



**For Immediate Release**

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**U.S. FDA Approves New THERAKOS™ CELLEX™ Photopheresis System**

**- Integrated System Treats Cutaneous T-cell Lymphoma -**

EXTON, Pa. (March 23, 2009) -- Therakos, Inc., a pioneer in immune cell therapy, today announced the U.S. Food and Drug Administration (FDA) approval of the THERAKOS™ CELLEX™ Photopheresis System for the palliative (reducing the severity of symptoms) treatment of the skin manifestations (appearance) of cutaneous T-cell lymphoma (CTCL) that are unresponsive to other forms of treatment. The THERAKOS™ CELLEX™ Photopheresis System is an easy-to-use, integrated system that uses extracorporeal (outside the body) photopheresis (ECP), an innovative cellular therapy, to relieve the symptoms of CTCL. The system also has been cleared recently in Canada and Europe.

The new THERAKOS™ CELLEX™ Photopheresis System features several improvements designed to enhance the patient treatment experience, such as shorter treatment times and reduced extracorporeal blood volume. The benefits of reduced risk of infection and reinfusion errors are maintained in the THERAKOS™ CELLEX™ Photopheresis System from the current THERAKOS™ UVAR™ XTS™ Photopheresis System. Specific features of the new system include an automated, closed system design that provides users the ability to switch between double and single needle treatment, if necessary. The system also utilizes a new, patented separation technology to separate white blood cells from whole blood.

“Advancements in the new THERAKOS™ CELLEX™ Photopheresis System have opened up this important treatment option to patients for whom it was previously unfeasible,” said Larisa J. Geskin, MD, FAAD, Director of Cutaneous Oncology and Photopheresis Unit and Dermatology Residency Program Director at the University

of Pittsburgh School of Medicine. “This new system requires less extracorporeal blood volume at any one time, making it possible to treat lower weight patients and others previously not considered for this therapy.” Dr. Geskin acted as a principal investigator for the CELLEX™ Photopheresis System and is a paid consultant for Therakos.

CTCL is a type of non-Hodgkin lymphoma, a condition in which lymphocytes, a type of white blood cell, become cancerous and affect the skin. “Treatment options for patients with CTCL have been limited because it is a rare disease,” said Judy Jones, the founder and President of the Cutaneous Lymphoma Foundation. “We are thrilled about the FDA’s decision to approve the new THERAKOS™ CELLEX™ Photopheresis System, which will give patients suffering from painful skin lesions an important new therapeutic option.” The Cutaneous Lymphoma Foundation is an independent, non-profit patient advocacy organization and provides educational programs which are partially supported by industry partners. In the past, they have received educational grants from Therakos, Inc.

Therakos, Inc. currently markets the world’s only approved integrated systems for extracorporeal photopheresis. “The new features of the THERAKOS™ CELLEX™ Photopheresis System were designed specifically to create a better treatment experience for both patients and the health care professionals administering the therapy,” stated Michael Yang, General Manager of Therakos, Inc. “This new system is an example of a medical device and a drug therapy combining in a unique and innovative way to deliver favorable outcomes for patients.”

In April 2008, the THERAKOS™ CELLEX™ Photopheresis System received a CE Mark for use in Europe and in January 2009 it received regulatory clearance from Health Canada.

### **About Extracorporeal Photopheresis (ECP)**

ECP is a therapeutic procedure performed outside the body using the THERAKOS™ CELLEX™ Photopheresis System to withdraw a volume of whole blood that is then centrifuged to separate the white blood cells from the red blood cells and plasma. The red blood cells and plasma are immediately returned to the

patient. The white blood cells are treated with methoxsalen, which is photoactivated after exposure to UVA light. The treated white blood cells are then reinfused into the patient. Clinical studies suggest that the treated white blood cells, when reinfused into the body, may bring the immune system into balance by controlling the activity of overactive immune cells.

### **About Cutaneous T-cell Lymphoma (CTCL)**

CTCL is a type of non-Hodgkin lymphoma (NHL), a condition in which lymphocytes, a type of white blood cell, become cancerous and affect the skin. Patients may experience symptoms of thickened, red, cracking, scaling or intensely itchy skin in localized areas or all over the body. Some patients experience blood, lymph node and/or internal organ involvement with serious complications. Many patients live normal lives during treatment and some are able to remain in remission for long periods of time. According to the Lymphoma Research Foundation, CTCL accounts for about 2 to 3 percent of all cases of NHL lymphoma and mostly affects adults. In the United States, there are about 1,500 new cases of CTCL per year.

### **About Therakos, Inc.**

Therakos, Inc., a Johnson & Johnson company, has been a pioneer for more than 20 years in immune cell therapies. Therakos, Inc. markets the only approved integrated systems for extracorporeal photopheresis. For more information, visit [www.therakos.com](http://www.therakos.com).

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