LIXELLE® β2-microglobulin Apheresis Column US FDA Approval

Kaneka received U.S. Food and Drug Administration (FDA) approval for Lixelle® Beta 2-microglobulin (β2M) Apheresis Column by humanitarian device exemption (HDE) (1) in March, 2015. Lixelle® is indicated for the treatment of patients with clinically diagnosed dialysis-related amyloidosis (DRA) (2) and is the first device in the USA to treat DRA.

DRA is a condition that occurs in patients who have been treated with hemodialysis for years. Lixelle® which removes β2M from the blood of hemodialysis patients has been commercially available in Japan since 1996 and in Europe in 2013. Improvements of symptoms related to DRA including joint pain, bone cysts, and carpal tunnel syndrome have been published through papers and presentations.

Kaneka will soon begin a Post Approval Study in the US as well as an application for Medicare. Kaneka has been distributing Liposorber® LDL Apheresis system in the US and will expand its blood purification product line in the US with the FDA approval of Lixelle®.

Health Care is one of Kaneka’s most important priorities and is listed as a strategic domain in our “Declaration of KANEKA UNITED” published in 2009. Kaneka will continue to create products and materials that support the medical treatment and health care needs of all people.

1) HDE is a special application for a diagnosis or a medical device that affects or is manifested in fewer than 4,000 individuals in the US per year. An HDE is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information of safety and that the probable benefit outweighs the risk from its use.

2) DRA is a complication of long-term hemodialysis (HD), leads to mobility and sensory disabilities due to abnormalities on bones, joints and tendons. Patients experience major difficulties in daily life as it manifests typically on neck, arms and legs. As a result of DRA, orthopedic surgery may be needed. While HD removes wastes in blood, HD is not able to remove enough β2M, thus the accumulation of β2M causes DRA. There are approximately 2,000 DRA patients in the USA. Lixelle® in combination with HD can effectively remove more β2M in blood.

Kaneka Pharma America LLC is an affiliated company of Kaneka Corporation. Our main offices are located in New York City, NY. If you are interested in hearing more about Lixelle®, please contact Kaneka Pharma America LLC by phone at +1-212-705-4340 or by email at Lixelle@kaneka.com.