Kewalramani Takes Helm at Vertex

In the spring of 2020, nephrologist Reshma Kewalramani, MD, FASN, will assume the mantle of president and CEO of Vertex (Boston), a biotechnology company with revenues of $3.04 billion for fiscal year 2018. She will move up from her current position as executive vice president for global medicines development and medical affairs and chief medical officer at the company.

Kewalramani will follow Jeffrey Leiden, MD, PhD, who served in these roles for seven years and who oversaw hearty growth. Under Leiden’s tenure with ASN and the U.S. Food and Drug Administration, Kewalramani received her MD from Boston University and trained at Brigham & Women’s Hospital in Boston.

While Leiden will stay on in the role of executive chairman through the first quarter of 2023, the company reported, working closely with Kewalramani as projects develop.

FDA Puts CKD Drug on Fast Track

The U.S. Food and Drug Administration (FDA) has given type 2 diabetes drug Farxiga (dapagliflozin) a fast track designation that aims to help chronic kidney disease (CKD) patients. AstraZeneca (Cambridge, UK) announced that the drug was fast tracked for development as a treatment to delay the progression of kidney failure and prevent cardiovascular and renal death in patients with CKD.

The company noted, however, the drug is contraindicated for patients with severe kidney impairment (with an eGFR <30 ml/min/1.73 m²), with end stage kidney disease, or who are on dialysis.

The drug is also not recommended for patients with type 1 diabetes. In July, the FDA rejected approval of Farxiga as "an add-on treatment for type 1 adults whose insulin therapy isn't enough to control their blood sugar levels," reported FiercePharma.com.

The drug is now on the fast track for CKD treatment. Results from a phase 3 trial showed that the drug reduced the "combined risk of kidney function decline, end-stage renal disease and renal death in Type 2 diabetes patients by 47%," according to FiercePharma.

The company and the FDA await results from the current phase 3 DAPA-CKD clinical trial to evaluate the effect of Farxiga on kidney outcomes and cardiovascular mortality. The trial is for CKD patients both with and without type 2 diabetes, versus placebo.

The FDA defines fast tracking as a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

"Serious conditions" are roughly defined as those needing a drug treatment that will have an impact on such factors as survival, day-to-day functioning, or the likelihood of the condition, if left untreated, will progress to a more serious one.

Farxiga is a sodium-glucose co-transporter 2 (SGLT-2) inhibitor. Type 2 diabetes patients have a renal threshold for glucose that is increased beyond the typical level. The general mechanism of the drug is to reduce the renal reabsorption of glucose by inhibiting SGLT-2 and clear more glucose from the patient. The drug increases renal urinary glucose excretion, and can be associated with hypotension, according to the farxiga.com website.