New Data on Patients with Cutaneous T-cell Lymphoma Treated with Extracorporeal Photopheresis from a Retrospective Study Presented at the American Society of Hematology Annual Meeting

December 13, 2021

Retrospective medical chart review study assessed real world treatment patterns and outcomes

DUBLIN, Dec. 13, 2021 /PRNewswire/ -- Mallinckrodt plc, (OTCMKTS: MNKKQ) a global biopharmaceutical company, today announced results of a retrospective, observational medical chart review study assessing real world treatment outcomes among cutaneous T-cell lymphoma (CTCL) patients who initiated therapy with extracorporeal photopheresis (ECP). Investigators presented the findings during a poster presentation at the annual meeting of the American Society for Hematology, taking place virtually and live in Atlanta, Ga. from December 11-14. The poster is available here on the company’s website.

Mallinckrodt Pharmaceuticals

In the United States, ECP is FDA-approved for the palliative treatment of the skin manifestations of CTCL that is unresponsive to other forms of treatment. UVADEX® (methoxsalen) Sterile Solution is used in combination with the THERAKOS® CELLEX® Photopheresis System and approved for use as a monotherapy. Safety and efficacy beyond six months have not been evaluated by the FDA.

The retrospective medical chart review study assessed the results of ECP in CTCL-diagnosed patients who initiated ECP treatment between January 1, 2017 and February 28, 2019. ECP was assessed as both a monotherapy and as a concomitant therapy. Physicians selected patients who were 18 years of age or older when they initiated ECP treatment, received at least three months of ECP treatment and had response data charted and available. Five U.S. clinical sites participated in the study and enrolled a total of 52 patients with a median age at ECP initiation of 69 years. Twenty-six patients (50 percent) were diagnosed with Sézary syndrome and 19 (36.5 percent) were diagnosed with mycosis fungoides. The median body surface area (BSA) involvement with plaques/patches was 77.5 percent at diagnosis.

The study examined patient data from CTCL diagnosis to 18 months post-initiation of ECP. Clinical outcomes collected every three months during treatment for up to 18 months included the BSA affected, appearance of new skin lesions and the physician-rated Clinical Global Impression-Improvement (CGI-I) scores. Patients may have been on concomitant therapies at the time of ECP treatment.

"It is important to continually evaluate real world patterns and outcomes of ECP treatment for CTCL to better understand patients’ response to ECP," said Michael Girardi, M.D., FAAD, lead investigator and Director of the Photopheresis and Phototherapy Unit at the Yale Comprehensive Cancer Center and Yale-New Haven Hospital.

The data analysis found that 19 patients (36.5 percent) had at least a 50 percent reduction in affected BSA with a median time to response of 6.5 months. New skin lesions appeared in 13 patients (25 percent) within a median time of 5.9 months from the initiation of ECP. Among those patients with available data, 27 out of 51 patients (52.9 percent) at three months and 16 out of 20 patients (80 percent) at 18 months, reported as improved (minimally, much or very much) in CGI-I severity scores. If exact timepoint was unavailable, physicians were advised to enter the date from closest visit (± four weeks). Per the Prescribing Information, there is no clinical evidence to show that treatment with UVADEX beyond six months provides additional benefit.

The limitations of this retrospective chart review include that the study relied on real world medical charts which could be missing data or may have used site-specific measurement schedules and procedures. Due to the retrospective nature of this analysis, it is hypothesis-generating; no formal conclusions should be drawn. Not all benefit from the analysis may be solely attributable to ECP treatment as patients may have been on multiple therapies at the time of ECP treatment. The study was granted a waiver for ethics review by the WCG [IRB], and when required, by the local IRB at each site.

"As a pioneer in immunomodulation therapy, Mallinckrodt is committed to furthering knowledge and data on the treatment outcomes for CTCL," said Steven Romano, M.D., Executive Vice President and Chief Scientific Officer at Mallinckrodt. "The results of this retrospective medical chart review analysis support the importance of continued collection of real-world data to help inform patients' treatment options."

The study was funded by Mallinckrodt.

About Cutaneous T-Cell Lymphoma (CTCL)

Cutaneous T-cell lymphoma (CTCL) is an umbrella term for a group of non-Hodgkin lymphomas involving T lymphocytes that localize in the skin. It is a relatively rare cancer that mostly impacts men between the ages of 40 and 60 and there are about 2,500 to 3,000 new cases of CTCL in the U.S. each
The age of onset is typically greater than 50 years, with the incidence rising significantly in the later decades of life. CTCL causes visible skin symptoms ranging from a small rash to extensive redness, peeling, burning, soreness, and itchiness all over the body. CTCL falls into different categories based on the severity of the disease and symptoms.

About Therakos Immunotherapy
Therakos immunotherapy is delivered through CELLEX systems to harness the power of the patient's immune system to treat the skin manifestations of CTCL, and is used by academic medical centers, hospitals, and treatment centers in more than 25 countries. Therakos photopheresis systems are fully integrated closed systems and U.S. Food and Drug Administration (FDA)-approved for the palliative treatment of the skin manifestations of CTCL in persons who have not been responsive to other forms of treatment.

IMPORTANT SAFETY INFORMATION

CAUTION: READ THE THERAKOS CELLEX PHOTOPHERESIS SYSTEM'S OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS CELLEX Photopheresis System. Please consult the CELLEX Operator's Manual before using this product.

CONTRAINDICATIONS

UVADEX is contraindicated in:

- Patients exhibiting idiosyncratic or hypersensitivity reactions to methoxsalen, other psoralen compounds, or any of the excipients
- Patients possessing a specific history of a light-sensitive disease state, including lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism
- Patients with aphakia because of significantly increased risk of retinal damage
- Patients that have contraindications to the photopheresis procedure

WARNINGS AND PRECAUTIONS

- Patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents such as anthralin, coal tar or coal tar derivatives, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides (bacteriostatic soaps), sulfonamides, tetracyclines, thiazides, and certain organic staining dyes such as methylene blue, toluidine blue, rose bengal, and methyl orange may be at greater risk for photosensitivity reactions with UVADEX
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Methoxsalen also causes DNA damage, interstrand cross-links and errors in DNA repair
- Methoxsalen may cause fetal harm when given to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant. If UVADEX is used during pregnancy, or if the patient becomes pregnant while receiving UVADEX, the patient should be apprised of the potential hazard to the fetus
- Severe photosensitivity can occur in patients treated with UVADEX. Advise patients to wear UVA absorbing, wrap-around sunglasses and cover exposed skin or use a sunblock (SPF 15 or higher), and avoid all exposure to sunlight for twenty-four (24) hours following photopheresis treatment
- After methoxsalen administration, exposure to sunlight and/or ultraviolet radiation may result in "premature aging" of the skin
- Since oral psoralens may increase the risk of skin cancers, monitor closely those patients who exhibit multiple basal cell carcinomas or who have a history of basal cell carcinomas
- Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions are not followed
- Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity
- Safety in children has not been established
- Thromboembolic events, such as pulmonary embolism and deep vein thrombosis, have been reported with UVADEX administration through photopheresis systems for treatment of patients with graft-versus-host disease, a disease for which UVADEX is not approved

ADVERSE REACTIONS

- Side effects of photopheresis (UVADEX used with THERAKOS Photopheresis Systems) were primarily related to hypotension secondary to changes in extracorporeal volume (>1%)

ABOUT MALLINCKRODT
Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active
pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS
This release includes forward-looking statements related to an ongoing, retrospective study in ECP. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: final results of the underlying study; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; and other risks identified and described in more detail in the "Risk Factors" section of Mallinckrodt’s most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on its website. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

CONTACT

Media Inquiries
Lisa Wolfe
Green Room Communications
914-588-4733
lwolfe@greenroompr.com

Investor Relations
Daniel J. Speciale
Vice President, Finance and Investor Relations Officer
314-654-3638
daniel.speciale@mnk.com

Government Affairs
Derek Naten
Vice President, Government Affairs & Patient Advocacy
derek.naten@mnk.com

Mallinckrodt, the "M" brand mark and the Mallinckrodt Pharmaceuticals logo are trademarks of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owners. ©2021 Mallinckrodt. US-2100806 12/21

References


View original content to download multimedia:

SOURCE Mallinckrodt plc