The Veeda Newsletter

May 2017

Clinical Research and Clinical Trial Approvals and Hurdles

European Commission Approves Bristol-Myers Squibb's Opdivo

Bristol-Myers Squibb was awarded European Commission approval of Opdivo (nivolumab) as a monotherapy for the treatment of squamous cell cancer of the head and neck in adults progressing on or after platinum-based therapy. The drug was approved based on a Phase III trial which showed significant improvement in overall survival for these patients. Opdivo uses the body's immune system to help restore anti-tumor immune response. The most frequent serious adverse reactions reported in at least 2 percent of patients receiving Opdivo were pneumonia, dyspnea, aspiration pneumonia, respiratory failure, respiratory tract infection and sepsis.
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FDA Gives Nod to Radius Health's Osteoporosis Drug Tymlos

Radius Health has gained FDA approval for Tymlos (abaloparatide) injection for the treatment of postmenopausal women with osteoporosis at high risk for fracture, multiple risk factors for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, the drug reduces the risk of vertebral and nonvertebral fractures. The approval was based on clinical trial results showing significant and rapid reductions in the risk of vertebral and nonvertebral fractures regardless of age, years since menopause, presence or absence of prior fracture and bone mineral density at baseline. The drug has also been shown to increase BMD and to increase a marker of bone formation. Tymlos will be available in the United States in June.
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Obstacles to the Adoption of Biosimilars for Chronic Diseases

Biologic agents have an increasingly important role in clinical care, accounting for 22% of new US Food and Drug Administration (FDA) drug approvals from 2010-2015 and comprising 28% of overall prescription drug revenue in 2015.1 Biologics are generally made from living organisms and are larger, more complex molecules than conventional small-molecule drugs. Commonly used biologics include adalimumab (Humira), etanercept (Enbrel), and infliximab (Remicade), protein-based drugs used to treat rheumatologic diseases. With the goal of facilitating competition and generating cost savings for consumers, the Biologics Price Competition and Innovation Act, part of the Affordable Care Act, authorized an approval pathway for "biosimilars." These are therapies with an active ingredient considered by the FDA to be highly similar to a reference biologic, such that there are no clinically meaningful differences in terms of safety, purity, and potency. Biosimilars can only be marketed after the reference biologic loses patent exclusivity.
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