New drug information

- **Zirabev™ (bevacizumab-bvzr):** The U.S. Food and Drug Administration (FDA) approved Pfizer’s biosimilar to Genentech’s Avastin® (bevacizumab), for the treatment of certain forms of metastatic or recurring cervical cancer, colorectal cancer, glioblastoma, non-squamous non-small cell lung cancer and renal cell carcinoma. Zirabev was not approved for three Avastin indications including: certain forms of ovarian, fallopian tube and primary peritoneal cancer due to protection by Orphan Drug Exclusivity (ODE). Allergan/Amgen’s Mvasi™ (bevacizumab-awwb) was FDA approved in September 2017, as another Avastin biosimilar for the same indications as Zirabev. Mvasi launched in July 2019 at a wholesale acquisition cost (WAC) 15% lower than Avastin. Launch plans and pricing for Zirabev are pending.

- **Xpovio™ (selinexor):** Karyopharm’s Xpovio received FDA accelerated approval for the treatment of adult patients with relapsed refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is resistant to several other forms of treatment, including at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. While this accelerated approval is based on the 25.3% response rate reported from the pivotal Phase 2b STORM study, the drug’s continued approval will be based on the outcomes of the confirmatory Phase 3 BOSTON study results. Other products that are FDA approved for multiple myeloma patients who have received prior therapies include BMS’ Empliciti®, Takeda’s Ninlaro®, and Novartis’ Farydak®. Xpovio has a WAC of $22,000 per month.

- **Xembify® (immune globulin subcutaneous, human-klhw):** Grifols gained FDA approval of Xembify, 20% subcutaneous immunoglobulin for primary humoral immunodeficiency in patients ages 2 and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Xembify will compete for market share with Octapharma USA’s Cutaquig® (subcutaneous 16.5% immune globulin) which is FDA approved for the same indication. Grifols plans to launch Xembify in the last quarter of 2019; price will be released at that time.

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● **Ruxience™ (rituximab-pvvr):** Pfizer received FDA approval of Ruxience, a biosimilar to Roche/Genentech’s Rituxan® (rituximab). Ruxience is indicated in certain patients with Non-Hodgkin’s lymphoma, chronic lymphocytic leukemia, and granulomatosis with polyangiitis and microscopic polyangiitis. Rituxan is also approved in certain patients with rheumatoid arthritis and pemphigus vulgaris. Ruxience is the second Rituxan biosimilar to be approved by the FDA. Celltrion/Teva’s Truxima® was approved in November 2018, but launch plans have not been announced. Pfizer and Roche reached a settlement agreement; however, the launch date has not been announced.7

● **Hadlima™ (adalimumab-bwwd):** The FDA approved Samsung Bioepis/Merck’s Hadlima, a biosimilar to AbbVie’s Humira® (adalimumab). Hadlima is indicated for the treatment of certain forms of: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn’s disease, ulcerative colitis, and plaque psoriasis. Humira is also approved for pediatric Crohn’s disease, hidradenitis suppurativa, and uveitis. This is the fourth Humira biosimilar approved by the FDA, none of which are expected to launch until 2023. Due to a settlement with Abbvie, Samsung Bioepis/Merck will not launch Hadlima until June 30, 2023.8

● **Vyleesi™ (bremelanotide):** The FDA approved AMAG Pharmaceuticals’ Vyleesi for premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress of interpersonal difficulty and is not due to: a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance. Vyleesi is a first-in-class injectable to be self-administered 45 minutes prior to sexual activity. Injections are limited to one in 24 hours and eight per month. AMAG plans to launch in September 2019 through select specialty pharmacies. Pricing has not yet been announced.9

### New indications

● **Doptelet® (avatrombopag):** The FDA expanded Dova’s Doptelet indication to include the treatment of chronic immune thrombocytopenia (ITP) in patients who have had an insufficient response to a previous treatment. Doptelet is also approved for treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

● **Soliris® (eculizumab):** Alexion Pharmaceuticals received FDA approval for Soliris for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 antibody positive. Soliris is also indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS) and generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive.

● **Dupixent® (dupilumab):** The FDA expanded Regeneron/Sanofi’s label of Dupixent to include add-on maintenance treatment in adult patients with inadequately chronic rhinosinusitis with nasal polyposis. Prior to this approval, Dupixent was approved for treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It is also approved as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
● **Symdeko® (tezacaftor/ivacaftor):** Vertex Pharmaceuticals received FDA approval for Symdeko to be used in cystic fibrosis (CF) patients ages 6 and older who are homozygous for F508del mutation or who have at least one mutation in the CF transmembrane conductance regulator gene that is responsive to Symdeko based on in vitro data and/or clinical evidence. Last year, the FDA approved Symdeko to treat patients ages 12 and older who had the same specific genetic mutations.

● **Botox® (onabotulinumtoxinA):** Allergan received FDA approval for the treatment of upper limb spasticity in patients ages 2 to 17 years old. Previously, Botox was approved for urinary incontinence due to detrusor overactivity associated with a neurologic condition, prophylaxis of headaches in adult patients with chronic migraines, upper limb spasticity in adult patients, cervical dystonia in adult patients, severe axillary hyperhidrosis, and blepharospasm associated with dystonia.

● **Emflaza® (deflazacort):** PTC Therapeutics received FDA approval for an expanded indication for Emflaza for the treatment of pediatric patients aged 2 to 5 years old with Duchenne muscular dystrophy (DMD). It was previously only approved in patients 5 years and older.

● **Keytruda® (pembrolizumab):** The FDA granted accelerated approval to Merck’s Keytruda for the treatment of patients with metastatic small cell lung cancer (SCLC) with disease progression following platinum-based chemotherapy and at least one other prior line of therapy. Keytruda is the first immunotherapeutic agent indicated for the treatment of patients with SCLC.

● **Nucala® (mepolizumab):** The FDA approved two new methods for administering GSK’s Nucala, an autoinjector and a pre-filled syringe both for self-administration or by caregiver administration. This is the first anti-IL5 biologic to be approved by the FDA for self-administration. In addition to severe asthma, Nucala is also approved for eosinophilic granulomatosis with polyangiitis (EGPA).

● **Otezla® (apremilast):** The FDA approved Celgene’s Otezla for the treatment of adult patients with oral ulcers associated with Behcet’s disease. Otezla is also approved for use in certain patients with plaque psoriasis and psoriatic arthritis.
July news

- “Influential cost-effectiveness watchdog (ICER) has determined that neither Aimmune and DBV Technologies peanut allergy therapies offer superior net health benefit compared to strict peanut avoidance. An FDA decision for AR101 is expected in January 2020, while DBV is expected to submit its marketing application later in 2019. The so far untapped market is expected to grow to $4.5 billion in 2027 globally, according to Global Data.”

- “The biotech BioMarin reported that its talks with the FDA and the EMA convinced execs to make a leap for an accelerated approval for the world’s first hemophilia A gene therapy with data on just a handful of patients. And they’re handing over Phase I/II and interim Phase III results in Q4 to make their case.”

- “Moving fast with what it believes is a blockbuster favorite in a crowded market, Gilead has confidently plotted an NDA filing for rival JAK inhibitor filgotinib by the end of the year, setting up a potential 2020 launch in rheumatoid arthritis.”

- “Alexion has scored an additional FDA OK for its keystone rare therapy Soliris, unlocking what a key analyst calls a significant part of its C5 franchise and elevating that portfolio further up the blockbuster ranks. The drug is now approved to treat neuromyelitis optica spectrum disorder, a rare autoimmune condition characterized by sudden attacks on the central nervous system. Alexion is soon starting a Phase III trial in the same indication for Ultomiris, its followup to Soliris that’s easier to use. By his estimates, between the two drugs the NMOSD sales alone will bring in around $1 billion in 2028, representing one-fifth of the total C5 franchise that year.”

- “The Institute for Clinical and Economic Review (ICER) released an Evidence Report assessing the comparative clinical effectiveness and value of two exon-skipping therapies to treat Duchenne muscular dystrophy (DMD) — eteplirsen (Exondys 51™, Sarepta Therapeutics) and golodirsen (Sarepta Therapeutics) — as well as deflazacort (Emflaza®, PTC Therapeutics), a corticosteroid. Concluding that no price can be suggested as a fair value-based price for eteplirsen or golodirsen because no persuasive evidence yet exists to demonstrate the clinical effectiveness of either drug.”

References