PRESS RELEASE

Positive outcome in clinical study to prevent radiation-induced dermatitis in breast cancer patients

Vienna, 5 March 2013 – APEIRON Biologics AG (Apeiron) today announced that the clinical trial with their liposomal formulation of recombinant superoxide dismutase (project APN201) which started in March 2012 concluded with positive outcomes in all endpoints analyzed.

Today, Apeiron announced that the clinical trial with APN201 (a liposomal formulation of human recombinant superoxide dismutase) has been completed and achieved all endpoints. The study was conducted at the Department of Therapeutic Radiology and Oncology of the Medical University Graz in a double blind, placebo-controlled fashion with 20 female breast cancer patients who received radiation therapy after breast-preserving surgery.

Superoxide dismutase (SOD) is nature's most potent antioxidant enzyme and renders harmless highly reactive oxygen radicals that are generated during radiation therapy, hence exerting a strongly anti-inflammatory effect. In general, about every other cancer patient receives radiation therapy in addition to chemotherapy and surgery. Often, concomitant acute skin damage occurs which is comparable to burns. The latter can be severe and even lead to discontinuation of radiation therapy. Today, this collateral damage of radiation therapy is only treated symptomatically with skin cremes.

In this pilot (phase Ib) study, APN201 was applied daily and shown to be safe and well tolerated with no drug related adverse events reported. Furthermore APN201 showed first signs towards efficacy with regard to pain, intensity of erythema (reddening of the skin) and time to occurrence of grade 2 dermatitis. Due to the small trial size, these results are not statistically significant. Thus, extended efficacy testing is now planned in head and neck cancer (HNC) patients, which are prone to a higher incidence of more severe radiation dermatitis.

APN201 is being developed clinically in collaboration with the Austrian CMO Polymun Scientific.

Hans Loibner, PhD, CEO of Apeiron: "We are very pleased with this first clinical experience of our liposomally formulated human SOD in cancer patients and the positive outcome of the study in Graz. We are convinced that APN201 has the potential to become the first causal therapy for radiation-induced dermatitis and other inflammatory conditions."

University Professor Karin S. Kapp, MD, Head and Chair of the Department of Therapeutic Radiology and Oncology, Medical University of Graz and principal investigator of the study, commented: "Acute skin toxicity which may occur during high dose radiation therapy is a severe problem for many cancer patients and can in some cases even force discontinuation of the therapy. Hence, it is of utmost clinical and scientific interest to alleviate or even prevent these side effects of radiation. It is very exciting to work on a solution for this together with Apeiron."

About Apeiron (as of March 2013):
Apeiron is a mainly privately financed biotech company in Vienna, developing immunologic and biologic therapies against cancer. Its portfolio consists of five clinical projects and some preclinical approaches. Its lead project, APN311, is in an ongoing phase III trial against high-risk neuroblastoma (a rare childhood cancer), with more than half of the patients already recruited. APN311 is a chimeric antibody targeting the GD2 antigen and is produced in CHO cells. Apeiron's second project, APN301, is an immunocytokine and currently in a phase II in the US and Canada against neuroblastoma (relapsed/refractory patients) and in a separate trial against melanoma. The recombinant human Angiotensin Converting Enzyme 2 (GSK2586881, fomerly APN01) was licensed to GlaxoSmithKline at the beginning of 2010 and is in an ongoing phase II study. Apeiron is operational since 2006 and currently employs 23 people.

About SOD:
SOD is a natural enzyme of our body with significant anti-oxidative properties. It catalyzes the breakdown of harmful superoxides and thereby reduces the extent of the concomitant tissue damage. Recombinant human SOD has already been tested in several clinical studies and has shown signs of efficacy in the treatment of certain inflammatory processes.

About Polymun (as of March 2013):
Polymun Scientific Immunbiologische Forschung GmbH was founded by professor Hermann Katinger in 1992 and has been offering contract development and production of biopharmaceuticals and liposomal formulations ever since. Moreover, Polymun holds a license for the production of pharmaceuticals according to the Austrian medicines law since 2001. Another area of activity is the production and distribution of research reagents, especially for HIV research. Polymun also develops products and is a partner in several international research projects (EU framework program for research, Bill and Melinda Gates Foundation).

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