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Clinical trial data for encapsulated cell product to improve cancer treatment published in the journal PLOS ONE

Clinical trial data shows encapsulated cells enhances effects of a breast cancer chemotherapeutic

Singapore July 17, 2014

Austrianova, and its partner Nuvilex Inc, announced today that important clinical data has been published in PLOS ONE, an international, rigorously peer-reviewed, open-access, online publication which covers primary research and clinical trial data. The manuscript reports key data from a phase I/II clinical trial, performed in collaboration with the University of Life Sciences at the Faculty of Veterinary Medicine, Lublin, Poland, in companion dogs with mammary tumours. The dogs received encapsulated cells overexpressing cytochrome P450 enzyme isoform 2B1 that were injected around malignant mammary tumours arising spontaneously in these pets. The companion animals were then given cyclophosphamide, one of the standard chemotherapeutic agents used for the treatment of mammary tumours in dogs (and breast cancer in humans). The dogs were assessed for a number of clinical parameters as well as for reduction in tumour size. Importantly, treatment was well tolerated with no evidence of adverse reactions or side effects being associated with the administration of the encapsulated cells. Reductions in tumour size were observed in all of the treated dogs that was above and beyond that of dogs receiving only cyclophosphamide alone. Taken together, this data suggests that encapsulated cytochrome P450 expressing cells combined with chemotherapy may be useful in the local treatment of a number of dog mammary tumours and support the performance of further clinical studies to evaluate this new treatment. Moreover the data suggests that encapsulated cells plus cyclophosphamide could also be beneficial for the treatment of certain forms of breast cancer in women.

The PLOS ONE article can be accessed online at: http://dx.plos.org/10.1371/journal.pone.0102061

Prof. Walter H Gunzburg, Chairman of the Board of Austrianova, said "Austrianova is a pioneer in the development of encapsulated cells for the treatment of solid tumours and this latest clinical data confirms this. Working closely together with Nuvilex Inc, this treatment will be advanced to the market for a variety of tumour types".

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Dr. Brian Salmons, CEO of Austrianova, stated "We are delighted that this data is in the public domain. It confirms and extends that safety and efficacy data that has been obtained in human clinical trials. These dogs were fully immunocompetent and the encapsulated cells were shown to survive after implantation for at least 20 weeks under challenging conditions. The treatment regime could form the basis for the treatment of a variety of cancers in companion animals as well as in humans".

About Austrianova:

Austrianova, part of the SG Austria Group, is a biotech company with a global footprint and headquarters in Singapore. Austrianova utilizes a novel and proprietary technology for the encapsulation of living mammalian (Cell-in-a-Box®) and bacterial (Bac-in-a-Box®) cells. Cell-in-a-Box® protects the encapsulated cells from rejection by the immune system, allows cells to be easily transported, stored and implanted at specific sites in patients. The technology, which has been proven safe and efficacious in clinical trials carried out in Europe, allows companies to develop any kind of cells as a one-for-all living pharmaceutical. Bac-in-a-Box® is a similar protective device adapted for encapsulation of probiotic bacteria where it has human food and animal feed applications due to its ability for extending storage under lyophilized conditions and protection in stomach acid.

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