



Current Agreements

Dealdoc

Collaboration agreement for Spectra Optia system

Terumo Blood and Cell Technologies
Kaneka

May 20 2014

Collaboration agreement for Spectra Optia system

Companies:	Terumo Blood and Cell Technologies Kaneka
Announcement date:	May 20 2014
Deal value, US\$m:	n/d

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Details

Announcement date:	May 20 2014
Industry sectors:	Biotech Pharmaceutical
Asset type:	Product
Therapy areas:	Cardiovascular
Technology types:	Small molecules
Deal components:	Collaborative R&D

Financials

Deal value, US\$m:	n/d
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Termsheet

Terumo BCT has entered into a business relationship with Kaneka to gain market authorization in the United States for the use of the Terumo BCT Spectra Optia Apheresis System with the Kaneka Liposorber LA-40S LDL Adsorption Column for cardiologists treating patients with high cholesterol.

Terumo BCT and Kaneka will collaborate to seek the required approvals for the use of the Spectra Optia system and the Liposorber column to treat patients with coronary heart disease and severe hyper cholesterolemia, thereby expanding clinical treatment options for clinicians in the U.S.

Press Release

Terumo BCT Enters Agreement with Kaneka Corporation

Multi-year collaboration agreement for the combined use of therapeutic apheresis and columns for LDL reduction

LAKESWOOD, Colo.--(BUSINESS WIRE)--Terumo BCT, a global leader in blood component, therapeutic apheresis and cellular technologies, has entered into a business relationship with Kaneka, a global leader in life science products, to gain market authorization in the United States for the use of the Terumo BCT Spectra Optia® Apheresis System with the Kaneka Liposorber® LA-40S LDL Adsorption Column for cardiologists treating patients with high cholesterol.

"Familial Hypercholesterolemia: Screening, Diagnosis and Management of Pediatric and Adult Patients." Through this new agreement, Terumo BCT and Kaneka will collaborate to seek the required approvals for the use of the Spectra Optia system and the Liposorber column to treat patients with coronary heart disease and severe hyper cholesterolemia, thereby expanding clinical treatment options for clinicians in the U.S.

Key Facts on the Regulatory Pathway: Kaneka will seek to obtain Investigational Device Exemption (IDE) for the Liposorber column

Terumo BCT will support the IDE application by providing data references for the Spectra Optia device, the Spectra Optia® SPD Holder and the Spectra Optia® SPD-C Connection Set. Terumo BCT and Kaneka will collaborate on a U.S. clinical trial that is planned to evaluate the Liposorber column when used with the Spectra Optia device. When the clinical trials are complete, Kaneka will submit a pre-market approval (PMA) application for the Liposorber column and Terumo BCT will submit a 510(k) for Spectra Optia Therapeutic Plasma Exchange (TPE) with a Secondary Plasma Device procedure (TPE-SPD procedure). The devices are expected to be used together in the treatment of patients with severe hypercholesterolemia once the necessary regulatory approvals are obtained. Key Facts on the Patient Condition: High LDL cholesterol (LDL-C) levels in the blood significantly increase the risk of coronary heart disease and heart attacks.

LDL-apheresis, when performed with an LDL adsorption column that binds to and removes LDL-C from a patient's plasma, is a treatment option for high-risk patient populations—such as those with familial hypercholesterolemia (FH) for whom diet, exercise and drug therapies such as statins have either been ineffective, or not tolerated. The number of FH patients in the U.S. is more than 600,000; it is estimated that 12,000 of these patients are unresponsive to standard therapies. *Despite the prevalence of FH and the availability of effective treatment options, FH is both underdiagnosed and undertreated.* When LDL-apheresis is prescribed, it is usually performed once every two weeks, or once per week in severe cases. *Goldberg, A. "Familial Hypercholesterolemia: Screening, Diagnosis and Management of Pediatric and Adult Patients." *The Journal of Clinical Lipidology* 2011; 5: 133–140.

Key Quote:

Bob Sullivan, Vice President, Therapeutic Systems, Terumo BCT

"This unique opportunity to collaborate with Kaneka enables Terumo BCT to advance apheresis on behalf of patients who need more support in managing LDL cholesterol levels. Because of the current broad geographic distribution of the Spectra Optia system in the U.S. today, we anticipate that this collaboration will enable access to this LDL reduction therapy for many more patients. With this agreement in place, Terumo BCT adds to the versatility of the Spectra Optia system, becomes a full system provider for columns, and truly unlocks the potential of blood."

About Terumo BCT: Terumo BCT, a global leader in blood component, therapeutic apheresis and cellular technologies, is the only company with the unique combination of apheresis collections, manual and automated whole blood processing, and pathogen reduction. We believe in the potential of blood to do even more for patients than it does today. This belief inspires our innovation and strengthens our collaboration with customers.

About Kaneka Corporation: Kaneka Corporation was established in 1949 as a spin-off from Kanegafuchi Spinning Co., Ltd. Initially, Kaneka's main products included caustic soda, soap, cosmetics, edible oils and fats, and electrical wires. The Company later diversified into polymers, fermentation, biotechnology and electronics, as well as other fields. Business activities now span a broad spectrum of markets ranging from chemicals, functional plastics, expandable plastics and products, foodstuffs products, life science products, electronic products, synthetic fibers and others. The Company has been a leader among Japanese chemical companies in establishing overseas operations, beginning in 1970 with a subsidiary in Belgium. Kaneka now has overseas subsidiaries in Belgium, Germany, the U.S., Singapore, Malaysia, Vietnam, China, India, South Korea, Taiwan and Australia.

Filing Data

Not available.

Contract

Not available.