



Vanda Announces New Study Results Showing a High Degree of Inbreeding in Beagle Dogs

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Questions the routine use of dogs in human drug toxicology studies.

WASHINGTON, Oct. 23, 2019 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (VANDA) (NASDAQ: VNDA) today announced results of a comparative genomics study presented at the 2019 American Society of Human Genetics (ASHG) conference on October 19, 2019, entitled "*Using Patterns in Regions of Homozygosity to Evaluate the Use of Dogs as Preclinical Models in Human Drug Development*".



Vanda researchers compared the degree of genetic inbreeding in Beagle dogs using the measure of Runs of Homozygosity (ROH). This analysis identifies contiguous regions of the genome that are inherited as identical from both parents. The study showed that unrelated humans show these regions of homozygosity in about 1/1000 of their genomes, while Beagle dogs do so in 12.8 percent of their genome.

This means that Beagle dogs are on average 100 times more inbred than humans. In the same study, Vanda researchers examined the degree of inbreeding in the genetic isolate of the Amish in Pennsylvania, which showed that they were approximately 12 times more inbred than the general population. It is well established in the drug efficacy and safety scientific literature that genetic isolates such as Amish populations cannot be generalized for the population at large.

Beagle dogs are routinely used for studying the safety of new pharmaceuticals. This practice has been in place for one hundred years and is still followed today by both pharmaceutical developers and regulators. The present study is significant and casts substantial doubt over the predictive validity of these commonly conducted dog studies. The high degree of inbreeding seen would suggest that the use of Beagle dogs is a poor model to predict toxicity even for other dog breeds and an inappropriate model to do so for humans. Therefore, Beagle dogs should be regarded as an inadequate model species for predicting drug safety in humans.

The results of this study should caution against the routine use of dogs in human drug toxicology studies. Instead, these results should encourage researchers and regulators to adopt appropriate and relevant scientific approaches to ensure human drug safety.

ABOUT VANDA PHARMACEUTICALS INC.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

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