Industry Spotlight

Short-Acting Insulin Drug Approved to Treat Diabetes

In mid-December, the U.S. Food and Drug Administration announced it had approved Sanofi-Aventis US's (Bridgewater Township, NJ) Admelog (insulin lispro injection), a short-acting insulin indicated to improve control of blood glucose levels in adults and pediatric patients 3 years and older with type 1 diabetes and adults with type 2 diabetes. Admelog is the first short-acting insulin approved as a "follow-on" product [submitted through the agency's 505(b)(2) pathway, a shortened route based on comparative evidence with an approved drug].

"With [the] approval, we are providing an important short-acting insulin option for patients that meets our standards for safety and effectiveness," said Mary T. Thanh Hai, MD, deputy director of the Office of New Drug Evaluation II in the FDA's Center for Drug Evaluation and Research.

Patients taking the drug should be monitored more closely with regard to changes in insulin dosage, co-administration of other glucose-lowering medications, meal pattern, and physical activity, as well as in patients with renal impairment, hepatic impairment, or hypoglycemia unawareness, the FDA noted.

Sanofi-Aventis submitted a 505(b)(2) application that relied, in part, on the FDA's finding of safety and effectiveness for Eli Lilly's Humalog (insulin lispro injection) to support approval for Admelog. The application aimed to demonstrate scientific justification for reliance on the FDA's finding of safety and effectiveness for the reference product Humalog and provided Admelog-specific data from two Phase 3 trials.

"One of my key policy efforts is increasing competition in the market for prescription drugs and helping facilitate the entry of lower-cost alternatives," said FDA Commissioner Scott Gottlieb, MD. "In the coming months, we'll be taking additional policy steps to help to make sure patients continue to benefit from improved access to lower cost, safe and effective alternatives to brand name drugs approved through the agency's abbreviated pathways."

He noted that these efforts are "particularly important for drugs like insulin that are taken by millions of Americans every day for a lifetime to manage a chronic disease."

Therapy round-up

A recent, albeit early, study found that a combination of two Genentech drugs, Tecentriq (atezolizumab) and Avastin (bevacizumab), reduced the risk of disease worsening or death as an initial treatment in some individuals with advanced kidney cancer. Genentech is a division of Roche, and is headquartered in South San Francisco, CA.

Compared with Sutent (sunitinib; Pfizer, New York, NY), the combination treatment provided a statistically significant and clinically meaningful co-primary endpoint result in kidney cancer patients whose disease expressed the biomarker PD-L1 protein. The co-primary endpoint was investigator-assessed, progression-free survival for the first-line treatment of individuals with advanced or metastatic renal cell carcinoma.

Another study found that a group of diabetic patients with chronic kidney disease who received treatment for type 2 diabetes fared better with the drug metformin compared with sulfonylurea. The observational study used data from electronic pharmacy records of the US Veterans Health Administration.

Among 175,296 new users (veterans) of either a metformin or sulfonylurea monotherapy, 5121 deaths were observed (1).

Metformin monotherapy across all ranges of estimated glomerular filtration rate evaluated was associated with a lower mortality hazard ratio than sufonylurea monotherapy, the researchers found. An analysis of mortality risk differences also favored metformin. The largest absolute risk reduction was found in the group with moderately to severely reduced kidney function.

1. Marcum ZA, et al. *J Gen Intern Med* 2017 doi https://doi.org/10.1007/s11606-017-4219-3.

UnitedHealth to Acquire DaVita Medical Group

In early December, UnitedHealth and Denver-based DaVita announced that UnitedHealth would spend $4.9 billion to acquire DaVita Medical Group, comprising a medical staff of about 2000 physicians in a group currently owned by one of the nation's largest dialysis companies. United Health Group's Optum segment has headquarters in Eden Prairie, MN, and has clinics or centers in more than 150 locations worldwide.

Under terms of the deal, Optum acquires from DaVita Medical Group physician groups in California, Colorado, Florida, Nevada, New Mexico, and Washington. The physician groups serve approximately 1.7 million patients per year in approximately 300 primary care centers, 35 urgent care centers, and six outpatient surgery centers. The acquisition will expand Optum's strategic care delivery portfolio, according to a joint statement from both companies.

According to UnitedHealth's third quarter 2017 highlights, all of Optum's segments showed double-digit percentage earnings growth. By the end of 2016, Optum had care management programs assisting people across the care continuum—physical and mental health, complex medical conditions, disease management and support, hospitalization, transplant, and post-acute care.

"Following this transaction, DaVita will continue to be a leader in population health management, with a focus on our US and international kidney care businesses," DaVita CEO Kent Thiry said. "We also expect to pursue other investments in health care services outside of kidney care."

Jeffrey Loo, an industry analyst with the investment research firm CFRA, noted that the acquisition "should mesh well with Optum's focus on primary care, urgent care, and outpatient care businesses."

According to MarketWatch.com, in dollar terms the acquisition is small potatoes compared with CVS's recent $69 billion acquisition of Aetna, a major health insurance company. UnitedHealth/Optum remains a step ahead of CVS, however, because it is now positioned to be a leading physician care platform for the transformed health care sector of the future, said Mizuho analyst Sheryl Skolnick.