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## Parnell Announces Results From the Successful Efficacy Study for Zydax(R)

### Zydax Effective in Reducing Osteoarthritis Pain and Interference in Dogs in Large-Scale Pilot Efficacy Study

OVERLAND PARK, Kan., Sept. 3, 2014 (GLOBE NEWSWIRE) -- Parnell Pharmaceuticals Holdings Ltd (Nasdaq:PARN) today announced the results from a successful, large-scale efficacy study of Zydax, for the treatment of the clinical signs of canine osteoarthritis, or OA. Zydax is intended to stimulate the growth of new cartilage and inhibit cartilage breakdown for the treatment of OA in dogs and horses.

The multi-site, double-blinded, randomized, placebo-controlled pilot study was designed to ascertain the effectiveness of Zydax in reducing pain and interference caused by osteoarthritis in dogs and to determine a prospective clinical endpoint to be used in an upcoming pivotal efficacy study. 140 dogs (94 treated and 46 control) completed the study, which required dog owners to use the Canine Brief Pain Inventory (CBPI) assessment tool. Developed by University of Pennsylvania, the CPBI uses a 10-point scale to score four Pain Criteria and six Interference Criteria. The four pain scores are averaged to provide the *Pain Severity Score* (PSS), and the six interference scores are averaged to give the *Pain Interference Score* (PIS). Both the Pain and Interference criteria are assessed at baseline, following two injections of Zydax (14 days after commencement) and one week after the last of four injections of Zydax (day 28 of the study).

The clinical endpoint was analyzed using a reduction of more than 2.5 points in either the PSS or PIS (with the other criteria not increasing by more than 0.5 point) and no reduction in a general Quality of Life Score. 54 percent of dogs treated with Zydax and 35 percent of dogs on placebo met the clinical endpoint, producing a statistically significant outcome ( $p=0.01$ ).

"Based on this successful study, Zydax has the potential to be the first OA treatment to target the core deficit of osteoarthritis rather than just focusing on inflammation. Not only does Zydax have disease-modifying characteristics, it has a very safe profile over long-term use," said Robert Joseph, President and CEO of Parnell. "We feel confident, based on our strong pilot study results, that we have adequately assessed various efficacy assessment tools, including the CBPI and will be able to effectively design and complete a Pivotal Efficacy study appropriate for achieving registration of Zydax in major markets. We are excited about the imminent commencement of the Zydax pivotal efficacy trial in October 2014, with results anticipated in the first half of 2015."

Further objective evidence of the efficacy of Zydax treatment in reducing the clinical signs of osteoarthritis included:

- A 43 percent improvement in the clinical signs of osteoarthritis was observed across all ten CBPI criteria for the Zydax treated group.
- At Day 28, there was a significant difference between Zydax and placebo-treated animals for *Pain at Worst* ( $p=0.02$ ), *Interference with General Activity* ( $p=0.02$ ), *Enjoyment of Life* ( $p=0.04$ ), *Ability to Rise Up* ( $p=0.04$ ), *Ability to Run* ( $p=0.03$ ), as well as for the PIS ( $p=0.03$ ).
- In addition to the CBPI efficacy model results, veterinarians conducted lameness examinations at baseline and at day 28. There was a significant difference between the Zydax and placebo groups for the criteria of *Lameness Assessed at a Trot* ( $p=0.03$ ), as well as for *Pain on Palpation* ( $p=0.03$ ).

#### About Zydax®

Zydax is Parnell's patented sulfate ester with disease-modifying characteristics for the treatment of OA in dogs and horses. Osteoarthritis is a slowly progressive and often severely degenerative joint disease. While currently available treatments for OA, such as anti-inflammatory drugs, ease the clinical signs of osteoarthritis for the short term. Zydax is designed to enable veterinarians and animal owners to safely and effectively manage the cause of OA over the life of the dog. Zydax targets the core deficit of OA by impacting both the anabolic and catabolic pathways of articular cartilage metabolism, stimulating the growth of new cartilage and inhibiting the Aggrecanase 1 enzyme, which is responsible for cartilage breakdown. Zydax is approved in Australia and New Zealand for the treatment of OA in dogs, and marketed in Asia and the Middle East for the treatment of OA in horses. With more than one-million doses sold, Zydax has led to the improved quality of life for dogs and improved performance of sport horses.

#### About Parnell

Parnell (Nasdaq:PARN) is a fully integrated pharmaceutical company focused on developing, manufacturing and commercializing innovative animal health solutions. Parnell currently markets five products for companion animals and

production animals in 14 countries and augments its pharmaceutical products with proprietary software platforms - iKAM and mySYNCH. These innovative technology solutions are designed to enhance the quality of life or performance of animals, while driving customers' operational efficiency and profitability. Parnell believes its value-added solutions help establish them as a business partner with customers rather than only as a commodity provider, differentiating them from competitors.

For more information on the Company and its products, please visit [www.parnell.com](http://www.parnell.com).

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements and information within the meaning of the U.S. Private Securities Reform Act of 1995. Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "develops," "believes," and words and terms of similar substance used in connection with any discussion of future operating or financial performance identify forward-looking statements. Forward-looking statements represent management's present judgment regarding future events and are subject to a number of risk and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to, risks and uncertainties regarding Parnell's research and development activities, its ability to conduct clinical trials of product candidates and the results of such trials, as well as risks and uncertainties relating to litigation, government regulation, economic conditions, markets, products, competition, intellectual property, services and prices, key employees, future capital needs, dependence on third parties, and other factors, including those described in Parnell's Form F-1 Registration Statement effective June 18, 2014. In light of these assumptions, risks, and uncertainties, the results and events discussed in the forward-looking statements contained in this press release might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Parnell is under no obligation, and expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events, or otherwise.

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