FDA Authorizes Intradermal Vaccine, Streamlines Rules to Increase Monkeypox Treatment Access

As monkeypox cases spread in the US, the Food and Drug Administration (FDA) is working with the Centers for Disease Control and Prevention (CDC) and other partners to increase the availability of vaccines, therapeutics, and diagnostics, according to an agency statement. The FDA also has established a dedicated monkeypox website. In addition, the FDA issued Emergency Use Authorization (EUA) that allows for intradermal, rather than subcutaneous, injection of JYNNEOS, the only FDA-approved vaccine for preventing monkeypox. This allows smaller doses to be used for adults, effectively increasing by as much as 5-fold the number of patients who can be treated with existing vaccine supplies. Supporting the decision, the agency mentioned a 2015 clinical study that found similar immune responses among patients vaccinated either subcutaneously (beneath the skin) or intradermally (between the layers of the skin).

The EUA also allows JYNNEOS to be used by subcutaneous injection in patients younger than 18 years who are at high risk of monkeypox infection. The vaccine was approved in 2019 for preventing smallpox and monkeypox in high-risk patients older than 18 years.

On the diagnostics front, the only FDA- cleared monkeypox diagnostic test is being offered by the CDC and throughout many laboratories that include the CDC’s public health Laboratory Response Network and through 5 large commercial laboratories. The FDA also cleared additional equipment and test reagent production. Developed by the CDC, the test requires swabbing a monkeypox lesion to detect the virus. The FDA issued a safety advisory that sample swabs should be taken directly from a monkeypox lesion because samples taken from blood, saliva, or other sites may yield false results.

Although there is no approved monkeypox therapeutic, the FDA has made the antiviral tecovirimat, marketed as Tpoxx, available through a compassionate use program with the CDC. The drug was approved for treatment of smallpox based on its efficacy in animals and safety in humans, but its efficacy for monkeypox has not been tested in humans. Two human trials are planned, according to FDA, CDC, and National Institute of Allergy and Infectious Diseases authors writing in the *New England Journal of Medicine*.

First Therapy Targeting **ERBB2-Low** Breast Cancer Approved

The first therapy targeting patients with epidermal growth factor receptor 2 (ERBB2, formerly HER2)-low breast cancer, a newly defined subset of ERBB2-negative breast cancer, gained Food and Drug Administration (FDA) approval, the agency said in a statement. 

ERBB2-low describes a new subtype of breast cancer with some ERBB2 proteins on the cell surface but not enough to classify as **ERBB2-positive**, according to the FDA. 

Fam-trastuzumab-deruxtecan-nxki, marketed as Enhertu, was approved as an intravenous infusion for treating patients with unresectable or metastatic **ERBB2-low** breast cancer. It was approved earlier for patients with advanced **ERBB2-positive** breast cancer.

To be eligible for Enhertu, patients with **ERBB2-low** breast cancer have received prior chemotherapy in the metastatic setting or their cancer returned during or within 6 months of completing adjuvant chemotherapy, the FDA said.

This latest approval was based on a clinical trial involving 557 patients with metastatic or unresectable **ERBB2-low** breast cancer. Among all patients, median progression-free survival was 9.9 months among patients receiving trastuzumab deruxtecan compared with 5.1 months for those receiving a physician’s choice of chemotherapeutic agents. Overall, survival was 23.4 months and 16.8 months, respectively.

The approved Enhertu product label includes a boxed warning of interstitial lung disease and fetal toxicity risks.

**Paxlovid Expiration Dates Extended**

Expiration dates have been extended from 9 months after manufacture to 12 months for 4 lots of the COVID-19 antiviral therapy Paxlovid, which consists of copackaged nirmatrelvir tablets and ritonavir tablets.

The lot numbers and original expiration dates are listed on the FDA website. The nirmatrelvir-ritonavir lots were manufactured before the FDA issued an Emergency Use Authorization (EUA) for the product, which specified a 12-month shelf life rather than the 9 months initially specified by the manufacturer. To be eligible for the extension, the drugs must have been stored under conditions outlined by the FDA in the EUA fact sheet.

The expiration extensions are part of a broader program designed to preserve COVID-19 treatments that are in potentially short supply as data accrue supporting a longer safe shelf life. Previous actions include extensions from 18 months to 24 months for monoclonal antibodies tixagevimab-copacbagged with cilgavimab, or Evusheld; and from 12 months to 18 months for bebtelovimab, both of which are currently available under EUAs. Expiration dates on other treatments not currently authorized due to ineffectiveness against Omicron subvariants also have been extended in case they prove effective against future variants.

**FDA Warns Against Certain UV Disinfection Wands**

Certain UV wands marketed for disinfecting household items may expose the user...
and those nearby to unsafe levels of UV-C radiation that may harm eyes and skin with a few seconds of exposure, the FDA warned. A continuously updated list of wands is on the agency’s website.

During FDA testing, some UV-C disinfection wands gave off more than 3000 times the UV-C radiation deemed safe under international standards at a distance of 2 inches. Exposure can quickly result in erythema of the skin and photokeratitis of the eye, or both. “When a product is advertised to disinfect in seconds, it likely means that it gives off an unsafe level of UV-C radiation,” the statement said.

The tested wands also lacked adequate safety features and instructions or information about the radiation emitted and associated risks.

In addition to avoiding their use, the agency advised consumers to report any suspected radiation injuries from UV-C disinfection wands, as well as any device that seems unsafe. The FDA has notified the manufacturers whose products were found unsafe and is working with them on corrective actions.

Improving Patient Communication on LASIK Benefits and Risks

In an effort to ensure that the benefits and risks of laser-assisted in situ keratomileusis (LASIK) are clearly communicated to patients, the FDA has drafted guidance detailing proposed recommendations for the content and format of patient labeling for LASIK devices, according to an agency statement. The nonbinding draft is open for comment through October 26.

The draft guidance provides detailed information on potential LASIK benefits, alternative treatments, and possible adverse events. In addition, it suggests patients be given a decision checklist detailing risks and outlining the physical conditions and lifestyle factors that may be incompatible with LASIK surgery. The guidance also suggests describing the LASIK procedure, what to expect after surgery, and who is a good LASIK candidate.

Laser refractive surgery volume, including LASIK, surged in 2021 to more than 833,000 procedures performed, according to the Refractive Surgery Council, an industry trade group.

— Howard D. Larkin

Note: Source references are available through embedded hyperlinks in the article text online.