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## News Release

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### **Aqua Pharmaceuticals, LLC Announces the U.S. Food and Drug Administration (FDA) Approval of ACTICLATE™ (doxycycline hyclate USP) Tablets, 150 mg and 75 mg**

West Chester, Pa. — July 28, 2014

West Chester-based Aqua Pharmaceuticals, an Almirall company, today announces the U.S. Food and Drug Administration (FDA) approval of the NDA for ACTICLATE™ (doxycycline hyclate USP) Tablets, 150 mg and 75 mg, thereby continuing Aqua's leadership in medical dermatology and oral antibiotics for acne. ACTICLATE™ is a tetracycline-class antibacterial indicated for the treatment of a number of infections, including adjunctive therapy in severe acne.

ACTICLATE™ will be entering the dermatology-focused, branded oral antibiotic market, which, according to IMS, is currently valued at \$798 million.

ACTICLATE™ 150 mg tablets have two functional scores, providing several dosing options to physicians and patients. The ACTICLATE™ film-coated, round 75 mg tablets and oval-shaped, dual-scored 150 mg tablets are designed to be small and easy to swallow. Utilization of the latest manufacturing technology has allowed 150 mg of doxycycline to be formulated in a substantially reduced tablet size for ACTICLATE™.

"We are pleased to bring ACTICLATE™ to market," said Craig Ballaron, Chief Executive Officer at Aqua. "This launch represents our commitment to Aqua's continuing legacy of bringing high-quality, effective drugs to the dermatology specialty. We plan to begin detailing physicians on the benefits of ACTICLATE™ in the coming weeks."

Aqua has already received positive feedback about the benefits of ACTICLATE™ from within the dermatology community.

According to Dr. James Del Rosso who is a recognized educator and researcher in dermatology that has been an invited lecturer both nationally and internationally on acne, has over 150 peer-reviewed publications, has co-edited a textbook on acne, and is Adjunct Clinical Professor of Dermatology at Touro University College of Osteopathic Medicine in Henderson, Nevada, "ACTICLATE™ is a new formulation of doxycycline that is a double-scored 150 mg tablet available in a much smaller tablet size than other available scored doxycycline tablets. This allows for dosing flexibility and may be easier for the patient to swallow."

### **Important Safety Information Regarding ACTICLATE™ (doxycycline hyclate USP) Tablets, 150 mg and 75 mg**

- ACTICLATE™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

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- ACTICLATE™ Tablets are contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
- The use of drugs of the tetracycline-class during tooth development (last half of pregnancy, infancy, and childhood to 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown).
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ACTICLATE™, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *Clostridium difficile* may need to be discontinued.
- Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Limit sun exposure.
- Intracranial Hypertension (IH) has been associated with the use of tetracyclines. Women of childbearing age who are overweight or have a history of IH are at greater risk for developing tetracycline-associated IH.
- Adverse reactions observed in patients receiving tetracyclines include the following: anorexia, nausea, vomiting, diarrhea, rash, photosensitivity, urticaria and hemolytic anemia. Additional adverse events identified after marketing doxycycline hyclate include: Stevens-Johnson syndrome, rise in BUN, angioneurotic edema, exacerbation of systemic lupus, thrombocytopenia, neutropenia and eosinophilia.
- Concurrent use of tetracycline may render oral contraceptives less effective.
- Pregnancy Category D. ACTICLATE™ use during nursing should be avoided, if possible.
- Patients are advised to drink fluids liberally along with doxycycline to reduce the risk of esophageal irritation and ulceration.

### **About Aqua Pharmaceuticals**

Headquartered in West Chester, Pennsylvania, Aqua Pharmaceuticals, an Almirall company, is dedicated to helping patients achieve their goals of healthy skin and a positive self-image. The company has leading branded prescription drugs in four therapeutic categories that include acne, steroid-responsive dermatoses, actinic keratoses and seborrheic dermatitis.

For more information and the Full Prescribing Information for ACTICLATE™, please visit [www.aquapharm.com](http://www.aquapharm.com).

### **About Almirall**

Almirall is a global company based in Barcelona dedicated to providing valuable medicines through its R&D, agreements and alliances. Our work covers the whole of the drug value chain. A consolidated profitable growth allows us to devote our talent and efforts in the respiratory and dermatology areas, with a focused interest in gastroenterology and pain. Our size enables us to be agile and flexible so that we can accomplish the purpose of taking our innovative products wherever they are needed.

Founded in 1943, Almirall is listed on the Spanish Stock Exchange (ticker: ALM) and it has become a source of value creation for society due to its vision and the commitment of its long-standing major shareholders. In 2013, its revenues totaled 825 million euros and, with more than 3,000 employees, it has gradually built up a trusted presence across Europe, as well as in the United States, Canada and Mexico.

For more information, please visit [www.almirall.com](http://www.almirall.com).