Terumo BCT and Marker Therapeutics received the first device FDA Emergency Use Authorization (EUA) to treat acute respiratory failure in COVID-19 patients

LAKEWOOD, CO. USA – **10 April 2020** – Terumo BCT, Inc. and Marker Therapeutics AG announced today that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the use of Terumo BCT's Spectra Optia® Apheresis System combined with Marker Therapeutics' D2000 Adsorption Cartridge to treat patients 18 years of age or older with confirmed Coronavirus Disease 2019 (COVID-19) admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure to reduce pro-inflammatory cytokine levels.

The devices work together by reducing the number of cytokines and other inflammatory mediators, i.e., small active proteins in the bloodstream that control a cell's immune response by filtering the blood and returning the filtered blood to the patient. The proteins that are removed are typically elevated during infections and can be associated with a "cytokine storm" that occurs in some COVID-19 patients, leading to severe inflammation, rapidly progressive shock, respiratory failure, organ failure and death.

"We thank the Food and Drug Administration for their expedited review, which provides another treatment option for patients in the ICU to help reduce the severity of the disease," say Antoinette Gawin, CEO and President of Terumo BCT, and David Cohen, Chairman of Marker.

About Terumo BCT and Marker Therapeutics Collaboration
Terumo BCT, a U.S. based leader in blood component, therapeutic apheresis and cellular technologies, and Marker Therapeutics AG, a Swiss-based diagnostic and therapeutics company, formed this collaboration to combine their existing technologies to provide an innovative approach to potentially treat severe respiratory symptoms caused by COVID-19.

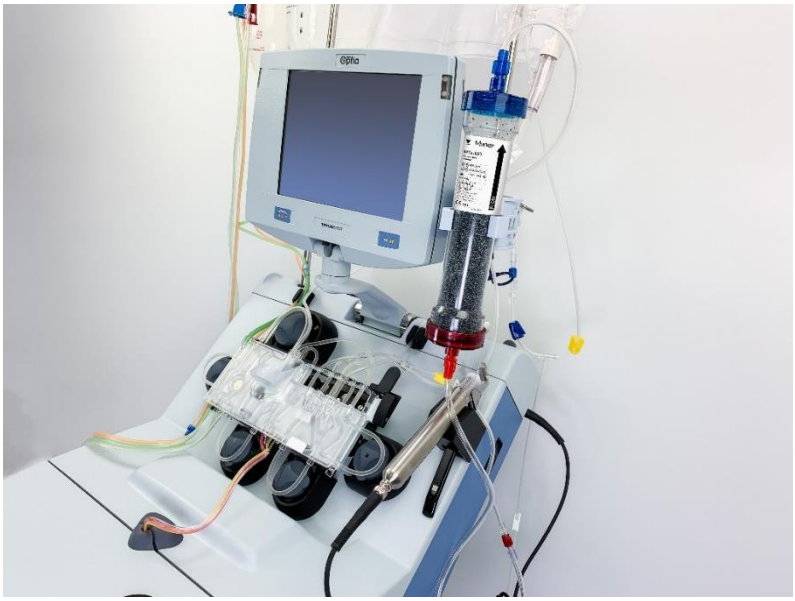
"The pace of this collaboration between the companies is incredible. We are leaving no stone unturned in exploring existing and new ways for our products to mitigate the impact of COVID-19," says Antoinette Gawin, CEO and President of Terumo BCT.

"By combining our plasma adsorption cartridge with Terumo BCT's technology, this partnership offers the potential to develop a unique global solution for treatment of acute respiratory failure in COVID-19," says David Cohen, Chairman of Marker.

About Emergency Use Authorization Status
The Spectra Optia Apheresis System with the D2000 Adsorption Cartridge has been neither cleared nor approved for the indication to treat patients with COVID-19 infection; it has been authorized by the FDA under EUA 200148 for emergency use to treat patients 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure to reduce pro-inflammatory cytokine levels, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

There are no FDA-approved, licensed, or cleared device treatments for COVID-19.

The Spectra Optia Apheresis System with the D2000 Adsorption Cartridge is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Spectra Optia Apheresis System with the D2000 Adsorption Cartridge under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



Terumo BCT's Spectra Optia® Apheresis System combined with Marker Therapeutics AG's D2000 Adsorption Cartridge has the potential to reduce the levels of inflammatory cytokines responsible for acute respiratory failure in COVID-19 patients.
(Photo: Terumo BCT, PR004)

About Terumo BCT
Terumo BCT is a global leader in blood component, therapeutic apheresis and cell therapy technologies. We believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers. www.terumobct.com

About Marker
Marker Therapeutics AG is a subsidiary of Marker AG, a Swiss-based diagnostics and therapeutics company. Marker Therapeutics has a patented and CE marked plasma cartridge for the removal of a range of inflammatory cytokines, metabolic waste, toxins and poisons from plasma in the mediation of acute life-threatening inflammatory conditions, including cytokine storms and Severe Inflammation Response Syndrome. Marker Diagnostics AG also has a patented and CE marked salivary clinical concussion diagnostic test in the rapidly emerging area of sncRNA-based diagnostics using qPCR analytical technology. www.markerhealth.com

If you have any questions or requests, please contact:

Terumo BCT
Christine Romero
+1 303 205 2599
press@terumobct.com

EMG
Varsha Lalla
+31 164 317 033
vlalla@emg-marcom.com

Marker Therapeutics AG
Sam Haddaway
+1 206 486 4186
press@markerhealth.com

###

This press release and relevant photography can be downloaded from www.PressReleaseFinder.com.

Alternatively, for very high-resolution pictures please contact Varsha Lalla (vlalla@emg-marcom.com, +31 164 317 033).

Notes to editor

- EUA:
  - The Emergency Use Authorization (EUA) authority allows the FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear defense (CBRN) threats by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies. *Adapted from FDA website.*
- Spectra Optia:
  - Terumo BCT's Spectra Optia Apheresis System is an industry-leading therapeutic apheresis, cell processing and cell collection platform for therapeutic plasma exchange that separates the patient's white blood cells from the plasma. It is designed to work with secondary plasma devices — including the Marker D2000 Adsorption Cartridge.
- Marker D2000 Adsorption Cartridge:
  - The Marker D2000 Adsorption Cartridge is a secondary plasma device, or SPD, designed to work with therapeutic plasma exchange and continuous renal replacement therapy devices — including Spectra Optia. It selectively removes cytokines, metabolic waste and toxins/poisons from the plasma, which can then be returned to the patient with no adverse effects.