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Volume 67 (Issue 1733)

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COVID-19 UPDATE

***m*NEXSPIKE – A New Moderna mRNA Vaccine for COVID-19**

The FDA has licensed *m*NEXSPIKE (Moderna), an mRNA vaccine, for prevention of COVID-19 in previously vaccinated adults ≥ 65 years old and in persons 12-64 years old who have a condition that puts them at high risk for severe outcomes from COVID-19.¹ *Spikevax*, the original Moderna mRNA COVID-19 vaccine, remains in production²; it is licensed for use in persons ≥ 12 years old and is available under an Emergency Use Authorization (EUA) for children 6 months to 11 years old.

THE NEW VACCINE – *Spikevax* and *Comirnaty*, the Pfizer/BioNTech mRNA COVID-19 vaccine, code for the whole spike protein of SARS-CoV-2. In contrast, *m*NEXSPIKE codes only for the N-terminal domain and the receptor-binding domain of the spike protein of the virus (Omicron variant JN.1); these domains are the targets of most effective anti-SARS-CoV-2 antibodies.³ The more targeted vaccine formulation allows for administration of a smaller mRNA dose (10 mcg vs 50 mcg with *Spikevax*).

CLINICAL STUDIES – Licensure of the new vaccine was based on the results of a randomized, observer-blind noninferiority trial (available as a presentation) in 11,454 persons ≥ 12 years old who had previously received a primary series of a COVID-19 vaccine (adults ≥ 18 years old had also received at least one booster dose). Subjects received a single dose of *m*NEXSPIKE or *Spikevax* (both bivalent formulations targeting the original and BA.4/5 Omicron strains of SARS-CoV-2). After a median follow-up of 8 months, the incidence of COVID-19 occurring ≥ 2 weeks after immunization was 9.9% with *m*NEXSPIKE and 10.8% with *Spikevax*; *m*NEXSPIKE met the prespecified criteria for noninferiority to *Spikevax* (relative efficacy 9.3% [95% CI -6.6% to 22.8%]). Results in adults ≥ 65 years old were similar to those in the overall population (relative vaccine efficacy 13.5% [95% CI -7.7% to 30.6%]). Seroresponse rates and geometric mean neutralizing antibody titer levels were higher with the new vaccine.⁴

ADVERSE EFFECTS – In the pivotal trial, adverse effects with *m*NEXSPIKE were similar to those with *Spikevax* and included injection-site pain, fatigue, headache, myalgia, arthralgia, chills, axillary swelling or tenderness, and nausea/vomiting. Serious adverse events occurred in 0.2% of patients who received *m*NEXSPIKE and in 0.3% of those who received *Spikevax*; no cases of myocarditis or pericarditis were reported with either vaccine.⁴

PREGNANCY AND LACTATION – The new vaccine has not been studied in pregnant women. In female rats, administration of an 80-mcg dose of *m*NEXSPIKE (8 times the recommended human dose) twice before mating and twice during gestation was not associated with impaired fertility or fetal harm. Administration of COVID-19 vaccines to nursing mothers is considered safe.⁵ The American College of Obstetricians and Gynecologists has recommended that all pregnant and breastfeeding women be vaccinated against COVID-19.⁶

DOSAGE, ADMINISTRATION, AND AVAILABILITY – The *m*NEXSPIKE vaccine is supplied in 10 mcg/0.2 mL prefilled syringes. The recommended dosage is a single 10-mcg intramuscular injection; *m*NEXSPIKE should not be given within 2 months after another COVID-19 vaccine. The syringes should be frozen during storage; after thawing, they can be kept in a refrigerator for up to 90 days or at room temperature for up to 24 hours (*Spikevax* can be refrigerated for up to 60 days or kept at room temperature for up to 12 hours after thawing). According to the manufacturer, *m*NEXSPIKE is expected to be available in the US for the 2025-2026 respiratory virus season.² ■

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