This press release has been adapted for audiences in the EMEA region

News Release

Media contacts:

Jake Sargent
+1 732-524-1090
JSargen3@its.jnj.com

Seema Kumar
+1 908-405-1144
SKumar10@its.jnj.com

Trish Garrity
+1 202-951-0265
TGarrity@its.jnj.com

Investor relations:
Jennifer McIntyre
+1 732-524-3922

Johnson & Johnson Ebola Vaccine Regimen Demonstrated Robust and Durable Immune Response in Adults and Children in Data Published in *The Lancet Infectious Diseases*

Data show the vaccine regimen induced neutralising antibody responses in nearly all participating adults and children 21 days after the second dose[1,2]

Adults receiving booster shots two years after initial vaccination regimen showed strong immune responses[1]

The data support the potential prophylactic use of the Johnson & Johnson Ebola vaccine regimen to protect adults and children[1,2]

NEW BRUNSWICK, N.J., 13 September 2021 – Data from two papers published in *The Lancet Infectious Diseases* demonstrated that the Johnson & Johnson (the Company) Ebola vaccine regimen, Zabdeno® (Ad26.ZEBOV) and Mvabea® (MVA-BN-Filo), generated robust humoral (antibody) immune responses in adults and children (ages 1-17) with the immune responses persisting in adults for at least two years.[1,2] The data also showed that booster vaccination with Ad26.ZEBOV, administered to adults two years after the initial vaccination, induced a strong anamnestic (immune) response within seven days.[1] These findings support the potential prophylactic use of the vaccine regimen,[1,2] which was developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) in collaboration with Bavarian Nordic A/S, and was granted Marketing Authorisation by the European Commission in July 2020[3] and Prequalification from the World Health Organization (WHO) in April 2021.[4]

The data is from the Phase 3 EBOVAC-Salone clinical study[5] and showed that the vaccine regimen was well-tolerated and induced antibody responses to the *Zaire ebolavirus* species 21 days after the second dose in 98 percent of all participants.[1] There were no safety signals of concern.[1]

This press release has been adapted for audiences in the EMEA region

"These peer-reviewed data support the prophylactic use of the Johnson & Johnson Ebola vaccine regimen to protect people at risk of Ebola, which is essential to our vision of preventing Ebola outbreaks before they can begin," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson. "Recent and ongoing outbreaks in Africa underscore that the threat of Ebola is not going away, which is why we collaborated to develop a vaccine regimen capable of inducing long-term immunity against Ebola and are now working to ensure that it is accessible to people in need."

The EBOVAC-Salone study was conducted in Sierra Leone and is the first to assess the safety and tolerability of the Johnson & Johnson Ebola vaccine regimen in adults in a region affected by the 2014-2016 West African Ebola outbreak.[5,6] It is also the first study evaluating the Johnson & Johnson Ebola vaccine regimen in a randomised, double-blind, controlled trial in a paediatric population.[5]

Phase 3 study design (NCT02509494)[5]
This Phase 3 study was designed to gather information on the safety and immunogenicity of the two-dose, heterologous (containing different vaccine components administered at different timepoints) Johnson & Johnson Ebola vaccine regimen.[5] In this regimen, Ad26.ZEBOV was administered intramuscularly as the first dose vaccination followed 56 days later by MVA-BN-Filo as the second dose vaccination.[5]

The study was divided into two stages. In stage one, 43 adults aged 18 years or older were vaccinated to gain information about the safety and immunogenicity of the two-dose vaccine regimen.[1,5] In stage two, 400 adults and 576 children or adolescents (including 192 in each of the three age cohorts of 1-3, 4-11 and 12-17 years of age) were vaccinated.[1,2,5] Consenting adults participating in stage one of the study were administered a booster dose of A26.ZEBOV two years after the first dose.[1,5]

The study was conducted at three clinics in Kambia District, Sierra Leone.[1,2] Long term follow-up of the study participants is underway.

Johnson & Johnson's commitment to Ebola & pandemic preparedness
Johnson & Johnson is one of the few innovative healthcare companies in the world today that is actively advancing science across multiple disease areas with the aim of strengthening public health.

The Company accelerated the development of its Ebola vaccine regimen in 2014 in response to the 2014-2016 outbreak in West Africa, which caused more than 11,000 deaths.[6] In 2019, in response to the second-worst outbreak, which took place 2018-2020 in the Democratic Republic of the Congo (DRC),[7] Johnson & Johnson announced it would provide its Ebola vaccine regimen to assist immunisation efforts in the affected region and in the neighbouring country, Rwanda, through the UMURINZI vaccination campaign.[8,9] This marked the first widespread deployment of Ebola vaccines in an outbreak setting. The UMURINZI campaign, which is led by the Rwandan Ministry of Health, recently achieved its endpoint of fully vaccinating more than 200,000 individuals against Ebola.[10]

In May 2021, Johnson & Johnson announced it would donate thousands of Ebola vaccine regimens in support of a WHO early access clinical programme launched in response to an outbreak in Guinea and aimed at preventing Ebola in West Africa.[11] The programme began by vaccinating health workers, other frontline workers and others at increased risk of exposure to the Ebola virus in Sierra Leone.[11]

In June 2021, Johnson & Johnson welcomed a new recommendation by the Strategic Advisory Group of Experts (SAGE) on Immunization for the WHO that supports the use of

This press release has been adapted for audiences in the EMEA region

the Johnson & Johnson Ebola vaccine regimen both during outbreaks for individuals at some risk of Ebola exposure, and preventively, in the absence of an outbreak, for national and international first responders in neighbouring areas or countries where an outbreak might spread.[12]

To date, more than 250,000 individuals participating in clinical trials and vaccination initiatives have received at least the first dose of the Johnson & Johnson Ebola vaccine regimen, including 200,000 who have been fully vaccinated.[13]

Johnson & Johnson Ebola vaccine regimen
The European Commission-approved and World Health Organization-Prequalified Johnson & Johnson preventive Ebola vaccine regimen, Zabdeno® (Ad26.ZEBOV) and Mvabea® (MVA-BN-Filo), utilises a non-replicating viral vector strategy in which viruses – in this case adenovirus serotype 26 (Ad26) and Modified Vaccinia Virus Ankara (MVA) – are genetically modified so that they cannot replicate in human cells.[1,2] In addition, these vectors carry the genetic code of several Ebola virus proteins in order to trigger an immune response.[1,2] The Ebola vaccine regimen was developed and is manufactured using Janssen's proprietary AdVac® technology.[14]

Johnson & Johnson's Ebola vaccine regimen originates from a collaborative research programme with the NIH and received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases, part of NIH, under Contract Number HHSN272200800056C. Further funding for the Ebola vaccine regimen has been provided in part with federal funds from the Office of the Assistant Secretary for Preparedness and Response, BARDA under Contract Numbers HHSO100201700013C and HHSO100201500008C.

The IMI provided funding through the IMI Ebola+ Programme to support a number of consortia that initiated multiple clinical trials and other vaccine development activities. The consortia funded by the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking are EBOVAC1 (grant nr. 115854), EBOVAC2 (grant nr. 115861), EBOVAC3 (grant nr. 800176), EBOMAN (grant nr. 115850) and EBODAC (grant nr. 115847). This Joint Undertaking receives support from the EU's Horizon 2020 Framework Programme for Research and Innovation and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Johnson & Johnson also acknowledges its many strategic partners in the ongoing global clinical programme for the vaccine regimen, including Bavarian Nordic A/S, Centre Muraz, Coalition for Epidemic Preparedness Innovations (CEPI), College of Medicine and Allied Health Sciences (COMAHS, University of Sierra Leone), Democratic Republic of the Congo Ministry of Public Health, Republic of Rwanda Ministry of Health and Rwanda Biomedical Center, Emory University's Project San Francisco (Kigali) / Center for Family Health Research, Emory University, Epicentre, Grameen Foundation, Inserm, Inserm Transfert, Institut National de Recherce Biomédicale (INRB), London School of Hygiene & Tropical Medicine (LSHTM), Médecins Sans Frontières (MSF), Rinda Ubuzima, Sierra Leone Ministry of Health and Sanitation, Uganda Virus Research Institute (UVRI), Université de Kinshasa (UNIKIN), University of Antwerp, University of Oxford, Walter Reed Army Institute of Research (WRAIR), World Health Organization, World Vision Ireland, Wellcome Trust, Vibalogics, and all the people who have participated in the Ebola vaccine clinical trials.

Learn more at https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines/pathogens-global-concern.

###

This press release has been adapted for audiences in the EMEA region

IMPORTANT SAFETY INFORMATION

What you need to know before you or your child are given Zabdeno® suspension for injection (Ad26.ZEBOV-GP [recombinant])[3]

To make sure that the vaccination course is suitable for you or your child, it is important to tell your doctor, pharmacist or nurse if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor, pharmacist or nurse to explain.

Do not have the vaccine if

- you or your child have ever had a severe allergic reaction to any of the active substances or any of the other ingredients listed in section 6 of the product leaflet.

If you are not sure, talk to your doctor, pharmacist or nurse before you are given the vaccine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Ad26.ZEBOV if you or your child:

- have ever had a severe allergic reaction after any other vaccine injection,
- have ever fainted, after having an injection,
- have a problem with bleeding or you bruise easily,
- currently have a fever or an infection,
- are taking medicines that weaken the immune system, such as high-dose corticosteroids (such as prednisone) or chemotherapy (cancer medicines),
- have a weak immune system – for example, due to HIV infection or an illness that runs in the family ('genetic disorder').

If any of the above apply to you or your child (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Ad26.ZEBOV.

If you are at high risk of being in contact with the Ebola virus, a booster vaccination with Ad26.ZEBOV may be recommended for you or your child. Talk to your doctor, pharmacist or nurse if this applies to you or your child.

If you or your child only has one of the vaccines, Ad26.ZEBOV or MVA-BN-Filo, it may give less protection from Ebola virus disease than having a course of both vaccines.

As with all vaccines, the Ad26.ZEBOV and MVA-BN-Filo 2-dose course of vaccination may not fully protect everyone from Ebola virus disease and it is not known how long you will be protected.

Possible side effects
Like all medicines, this vaccine can cause side effects, although not everybody gets them. Most of the side effects happen within 7 days of getting the injection.

<u>The following side effects can happen in adults.</u>
Very common (may affect more than 1 in 10 people):

- pain, warmth, or swelling where the injection is given
- feeling very tired
- headache or muscle ache
- joint pain
- chills

Common (may affect up to 1 in 10 people)

- being sick (vomiting)
- itching where the injection is given
- generalised itching
- fever

Uncommon (may affect up to 1 in 100 people):
- feeling dizzy
- redness and skin hardness where the injection is given

The following side effects can happen in children and young people 1 to 17 years of age.
Very common (may affect more than 1 in 10 people)
- pain where the injection is given
- decreased activity
- decreased appetite
- feeling irritable
- feeling very tired

Common (may affect up to 1 in 10 people):
- swelling, itching or redness where the injection is given
- being sick (vomiting)
- feeling sick (nausea)
- joint pain
- muscle ache
- fever

Most of these side effects are mild to moderate in intensity and are not long-lasting.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, please seek immediate medical care. Afterwards you should report adverse reactions to Janssen in your region. Contact details can be found here:
www.janssen.com/sites/www_janssen_com/files/janssen_site_q3_2020.pdf.

For more information on Zabdeno® (Ad26.ZEBOV), the EMA Summary of Product Characteristics is available at:
https://www.ema.europa.eu/en/documents/product-information/zabdeno-epar-product-information_en.pdf.

IMPORTANT SAFETY INFORMATION[15]

What you need to know before you or your child are given Mvabea® suspension for injection (MVA-BN-Filo [recombinant])

To make sure that the vaccination course is suitable for you or your child, it is important to tell your doctor, pharmacist or nurse if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor, pharmacist or nurse to explain.

Do not have the vaccine if:
- you or your child have ever had a severe allergic reaction to any of the active substances or any of the other ingredients listed in section 6 of the product leaflet.
- you or your child have ever had a severe allergic reaction to chicken or eggs or an antibiotic known as 'gentamicin'.

If you are not sure, talk to your doctor, pharmacist or nurse before you are given the vaccine.

This press release has been adapted for audiences in the EMEA region

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Mvabea if you or your child:

- have ever had a severe allergic reaction after any other vaccine injection,
- have ever fainted, after having an injection,
- have a problem with bleeding or you bruise easily,
- currently have a fever or an infection,
- are taking medicines that weaken the immune system, such as high-dose corticosteroids (such as prednisone) or chemotherapy (cancer medicines),
- have a weak immune system – for example, due to HIV infection or an illness that runs in the family ('genetic disorder').

If any of the above apply to you or your child (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Mvabea.

If you are at high risk of being in contact with the Ebola virus, a booster vaccination with Zabdeno may be recommended for you or your child. Talk to your doctor, pharmacist or nurse if this applies to you or your child.

If you or your child only have one of the vaccines, Zabdeno or Mvabea, it may give less protection from Ebola virus disease than having a course of both vaccines.

As with all vaccines, the Zabdeno and Mvabea 2-dose course of vaccination may not fully protect everyone from Ebola virus disease and it is not known how long you will be protected.

Possible side effects
Like all medicines, this vaccine can cause side effects, although not everybody gets them. Most of the side effects happen within 7 days of getting the injection.

<u>The following side effects can happen in adults.</u>
Very common (may affect more than 1 in 10 people)

- pain, warmth, or swelling where the injection is given
- feeling very tired
- muscle ache
- joint pain

Common (may affect up to 1 in 10 people)

- being sick (vomiting)
- itching where the injection is given

Uncommon (may affect up to 1 in 100 people)

- redness and skin hardness where the injection is given
- generalised itching

<u>The following side effects can happen in children and young people 1 to 17 years of age.</u>
Very common (may affect more than 1 in 10 people)

- pain where the injection is given
- feeling very tired

Common (may affect up to 1 in 10 people)

- swelling, itching or redness where the injection is given
- fever
- chills
- muscle ache
- joint pain

This press release has been adapted for audiences in the EMEA region

Most of these side effects are mild to moderate in intensity and are not long-lasting.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, please seek immediate medical care. Afterwards you should report adverse reactions to Janssen in your region. Contact details can be found here:
www.janssen.com/sites/www_janssen_com/files/janssen_site_q3_2020.pdf.

For more information Mvabea® (MVA-BN-Filo), the EMA Summary of Product Characteristics is available at:
https://www.ema.europa.eu/en/documents/product-information/mvabea-epar-product-information_en.pdf.

About Johnson & Johnson
At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA.

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Janssen Research & Development, LLC and Janssen Vaccines and Prevention B.V. are members of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a program related to the Johnson & Johnson Ebola Vaccine Regimen. 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

This press release has been adapted for audiences in the EMEA region

"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.

REFERENCES

1 Ishola D., Manno D., et al. Safety and long-term immunogenicity of the two-dose heterologous Ad26.ZEBOV and MVA-BN-Filo Ebola vaccine regimen in adults in Sierra Leone: a combined open-label, non-randomised stage 1, and a randomised, double-blind, controlled stage 2 trial. Lancet Infect Dis 2021. https://doi.org/10.1016/S1473-3099(21)00125-0

2 Afolabi M O., Ishola D., Manno D., et al. Safety and immunogenicity of the two-dose heterologous Ad26.ZEBOV and MVA-BN-Filo Ebola vaccine regimen in children in Sierra Leone: a randomised, double-blind, controlled trial. Lancet Infect Dis 2021. https://doi.org/10.1016/S1473-3099(21)00128-6.

3 European Medicines Agency. Zabdeno. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/zabdeno. Last accessed: October 2021.

4 Ebovac projects. Vaccine development. Available at: https://www.ebovac.org/sample-page/vaccine-development/. Last accessed: October 2021.

5 Clinicaltrials.gov. Staged Phase 3 Study to Assess the Safety and Immunogenicity of Ebola Candidate Vaccines Ad26.ZEBOV and MVA-BN-Filo (EBOVAC-Salone) NCT02509494. Available at: https://clinicaltrials.gov/ct2/show/NCT02509494. Last accessed: October 2021.

6 The Centers for Disease Control and Prevention. Years of Ebola Virus Disease Outbreaks March 8, 2019. Available at: https://www.cdc.gov/vhf/ebola/history/chronology.html. Last accessed: October 2021.

7 World Health Organization. 2020. Ebola Health Update. Available at: https://www.who.int/emergencies/diseases/ebola/drc-2019. Last accessed: October 2021.

8 Johnson & Johnson. Johnson & Johnson Announces Donation of up to 500,000 Regimens of Janssen's Investigational Ebola Vaccine to Support Outbreak Response in Democratic Republic of the Congo (DRC). Available at: https://www.jnj.com/johnson-johnson-announces-donation-of-up-to-500-000-regimens-of-janssens-investigational-ebola-vaccine-to-support-outbreak-response-in-democratic-republic-of-the-congo-drc. Last accessed: October 2021.

9 Johnson & Johnson. Johnson & Johnson Announces Commitment to Support Republic of Rwanda's Preparedness Against Ebola Outbreak. Available at: https://www.jnj.com/johnson-johnson-announces-commitment-to-support-republic-of-rwandas-preparedness-against-ebola-outbreak. Last accessed: October 2021.

10 Janssen Data on File. UMURINZI campaign. 2021.

11 Johnson & Johnson. Johnson & Johnson Joins World Health Organization in Efforts to Prevent Spread of Ebola in West Africa. Available at: https://www.jnj.com/johnson-johnson-joins-world-health-organization-in-efforts-to-prevent-spread-of-ebola-in-west-africa. Last accessed: October 2021.

12 World Health Organization. Weekly epidemiological record. Available at: https://apps.who.int/iris/bitstream/handle/10665/341623/WER9622-eng-fre.pdf?sequence=1&isAllowed=y. Last accessed: October 2021.

13 Janssen Data on File. Ebola vaccine doses given. 2021.

14 Custers J et al. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. Vaccine. 2020;39(22):3081-3101.

[15] European Medicines Agency. Mvabea Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/mvabea-epar-product-information_en.pdf. Accessed October 2021.