



ALIGN Pharmaceuticals, LLC

P R E S S R E L E A S E

**XCLAIR® REPORTED TO BE SAFE AND EFFECTIVE  
IN STUDY PUBLISHED IN EUROPEAN JOURNAL OF DERMATOLOGY**

**BERKELEY HEIGHTS, NJ, July 7, 2008** – ALIGN Pharmaceuticals, LLC, a wholly owned subsidiary of Cyclacel Pharmaceuticals, Inc., (NASDAQ: CYCC, CYCCP) announced results of a double-blinded, randomized, vehicle-controlled clinical study showing that Xclair® cream (formerly MAS065D) is safe and effective in the treatment and prevention of radiation dermatitis. These results were published in the May-June 2008 issue of the European Journal of Dermatology. <sup>(1)</sup>

**About the Study**

Forty women who received radiotherapy following conservative breast cancer surgery were randomized to receive either Xclair cream (22 patients) or a cream containing a control vehicle (18 patients). They received Xclair during their radiation therapy and for three weeks after completion of radiation. Patients treated with Xclair demonstrated a statistically significant improvement compared to controls in maximum severity of skin toxicity ( $p < 0.0001$ ), burning within the radiation field ( $p = 0.039$ ) and desquamation or shedding of outer skin layers ( $p = 0.02$ ). Desquamation, especially when it reaches the moist stage, can become a morbidity and quality of life challenge to radiation therapy patients.

Doctor Maria Cristina Leonardi of the Division of Radiation Oncology at the European Institute of Oncology in Milan, Italy was the lead author. The study authors concluded that Xclair cream is an effective treatment regimen for the prevention of radiation-induced skin reactions and promotion of symptomatic relief.

The authors discussed Xclair's unique triple mechanism of action. In particular Xclair has anti-inflammatory, barrier-forming and hydrating properties that can minimize the side effects of radiation therapy on the skin. The authors noted that currently there is no universally accepted standard approach for the management of radiation dermatitis. No adverse events were observed or reported and none of the patients on the Xclair arm were required to stop radiotherapy as a consequence of the effects of their radiation dermatitis. The authors concluded that Xclair is "effective in the prevention of radiation skin reactions and the promotion of symptomatic relief."

**About Xclair**

Xclair has a unique mechanism. Its multiple ingredients help to hydrate and moisturize damaged skin and slow down immune system reactions to radiation. Hyaluronic acid, one of Xclair's main ingredients, has been shown to retain up to 1000 times its weight in water and is a major component of the extracellular matrix of the skin. Hyaluronic acid is also important in wound healing and helps to stimulate fibroblasts and fibrin development. Telmesteine helps to maintain hyaluronic acid at the site of radiation damage and has anti-elastase and anti-collagenase activity. Glycyrrhetic acid confers anti-inflammatory properties which help accumulate endogenous hydrocortisone at the radiation site. Xclair's properties address the three main challenges in the management of radiation dermatitis: moisturize, reduce inflammation and facilitate wound healing.

(1) Source: Leonardi, MC et al, European Journal of Dermatology 2008; 18 (3): 317-21.

Xclair is marketed directly in the U.S. by ALIGN Pharmaceuticals, LLC, a subsidiary of Cyclacel Pharmaceuticals, Inc. ALIGN also markets directly in the U.S. Numoisyn Liquid™ and Numoisyn™ Lozenges for xerostomia.

Please visit [www.alignpharma.com](http://www.alignpharma.com) or call ALIGN at (908) 834-0960 to request additional information, including full U.S. prescribing information.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Three orally-available Cyclacel drugs are in clinical development. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly and cutaneous T-cell lymphoma. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer and in Phase 1 in combination with Tarceva<sup>®</sup>. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair<sup>®</sup> Cream for radiation dermatitis, Numoisyn<sup>™</sup> Liquid and Numoisyn<sup>™</sup> Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology, oncology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Please visit [www.cyclacel.com](http://www.cyclacel.com) for additional information. Note: The Cyclacel logo and Cyclacel<sup>®</sup> are trademarks of Cyclacel Pharmaceuticals, Inc. Numoisyn<sup>™</sup> and Xclair<sup>®</sup> are trademarks of Sinclair Pharma plc. Tarceva<sup>®</sup> is a trademark of OSI Pharmaceuticals, Inc.

#### Risk Factors

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety, and intended utilization of Cyclacel's product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, the risk that Cyclacel will not obtain approval to market its products, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. These factors and others are more fully discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2007, as supplemented by the interim quarterly reports, filed with the SEC.

#### *Contacts for Cyclacel:*

Cyclacel Pharmaceuticals, Inc.  
Corey Sohmer  
(908) 517-7330

WeissComm Partners  
Aline Schimmel  
(312) 284-4706

College Hill, Life Sciences  
Sue Charles & Justine Lamond  
+44 (20) 7866 7857