BULLET BACKGROUND PAPER

ON

NOVAVAX COVID-19 VACCINE

PURPOSE

To summarize information on Novavax Coronavirus Disease 2019 (COVID-19) vaccine.

DISCUSSION

Vaccine Technology:

- Novavax COVID-19 vaccine is a recombinant protein subunit vaccine, which is different technology than other COVID-19 vaccines authorized/approved in the U.S.

  -- Recombinant protein vaccine technology is used in other vaccines. Examples include Hepatitis B, Human Papillomavirus, Herpes Zoster (Shingrix), and Influenza (Flublok).[1]

  -- Novavax COVID-19 vaccine targets SARS-CoV-2 (virus that causes COVID) spike protein.

- Novavax vaccine contains no live virus. It can neither replicate, nor cause COVID-19.

- This vaccine also uses an adjuvant (Matrix-M), added to enhance immune response and lower the amount and number of vaccine doses needed to reach protective immunity.[2] Matrix-M is a naturally occurring compound from the soapbark tree.[3]

- Novavax COVID-19 vaccine is administered intramuscularly and given as a 2-dose primary series at least 21 days apart.

Vaccine Production:

-- An insect cell line is used to produce the spike protein in large quantities.[4]

-- No human fetal cell lines are used to manufacture, test, or produce Novavax vaccine.

-- Pre-clinical work from Novavax compared the structure of its vaccine spike protein to existing literature where the spike protein was produced from fetal cells by non-Novavax researchers.[5]

[1] https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. Accessed 4 May 22.
[2] Children's Hospital of Philadelphia Vaccine Education Center. Vaccine Ingredients. https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients. Accessed 4 May 22.
[3] https://www.novavax.com/science-technology/matrix-m-adjuvant-technology. Accessed 4May22.
[4] https://www.novavax.com/science-technology/recombinant-protein-based-nanoparticle-vaccine-technology. Accessed 5 May 22.
[5] Bangaru, Sandhya, et al. "Structural analysis of full-length SARS-CoV-2 spike protein from an advanced vaccine candidate." *Science* 370.6520 (2020): 1089-1094.

Safety[6]:

- Reported side effects from Novavax COVID-19 vaccine clinical trials were similar in type and frequency to Pfizer and Moderna (mRNA) COVID-19 vaccines.

  -- Side effects were more common in 18-64 years of age and after the second dose.

  -- Typical side effects include: local (i.e. pain, redness, swelling at the site of injection) or systemic (i.e. fever, fatigue, headache).

  -- Heart inflammation (myocarditis/pericarditis) has been reported after Novavax COVID-19 vaccine similar to cases after mRNA COVID-19 vaccines.

    --- Chances of having heart inflammation are very low.

    --- Symptoms began within 10 days of vaccination. Seek prompt medical care if any concerning symptoms (such as chest pain, shortness of breath, heart pounding or fluttering) occur.

Effectiveness:

- In the clinical trial (25,500 total people), the vaccine was 90.4% effective in preventing mild, moderate, or severe COVID-19.[7]

- No cases of moderate or severe disease occurred in vaccine group, compared to 9 cases of moderate disease and 4 cases of severe COVID-19 in the placebo group.[8]

- While the clinical trial was performed before the emergence of the delta and omicron variants, antibody and memory cell responses to the Novavax COVID-19 vaccine are similar to mRNA vaccines suggesting similar performance against omicron and omicron sub-variants.[8,9]

CONCLUSION

Novavax COVID-19 vaccine offers an alternative vaccine choice to meet the Department's COVID vaccine mandate. Safety information and effectiveness from its clinical trial is similar to mRNA vaccines. Studies have consistently concluded that vaccinated people are much less likely to experience severe symptoms than people who are unvaccinated. Additional questions regarding this vaccine may be discussed with your healthcare provider.

[6] https://www.fda.gov/media/159898/download. Accessed 13 Jul 22.
[7] https://www.fda.gov/media/158912/download. Accessed 7 Jun 22.
[8] Bowen, John E., et al. "Omicron BA. 1 and BA. 2 neutralizing activity elicited by a comprehensive panel of human vaccines." *bioRxiv* (2022).
[9] Minka, S. O., and F. H. Minka. "A tabulated summary of the evidence on humoral and cellular responses to the SARS-CoV-2 Omicron VOC, as well as vaccine efficacy against this variant." *Immunology Letters* 243 (2022): 38-43.