

May 21 2014

Agreement Signed for Collaboration with Terumo BCT, Inc. Applying for US Clinical Trials for New LDL Adsorption System

Kaneka Corporation (Osaka, Japan; President: Mamoru Kadokura) and Terumo BCT, Inc. (Colorado, USA; President and CEO: David Perez) have signed a collaboration agreement and will pursue US clinical trials for the new LDL adsorption system.

Signing this contract means that we may seek market authorization for use of our Liposorber LA-40S LDL adsorption column with Terumo BCT's Spectra Optia® Apheresis System. Compared to the Liposorber LA-15, which is currently authorized by the US Food and Drug Administration (FDA), this new product is easier to use and helps reduce treatment times. In addition, Spectra Optia system is found in hospitals throughout the US, so, unlike the existing situation, there will be no need to bring in specialized devices, nor train hospital staff in how to use the device. It will allow patients who otherwise would be forced to travel to distant hospitals to undergo treatment close to home.

Liposorber is a type of LDL apheresis, an extracorporeal therapy used in treating familial hypercholesterolemia, which comes with a high risk of causing angina or myocardial infarction in younger patients who have genetically high levels of LDL cholesterol (the so-called "bad cholesterol"). We have been building up our business in Japan, the US, Canada, and major nations in Europe and other areas with a focus on our Liposorber LA-15 System, but in light of medical practices in the United States, we have decided it will be possible to expand our business through collaboration with Terumo BCT, which has a solid business infrastructure.

In our "Declaration of Kaneka United," which we established in 2009, we have positioned health-related fields as one of our core areas. We will continue to actively expand research and product development that contributes to medical treatment and health care.

Indications for Liposorber (details)

- LDL apheresis is used on patients who have familial hypercholesterolemia, which comes with a high risk of causing angina or myocardial infarction in younger patients who have genetically high levels of LDL cholesterol, who cannot gain sufficient effects from diet and exercise treatment or drug treatment. There are about 12,000 affected people in the United States.
- LDL apheresis is carried out about once every two weeks, or once every week for serious cases.