

FDA Approves Tolvaptan for ADPKD

Otsuka Pharmaceutical's drug Jynarque (tolvaptan) received US Food and Drug Administration (FDA) approval as the first drug treatment in the United States to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). The drug is a selective vasopressin V2-receptor antagonist.

Tolvaptan showed a greater reduction in estimated glomerular filtration rate compared to placebo, meeting the primary endpoint of the REPRISÉ trial (Replicating Evidence of Preserved Renal Function: an Investigation of Tolvaptan Safety and Efficacy in ADPKD).

The data appeared in a late-breaking abstract at ASN Kidney Week 2017 and were simultaneously published online in the *New England Journal of Medicine* (1).

Tolvaptan caused "more elevations in aminotransferase and bilirubin levels," according to the *NEJM*. "The efficacy and safety of tolvaptan in patients with later-stage ADPKD are unknown." After tolvaptan therapy ended, the results were reversible for aminotransferase, and bilirubin levels did not exceed twice the upper limit of the normal bilirubin range, the *NEJM* noted.

"We are thrilled to be a part of this first milestone in treatment for ADPKD," said PKD Foundation CEO Andy Betts. "For the past 35 years, our goal has been to walk with PKD patients every step of the way. It is gratifying to play a part in the inception of the discovery of this treatment, and to see it come to fruition. We hope that this is just the beginning of a new chapter for adults at risk of rapidly progressing ADPKD who suffer from the disease."

Jynarque is available only through a restricted distribution program, according to FirstWord Pharma. Patients must have testing for blood alanine and aspartate aminotransferases levels, as well as bilirubin, before initiating treatment with tolvaptan. Patients also must be tested at two weeks and four weeks after treatment begins, as well as monthly for 18 months and every three months afterward.

The company noted that the drug will be sold in a 28-day treatment pack at a wholesale cost of \$13,041.10. ■

Reference

1. Torres V, et al. Tolvaptan in later-stage autosomal dominant polycystic kidney disease. *N Engl J Med* 2017; 377:1930–1942.

CVS Enters Kidney Care Market

Pharmacy giant CVS (Woonsocket, RI) recently announced that it will enter the kidney care market. The company will take a stepwise approach in a new initiative that will focus on chronic kidney disease and home-based dialysis.

The company's first focus will be on patient education and early detection of kidney disease. It also plans to introduce a new home hemodialysis technology designed to make home hemodialysis simple and safe for patients, and to facilitate longer and more frequent treatments.

"While in-center dialysis clinics are currently the most common choice for hemodialysis treatment, published clinical research has shown improved cardiac health, metabolic control, and survival for patients who are treated with longer, more frequent dialysis treatments," said Bruce Culleton, MD, vice president and chief medical officer, CVS Specialty. "This treatment paradigm is best delivered in the convenience of

a patient's home. CVS Health is uniquely positioned to build a solution that will enable us to identify and intervene earlier with patients to optimize the management of chronic kidney disease, while at the same time making home dialysis therapies a real option for more patients."

CVS runs walk-in "Minute Clinics" in some CVS and Target stores. These clinics offer treatment for minor illnesses and injuries, vaccinations, and other services.

CVS decided to enter the kidney care field partly owing to its ". . . deep payer relationships at CVS Caremark," said Alan Lotvin, MD, executive vice president and head of CVS Specialty. "When we get ready to launch this, presumably there's going to be a payer angle," Lotvin told MarketWatch, adding that CVS is "looking to work within existing systems."

In 2017, CVS signed a deal to acquire major health insurer Aetna for \$69 billion. ■

Fresenius Launches Foundation to Raise CKD Awareness

Fresenius Medical Care North America (FMCNA, Waltham, MA), has launched a foundation to create awareness and a national dialog about chronic kidney disease (CKD) and transplantation.

The funding will come from FMCNA employees and medical staff and other individuals, with FMCNA pledging to match up to \$1 million of contributions during the first year.

The nonprofit Fresenius Medical Care Foundation will address the social and economic conditions that increase the risk for developing CKD, with a focus on population health, childhood obesity, and transplant and donor awareness. The foundation will aim to engage with nonprofit organizations and with communities that include individuals at risk for developing

type 2 diabetes and high blood pressure.

Addressing the health of young people in particular, FNMCA kicked off the launch by assembling 4000 Healthy Eating, Active Lifestyle (HEAL) kits that included sports balls and air pumps for Chicago public school students. The foundation will also donate \$50,000 to the YMCA of metropolitan Chicago to support its summer camp program for children who have diabetes and kidney disease.

"When we look outside the walls of our dialysis clinics, we know we must help people at risk for developing kidney disease, and our new foundation is a significant step toward that important, long-term goal," said Bill Valle, FMCNA CEO and president of the Fresenius Medical Care Foundation. ■



Puerto Rican Patients, Saline Industry Still Recovering

In mid-April 2018, Puerto Rico again experienced a total blackout, this time because of an electrical subcontractor's mistake, not an act of nature like Hurricane Maria, which devastated the island in September 2017.

Many patients have to travel far—sometimes up to 12 hours—to find functional dialysis opportunities. In March 2018, Puerto Rico's health secretary said the department was working to bring in mobile units for dialysis. Luis Emanuelli, regional vice president of Fresenius Kidney Care, said he is aware of plans for the mobile units but is unaware of the timeline for bringing them on line.

To assist in getting help to people affected by Hurricane Maria, the National Kidney Foundation (NKF) set up a special fund for those needing dialysis. ASN joined NKF as a sponsor in the effort to raise money. Other organizations, and dialysis manufacturers and providers, joined in the effort:

- Akebia Therapeutics, Inc.
- Alliant Health Solutions
- Amgen Foundation
- American Renal Associates
- American Medical Technologists
- American Society of Nephrology
- American Society of Pediatric Nephrology
- DaVita Healthcare Partners
- Dialysis Clinic, Inc.
- Fresenius Medical Care
- Keryx Biopharmaceuticals
- National Renal Administrators Association
- OPKO Renal
- Relypsa, Inc.
- U.S. Renal Care

The hurricane-induced problems are a two-way street of dependence. The United States is very low on saline bags for dialysis, many of which are manufactured in Puerto Rico. The *Washington Post* reported that supply issues were made worse by the impact of Hurricane Maria on the medical products manufacturing sector in Puerto Rico, which affected small volume IV bags.

A statement from the US Food and Drug Administration (FDA) noted an effort to preserve the current stock of resources provided by Puerto Rican manufacturers. The FDA urged companies to submit data to extend expiration dates on products that could be stored for longer periods without safety issues. ■