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Media Statement

2 April, 2021

Johnson & Johnson Expands Phase 2a Clinical Trial of COVID-19 Vaccine Candidate to Include Adolescents

Expansion of ongoing trial to include adolescents 12-17 years of age[1] reflects commitment to people of all ages affected by pandemic

Johnson & Johnson (the Company) has begun vaccinating adolescent participants in the ongoing Phase 2a clinical trial for its COVID-19 vaccine candidate, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson.

"The COVID-19 pandemic has had a profound impact on adolescents, not just with the complications of the disease, but with their education, mental health, and wellbeing," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "It is vital that we develop vaccines for everyone, everywhere, to help combat the spread of the virus with the goal to return to everyday life."

The randomised, double-blind, placebo-controlled Phase 2a study (VAC31518COV2001)[1] has been ongoing since September 2020, and was initially designed to evaluate the safety, reactogenicity (expected reactions to vaccination, such as swelling or soreness) and immunogenicity (ability to induce an immune response) of single-dose and two-dose regimens of the Johnson & Johnson COVID-19 vaccine candidate in healthy adults aged 18 to 55 years, as well as adults aged 65 years and older.[1] The study is now including adolescents 12 to 17 years of age.[1]

Among the study's goals are to evaluate reactogenicity and immunogenicity of two dose levels of the vaccine candidate, and to evaluate potential vaccination schedules at one, two and three-month intervals in two-dose vaccine regimens.[1]

"Our COVID-19 vaccine candidate development programme is designed to deliver on our commitment to protect people of all ages from this pandemic," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "In addition to expanding this ongoing study to include adolescents, we are in discussions with health authorities and are hard at work to initiate studies in pregnant women, and children under 12 in the near future."

The Johnson & Johnson COVID-19 vaccine candidate will initially be tested in a small number of adolescents aged 16-17 years. Following the review of initial data in this Phase 2a trial, the study will be expanded to a larger group of younger adolescents in a stepwise approach.[2]

This trial is currently enrolling participants in Spain and the United Kingdom; enrolment will commence shortly in the United States, the Netherlands and Canada, with Brazil and Argentina to follow.

Janssen's COVID-19 vaccine candidate

The Company's Janssen COVID-19 vaccine leverages the AdVac® vaccine platform, a proprietary technology that was also used to develop and manufacture Janssen's

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European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.[3]

Research and development activities for the Company's COVID-19 vaccine, including the delivery of doses to the U.S., have been funded in part with federal funds from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

Johnson & Johnson has worked with BARDA since 2015 on innovative solutions for influenza; chemical, biological, radiation and nuclear threats; and emerging infectious diseases such as Ebola.[4]

Regulatory filings
The Johnson & Johnson single-shot COVID-19 vaccine was granted Emergency Use Listing from the World Health Organization (WHO) on March 12,[5] Conditional Marketing Authorisation from the European Commission on March 11[6] and Emergency Use Authorisation by the U.S. Food and Drug Administration on February 27, 2021.[4] The single-shot COVID-19 vaccine has also been granted Interim Order authorisation in Canada,[7] and additional rolling submissions have been initiated in several countries worldwide.

For more information on the Company's multi-pronged approach to helping combat the COVID-19 pandemic, visit: https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines/respiratory-infections/covid-19.

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Authorised Use
The EMA has recommended granting a conditional marketing authorisation for COVID-19 Vaccine Janssen to prevent COVID-19 in people from 18 years of age.[8]

Important Safety Information[9]
WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?[9]
Tell the vaccination provider about all of your medical conditions, including if you:
· have ever had a severe allergic reaction after injection of any other vaccine
· have ever fainted following any needly injection
· you have a severe infection with a high temperature (over 38C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold
· you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots)
· your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines).

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?[9]
You should not get the Janssen COVID-19 Vaccine if you:
· you are allergic to the active substance or any of the other ingredients of this vaccine

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HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?[9]
Your doctor, pharmacist or nurse will inject the vaccine into the muscle – usually in the upper arm.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?[9]
Like all vaccines, COVID-19 Vaccine Janssen can cause side effects, although not everybody gets them. Most of the side effects occur in the 1 or 2 days of getting the vaccination.

Get urgent medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, please seek immediate medical care. Afterwards you can find out how to report adverse reactions at: www.janssen.com/sites/www_janssen_com/files/janssen_site_q3_2020.pdf.

For more information, the EMA Summary of Product Characteristics is available at: www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf.

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Cautions Concerning Forward-Looking Statements

This statement contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of a potential preventive vaccine for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and

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"Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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