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Allos Therapeutics' FOLOTYN™ First and Only FDA-Approved Therapy for Relapsed or Refractory Peripheral T-cell Lymphoma

WESTMINSTER, Colo., September 25, 2009 -- Allos Therapeutics, Inc. (Nasdaq: ALTH) today announced that last night the U.S. Food and Drug Administration (FDA) granted accelerated approval for FOLOTYN™ (pralatrexate injection) for use as a single agent for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). FOLOTYN is the first and only drug approved by the FDA for this indication and represents a new treatment option for patients with relapsed or refractory PTCL. This indication is based on overall response rate. Clinical benefit such as improvement in progression free survival or overall survival has not been demonstrated. Allos expects to make FOLOTYN available to patients in the U.S. in October.

"Individuals with peripheral T-cell lymphoma have a very poor prognosis and almost always relapse or become refractory to initial therapy.¹ As a result, there is an urgent need for new therapies to treat patients with this challenging disease. FOLOTYN has demonstrated its efficacy and safety in the PROPEL clinical trial, and I believe it will be a welcome addition for physicians who treat patients with relapsed or refractory PTCL," stated Owen A. O'Connor, MD, PhD, principal investigator in the PROPEL study of FOLOTYN; deputy director for Clinical Research and Cancer Treatment, NYU Cancer Institute; chief, Division of Hematologic Malignancies and Medical Oncology; professor of Medicine and Pharmacology at the NYU Langone Medical Center.

PTCL comprises a biologically diverse group of aggressive blood cancers that has a poor prognosis.² The Company's New Drug Application (NDA) for FOLOTYN was based on data from the PROPEL trial. The Company believes PROPEL is the largest prospective, multicenter, international trial ever conducted in patients with relapsed or refractory PTCL.

"We are enthusiastic about providing this new therapy to patients with relapsed or refractory PTCL," said Paul L. Berns, president and chief executive officer at Allos Therapeutics, Inc. "The approval of FOLOTYN is a transformative event for Allos representing our first U.S. indication. We thank the many patients and clinical investigators who participated in the PROPEL study. Moving forward, we plan to continue advancing the FOLOTYN clinical development program."

"Aggressive peripheral T-cell lymphomas have been a largely ignored group of diseases," said James O. Armitage, MD, The Joe Shapiro Professor of Medicine, Department of Internal Medicine, University of Nebraska Medical Center. "It is exciting to have the first FDA-approved therapy for relapsed or refractory peripheral T-cell lymphoma."

Allos is dedicated to patient access and has established a patient assistance program named ASAP (Allos Support for Assisting Patients) to provide reimbursement support. Commencing in October, more information regarding ASAP will be available by calling the Hotline at 1-877-ASAP102 (272-7102), Monday to Friday, 8 am to 7 pm Central Time or by visiting www.getASAPinfo.com.

“The approval of FOLOTYN brings a new treatment option to patients afflicted with peripheral T-cell lymphoma,” said Peter L. Saltonstall, president and chief executive officer of the National Organization for Rare Disorders (NORD). “We at NORD are excited about this approval and will continue our efforts to focus national attention on rare diseases and on the fact that most rare diseases have no FDA-approved treatment at this time.”

In connection with the accelerated approval, Allos has agreed to undertake additional clinical studies to further verify and describe the clinical benefit of FOLOTYN in patients with T-cell lymphoma.

FOLOTYN was discovered by Sloan-Kettering Institute for Cancer Research, SRI International and Southern Research Institute and developed by Allos Therapeutics.

About PROPEL

The FOLOTYN approval was based on the results from PROPEL, an open-label, single-arm, multi-center, international clinical trial that enrolled 115 patients with relapsed or refractory PTCL, 109 of whom were considered evaluable for efficacy according to the trial protocol. Patients were considered evaluable if they received at least one dose of FOLOTYN, their diagnosis of PTCL was confirmed by independent pathology review, and they had relapsed or refractory disease after at least one prior treatment. Patients were treated with FOLOTYN at 30 mg/m² once weekly by IV push over 3-5 minutes for 6 weeks in 7-week cycles until disease progression or unacceptable toxicity. In addition, patients received 1mg of vitamin B₁₂ intramuscularly every 8-10 weeks and 1.0-1.25 mg of folic acid orally on a daily basis.

The primary efficacy endpoint was overall response rate (complete response, complete response unconfirmed and partial response) as assessed by International Workshop Criteria (IWC). The key secondary efficacy endpoint was duration of response. Response assessments were scheduled at the end of cycle 1 and then every other cycle (every 14 weeks). Duration of response was measured from the first day of documented response to disease progression or death. Response and disease progression were evaluated by independent central review using the IWC.

The results of the trial demonstrated that 29 of 109 evaluable patients, or 27%, responded to FOLOTYN. The median duration of response was 287 days, or 9.4 months (range 1-503 days). Thirteen of 109 evaluable patients had a duration of response ≥ 14 weeks (range 98-503 days). The most common grade 3/4 adverse events were thrombocytopenia, which was observed in 33% of patients; mucositis in 21% of patients; neutropenia in 20% of patients; and anemia in 17% of patients. See below for Important Safety Information.

The median number of prior systemic therapies was 3 (range 1-12). Approximately one-fourth of patients (24%, n = 27) did not have evidence of response to any previous therapy. Approximately two-thirds of patients (63%, n = 70) did not have evidence of response to their most recent prior therapy before entering the trial. The initial response assessment was scheduled at the end of cycle 1. Of the responders, 66% responded within cycle 1. The median time to first response was 45 days (range 37-349 days).

Important Safety Information

Warnings and Precautions:

FOLOTYN may suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Monitor blood counts and omit or modify dose for hematologic toxicities.

Mucositis may occur. If ≥ Grade 2 mucositis is observed, omit or modify dose.

Patients should be instructed to take folic acid (1.0 -1.25 mg orally on a daily basis) and receive vitamin B₁₂ (1 mg intramuscularly every 8-10 weeks) to potentially reduce treatment-related hematological toxicity and mucositis.

FOLOTYN can cause fetal harm. Women should avoid becoming pregnant while being treated with FOLOTYN, and pregnant women should be informed of the potential harm to the fetus.

Use caution and monitor patients when administering FOLOTYN to patients with moderate to severe renal function impairment.

Elevated liver function test abnormalities may occur and require monitoring. If liver function test abnormalities are \geq Grade 3, omit or modify dose.

Adverse Reactions:

The most common adverse reactions observed in PROPEL were mucositis (70%), thrombocytopenia (41%), nausea (40%), and fatigue (36%). The most common serious adverse events (>3%), regardless of causality, were pyrexia, mucositis, sepsis, febrile neutropenia, dehydration, dyspnea and thrombocytopenia. Forty-four percent of patients experienced a serious adverse event while on study or within 30 days after their last dose of FOLOTYN. Twenty-three percent of patients discontinued treatment due to adverse reactions.

Drug Interactions:

Co-administration of drugs subject to renal clearance (e.g., probenecid, NSAIDs, and trimethoprim/sulfamethazole) may result in delayed renal clearance.

Use in Specific Patient Population:

Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

For additional important safety information, please see the full [prescribing information](#) for FOLOTYN at www.allos.com.

Conference Call and Webcast Information

Allos will host a webcast conference call on Friday, September 25, 2009 at 9:00 a.m. ET. Participants can access the call at 877-941-8631 (U.S. and Canada) or +480-629-9820 (international). To access the live audio webcast or the subsequent archived recording, visit the “Investors - Presentations and Events” section of the Company’s website at www.allos.com. Webcast and telephone replays of the conference call will be available approximately two hours after the completion of the call. Callers can access the replay by dialing 800-406-7325 (domestic) or 303-590-3030 (international). The passcode is 4164756#. The webcast will be recorded and available for replay on the Company’s website until October 7, 2009.

About Allos Therapeutics

Allos Therapeutics, Inc. (Nasdaq: ALTH) is a biopharmaceutical company committed to the development and commercialization of innovative anti-cancer therapeutics. FOLOTYN is the first and only drug approved in the U.S. for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. Allos is also developing FOLOTYN in other potential indications. Allos retains exclusive worldwide rights to FOLOTYN for all indications. The Company is headquartered in Westminster, CO. For additional information, please visit www.allos.com.

Safe Harbor Statement

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include the Company’s statements regarding the potential for FOLOTYN to offer an important new treatment option or become a new standard for patients with relapsed or refractory PTCL; the Company’s anticipated timeline for making FOLOTYN available to patients in the U.S.; the Company’s intent to advance the FOLOTYN clinical development program; and other statements that are other than statements of historical facts. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” “continue,” and other similar terminology or the negative of these terms, but their absence does not mean that a particular statement is not

forward-looking. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those anticipated by the forward-looking statements. Important factors that may cause actual results to differ materially include, but are not limited to, the risks and uncertainties associated with developing adequate sales, marketing and distribution capabilities; the acceptance of FOLOTYN in the marketplace; the status of reimbursement from third party payors; the Company's dependence on third party manufacturers; the Company's compliance with applicable regulatory requirements, including the healthcare fraud and abuse laws and the Company's post-marketing requirements; and the Company's access to capital to support its future operations, including product development and commercialization plans for FOLOTYN. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this presentation, except as required by law.

Note: The Allos logo and FOLOTYN name are trademarks of Allos Therapeutics, Inc.

References:

¹Savage KJ, Chhanabhai M, Gascoyne RD, et al. Characterization of peripheral T-cell lymphomas in a single North American institution by the WHO classification. *Ann Oncol* 2004;15(10):1467-75.

²Armitage J, Vose J, Weisenburger D. International peripheral T-cell and natural killer/T-cell lymphoma study: pathology findings and clinical outcomes. *J Clin Oncol* 2008;26(25):4124-30.

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