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 Hirotope 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.

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 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.

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.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8555 Japan
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA
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April 2018
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