Zenoaq and Nexvet Announce PD-1 mAb Candidate for Canine Cancer

USDA Regulatory Jurisdiction Confirmed

FUKUSHIMA, Japan – May 2, 2016 – Zenoaq (Nippon Zenyaku Kogyo Co., Ltd.), a leading Japanese animal health company and Nexvet Biopharma (Nasdaq: NVET), a veterinary biologics developer, announced today their research and development collaboration has yielded fully caninized, or ‘100% dog’, monoclonal antibodies (mAbs) that bind and potently inhibit the immuno-oncology target programmed cell death protein 1 (PD-1). The United States Department of Agriculture Center for Veterinary Biologics has confirmed jurisdiction over the regulatory path for this program, providing an opportunity for conditional licensure*. The anti-PD-1 program will now enter further safety, pharmacokinetic and immunogenicity studies. Results will inform decisions regarding candidate suitability and the design of any further studies required for regulatory approval.

The research and development collaboration between Zenoaq and Nexvet is focused on PETizing mAbs identified by Zenoaq to create candidates in immuno-oncology and allergy/inflammation for companion animals. Zenoaq and Nexvet will share the development costs of their collaboration programs. Zenoaq will retain European and Asian marketing rights to any resulting products, with Nexvet retaining rights to the rest of the world, including North America.

“Nexvet’s PETization technology and expertise with veterinary mAb development have delivered the first key milestone for our collaboration. We are extremely pleased the starting anti-PD-1 mAbs first identified by Zenoaq’s collaborator, Professor Takuya Mizuno of the Joint Faculty of Veterinary Medicine, Yamaguchi University, have PETized so successfully and delivered such robust binding and potency characterization against canine PD-1,” said Mr. Keiichi Takano, President of Zenoaq.
“Cancer therapeutics is an area where veterinary medicine has not benefited from the many major advances in human biologics development. Cancer leads to significant morbidity and mortality in pet dogs, and the incidence of cancer will only increase as dogs live longer. Given the wealth of data generated in humans supporting the attractive safety profile and efficacy of PD-1 inhibitors against a variety of tumor types, we are excited to be advancing an anti-PD-1 antibody program for dogs with Zenoaq,” said Dr. Mark Heffernan, Chief Executive Officer of Nexvet.

About PD-1 and canine cancer

The PD-1 protein and a partner molecule, programmed death-ligand 1 (PD-L1), act in concert to reduce the immune system’s anti-tumor activity, allowing cancer growth and spread. In human medicine, blocking the interactions of PD-1 and PD-L1 has resulted in approved therapies with attractive safety profiles that demonstrate efficacy against multiple tumor types. These advancements have led to immuno-oncology (also called cancer immunotherapy) being hailed as a breakthrough for oncology, and a major investment target. The first human PD-1 inhibitor received regulatory approval in late 2014, and PD-1 inhibitors alone are predicted to achieve human sales of approximately $14 billion by 2020.

Zenoaq and Nexvet believe the clinical successes seen in human disease can be replicated in canine disease to produce effective therapies for multiple tumor types in dogs. Successful cancer immunotherapies would be a new paradigm in veterinary oncology where current standards of care, including surgery, chemotherapy and radiotherapy, have exhibited significant treatment limitations.

Nexvet’s PETization platform is designed to build upon the safety and efficacy data from clinically tested human therapies to create new candidates for companion animals, thereby reducing clinical risk and development cost. Blocking canine PD-1/PD-L1 interactions has been shown to result in an increase of immune cell activity, via a similar mechanism to that observed in humans. In related research, high levels of PD-L1 expression were detected in a majority of tumor samples taken from several types of canine cancer, suggesting that PD-1/PD-L1 interactions may be exploited by the cancers.
Dogs are susceptible to many of the same types of cancers that afflict people. Epidemiological studies have indicated that cancer is the leading cause of death in dogs over 10 years of age, with 50 percent of older dogs developing cancer and approximately one in four dogs eventually dying from cancer.

* Conditional licensure allows for market entry of a product on a comparatively rapid basis, under certain conditions, after a demonstration of purity, safety and a reasonable expectation of efficacy. While a conditional licensure is in place, the license holder continues to develop efficacy data.

**About Nexvet (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, conducts clinical development in the United States and Europe and is growing its biomanufacturing capabilities in Ireland.

**About Zenoaq (http://www.zenoaq.jp/english/)**
Established in 1946, Zenoaq (Nippon Zenyaku Kogyo Co., Ltd.) is a leading animal health company in Japan and will be welcoming its 70th Anniversary this summer. With a workforce of nearly 700 employees and the generation of ¥28 billion in sales (approximately US$248.5 million) in the 2015 fiscal year, Zenoaq has a solid business model focused on R&D, manufacturing and importation of animal health products, contributing to a broad product portfolio for production and companion animals. In addition, Zenoaq, headquartered in Fukushima, has the widest distribution network for veterinary products in Japan, supported by a strong direct sales force. In June 2014, Zenoaq launched Allermmune HDM, a first-of-its-kind desensitization therapy for house dust mite-induced canine atopic dermatitis, reflecting the company’s increased focus on
an innovative pipeline for the companion animal market. Zenoaq's partners include Merial, Vetoquinol, Mars, Intervet, DSM Nutrition as well as IDEXX Laboratories.

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