

Janssen COVID-19 Vaccine

Janssen Pharmaceutical Companies of Johnson & Johnson

Advisory Committee on Immunization Practices

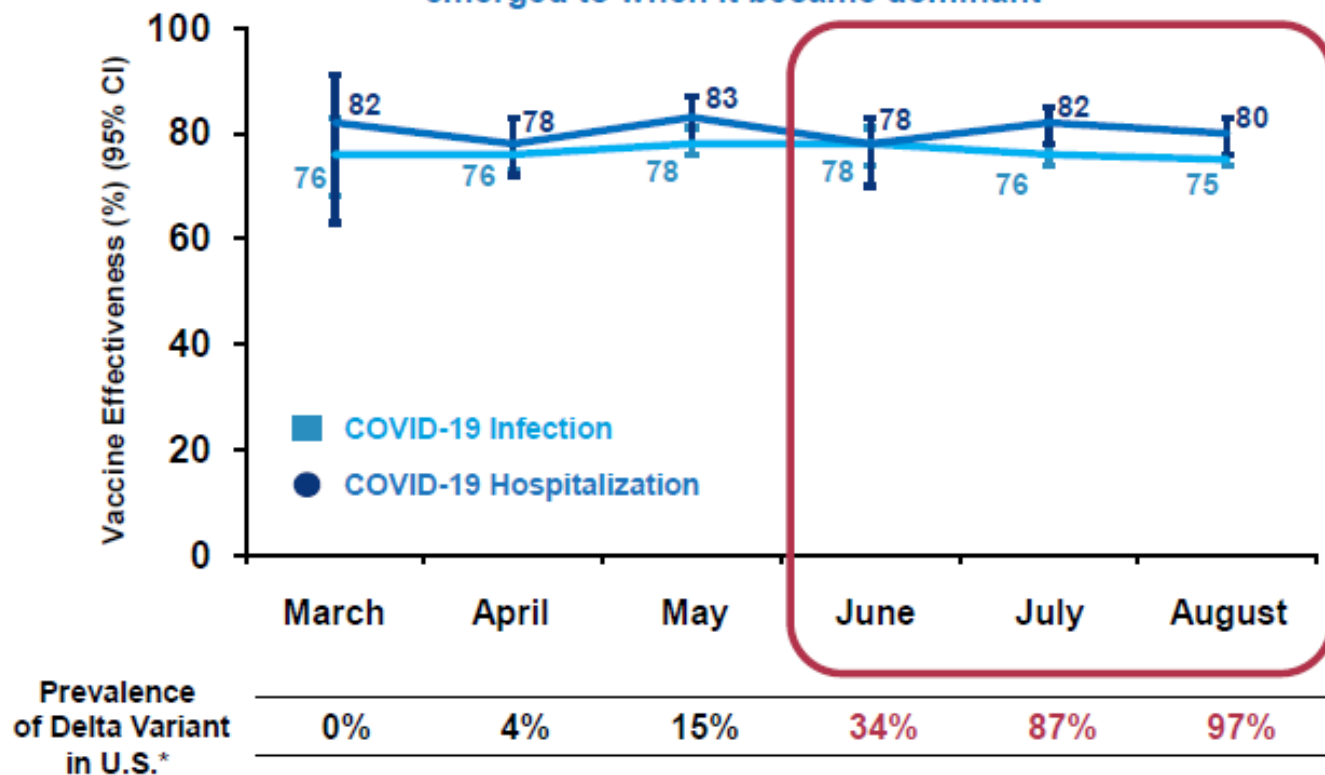
December 16, 2021

Penny Heaton, M.D.

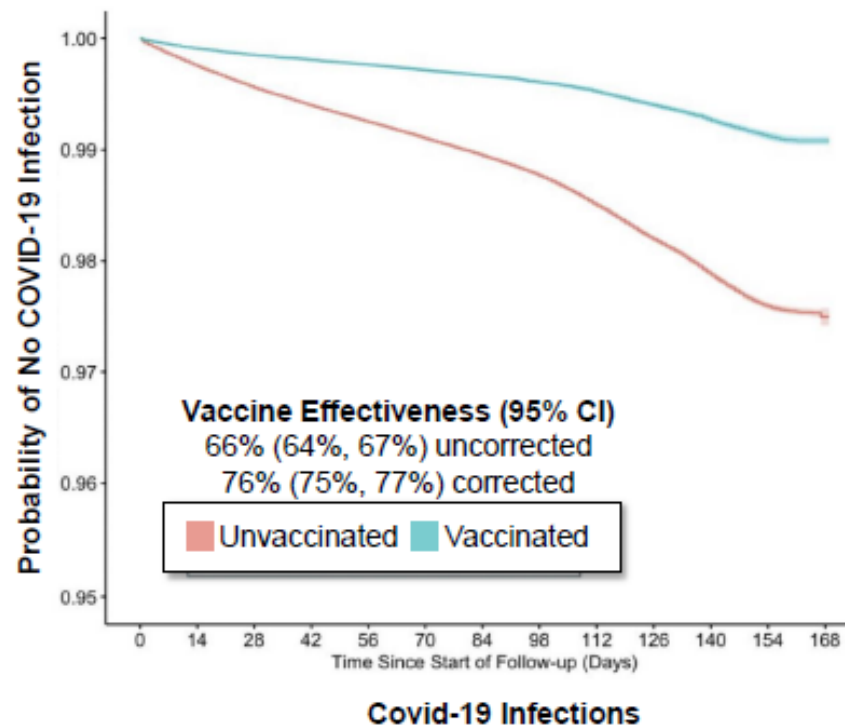
Global Therapeutic Area Head, Vaccines,
Janssen Research & Development

Month-Over-Month and Kaplan-Meier Plot Demonstrate Good and Durable Vaccine Effectiveness of Single-Dose Vaccine During July-August 2021, When Delta Dominant in US

Stable month-over-month vaccine effectiveness including when Delta emerged to when it became dominant



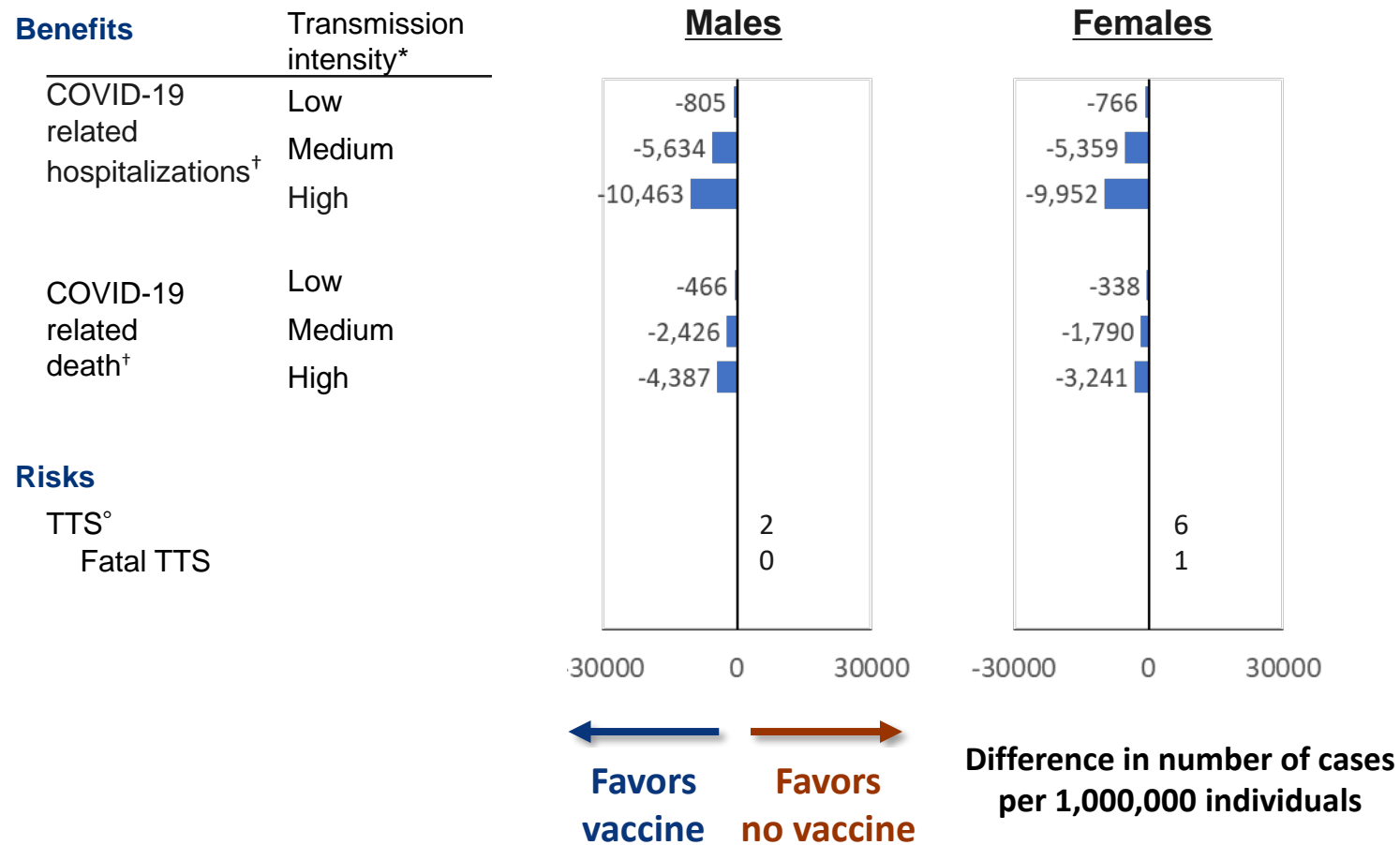
Time-to-event analyses show stable vaccine effectiveness during 183 days after vaccination



Median follow-up = 129 days; Schoenfeld residuals show proportional hazards throughout 183 days of follow-up (p=0.53);
 Uncorrected vaccine effectiveness was equally stable over 183 days

*www.nextstrain.org; **Corrected vaccine effectiveness estimates are presented in this slide – Month-over-Month uncorrected vaccine effectiveness estimates are 64%-69% for Covid-19 infections and 68%-75% for Covid-19 related Hospitalization

Benefit-Risk Assessment by Transmission Intensity and Gender: Janssen vaccine (primary dose) vs. no vaccine, Age 18+

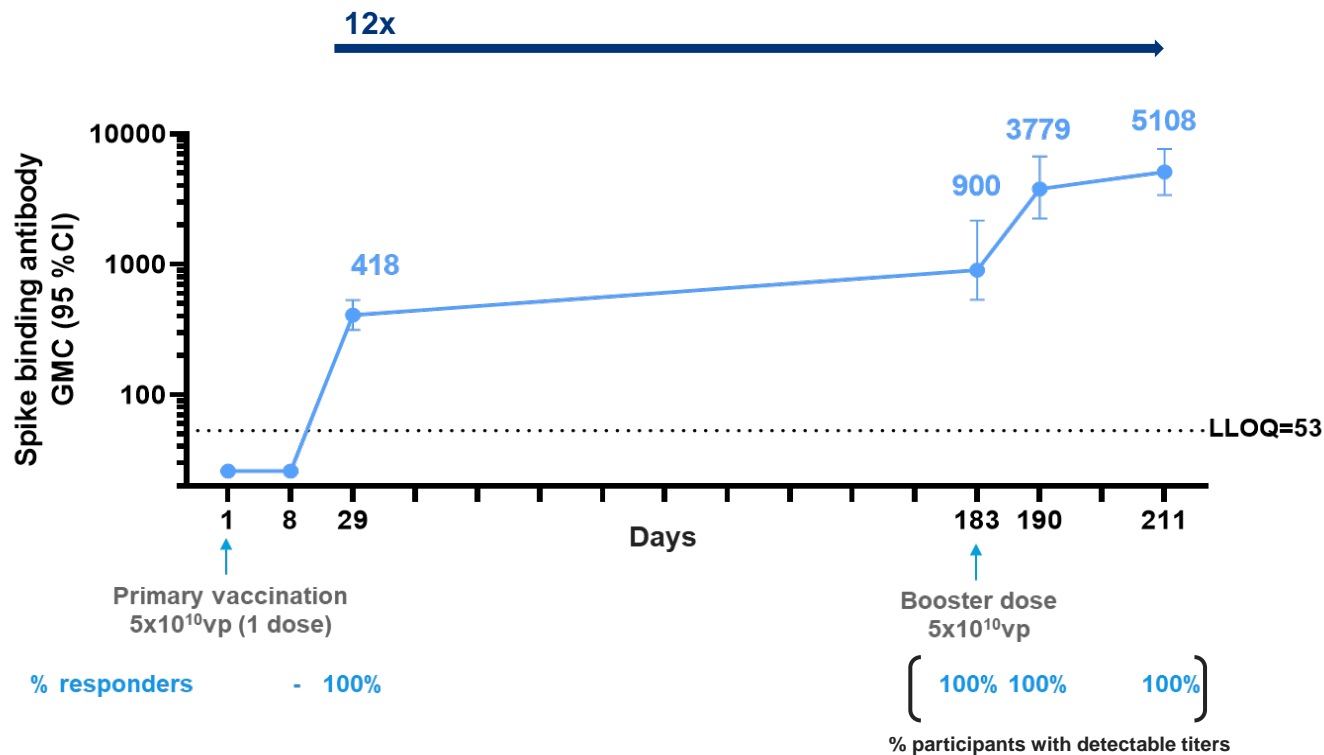


* Using rate of COVID-19 hospitalization as a proxy (low: week July 3, 2021; high: Jan 1, 2021; medium: Average of high and low)

† CDC hospitalization and death rates (<https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-S/9bhg-hcku> (Accessed Dec 13th); 2018 US census population; https://gis.cdc.gov/grasp/covidnet/covid19_3.html (Accessed Dec 13th))

° US TTS case reporting rates from CDC; assuming a 100% reporting rate; vaccine exposure numbers from CDC. Assumed 75.5% effectiveness for 12 months, risks are risk period adjusted

Phase 3 clinical study showed JNJ booster dose increased protection against symptomatic COVID-19 to 94% in the U.S

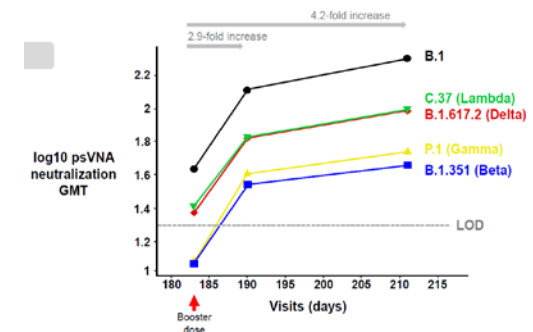


ENSEMBLE 2 study showed that a booster given ~56 days after primary vaccine provided:

- 100 percent protection against severe/critical COVID-19
- 75 percent protection against symptomatic (moderate to severe/critical) COVID-19 globally

A booster generated:

- 12-fold increase in antibodies when booster given at six months with breadth against variants



Not approved by FDA, Safety & Efficacy not established

Ab, antibody; BA₂, Spike binding antibodies; CI, confidence interval; ELISA, enzyme-linked immunosorbent assay; GMC, geometric mean concentrations; LLOQ, lower limit of quantification; ULOQ, upper limit of quantification; PD1, post-dose 1, vp, viral particles.

Sadoff J, et al. Available from: <https://www.medrxiv.org/content/10.1101/2021.08.25.21262569v1>. Accessed August 26, 2021

Humoral and Cellular Immune Responses after Ad26.COV2.S primary single dose Vaccination



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