Drug Insights ‣ November 2015

Specialty Pipeline Update

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New Drug Information

- **Coagadex®** (factor X concentrate): The Food and Drug Administration (FDA) approved Bio Products Laboratory’s Coagadex, the first replacement therapy for hereditary Factor X deficiency. Factor X deficiency is similar to hemophilia in that patients have clotting dysfunction leading to bleeding episodes.

- **Adynovate™** (Factor VIII, recombinant, pegylated): Baxalta received FDA approval for their treatment for hemophilia A. Adynovate is a longer-acting hemophilia factor that can be used for prophylaxis and on demand.

- **Strensiq™** (asfotase alfa): Alexion Pharmaceuticals received FDA approval for their enzyme replacement therapy. Strensiq is approved for patients who develop hypophosphatasia, a rare metabolic bone disorder that can be life-threatening. Strensiq is anticipated to cost $285,000 annually.

- **Genvoya®** (elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide): The FDA approved Gilead’s combination HIV treatment. Genvoya is similar to Stribild®, but contains a new dosage form of tenofovir that is anticipated to decrease some side effects.

- **Nucala®** (mepolizumab): GlaxoSmithKline obtained FDA approval for their monoclonal antibody for the treatment of asthma. Nucala is indicated for use in combination with other medications for maintenance treatment of severe asthma in patients 12 or older and with an eosinophilic phenotype.

- **Tagrisso™** (osimertinib): AstraZeneca received FDA approval for their orally administered treatment for patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC). Tagrisso was approved along with a companion diagnostic test to identify eligible patients.

- **Cotellic™** (cobimetinib): Genentech and Exelixis received FDA approval for their oral MEK inhibitor to be used in combination with Zelboraf® (vemurafenib) for the treatment of BRAF V600 mutation-positive advanced melanoma. This combination will compete against Novartis’ Tafinlar® (dabrafenib) and Mekinist® (trametinib).

- **Imlygic™** (talimogene laherparepvec): The FDA approved Amgen’s Imlygic for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery. Imlygic is the first oncolytic viral therapy approved by the FDA.

- **Yondelis®** (trabectedin): Janssen received FDA approval for Yondelis, a chemotherapy drug administered by intravenous infusion. It is used for the treatment of liposarcoma and leiomyosarcoma (soft tissue sarcoma) that cannot be removed by surgery or is metastatic.

- **Onivyde™** (irinotecan liposome injection): Merrimack Pharmaceuticals received FDA approval for their intravenously administered chemotherapy. Onivyde is approved for patients with metastatic pancreatic cancer who have previously been treated with gemcitabine-based chemotherapy.

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Darzalex™ (daratumumab): The FDA approved Janssen’s Darzalex, a monoclonal antibody, for the treatment of multiply myeloma patients who have tried at least three other drug therapies. Darzalex is administered by intravenous infusion.

New Indications

Yervoy® (ipilimumab): Bristol-Myers Squibb received FDA approval for an additional indication for Yervoy. The drug is now approved as adjuvant therapy for patients with stage III melanoma.

Harvoni® (ledipasvir/sofosbuvir): The FDA approved Gilead’s Harvoni for use in patients with genotype 4, 5 and 6 chronic hepatitis C virus (HCV) infection and in patients co-infected with HIV. Additionally, Harvoni is now approved with ribavirin for 12 weeks (as an alternative to a 24-week course) for treatment-experienced, genotype 1 patients with cirrhosis.

November News

“Merck, known as MSD outside the United States and Canada, announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to Keytruda® (pembrolizumab), the company’s anti-PD-1 therapy, for the treatment of patients with microsatellite instability high (MSI-H) metastatic colorectal cancer. This is the third Breakthrough Therapy Designation granted for Keytruda.”

“Gilead Sciences, reaping billions from its duo of approved hepatitis C therapies, is moving toward the market with a third pill that promises to cure a wider range of patients with the virus. The company submitted an FDA application for its fixed-dose combination of sofosbuvir, approved as Sovaldi®, and an investigational NS5A inhibitor called velpatasvir. The combo, which received the agency’s breakthrough therapy designation, has demonstrated stellar results in hep C genotypes 1 through 6, curing 98% of patients within 12 weeks across three Phase III trials.”

“Sandoz, a Novartis company and the global leader in biosimilars, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) under the 351 (k) pathway for its proposed biosimilar to Amgen’s US-licensed Neulasta® (pegfilgrastim) — a recombinant human granulocyte colony-stimulating factor (G-CSF). Sandoz is seeking approval for the same indication as the reference product. Pegfilgrastim is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in patients with cancer (non-myeloid) who receive chemotherapy that can cause fever and a low blood cell count (febrile neutropenia).”

References

3 http://www.fiercebiotech.com/press-releases/regulatory-submission-sandoz-proposed-biosimilar-pegfilgrastim-accepted-fda?mkt_tok=3RkMMJWWF9wsRonva3jPce%2FhmjTEU5z3kkWqeoM1%2FoeRjfoPVflj4ARcBnPK%2BTFAwTG5ozIv8R7LMKM1ty9MQwXb0k