Reata Gets $30 Million Milestone Payment

Reata Pharmaceuticals (Irving, TX) has received a $30 million milestone payment from its licensee, Kyowa Hakko Kirin as part of a corporate agreement.

In 2017, Kyowa Hakko Kirin reported positive results from the phase 2 TSUBAKI trial of bardoxolone methyl (bardoxolone) in patients with type 2 diabetes and chronic kidney disease. Initiation of the AYAME phase 3 clinical trial to assess the efficacy and safety of bardoxolone for the treatment of diabetic kidney disease in Japan was the trigger for the payment.

In July 2017, the FDA granted orphan drug designation to bardoxolone for the treatment of Alport syndrome and pulmonary arterial hypertension. Orphan drug designation is given to treatments for diseases that affect fewer than 200,000 people in the United States. About 12,000 people in the United States have Alport syndrome and most develop end stage kidney disease. The disease also affects the ear and eye.

The orphan designation will provide Reata with development incentives, including tax credits for clinical testing, exemption from a prescription drug user fee, and seven years of market exclusivity. The European Commission likewise granted orphan drug designation in Europe to bardoxolone for treatment of Alport syndrome.

Bardoxolone is an investigational medication taken orally, once a day. It is an activator of Nrf2, a transcription factor that induces molecular pathways that decrease inflammation. The pathways help to restore mitochondrial function, reduce oxidative stress, and block signals that cause an inflammatory response.

Recycling Used Dialysis Products

As more consumers eschew plastic straws and water bottles, the dialysis manufacturing sector is taking a closer look at the possibilities of reusing resources used in dialysis, including water and plastic. Water is also being analyzed as a commodity that could be used more sparingly throughout dialysis.

John Agar, a nephrologist at University Hospital, Barwon Health, in Geelong, Victoria (Australia), noted that the "total feed water draw per treatment [approaches] about 500 liters (or about 132 gallons) in typical hemodialysis," and that about 60% of the water is flushed away to drains (1).

Agar suggested that for hospital-based dialysis units, a reuse system for reverse-osmosis rejected water is feasible, with discarded water moving from the system in the dialysis unit to an elevated water storage tank that could provide water suitable for use in gardens, hospital sterilization department needs, janitorial stations, and window cleaning, for example.

Arguing for such reuse ideas hinges on clear communication, Agar said. For example, it's important to emphasize that the recycled water has not had exposure to patients. Instead, the reject water is generated by a filtration process before patient exposure, as opposed to water from the effluent dialysate that contains the products of the dialysis process after a patient has been dialyzed.

In other work, researchers in Bogota, Colombia, reported on using less water in dialysis, particularly for patients with lower body weights. Nephrologist Alejandra Molano-Triviño of Fundacion Cardioinfantil and colleagues found in a systematic review of literature that use of lower dialysate flow rates would "lead to significant water conservation without much compromise on dialysis efficacy and efficiency in small patients," those weighing less than 70 kg (154 pounds) (2). She and her team conducted a clinical trial that explored using different dialysate flow rates for lighter-weight patients (3).

Converting plastic dialysis waste into other products is another avenue of reuse for dialysis products. Working with a structural engineer at Deakin University, Melbourne, Australia, Dr. Agar says shredded plastic dialysis waste could be used to formulate an agent that lends strength to concrete by reducing the corrosion of steel bars used in its construction.

References

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3. Molano-Triviño A, et al. Fluid flow rate on dialysis efficacy and interdialytic weight gain in chronic patients with hemodialysis – FLUGAIN study. *Neph Dial Transpl* 2018; 33(suppl):i514–i515.