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Mallinckrodt, Terumo BCT announce UVADEX approval in Australia

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UVADEXÃ?Â® (Methoxsalen) Approved in Australia for use with the THERAKOSÃ?Â® CELLEXÃ?Â® Photopheresis System for the Treatment of Chronic Graft Versus Host Disease (cGvHD) and Skin Manifestations of Cutaneous T-Cell Lymphoma (CTCL) in Adults



Mallinckrodt plc, a global biopharmaceutical company, and Terumo BCT, a global leader in blood component, therapeutic apheresis and cellular technologies have announced that UVADEX® (methoxsalen) has received regulatory approval in Australia by the Australian Therapeutic Goods Administration (TGA) for extracorporeal administration with the THERAKOS® CELLEX® Photopheresis System.

The treatment is indicated for steroid-refractory and steroid-intolerant chronic graft versus host disease (cGvHD) in adults following allogeneic hematopoietic stem cell (HSC) transplantation. The TGA also approved UVADEX in conjunction with the THERAKOS CELLEX Photopheresis System for the palliative treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.

The TGA approval marks the first combined label indication and the first regulatory approval in the world for UVADEX in conjunction with the THERAKOS Extracorporeal Photopheresis (ECP) System for the treatment of chronic graft versus host disease in adults.

Terumo BCT is the exclusive distributor of the Therakos ECP platform in Australia, as well as Latin America and select countries in Europe.

"The TGA approval of UVADEX with the Therakos ECP platform opens up new treatment options for patients with these challenging conditions," said Steven Romano, M.D., Executive Vice President and Chief Scientific Officer, Mallinckrodt. "The cGvHD indication is also an important milestone for Mallinckrodt, confirming the potential benefit of this therapeutic option for patients who are refractory to or intolerant of steroid treatments."

"Both cGvHD and CTCL are rare conditions with high unmet patient needs," said Julia Wenner, Ph.D., General Manager Australia, Terumo BCT. "We are pleased that this approval, with a combined label indication, will help meet those needs for patients in Australia. We look forward to continued partnerships like this one that allow us to positively impact patients."

UVADEX (methoxsalen) is indicated for extracorporeal administration with the THERAKOS CELLEX Photopheresis System for the:

- treatment of steroidÃ¢â?¬â??refractory and steroidÃ¢â?¬â??intolerant chronic graft versus host disease (cGVHD) in adults following allogeneic HSC transplantation.
- palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.