Paratek to Receive $4 Million Payment From Actavis With Initiation of Phase 3 Trial of Sarecycline

BOSTON, Jan. 6, 2015 (GLOBE NEWSWIRE) -- Paratek Pharmaceuticals, Inc. (Nasdaq:PRTK) today announced Actavis will be making a $4 million milestone payment to Paratek under the terms of the parties' collaboration for the development of sarecycline (WC3035). Under the collaboration, Actavis has initiated Phase 3 clinical trials of sarecycline in moderate to severe acne. Paratek will be entitled to additional payments upon the achievement of regulatory and commercialization milestones, including the FDA's acceptance of a new drug application (NDA) from Actavis, FDA approval and royalties on future sales.

"The commencement of the Phase 3 clinical trials by our collaboration partner Actavis is a significant step forward towards the potential commercialization in the U.S. of our proprietary compound sarecycline. We believe that sarecycline has the potential to be an important new once-daily oral medication for the treatment of moderate to severe acne," said Evan Loh President and Chief Medical Officer Paratek.

In July 2007, Paratek entered into a collaboration and exclusive US research, license, development and commercialization agreement with Warner Chilcott (which was subsequently acquired by Actavis) for sarecycline. The companies are currently developing sarecycline as a potential treatment for moderate to severe acne vulgaris. Paratek designed and developed sarecycline specifically for the treatment of acne. Sarecycline is a tetracycline-derived compound that, based on pre-clinical studies, Paratek believes demonstrates a narrow spectrum of antibacterial activity against relevant skin bacterial pathogens and will demonstrate a favorable tolerability profile compared to existing oral tetracycline antibiotics that are the standard of care today. Paratek retains the rights to develop and commercialize sarecycline in all territories outside the US.

About Sarecycline

Sarecycline is a novel, tetracycline-derived, narrow-spectrum antibiotic being developed for use as an oral once daily antibiotic treatment for patients suffering from moderate to severe acne vulgaris. Sarecycline was designed by Paratek as a narrow-spectrum antibiotic with anti-inflammatory activity and the potential for a favorable tolerability profile.

About Acne

Acne vulgaris is a chronic inflammatory dermatosis which is notable for open and/or closed comedones (blackheads and whiteheads) and inflammatory lesions including papules, pustules, or nodules.

Acne occurs most commonly during adolescence and affects a majority of teenagers in the western world[1,2]. As reported in The Journal of Investigative Dermatology, in 2010 acne was estimated to be one of the top ten most common diseases globally, affecting approximately 650 million people[3].

About Paratek

Paratek Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapies based upon its expertise in novel tetracycline chemistry. Paratek's lead product candidate, omadacycline, is a new tetracycline-derived, broad-spectrum antibiotic being developed in both once-daily oral tablet and intravenous formulations for potential use as a first-line monotherapy antibiotic for ABSSSI, CABP, urinary tract infections (UTI) and other serious community-acquired bacterial infections, particularly when antibiotic resistance is of concern. Omadacycline has received Qualified Infectious Disease Product (QIDP) designation by the U.S. Food and Drug Administration for both the oral and intravenous formulations in all three of these infectious disease categories. Paratek has Special Protocol Assessment agreements with the FDA for the phase 3 trials planned in ABSSSI and CABP.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives, intentions, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to the possibility that Paratek will receive additional milestone payments from Actavis or that Actavis will generate sales of sarecycline that will result in the payment of royalties to Paratek, the potential use and effectiveness of sarecycline for the treatment of moderate to severe acne, the timing of Actavis' phase 3 clinical trials in moderate-severe acne for sarecycline, the ability of Actavis to secure regulatory approval of sarecycline for the treatment of moderate to severe acne, the size of the potential market for medications to treat acne, Paratek's ability to develop its drug candidates for potential commercialization, the potential for omadacycline to be successfully developed for use as a first-line monotherapy for patients suffering from serious community-acquired bacterial infections, the potential of omadacycline to become the primary antibiotic choice of physicians for the treatment of serious community-acquired bacterial infections, including ABSSSI, CABP and UTI. Paratek may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Paratek makes, including the risks that Paratek's or Actavis' planned clinical trials may be prolonged or delayed which may require Paratek to incur additional costs or which may delay or permanently postpone Paratek's receipt of milestone payments from Actavis; that planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities; that Paratek's

product candidates may have undesirable side effects which may delay or prevent marketing approval; that, even if approved by the FDA or non-U.S. regulatory authorities, Paratek's product candidates may not achieve broad market acceptance; and the risks described in the "Risk Factors" sections of the Registration Statement on Form S-4 (file no. 333-298464) and of Paratek's periodic reports filed with the SEC. Paratek does not assume any obligation to update any forward-looking statements, except as required by law.

1)Taylor, Marisa; Gonzalez, Maria; Porter, Rebecca (May–June 2011). "Pathways to inflammation: acne pathophysiology." European Journal of Dermatology **21** (3): 323–33.

2)Dawson, A. L.; Dellavalle, R. P. (2013). "Acne vulgaris." BMJ **346: f2634**

3)Hay, RJ; Johns, NE; Williams, HC; Bolliger, IW; Dellavalle, RP; Margolis, DJ; Marks, R; Naldi, L; Weinstock, MA; Wulf, SK; Michaud, C; J L Murray, C; Naghavi, M (Oct 28, 2013). "The Global Burden of Skin Disease in 2010: An Analysis of the Prevalence and Impact of Skin Conditions." The Journal of Investigative Dermatology **134** (6): 1527–34

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