



## **Fresenius Kabi Receives CE Mark Approval for the Amicus® Extracorporeal Photopheresis Protocol**

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**Friedberg, Germany, 16. May 2019 – Fresenius Kabi’s Transfusion and Cell Technologies Division today announced it has received CE Mark approval for the Amicus® Extracorporeal Photopheresis (ECP) System for the indication of CTCL in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.**

Fresenius Kabi is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition.

The Amicus ECP system includes the Amicus Separator, the Phelix Photoactivation Device, and a single-use disposable kit to create an online, closed system to perform photopheresis. Amicus’ MNC collection technology is the foundation for the new ECP procedure. The patient remains connected to the Amicus device throughout the entire procedure. After photoactivation, Amicus reinfuses the treated cells back to the patient.

Until now, only one supplier of online photopheresis has been available in Europe.

Fresenius Kabi also announced a rebranding of the Amicus System. The new brand, Amicus Blue, refers to a single solution to support patients’ needs, and encompasses the devices and protocols used to bring therapeutic apheresis and cell collection options to customers. The rebranding includes a new Amicus Blue logo and launch of a new website <https://amicusblue-fresenius-kabi.com/> [1].

“Our vision has been to methodically build on the time-tested technology of the Amicus Separator to provide a versatile, multi-procedural instrument to support patients’ individual needs,” said Christian Hauer, President Transfusion and Cell Technologies Division. “With the launch of Amicus ECP, we are now unifying all of these capabilities behind a clear, revitalized brand, Amicus Blue.”

The Amicus Separator is also cleared in Europe and the United States for therapeutic plasma exchange (TPE), red blood cell exchange (RBCx), mononuclear cell (MNC) collection and platelet collection.

### **About Extracorporeal Photopheresis**

Extracorporeal photopheresis or ECP is a leukapheresis-based therapeutic procedure. The technology is currently approved for the treatment of: cutaneous T-cell lymphoma (CTCL). Literature shows that it has also been used for graft versus host disease(GvHD) following bone marrow or stem cell transplant, the rejection of solid organ transplants, and autoimmune diseases where cell-mediated mechanisms are dominant. An online ECP procedure involves collection of mononuclear cells from the patient, treatment of collected cells with a light sensitive drug, 8-methoxypsoralen and exposure of cells to UV-A light, followed by the reinfusion of treated cells back to the patient. After reinfusion, the treated cells become apoptotic and are believed to be taken up by antigen presenting cells resulting in an immune response. The online ECP process combines cell separation and photoactivation into a single, sterile circuit reducing the risk of infection and cross-contamination.

### **About Cutaneous T-cell Lymphoma**

Cutaneous T-cell lymphomas are a heterogenous group of T-cell lymphoproliferative disorders involving the skin, the most common variants classified as Mycosis Fungoides (MF) or Sézary Syndrome (SS). Patients may experience itchy, scaly patches or plaques of the skin. As the disease progresses, some patients may experience growth of nodular lesions and large



tumors, and internal organ involvement. Treatment is palliative, with the aim to induce long-term remissions and improve patient quality of life.

### About Fresenius Kabi

Fresenius Kabi ([www.fresenius-kabi.com](http://www.fresenius-kabi.com) [2]) is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. The company's global headquarters is in Bad Homburg, Germany.

Zeichen 3.982 (inkl. Leerzeichen)

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<a href="#">Amicus-Device-web.jpg</a> [4]	42.45 KB

- [Krankheiten und Therapien](#)

**Quellen URL (aufgerufen am 27 Feb 2021 - 14:29):** <https://medcom24.de/node/24017>

### Links:

[1] <https://amicusblue-fresenius-kabi.com/>  
[2] <http://www.fresenius-kabi.com>  
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[4] <http://www.medcom24.de/files/active/0/Amicus-Device-web.jpg>