

Otsuka acquires a kidney care partner

Otsuka Pharmaceutical (Tokyo) has signed a merger agreement to acquire the clinical-stage biotechnology company Visterra (Waltham, MA) for about \$430 million in cash.

The company is attractive to Otsuka because of its pipeline of programs, including those targeting IgA nephropathy and other kidney diseases, cancer, infectious diseases, and chronic pain. In IgA

nephropathy, the antibody IgA builds up in the kidneys, affecting the glomeruli and causing irreversible scarring of nephrons. The National Institute of Diabetes and Digestive and Kidney Diseases notes that researchers have not found a specific cure for the disease.

Visterra offers a platform for the design and engineering of antibody-based drug candidates designed to bind to and

modulate disease targets. The Visterra Hi-erotope platform targets drug candidates that are not adequately addressed by traditional approaches to creating and developing drugs.

The platform also includes fragment crystallizable (Fc) engineering capabilities for half-life extension of a drug, bispecific antibodies, and antibody-drug conjugates.

“I am highly gratified that Visterra’s exceptional antibody platform technology, promising pipeline, and talented researchers will join up with Otsuka,” said Otsuka Pharmaceutical President Tatsuo Higuchi.

FierceBiotech website reported that VIS410 is Visterra’s most advanced pipeline candidate. The compound is in phase 2 development for hospital-based influenza. ■

FDA approves smartphone camera–based dipstick product

Healthy.io, based in Tel Aviv, Israel, has obtained U.S. Food and Drug Administration (FDA) marketing clearance for its first digital dipstick kit offering. The Dip.io is advertised on the company’s website as having the accuracy of “the standard lab-based urinalysis analyzer.”

The dipstick is being marketed in Europe and is certified by CE and International Organization for Standardization

(ISO) 13485 for sale in the European Union. The urinalysis dipstick includes 10 determinations, including indicators for possible CKD, on the strip.

With the FDA nod, Healthy.io stated in its news release: “This approval opens the door for improved screening for kidney disease, a condition which affects over 10 percent of the population globally. Dip.io home testing for protein, glucose, and blood in urine can be enormously

helpful for patients. It is also a welcome tool helping improve diagnosis and awareness of chronic kidney disease.”

According to Josef Coresh, MD, PhD, professor of epidemiology at Johns Hopkins Medicine and chair of Healthy.io’s medical advisory board, “It’s exciting to see the FDA applying its rigor and enabling the use of the smartphone for better patient care.”

The dipstick uses “computer vision

algorithms” and a “unique calibration method” to ensure accurate reading and interpretation of results, accounting for the many different smartphone cameras available and “infinite lighting conditions,” according to the company’s website.

A photo of the dipstick with its color changes as test results will then be automatically sent to a patient’s electronic medical record so a clinical professional can follow up. ■

JYNARQUE™ (tolvaptan)

experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Use in Patients with Hepatic Impairment: Because of the risk of serious liver injury, use is contraindicated in patients with a history, signs or symptoms of significant liver impairment or injury. This contraindication does not apply to uncomplicated polycystic liver disease which was present in 60% and 66% of patients in TEMPO 3:4 and REPRISÉ, respectively. No specific exclusion for hepatic impairment was implemented in TEMPO 3:4. However, REPRISÉ excluded patients with ADPKD who had hepatic impairment or liver function abnormalities other than that expected for ADPKD with typical cystic liver disease.

Use in Patients with Renal Impairment: Efficacy studies included patients with normal and reduced renal function. TEMPO 3:4 required patients to have an estimated creatinine clearance ≥ 60 mL/min, while REPRISÉ included patients with $eGFR_{CKD-EPI}$ 25 to 65 mL/min/1.73m².

OVERDOSAGE: Single oral doses up to 480 mg (4 times the maximum recommended daily dose) and multiple doses up to 300 mg once daily for 5 days have been well tolerated in trials in healthy subjects. There is no specific antidote for tolvaptan intoxication. The signs and symptoms of an acute overdose can be anticipated to be those of excessive pharmacologic effect: a rise in serum sodium concentration, polyuria, thirst, and dehydration/hypovolemia.

No mortality was observed in rats or dogs following single oral doses of 2000 mg/kg (maximum feasible dose). A single oral dose of 2000 mg/kg was lethal in mice, and symptoms of toxicity in affected mice included decreased locomotor activity, staggering gait, tremor and hypothermia.

In patients with suspected JYNARQUE overdose, assessment of vital signs, electrolyte concentrations, ECG and fluid status is recommended. Continue replacement of water and electrolytes until aquaresis abates. Dialysis may not be effective in removing JYNARQUE because of its high binding affinity for human plasma protein (>98%).

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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