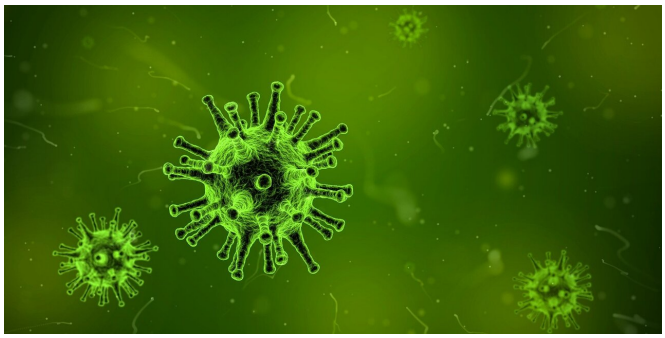

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US pharmaceutical giant Johnson & Johnson has applied for authorisation for its coronavirus vaccine in the EU with a decision possible by the middle of March, Europe's drugs regulator said Tuesday.

The single-shot vaccine would be the fourth jab to be approved for use across the 27-nation European Union if it gets the green light from the Amsterdam-based European Medicines Agency.

"EMA has received an application for conditional marketing authorisation for a COVID-19 vaccine developed by Janssen-Cilag International", J&J's European subsidiary, the watchdog said.

The regulator "could issue an opinion by the middle of March 2021, provided the company's data on the vaccine's efficacy, safety and quality are sufficiently comprehensive and robust."

With delays to deliveries of three already-authorised vaccines by AstraZeneca, Pfizer/BioNTech and Moderna, the EMA is under pressure from European capitals to speed more into service.

European Commission chief Ursula von der Leyen hailed the news and said Brussels "will be ready to grant authorisation as soon as EMA delivers a positive scientific opinion."

"More safe and effective vaccines are on their way," she added.

J&J's vaccine has been under a "rolling review" by the EMA since December 1.

Two other vaccines are under rolling review with the EMA: by German firm CureVac and US biotech firm Novavax.

The European Commission has ordered 200 million doses of the Johnson & Johnson vaccine with an option for 200 million more. It says 100 million doses should be delivered by June if it is approved.

Johnson & Johnson has asked US regulators for emergency authorisation for the United States.

The vaccine offers logistical advantages because it does not require two doses and the deep-freeze storage needed for some already-approved shots.

J&J announced in late January that clinical trials showed the vaccine was overall 66 percent effective and 85 percent effective in preventing severe forms of the disease.

But it did not protect as well against a highly transmissible virus variant first identified in South Africa, which is spreading rapidly around the world

The J&J shot uses a common-cold causing adenovirus, modified so it cannot replicate, as a "vector" to shuttle genetic instructions into human cells, telling them to create a protein of the coronavirus.

This trains the immune system to be ready for the live coronavirus.