mNEXSPIKE® (COVID-19 vaccine, mRNA) – New drug approval

- On May 31, 2025, Moderna announced the FDA approval of mNEXSPIKE (COVID-19 vaccine, mRNA), for **active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)**.

  mNEXSPIKE is approved for use in individuals who have been previously vaccinated with any COVID-19 vaccine and are:

  - 65 years of age and older, or
  - 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

- The approval of mNEXSPIKE was based on results from a randomized, observer-blind, active-controlled study in participants aged 12 years and older. The primary efficacy population included 11,366 participants, and patients were randomized to mNEXSPIKE or a comparator vaccine, Spikevax®, Moderna's original COVID-19 vaccine.

  - mNEXSPIKE showed a 9.3% higher relative vaccine efficacy (rVE) compared to Spikevax, and in a descriptive sub-group analysis, a 13.5% higher rVE in adults aged 65 and older.

- Warnings and precautions for mNEXSPIKE include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.

- The most common adverse reactions (≥ 10%) with mNEXSPIKE use were:

  - Participants 12 years through 17 years of age: pain at the injection site, headache, fatigue, myalgia, axillary swelling or tenderness, chills, arthralgia, and nausea/vomiting
  - Participants 18 years through 64 years of age: pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, axillary swelling or tenderness, and nausea/vomiting
  - Participants 65 years of age and older: pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, and axillary swelling or tenderness.

- mNEXSPIKE is administered intramuscularly as a single 0.2 mL dose **at least 3 months after the last dose of COVID-19 vaccine**.

- Moderna expects to have mNEXSPIKE available for eligible populations for the 2025-2026 respiratory virus season, alongside Spikevax. mNEXSPIKE will be available as a 0.2 mL injectable suspension in a prefilled syringe.