New approvals

- **Braftovi™ (encorafenib) + Mektovi® (binimetinib):** Array BioPharma received U.S. Food and Drug Administration (FDA) approval for Braftovi and Mektovi, to be used in combination for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. The FDA also granted approval of the THxID BRAF Kit (bioMerieux) as a companion diagnostic for these therapeutics. The recommended doses are Mektovi 45 mg orally twice daily and Braftovi 450 mg orally once daily.

- **Tibsovo (ivosidenib):** Agios Pharmaceuticals received FDA approval for the treatment of relapsed or refractory acute myeloid leukemia (r/r/AML) with susceptible IDH1 mutation. Tibsovo is taken orally once daily until disease progression or unacceptable toxicity. It is estimated that 6 – 10% of AML patients have the IDH1 mutation.

- **Nivestym™ (filgrastim-aafi):** The FDA approved Pfizer’s Nivestym, a filgrastim biosimilar to Amgen’s Neupogen®, for the same indications as Neupogen, except for the treatment of patients acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome). Nivestym follows Sandoz’s biosimilar to Neupogen, Zarxio®, which has been available since 2015.

New indications

- **Cinryze® (C1 esterase inhibitor [human]):** The FDA expanded the indication for Shire’s Cinryze to include pediatric patients with hereditary angioedema (HAE) to use for routine prophylaxis against HAE attacks in children 6 years of age and older.

- **Keytruda (pembrolizumab):** Merck received FDA approval for Keytruda for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL) who relapsed after, were refractory to, or were ineligible for bone marrow transplant and failed two or more prior lines of therapy.

- **Xeomin (incobotulinumtoxinA):** Merck received FDA approval for Xeomin for the treatment of chronic sialorrhea, excessive drooling, in adult patients. This is the first FDA approval for chronic sialorrhea.
New indications (continued)

- **Opdivo® (nivolumab) + Yervoy® (ipilimumab):** The FDA granted accelerated approval to Bristol-Myers Squibb’s Opdivo plus Yervoy for the treatment of adults and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan.

- **Xtandi® (enzalutamide):** The FDA approved a new indication for Astellas’ Xtandi for the treatment of non-metastatic castration-resistant prostate cancer (NM-CRPC). Johnson & Johnson received FDA approval for Erleada to treat NM-CRPC in February 2018.

- **Kisqali® (ribociclib):** Novartis received FDA approval for Kisqali to treat postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. The FDA also approved Kisqali to be used in combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.

July news

- “Realizing that something is very wrong with the speed of biosimilar access and uptake in the United States, Food and Drug Commissioner Scott Gottlieb announced a plan to address multiple factors slowing competition in these markets.”

- “There’s been one glaring absence on the list of pharmaceutical company breakthroughs in recent decades: a drug to treat Alzheimer’s Disease, the most common form of dementia that some experts believe could single-handedly bankrupt Medicare in a matter of decades. As cancer drugs going through clinical trials have reached a 20 percent success rate, the search for a drug to treat dementia has been one of modern medicine’s greatest frustrations: a 99.6 percent failure rate.”

- “Allergan Plc and the St. Regis Mohawk Indian Tribe can’t use tribal sovereign immunity to shield patents on the dry-eye drug Restasis® from challenges at the U.S. Patent and Trademark Office, an appeals court ruled.”

- “Enzyvant announced that it has initiated its rolling submission of a Biologics License Application (BLA) for RVT-802 to the FDA. RVT-802 is a thymic-tissue based regenerative therapy for the treatment of primary immune deficiency resulting from congenital athymia associated with complete DiGeorge Anomaly (cDGA), or forkhead box protein N1 deficiency. The company expects to complete its BLA submission by the end of 2018.”

- “GlaxoSmithKline faces a steep, uphill climb in its quest to gain an approval for Nucala® (mepolizumab) as a therapy for COPD.”

- “Alexion hopes that its long-acting drug ALXN1210, now known as ravulizumab, will become standard of care in the rare disease paroxysmal nocturnal haemoglobulinuria (PNH), a life-threatening condition where the complement system turns against the body’s own red blood cells.”

References


All brand names are property of their respective owners.

2992-B1 © Prime Therapeutics LLC 07/18