Press Releases

Nexvet Announces Positive Results From NV-01 Pivotal Study in Dogs With Osteoarthritis

Primary Endpoint Achieved

Conference Call November 16th at 9:00AM ET

DUBLIN, Ireland, Nov. 16, 2015 (GLOBE NEWSWIRE) -- Nexvet Biopharma (Nasdaq:NVET), a veterinary biologics developer, today announced positive results from its pivotal safety and efficacy study of NV-01, the Company's anti-nerve growth factor (NGF) monoclonal antibody (mAb) therapy in development for the control of pain associated with osteoarthritis in dogs. The study met its primary endpoint as agreed under protocol concurrence with the Center for Veterinary Medicine (CVM) at the U.S. Food and Drug Administration (FDA). The primary endpoint achieved was a statistically significant (p=0.038) improvement over placebo in the assessed level of pain as measured using changes in Client-Specific Outcome Measures (CSOM) score between enrolment and day 28. Additionally, NV-01 was found to be safe and well-tolerated with no significant adverse safety signals observed in the study.

Clinically meaningful magnitudes of benefit and statistically significant differences over placebo were also achieved for the majority of the secondary endpoints measured in the study. These included pain assessments measured using the validated pain scoring protocols CSOM and CBPI (Canine Brief Pain Inventory) at various points in time. Collectively, the results of this study constitute a substantial body of efficacy data that Nexvet intends to use as the basis of its planned submissions for marketing authorizations in both the U.S. and Europe.

A conference call will take place today at 9:00AM ET where management will discuss the results. Dial-in information is posted below.

"This is a tremendous outcome for Nexvet and we are particularly pleased to receive strong data supporting the long duration of efficacy following a single monthly injection, a key advantage for monoclonal antibody therapies over small molecules. This achievement is a testament to the power and potential of our proprietary PETization platform, invented by our Chief Scientific Officer Dr. David Gearing, to produce effective 100% species-specific veterinary therapeutic candidates," commented Dr. Mark Heffernan, Chief Executive Officer of Nexvet.

This pivotal, multi-center, placebo-controlled, randomized, double blind study was conducted at 12 sites (6 in the U.S. and 6 in Europe). Protocol concurrence was received from the FDA CVM in August 2014. The final number of evaluable dogs in the study was 246, with 80 receiving placebo and 166 receiving NV-01. Dogs participating in the study received a subcutaneous injection of NV-01 once per month for three months. Nexvet plans to publish the final study report in a peer-reviewed journal in due course.

The Company plans to discuss further details regarding the NV-01 pivotal study and its other programs at its Animal Health Symposium, taking place in New York City on November 23, 2015. Parties interested in attending should email ir@nexvet.com (http://www.globenewswire.com/newsroom/ctr?d=10156353&l=8&a=ir%40nexvet.com&u=mailto%3Air%40nexvet.com).

Conference Call Information:

Interested participants and investors may access today's conference call regarding the NV-01 study results by dialing:

Participant dialing from the U.S.: (877) 303-1599

Participant dialing from outside the U.S.: +1 (440) 996-5696

Conference ID: 82527564

To access a live webcast of the conference call, please visit the Investor Relations section of the Nexvet website at http://ir.nexvet.com/ (http://www.globenewswire.com/newsroom/ctr?d=10156353&l=14&u=http%3A%2F%2Fir.nexvet.com%2F), where an audio archive of the webcast will also be available following the call.

About Nexvet ((http://www.globenewswire.com/newsroom/ctr?d=10156353&l=15&a=www.nexvet.com&u=http%3A%2F%2Fwww.nexvet.com%2F)**www.nexvet.com (http://www.nexvet.com))**

Nexvet is a veterinary biologics developer focused on transforming the therapeutic market for companion animals, such as dogs and cats, by developing and commercializing novel, species-specific biologics. Nexvet's proprietary PETization™ platform is designed to rapidly design monoclonal antibodies ("mAbs") that are recognized as "self" or "native" by an animal's immune system, a property Nexvet refers to as "100% species-specificity." Nexvet's product candidates also build upon the safety and efficacy data from clinically tested human therapies, thereby reducing clinical risk and development cost.

Nexvet is leveraging diverse global expertise and incentives to build a vertically integrated biopharmaceutical company, which conducts drug discovery in Australia, clinical development in the United States and Europe and is growing its biomanufacturing capabilities in Ireland.

Forward-Looking Statements

All statements in this press release other than statements of historical fact are forward-looking statements. This includes statements regarding planned regulatory submissions for NV-01 marketing approvals, the timing and cost of pursuing such approvals, future presentations regarding the NV-01 study, and other express or implied statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to materially differ from the results, performance or achievements expressed or implied by the forward-looking statements. The words "may," "plan," "potential," "will" or similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future results, performance or achievements. Factors that could cause actual results, performance or achievements to differ materially include those summarized under Risk Factors in our reports on Forms 10-Q and 10-K and the other documents we file from time to time with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements. We undertake no obligation to revise or update these forward-looking statements, except as required by law.

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