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J&J Secures Additional $1 Billion in Funding for COVID-19 Vaccine

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Johnson & Johnson secured more than $1 billion in additional funding for its COVID-19 vaccine research through an expansion of its partnership with the **Biomedical Advanced Research and Development Authority** (BARDA), a division of the U.S. Department of Health and Human Services.

Over the weekend, life sciences giant J&J said BARDA will **provide an additional $454 million** to the Phase III ENSEMBLE trial evaluating the company's investigational vaccine for the novel coronavirus. These funds are on top of additional funding of more than $1 billion the company previously received

from the federal government for the development of the COVID-19 vaccine candidate. The federal dollars will be paired with $604 million invested by J&J pharmaceutical subsidiary Janssen. The finances will be used to continue the late-stage study of the company's single-dose vaccine treatment in up to 60,000 volunteers across the globe.

J&Js experimental vaccine JNJ-78436735 began Phase III testing in September. However, in October, the trial was briefly **paused** following an "unexplained illness" in a trial participant. The trial resumed later that month after the independent Data Safety and Monitoring Board recommended the trial **resume**. The company said there was no evidence that its experimental vaccine was the cause of the unexplained illness in the patient.

Only weeks before the trial was paused, J&J announced **encouraging data** from an interim analysis of its Phase I/IIa study. The data showed a single dose of JNJ-78436735

induced a strong neutralizing antibody response in nearly all participants and was well-tolerated. Johnson & Johnson said the presence of antibodies to COVID-19 was observed in 99% of participants aged 18-55 years of age. Also, 98% of participants were positive for neutralizing antibodies against SARS-CoV-2, the virus that causes COVID-19, at day 29 post-vaccination.

J&J Chief Scientific Officer Paul Stoffels touted the latest investment from BARDA as a sign of the federal government's confidence in the vaccine candidate.

"We greatly value the ongoing confidence and support of our investigational COVID-19 vaccine candidate development program. Combined with our own significant investment, this agreement has enabled our vital research and development and underscores the importance of public-private partnerships to tackle the worldwide COVID-19 pandemic," Stoffels said in a statement.

J&J's vaccine news followed the announcement of **90% efficacy** at an interim analysis from Pfizer and its development partner BioNTech for its experimental mRNA vaccine candidate. The two companies anticipate seeking Emergency Use Authorization by the end of November. Moderna, which is also developing

an mRNA vaccine against COVID-19 announced **94% efficacy** following an interim analysis of its Phase III data this morning.

If J&J's vaccine becomes an approved preventative medication, it will have some advantages over the two mRNA candidates. Both mRNA vaccines require two doses about 28 days apart, while Johnson & Johnson's vaccine is a single dose. Additionally, the mRNA vaccines face significant **logistical hurdles** due to the cold storage required to preserve the medication. The J&J vaccine is believed to remain stable for two years at -20 degrees C and at least three months at 2-8 degrees C.

J&J's Ad26.COV2-S is an investigational SARS-CoV-2 vaccine built using the AdVac recombinant technology. The AdVac and PER.C6 technology have been used to develop and manufacture the company's Ebola vaccine as well as to develop its vaccine candidates for Zika, RSV and HIV.

In addition to the single-dose regimen, this morning, J&J announced it was initiating a second Phase III study assessing its vaccine candidate in **a two-dose regimen**. The company said it wants to ensure that patients who receive its vaccine receive the highest levels of protection, which prompted the latest study.

As Johnson & Johnson moves through clinical testing of its vaccine candidate, the company has been laying the groundwork for potential mass manufacturing of the preventative medication. Earlier this month, the life sciences giant inked a **five-year manufacturing deal** with Emergent BioSolutions.

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