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DHSS issues statewide order for Janssen COVID-19 vaccine administration

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JEFFERSON CITY, MO -- Today, Dr. Randall Williams, director of the Missouri Department of Health and Senior Services (DHSS) signed the **standing order (https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/so-janssen-vaccine.pdf)** for Janssen Biotech, Inc. COVID-19 vaccine administration after review of preliminary recommendations made today by the Centers for Disease Control and Prevention (CDC).

"We are incredibly appreciative to be receiving additional vaccines in Missouri, and we remain committed to making it available for a variety of vaccinators to get it into arms as efficiently as possible," said Williams. "The order issued today will authorize approved vaccinators to vaccinate using the Janssen vaccine as soon as they receive it from our federal partners."

Janssen's single-dose COVID-19 vaccine was authorized for emergency use for the prevention of COVID-19 in those 18 or older by the U.S. Food and Drug Administration on Feb. 27. It is the third COVID-19 vaccine authorized for use in the United States. Approximately 50,000 doses are now expected in Missouri this week.

"During these initial weeks that the Janssen vaccine is available, we will be allocating it across all current delivery channels providing vaccinations for Missourians," said Governor Mike Parson. "Hospitals, local public health agencies, federally-qualified health centers and mass vaccination clinics will be included in the plan to distribute the Janssen vaccine so local providers can help determine which populations could be best served with a single-dose regimen."

The effectiveness data to support the Emergency Use Authorization (EUA) include an analysis of 39,321 participants in the ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the U.S. who did not have evidence of SARS-CoV-2 infection prior to receiving the vaccine. More than half of the participants in the study received the vaccine. At least 28 days after vaccination, the vaccine was 85% effective in preventing severe or critical COVID-19.

Janssen's data shows while it is effective against asymptomatic infection, it is even more effective against more

severe forms of the disease.

"The best COVID-19 vaccine you can get is the one you are able to get the soonest after becoming eligible," said Williams. "The scientific evidence shows that the Janssen vaccine does a great job at preventing hospitalizations and deaths which is the main goal for COVID-19 vaccines."

Different from Pfizer and Moderna's mRNA vaccines, the Janssen COVID-19 vaccine is **manufactured using a specific type of virus (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html)** called adenovirus type 26 (Ad26). The vaccine uses Ad26 to deliver a piece of the DNA, or genetic material that is used to make the distinctive "spike" protein of the SARS-CoV-2 virus. While adenoviruses are a group of viruses that are relatively common, Ad26, which can cause cold symptoms and pink eye, has been modified for the vaccine so that it cannot replicate in the human body to cause illness. After a person receives this vaccine, the body can temporarily make the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

Reported side effects include pain or redness/swelling at the injection site, tiredness, headache, muscle pain, nausea and fever. Those who should not get the Janssen COVID-19 vaccine are those under age 18 and those who have had a severe allergic reaction to any ingredient of the vaccine.

Ingredients of the Janssen COVID-19 vaccine include recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride. Individuals who question their ability to receive this vaccine should consult with their medical provider.

These precautions and contraindications are subject to change following the impending final release of the Advisory Committee on Immunization Practices and CDC recommendations.

While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for **how to protect yourself and others (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html)** will offer the best protection from getting and spreading COVID-19.

Residents and providers are encouraged to learn more about COVID-19 vaccines in Missouri at **www.MOStopsCovid.com (http://www.mostopscovid.com/)**.

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Additional Janssen Resources:

- **Letter of Authorization (https://www.fda.gov/media/146303/download)**
- **Fact Sheet for Healthcare Providers Administering Vaccine (https://www.fda.gov/media/146304/download)**
- **Fact Sheet for Recipients and Caregivers (https://www.fda.gov/media/146305/download)**
- **Press Release (https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine)**

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