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FDA Approves 18 New Molecular Entities/Biologics

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New Drugs

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FDA Approves 18 New Molecular Entities/Biologics

The FDA has approved 18 new molecular entities/biologics since our last column, with several receiving special designation as qualified infectious disease products, orphan drugs, or undergoing accelerated review.

Infectious Disease: Avycaz™ (ceftazidime/avibactam) and Zerbaxa™ (ceftolozane/tazobactam), the first cephalosporin/β-lactamase inhibitor combination products, were approved to treat complicated intra-abdominal or urinary tract infections. Xtoro™ (finafloxacin) is a quinolone approved for acute otitis externa caused by Pseudomonas aeruginosa and Staphylococcus aureus. Cresemba® (isavuconazonium), an azole antifungal used to treat invasive aspergillosis and mucormycosis, was given priority review and orphan drug status. Rapivab™ (peramivir), the first intravenous neuraminidase inhibitor to treat acute uncomplicated influenza, is approved as a single-dose for patients who have been symptomatic fewer than two days. Viekira Pak™ (ombitasvir, paritaprevir, dasabuvir, ritonavir) is approved to treat hepatitis C including patients with compensated cirrhosis, and is used with/without ribavirin depending on the genotype and presence of cirrhosis. Bexsero® is the second vaccine approved to prevent meningococcal disease caused by Neisseria meningitidis serogroup B in individuals aged 10-25 years. Gardasil®9, a new vaccine that protects against five additional HPV types, has the potential to prevent genital warts as well as 90% of cervical, vaginal, and anal cancers. The dosing schedule is the same as Gardasil® and is approved for females (9-26 years) and males (9-15 years).

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Oncology: Ibrance® (palbociclib), used with Letrozole, was granted accelerated approval for advanced breast cancer in postmenopausal women. Lynparza™ (olaparib), an innovative first-in-class poly(ADP)-ribose polymerase inhibitor, was granted accelerated approval to treat advanced BRCA-mutated ovarian cancer. Lenvima™ (lenvatinib) was granted priority review and orphan drug status to treat differentiated thyroid cancer in patients whose disease has progressed despite radioactive iodine therapy. Opdivo® (nivolumab) was granted accelerated approval in December to treat advanced melanoma, and then recently received expanded approval for metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy. Unituxin™ (dinutuximab) is a first for therapy aimed at high-risk neuroblastoma. Unituxin™ has been shown to prolong survival in children when used as part of a multimodality regimen (surgery, chemotherapy, and radiation). Farydak® (panobinostat) received accelerated approval as the first histone deacetylase inhibitor to treat multiple myeloma. However, the drug has a boxed warning for severe and potentially fatal diarrhea and cardiac toxicities and is approved with a Risk Evaluation and Mitigation Strategy (REMS) program.

Chronic Care and Specialty Products: Savaysa™ (edoxaban) is a new oral factor Xa inhibitor anticoagulant indicated to reduce stroke risk from nonvalvular atrial fibrillation in renally impaired patients and in treating DVT and PE. Savaysa™ has boxed warnings that caution against: reduced efficacy in patients with normal renal function (CrCl >95ml/min); risk of ischemic events due to premature discontinuation; and spinal/epidural hematoma. Cosentyx™ (secukinumab), a first-in-class interleukin antagonist and first subcutaneous monoclonal antibody, was approved to treat plaque psoriasis. Natpara® (parathyroid hormone) was approved as adjunct to calcium/vitamin D to control hypocalcaemia in hypoparathyroidism but with a boxed warning for osteosarcoma and approved with a REMS program. Cholbam® (cholic acid) was granted a rare pediatric disease priority review as the first treatment for bile acid synthesis disorders in both pediatrics and adults, but a post-approval long-term observational safety study is required.

New Dosage Forms: Significant dosage forms that were approved include: Dyloject™ (diclofenac injection) for mild-to-moderate pain; Duopa™ (carbidopa/levodopa, enteral suspension) and Rytary™ (carbidopa/levodopa, ER capsule) for Parkinson's disease; Dutrebis™ (lamivudine/raltegravir), Evotaz™ (atazanavir/cobicistat) and Prezcobix™ (darunavir/cobicistat) for HIV-1 infection; Glyxambi® (empagliflozin/linagliptin) for type 2 diabetes; Toujeo® (insulin glargine, U-300 strength) for diabetes; Prestalia® (perindopril/amlodipine) for hypertension; Triferic® (iron replacement) via hemodialysate; Signifor®LAR (pasireotide intramuscular suspension) for acromegaly; Soolantra® (ivermectin cream) for rosacea; Saphris® (asenapine sublingual) for pediatric bipolar I; Saxenda® (liraglutide, higher dose) for chronic weight management; an abuse-deterrent Zohydro™ formulation; and Zarxio™ (filgrastim-sndz), the first biosimilar product in the US. §

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