
Proof of Concept in Animals for AdaptVac's breast cancer vaccine published in scientific journal

Hørsholm, Denmark, November 28, 2017 – AdaptVac announces that the scientific article "Virus-like particle display of HER2 induces potent anti-cancer responses" is published in the peer reviewed journal 'OncoImmunology', and will be available online on November 28, 2017. The paper presents proof of concept in animals (POCA) for AV001, AdaptVac's novel vaccine targeting HER2 positive breast cancer tumours. The vaccine is demonstrated to be effective both in prevention and therapy of mammary carcinomas in HER2 transgenic mice.

"This publication demonstrates the potential of AdaptVac's platform technology to deliver effective and affordable cancer immunotherapies to address significant unmet medical needs throughout the world", says Dr. Wian de Jongh, AdaptVac's CEO.

AV001 demonstrated as an effective treatment of HER2+ cancer in animal models

The study was conducted as a collaboration between the groups of Professor Pier-Luigi Lollini, Department of Experimental, Diagnostic and Specialty Medicine at the University of Bologna in Italy, and Adam Sander, CSO AdaptVac and Associate Professor at the Centre for Medical Parasitology at the Department of Immunology and Microbiology, University of Copenhagen.

Vaccination of mice from the state of the art advanced breast cancer mouse model, which develop mammary carcinomas expressing HER2, lead to 50% to 100% tumour-free survival. Furthermore, vaccinated mice developed significantly fewer and slower growing tumours than untreated mice. These results compare very well to data generated in this mouse model using the monoclonal antibody HERCEPTIN, a marketed therapy for HER2 Positive Metastatic Breast Cancer and HER2 Positive Gastric Cancer, in published studies. HER2 (human epidermal growth factor receptor 2) is a specific gene that plays a significant role in the development of breast cancer.

AdaptVac AV001 vaccine aims to be an affordable HER2+ cancer treatment

AdaptVac's Virus-Like Particle platform aims to eliminate the need for expensive monoclonal antibody treatment by making the body produce its own antibodies against the HER2 tumour target. AV001 is expected to be given similarly to a flu vaccination, requiring micrograms of vaccine, instead of intravenous infusions of grams of antibodies throughout a treatment course of one year. This suggests that the cost of treatment can be reduced dramatically.

Few can afford current monoclonal antibody treatments

Current monoclonal antibodies therapies, such as HERCEPTIN, have enabled breakthroughs in cancer care, but at a high cost. The current price for a full course of HERCEPTIN is 340,000 DKK in the USA, and the UK alone spent more than 1 Billion DKK in 2014 on HERCEPTIN treatments. Beside the burden to the health care systems in the Western world, the high price means that most people throughout the world presently cannot afford treatment, leaving a large unmet medical need for an effective and affordable HER2+ cancer treatment.

AV001 shows promise as a rescue therapy for HERCEPTIN non-responders or patients that develops resistance to monoclonal antibody therapy

Treatment of HER2-positive breast cancer with monoclonal antibodies can unfortunately lead to severe side effects, as well as drug resistance development. The need to immunise patients every third week with high doses of drug often results in immune reactions against the therapeutic, which in turn can lead

to treatment failure. Most patients with HER2-positive breast cancer acquire resistance to HERCEPTIN within the first year, leading to reduced efficacy or requiring the treatment to be stopped prematurely.

In our study, wild-type mice were injected with either a HERCEPTIN resistant HER2+ cancer cell line or a HERCEPTIN sensitive HER2+ cancer cell line, followed by injection of AV001. Our results show that AV001 could significantly delay tumour growth in the mice. Furthermore, it was demonstrated that AV001 induced antibodies inhibiting growth of both HERCEPTIN-sensitive and HERCEPTIN-resistant human breast cancer cells expressing HER2 *in vitro*. These results document the potential of AV001 as a rescue treatment for HERCEPTIN non-responders and patients with negative reactions, or for whom the treatment fails.

Strong market potential in breast cancer

Breast cancer is a widespread oncology indication affecting more than 1.3 million worldwide annually, resulting in more than 450,000 deaths (Tao, 2015: www.ncbi.nlm.nih.gov/pubmed/25543329). The most common treatment today is based on monoclonal antibodies, where the dominating therapy HERCEPTIN (trastuzumab) generates annual global sales of US\$ 7 billion. The target product profile of AdaptVac's lead breast cancer project is tailored to be highly competitive both in terms of cost and efficacy, thus aiming at a significant market share.

About AdaptVac ApS

AdaptVac is a joint venture between ExpreS²ion Biotechnologies and NextGen Vaccines, combining ExpreS²ion's platform with novel proprietary and ground-breaking Virus-Like Particle (VLP) technology, developed at the University of Copenhagen. The company aims to accelerate the development of highly efficient therapeutic and prophylactic vaccines within high value segments of oncology, infectious diseases and immunological disorders.

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