FDA Approves Anacor Pharmaceuticals' KERYDIN™ (Tavaborole) Topical Solution, 5% for the Treatment of Onychomycosis of the Toenails

PALO ALTO, Calif. -- (BUSINESS WIRE) -- Anacor Pharmaceuticals, Inc. (NASDAQ: ANAC) today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application for KERYDIN™ (tavaborole) topical solution, 5%, the first oxaborole antifungal approved for the topical treatment of onychomycosis of the toenails. Onychomycosis is a fungal infection of the nail and nail bed that affects approximately 35 million people in the United States, according to Podiatry Today.

"We are pleased to announce the FDA approval of KERYDIN, which provides an important new topical treatment option for the millions of people in the United States who are infected with onychomycosis of the toenails," said Paul Berns, Chief Executive Officer of Anacor Pharmaceuticals. "We expect to launch KERYDIN in the U.S., either alone or with a partner, as early as the end of this quarter."

"Onychomycosis is one of the most common diseases diagnosed and treated by podiatrists. Historically, a large number of patients with onychomycosis would choose not to treat their infection," said Warren Joseph, D.P.M., lower extremity Infectious Diseases consultant at Roxborough Memorial Hospital in Philadelphia, Pennsylvania. "With the approval of KERYDIN, physicians can now offer patients a safe, effective and easy-to-use topical treatment for their onychomycosis of the toenail, which I think will be well-received by patients."

"I am very excited about the release of this therapy for an infection that is very difficult to treat," said Boni Elewski, M.D., Vice Chair of Clinical Affairs and Professor of Dermatology at the University of Alabama at Birmingham. "KERYDIN will offer patients a new, safe and effective treatment option for onychomycosis."

"KERYDIN was designed to be convenient for patients to use and has demonstrated efficacy in the treatment of the fungal infection, thus allowing growth of new uninfected nail," said Vince Ippolito, Chief Commercial Officer of Anacor Pharmaceuticals. "In market research conducted by Anacor, KERYDIN's product profile was received with great enthusiasm by the participating physicians and we believe this response demonstrates the need for a safe topical treatment for onychomycosis of the toenails."

**About KERYDIN™ (tavaborole) topical solution, 5%**

KERYDIN (tavaborole) topical solution, 5%, is the first oxaborole antifungal agent developed for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

KERYDIN is a clear, colorless, alcohol-based solution applied with a dropper to the infected toenail once daily for 48 weeks. Debridement of the nail is not required during the treatment period. Due to its topical application, KERYDIN has low systemic absorption and has not demonstrated systemic side effects.

The efficacy and safety of KERYDIN was evaluated in two multicenter, double-blind, randomized, vehicle-controlled trials. KERYDIN or vehicle was applied once daily for 48 weeks in subjects with 20% to 60% clinical involvement of the target toenail, without dermatophytomas or lunula (matrix) involvement. A total of 1194 subjects (795 KERYDIN, 399 Vehicle) 18 to 88 years of age, participated in these two trials. Efficacy assessments were made at 52 weeks following a 48-week treatment period.

The primary efficacy endpoint was "Complete Cure" at Week 52. "Complete Cure" is defined as "Completely Clear Nail" (0% clinical involvement of the target toenail) plus "Mycological Cure" (negative KOH wet mount and negative fungal culture). In the first trial, 6.5% of subjects treated with KERYDIN reached the primary endpoint, compared to 0.5% of subjects treated with vehicle. In the second trial, 9.1% of subjects treated with KERYDIN reached the primary endpoint, compared to 1.5% of subjects treated with vehicle.

Secondary endpoints in the pivotal trials included "Complete or Almost Complete Cure" (less than or equal to 10% affected target toenail area involved plus "Mycological Cure") and "Mycological Cure." 15.3% and 17.9% of patients treated with KERYDIN achieved "Complete or Almost Complete Cure" compared to 1.5% and 3.9% of patients treated with vehicle in the first and second trials, respectively. 31.1% and 35.9% of patients treated with KERYDIN achieved "Mycological Cure" compared to 7.2% and 12.2% of patients treated with vehicle in the first and second trials, respectively.

Common adverse reactions occurring in at least 1% of subjects treated with KERYDIN included application site exfoliation, ingrown toenail, application site erythema, and application site dermatitis. For information on dosage and administration,
adverse reactions and other important safety and prescribing information please visit the page on KERYDIN, under the Pipeline tab on our website at www.anacor.com.

About Onychomycosis

Onychomycosis is a progressive, recurring fungal infection of the nail and nail bed. According to Podiatry Today, approximately 35 million people in the United States have onychomycosis, but only 5-6 million have been diagnosed by a physician.

About Anacor Pharmaceuticals

Anacor is a biopharmaceutical company focused on discovering, developing and commercializing novel small-molecule therapeutics derived from its boron chemistry platform. Anacor's first approved drug, KERYDIN™ (tavaborole) topical solution 5%, is an oxaborole antifungal approved by the U.S. Food and Drug Administration for the topical treatment of onychomycosis of the toenails. Anacor's lead product candidate is AN2728, an investigational anti-inflammatory PDE-4 inhibitor in development for the potential treatment of mild-to-moderate atopic dermatitis. In addition, Anacor has discovered three other wholly-owned investigational product candidates — AN2718 and AN2898, which are backup compounds to KERYDIN and AN2728, respectively, and AN3365, an investigational antibiotic for the potential treatment of infections caused by Gram-negative bacteria. Anacor has also discovered three additional investigational compounds that have been out-licensed for further development — one is licensed to Eli Lilly and Company for the potential treatment of an animal health indication; the second compound, AN5568, also referred to as SCYX-7158, is licensed to Drugs for Neglected Diseases initiative, or DNDi, for the potential treatment of human African trypanosomiasis (HAT, or sleeping sickness); and the third compound is licensed to GlaxoSmithKline, LLC for development in tuberculosis. Anacor also has a pipeline of other internally discovered topical and systemic boron-based investigational compounds in development. For more information, visit http://www.anacor.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the progress, timing and results of Anacor's clinical trials, safety and efficacy of Anacor's product candidates, timing and potential approval of Anacor's product candidates and timing and potential commercial success of Anacor's products. These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "may," "might," "will," "should," "estimate," "project," "plan," "anticipate," "expect," "intend," "outlook," "believe" and other similar expressions are intended to identify forward looking statements. Readers are cautioned not to place undue reliance on these forward looking statements, which speak only as of the date of this release and Anacor undertakes no obligation to update any forward-looking statement in this press release except as required by law. These forward-looking statements are based on estimates and assumptions by Anacor's management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks and uncertainties. The following represent some, but not necessarily all, of the factors that could cause actual results to differ from historical results or those anticipated or predicted by Anacor’s forward-looking statements: Anacor's ability to timely and successfully launch, either alone or with a partner, KERYDIN; any issues or delays arising during the course of Anacor's Phase 3 studies or other clinical trials relating to AN2728; any delay or failure by the FDA to approve AN2728; Anacor's ability to timely and successfully launch, either alone or with a partner, AN2728; and the other risks identified in Anacor's periodic filings, including Anacor's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.

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