Industry Spotlight

Diabetic Kidney Disease Drugs Show Promise

Two recent studies show promise for people with type 2 diabetes with kidney disease.

Bayer announced that results of the phase 3 FIDELIO-DKD study of the drug finerenone met its primary endpoint of delaying progression of chronic kidney disease (CKD) in type 2 diabetes patients. CKD progression was delayed through reduction of the combined risk of time to first occurrence of kidney failure, a sustained decrease of estimated glomerular filtration rate (eGFR) greater than or equal to 40% from baseline over a period of at least four weeks, or renal death.

The drug is the first investigational non-steroidal, selective mineralocorticoid receptor antagonist that demonstrates risk reduction in kidney and cardiovascular events, according to Bayer, a worldwide pharmaceutical company based in Leverkusen, Germany, with Bayer US located in Whippany, NJ.

FIDELIO-DKD is a randomized, double-blind, placebo-controlled, parallel-group, multicenter phase 3 study and includes 5700 patients from more than 1000 sites across 48 countries. Patients were randomized to receive either finerenone 10 mg or 20 mg orally once daily or placebo when added to standard of care, which included blood glucose–lowering therapies and maximum tolerated dose of renin–angiotensin system (RAS)-blocking therapy.

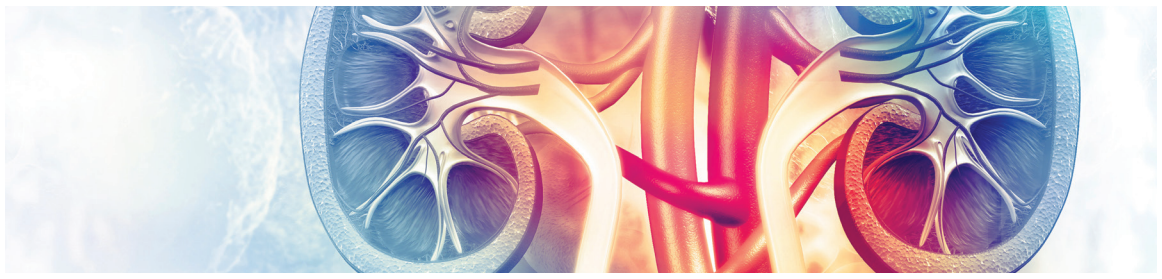
Second, AstraZeneca's dapagliflozin (brand name Farxiga, Cambridge, UK) is again showing usefulness for CKD patients with type 2 diabetes. As the company awaits an FDA decision on its application to use the drug as a treatment for patients who have CKD but not diabetes, the firm announced that the drug could reduce the proportion of patients with declining eGFR. The DECLARE-TIMI 58 trial showed that among patients taking dapagliflozin—both type 2 diabetes patients and those with an established or increased risk of cardiovascular disease—eGFR levels declined rapidly in 26.8% versus 37.1% of patients taking a placebo, according to MDMag.com

Terlipressen Makes it Out of FDA Advisory Committee

The drug Terlipressin (Mallinckrodt, Staines-upon-Thames, UK) made it out of an FDA advisory committee with an 8-7 vote for approval. At the recent Cardiovascular and Renal Drugs Advisory Committee meeting, participants pointed out benefits, but also some weaknesses of the drug, which was evaluated for its use in the treatment of hepatorenal syndrome type 1 (HRS-1). This kidney condition can develop in patients with acute or chronic liver disease with advanced liver failure and portal hypertension, and patients have poor survival rates.

Among other data, the FDA panel looked at data from a phase 3 trial of 300 patients, which showed a risk of respiratory failure that affected 10% of patients taking Terlipressin, but only 3% of those on placebo. Deaths from sepsis and septic shock were also more prevalent in the Terlipressin arm when compared with the placebo arm.

Regarding the drug's risks, Daniel Bonner, the advisory committee's patient representative, said the choice to take such risks should be up to the patients, who should be able to weigh a medicine's complications with the possibility of having more time to live.



AKI Algorithm Gets FDA Breakthrough Designation

Dascena (Oakland, CA) received FDA breakthrough device designation for its Previse machine-learning algorithm to predict acute kidney injury (AKI). The Breakthrough Devices Program provides a prioritized review of a device submission to the FDA and lets manufacturers interact with agency experts to address topics as they arise during the premarket review phase.

The algorithm uses values of various heart rates, respiratory rate, temperature, serum creatinine, Glasgow Coma Scale score, and patient age to predict likelihood of AKI. The company demonstrated that its algorithm predicted AKI more than one day before patients would meet the clinical criteria for diagnosis, which is based on changes in serum creatinine, urine output, or both, according to the National Center for Biotechnology information. In validation studies, Previse demonstrated higher sensitivity and predictive value than a clinician's assessment based on clinical criteria.

Diabetic Kidney Disease Collaborative Plans Free Roundtable Discussions

By Karen Blum

The ASN's Diabetic Kidney Disease Collaborative (DKD-C) has organized a series of three virtual roundtable discussions on the management of diabetic kidney disease to occur this summer and fall. Registration is free and open to all ASN members and partner organizations.

The first session, "Management of Diabetes and Kidney Disease Through COVID-19," will be held on Tuesday, Aug. 18, from noon to 1:30 p.m. EDT. The discussion will detail the care needs and patient experience managing diabetes and kidney disease during the COVID-19 pandemic, outline frequent patient concerns, and provide strategies for maintaining health. The conversation will touch on population susceptibility to diabetes, a personal journey of COVID-19 and DKD management, patient access to new therapies, and coordinating DKD care.

The second session, "Goal-Directed Medical Therapies for Patients with Diabetic Kidney Disease," will be held on Tuesday, Sept. 29, from noon to1:30 p.m. EDT. During this event, leading experts in the care of individuals with diabetic kidney disease will describe the new standard of care for DKD, discuss the clinical indications for SGLT2 (sodium-glucose cotransporter-2) inhibitors, and consider payment issues associated with new therapies. The session will address topics such as paying for new therapies and will conclude with a roundtable discussion.

"New Approaches to Transform Outcomes for Kidney Disease and Heart Disease in Diabetes," is the topic of the final webinar, which will be held Thursday, Dec. 10, from 4 p.m. to 5:30 p.m. EST. Clinical experts in this session will review the latest guidelines for both kidney and heart disease, discussing the evolving landscape for diabetic kidney disease as well as the most recent trials and promising therapies. A roundtable of experts from nephrology, cardiology and endocrinology will note the implications for diabetes, kidney, and heart disease treatment as we head into 2021.

The events are sponsored by Bayer, AstraZeneca, Janssen, Eli Lilly, and Baxter International.

"After decades of waiting, we have entered an exciting new era where nephrologists have powerful new treatments to dramatically slow and even halt the progression of kidney disease in patients," said Susan Quaggin, MD, FASN, chair of the DKD-C Task Force. "The DKD-C Task Force has a goal to make sure these treatments reach the patients who need them."

The DKD-C was launched by ASN in July 2019 in response to the recent development of new therapies for people with diabetic kidney disease. The collaborative works to increase coordination among primary care physicians, nephrologists, and other specialists to deliver appropriate therapies to people living with DKD. It also aims to provide educational information to help nephrologists and other health professionals provide high-quality care to people with DKD and to address legislative, regulatory, and policy issues that affect the ability of nephrologists and other health professionals to provide high-quality care to people with DKD. DKD remains one of the most common and serious complications of type 2 diabetes.