New Approvals

- **Lartruvo™ (olaratumab):** The Food and Drug Administration (FDA) approved Lilly’s Lartruvo for use in combination with doxorubicin for the treatment of advanced soft tissue sarcoma (STS) not amenable to curative treatment with radiotherapy or surgery. The indication is approved under Accelerated Approval, continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial. Lartruvo is administered as an intravenous infusion and is the first monoclonal antibody approved to treat STS.¹

- **Zinplava™ (bezlotoxumab):** The FDA approved Merck’s Zinplava to reduce recurrence of Clostridium difficile infection (CDI) in patients who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. Zinplava is not indicated for the treatment of CDI, it should only be used in conjunction with antibacterial drug treatment for CDI. It is administered as a single-dose intravenous infusion.

New Indications

- **Tarceva® (erlotinib):** The FDA modified Genetech’s Tarceva indication for metastatic non-small cell lung cancer (NSCLC) to limit use to patients whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Prior to this modification, only first-line patients were limited to these specific EGFR mutations.

- **Enbrel® (etanercept):** The FDA approved Amgen’s Enbrel to treat pediatric patients 4 years and older with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy; prior to this approval only adults aged 18 years and older were approved for this indication. Enbrel is the first and only systemic therapy to treat pediatric patients (ages 4–17) with chronic, moderate-to-severe plaque psoriasis.²

- **Keytruda® (pembrolizumab):** The FDA approved Keytruda, a checkpoint inhibitor, for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test. This approval also expands the indication in second-line treatment of lung cancer to include all patients with PD-L1-expressing NSCLC. This was the first FDA approval of a checkpoint inhibitor for first-line treatment of lung cancer.³

- **Opdivo® (nivolumab):** The FDA approved Bristol-Myers Squibb’s Opdivo, a checkpoint inhibitor, to treat metastatic or recurrent squamous cell carcinoma of the head and neck following disease progression on or after platinum-based therapy.

- **Darzalex® (daratumumab):** The FDA approved the use of Janssen’s Daralex in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.
November news

- “Partners Mylan and Biocon announced that they had submitted an application for the breast cancer biosimilar version of the Roche cancer-fighter, Herceptin®, to the FDA. It’s the first submission for the team, which has a portfolio of meds still in clinical development.”

- “Merk has cut short its Phase III trial of Keytruda in advanced bladder cancer, saying it hit its endpoint, and so is moving on to present the data to regulators. This is particularly good news for the drugmaker since it is playing catch-up to competitors Roche and Bristol-Myers Squibb for this condition.”

- “Johnson & Johnson said its experimental sirukumab treatment for rheumatoid arthritis showed mixed results against AbbVie Inc.’s top-selling Humira® in a large trial. By one measure, patients with moderate to severe disease who took sirukumab showed significantly greater improvement in the Phase III study than those taking Humira, J&J said on Saturday. But another comparison showed no significant benefit of one drug over the other.”

- “Amgen Inc. and Allergan said they submitted a Biologic License Application (BLA) to FDA for ABP 215, a biosimilar of Avastin® (bevacizumab) from the Genentech unit of Roche. The partners said they believe the submission is the first for an Avastin biosimilar in the U.S. In September 2015, Amgen and Allergan said ABP 215 showed clinical equivalence to Avastin, meeting the primary and secondary endpoints of a Phase III study to treat non-small cell lung cancer (NSCLC).”

- “Spectrum Pharmaceuticals Inc said the FDA has rejected the drugmaker’s bladder cancer treatment, apaziquone.”

References

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