New Approvals

- **Spinraza™ (nusinersen):** The Food and Drug Administration (FDA) approved Ionis/Biogen’s Spinraza to treat spinal muscular atrophy (SMA) in pediatric and adult patients. Spinraza is the first and only treatment for SMA. Spinraza is administered intrathecally by a healthcare professional experienced in performing lumbar punctures. The wholesale acquisition cost (WAC) for each injection of Spinraza is $125,000. The first year includes four loading doses, the first three administered at 14-day intervals. The fourth loading dose is administered 30 days after the third dose. Thereafter, a maintenance dose should be administered once every four months. The first year of treatment will cost $750,000; treatment will cost $375,000 each following year. Patients are expected to remain on Spinraza throughout their lifetime.¹

New Indications

- **Adynovate® (Antihemophilic Factor, (Recombinant), PEGylated):** The FDA has granted Baxalta’s Adynovate approval to treat pediatric hemophilia A patients who are 12 years of age and younger, as well as for use in surgical settings for children and adults. Treatment was previously approved for on-demand treatment and control of bleeding episodes, as well as routine prophylaxis in patients at least 12 years old with hemophilia A.

- **Lucentis® (ranibizumab):** Genetech’s Lucentis has been approved for the treatment of myopic choroidal neovascularization (mCNV). Lucentis was previously approved for the treatment of patients with wet age-related macular degeneration (AMD), macular edema after retinal vein occlusion (RVO), diabetic macular edema (DME), and diabetic retinopathy (DR) in people with DME.

- **Imbruvica® (ibrutinib):** The FDA granted accelerated approval to AbbVie’s Imbruvica for the treatment for marginal zone lymphoma (MZL) in patients who need systemic therapy after receiving one or more prior anti-CD20-based treatments. The accelerated approval for MZL is contingent upon findings from a larger confirmatory study. Imbruvica had been previously approved for the treatment of patients with mantle cell lymphoma, chronic lymphocytic leukemia and small lymphocytic lymphoma and Waldenstrom’s macroglobulinemia.
January news

● “Biogen reported at the British Pediatric Neurology Association (BPNA) conference on its trial of Spinraza™. In August, the company indicated that the trial met its pre-specified primary endpoint at the interim analysis. In fact, it was so successful that the study ended early so that all the trial participants would have the option to receive the drug in an open-label extension study. The data shows why. What it broadly breaks down to is that in the infants in the trial who did not receive the drug, 68 percent either died or needed permanent ventilation. In the portion receiving the drug, only 39 percent died or required permanent ventilation. What that comes to is a 47 percent decrease in the risk of death or permanent ventilation.”

● “Roche announced that the FDA has extended the Prescription Drug User Fee Act (PDUFA) date for its review of the Biologics Licence Application (BLA) of Ocrevus™ (ocrelizumab) to March 28, 2017. The extension is the result of the submission of additional data by Roche regarding the commercial manufacturing process of Ocrevus, which required additional time for FDA review. The extension is not related to the efficacy or safety of Ocrevus.”

● “The FDA has issued a complete response letter (CRL) to Advanced Accelerator Applications informing the company that its new drug application for Lutathera™ (177Lutetium DOTA-octreotate) as a treatment for patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs) would need to be resubmitted.”

● “Eli Lilly and Company and Incyte Corporation announced today that the FDA has extended the review period for the new drug application (NDA) for investigational baricitinib, a once-daily oral medication for the treatment of moderate to severe rheumatoid arthritis (RA). The NDA for baricitinib was submitted to the FDA in January 2016. The FDA extended the action date to allow time to review additional data analyses recently submitted by Lilly in response to the FDA’s Information Requests. The submission of the additional information has been determined by the FDA to constitute a Major Amendment to the NDA, resulting in an extension of the PDUFA goal date by three months.”

● “Regeneron Pharmaceuticals and Sanofi said they would appeal the U.S. District Court ruling which banned the two companies from selling their cholesterol drug, Praluent® (alirocumab), on grounds of patent infringement.”

● “Bristol-Myers announced that it would not be chasing an accelerated filing for its pairing of checkpoint inhibitor Opdivo® and fellow immunotherapy Yervoy® in the first-line lung cancer space, a decision it based ‘on a review of data available at this time.’ The company was mum on the details, citing an obligation to ‘protect the integrity of ongoing registrational studies’.”

References

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7. https://www.fiercepharma.com/pharma/another-opdivo-setback-for-bristol-time-combo-front-widens-mercks-immuno-oncology-lead?utm_medium=nl&utm_source=internal&mktid=36641180&mkt-tok=eypjoZjldOOU5z2E5o3RRUuZ4hWpRcLs#iQbQydOFCZEUkUZ2H9Y1TkUWfoQzZQ0k8b8lbzHTUDKdHLhIzGzZsgo05T0kNH2kz0fsI0vRdmd39yYMz1ud
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