New Flu Vaccine Approved for Older Adults

On Nov. 24, 2015, the U.S. Food and Drug Administration (FDA) approved Fluad™, an inactivated trivalent influenza virus vaccine made by Seqirus. Trivalent vaccines protect against two strains of type A influenza virus and one strain of type B. Indicated for individuals age 65 years and older, Fluad is the first vaccine approved in the U.S. that includes an adjuvant to boost the body’s immune response. It is given as one intramuscular (IM) injection into the upper arm. Fluad will be supplied in single-dose, pre-filled syringes with 0.5mL of vaccine. Like other seasonal flu vaccines, it should be administered before each flu season starts to be the most effective. A launch date and pricing for Fluad have not yet been released. Sanofi-Pasteur’s Fluzone® High-Dose (influenza vaccine) is the only other flu vaccine specifically designed for immunizing individuals who are 65 years old or older. Typically, the highest numbers of flu-related complications, hospitalizations and deaths are among the older population. Seqirus is a new company created from the merger of bioCSL and the vaccines division of Novartis. Currently, Seqirus markets three other trivalent flu vaccines (Afluria®, Flucelvax® and Fluvirin®), as well as Rapivab™ (peramivir), a neuraminidase inhibitor for treating flu symptoms.

Updated Approval for Tafinlar and Mekinist

On Nov. 20, 2015, the FDA granted regular approval for GlaxoSmithKline’s Mekinist® (trametinib) and Tafinlar® (dabrafenib) as combination therapy to treat patients with advanced melanoma that has metastasized or that cannot be surgically removed, and that has been tested as positive for specific genetic mutations – BRAF V600E or BRAF V600K. In January 2014, Mekinist and Taflinar received accelerated approval for this use. This regular approval was based on two, Phase III confirmatory studies that found that the combination improved overall survival and progression-free survival compared to Tafinlar alone. In the COMBId trial, treatment with Mekinist plus Tafinlar improved overall survival by 6.4 months compared to Tafinlar alone (25.1 months versus 18.7 months). In the COMBIv trial, the combination improved progression-free survival by 4.1 months compared to Tafinlar alone (11.4 months versus 7.3 months). Mekinist and Tafinlar are oral kinase inhibitors; Mekinist inhibits MEK and Tafinlar inhibits BRAF. Full prescribing information can be found at:

http://www.us.tafinlarmekinist.com/

New Indications Approved for Opdivo

Opdivo® (nivolumab) injection is a human programmed death receptor-1 (PD-1) immune checkpoint inhibitor that was first approved by FDA in December 2014. It enhances immune response by blocking specific receptors that deactivate immune cells. Previously, it has been FDA approved for treating progressed melanoma after treatment with Yervoy and a BRAF inhibitor, for second-line, single-agent therapy for advanced squamous and non-squamous-cell non-small cell lung cancer (NSCLC) following chemotherapy with a platinum-based drug and, in combination with Yervoy® (ipilimumab – Bristol-Myers Squibb), for treating malignant melanoma.
Bristol-Myers Squibb has now received FDA approval for two additional Opdivo indications. On Nov. 23, 2015, Opdivo was approved to treat metastatic renal cell carcinoma (RCC) for patients who have had prior treatment with an angiogenesis inhibitor, such as Nexavar® (sorafenib – Bayer). In a clinical study of RCC patients, overall survival for those treated with Opdivo was about five months longer than for study participants receiving a different type of renal cancer drug. The following day, FDA approved another indication for Opdivo – as first-line monotherapy for treating patients with inoperable or metastatic BRAF V600 wild-type melanoma. In the clinical study of Opdivo versus chemotherapy for this indication, overall survival for patients in the Opdivo group was about five months as compared to a little over two months for patients on chemotherapy. Opdivo’s dosing for both new indications is 3mg/kg of body weight given as an intravenous (IV) infusion once every two weeks until the cancer worsens or side effects become too severe. Prescribing information for Opdivo is at: http://packageinserts.bms.com/pi/pi_opdivo.pdf

Pradaxa Indications Expanded

On Nov. 23, 2015, Boehringer Ingelheim’s direct thrombin inhibitor, Pradaxa® (dabigatran), was approved to prevent deep venous thrombosis (DVT) and pulmonary embolism (PE) for patients having hip replacement procedures. Dosing for most patients undergoing hip replacement is one 110mg capsule one hour to four hours after surgery on day 1; followed by 220mg (two 110mg capsules) once a day for 28 days to 35 days. Pradaxa has been on the U.S. market for about five years and also has indications for preventing strokes among patients with non-valvular atrial fibrillation, for treating DVT and PE among patients who have received injected anti-clotting agents for five days to 10 days and for decreasing the risk of additional DVTs or PEs among patients already treated for prior DVTs or PEs. Pradaxa’s labeling carries a boxed warning that stopping it too soon may increase the risk of a DVT or PE. It also cautions that patients receiving a spinal procedure, such as spinal anesthesia, while taking Pradaxa have a greater chance of a hematoma (a solid, blood-filled swelling) in the spinal cord or its covering. Pradaxa’s full prescribing information is available at: https://www.pradaxa.com/

Additional Indication Approved for Anthrax Vaccine

BioThrax® (anthrax vaccine adsorbed – Emergent BioSolutions) gained a new FDA-approved indication on Nov. 23, 2015. Previously approved to prevent anthrax before exposure for individuals aged 18 years to 64 years old, BioThrax also is now indicated for patients in the same age range who have already been or suspect they have been exposed to anthrax. It is injected subcutaneously in three doses – one immediately, a second after two weeks and the third at four weeks after exposure. An effective antibiotic, such as ciprofloxacin or doxycycline, must be taken, along with one or more other antibiotics, for at least 60 days, as well. Although the safety of post-exposure BioThrax was confirmed on healthy individuals in human clinical trials, its effectiveness for preventing anthrax after exposure was tested only in laboratory animals because deliberately exposing humans to anthrax is unethical. Between 70% and 100% of treated test animals survived anthrax exposure. BioThrax is the first vaccine to be approved based only on data from animal studies. Complete prescribing information for BioThrax is at: http://www.biothrax.com/