Apeiron Acquires Rights for a Phase II Biologic Against Neuroblastoma and Other Cancers from Merck KGaA, Germany

Vienna, Austria, 1 February 2011 - Vienna-based biotech company Apeiron Biologics AG strengthens its cancer immunotherapy portfolio by acquiring rights to further develop and commercialize the immunocytokine hu14.18-IL2 from Merck KGaA, Germany. This investigational antibody-based biologic has met drug development checkpoints to proceed to Phase III in certain pediatric neuroblastoma subjects in a Phase II clinical study and Apeiron plans to continue clinical development of hu14.18-IL2 in 2011. Following a first in-licensing deal closed in October 2010 (project rhSOD from Polymun), this agreement complements the company's successful program to broaden its clinical development pipeline. This project expansion was initiated as a consequence of Apeiron's out-licensing of the Phase I project APN01 to GSK in January 2010.

Apeiron Biologics AG, Vienna (Austria) announced today the signing of an agreement that will grant Apeiron the rights to further develop and commercialize the investigational immunocytokine hu14.18-IL2. This recombinant protein (immunocytokine) consists of the hu14.18 monoclonal antibody against the GD2 antigen, expressed on neuroblastoma, melanoma and other malignant tissues, fused to the cytokine interleukin-2 (IL2). hu14.18-IL2 has recently shown preliminary activity in a subset of children suffering from neuroblastoma in a Phase II clinical study*. Apeiron will continue the clinical development to further investigate the protein's therapeutic potential for pediatric neuroblastoma, an indication with high unmet medical need, and will evaluate strategies to advance it in other cancer indications, e.g. melanoma.

Dr. Hans Loibner, CEO of Apeiron, on the deal: "It is great for Apeiron to obtain the rights to this compound from Merck KGaA for further development and commercialization. I am glad that we managed to acquire an advanced clinical-stage project from one of the top international pharmaceutical companies." He added: "Pediatric neuroblastoma is a rare and life-threatening cancer and one which has limited treatment options. We will certainly look into other indications as well."

No financial details are disclosed.

*Original Publication: Antitumor Activity of Hu14.18-IL2 in Patients With Relapsed/Refractory Neuroblastoma: A Children's Oncology Group (COG) Phase II Study. Suzanne S. Shusterman, Wendy B. London, Stephen D. Gillies, Jacquelyn A. Hank, Stephan D. Voss, Robert C. Seeger, C. Patrick Reynolds, Jennifer Kimball, Mark R. Albertini, Barrett Wagner, Jacek Gan, Jens Eickhoff, Kenneth B. DeSantes, Susan L. Cohn, Toby Hecht, Brian Gadbaw, Ralph A. Reisfeld, John M. Maris, and Paul M. Sondel. Journal of Clinical Oncology (2010) 28: 4969-4975

About Apeiron (February 2011)
Apeiron Biologics AG is a privately financed Biotech company based in Vienna. In January 2010, the then lead product APN01 (recombinant human Angiotensin Converting Enzyme 2, rhACE2), an enzyme-based biotherapeutic for treatment of Acute Respiratory Distress Syndrome (ARDS) and a series of other diseases, was licensed out to GSK in a milestone-based agreement for approx. EUR 236 million. Currently, building on an existing set of innovative in-house projects, Apeiron is expanding its portfolio with clinical projects up to Phase II with a focus on biologic / immunologic therapy of cancer. In November 2010 the company concluded its first in-licensing deal: Recombinant human Superoxide Dismutase (SOD), a naturally occurring enzyme with important antioxidant properties.

About hu14.18-IL2:
Hu14.18-IL2 is a recombinant fusion protein that links the hu14.18 monoclonal antibody with interleukin-2 (IL2). As shown in laboratory studies, the antibody specifically binds to the GD2 antigen that is frequently expressed on tumors of neuroectodermal origin such as neuroblastoma and melanoma, and also on renal cell carcinoma and small cell lung cancer. IL2 is a cytokine that recruits multiple immune effector cell types. In patients, hu14.18-IL2 may localize to GD2-positive tumor cells via the antibody component. The fused IL2 is designed to stimulate the patient's immune system against tumor by activation of both NK and T cells, whereas the Fc portion of the antibody is designed to trigger tumor cell killing by ADCC (antibody-dependent cellular cytotoxicity) and CDC (complement-dependent cytotoxicity). The immunocytokine has shown preliminary activity in a Phase II clinical study in certain children with neuroblastoma* and was also tested in a Phase I/II study in late stage malignant melanoma, showing immune activation.

Contact Apeiron:
Dr. Hans Loibner, CEO
Campus-Vienna-Biocenter 5
1030 Vienna
Austria
T +43 / 1 / 865 6577
E apeiron@apeiron-biologics.com
W www.apeiron-biologics.com

Copy Editing & Distribution:
PR&D - Public Relations for Research & Education
Mariannengasse 8
1090 Vienna
Austria
T +43 / 1 / 505 70 44
E contact@prd.at
W www.prd.at

Dechert LLP acted as legal advisor to Apeiron

Vienna, Darmstadt, 1 February, 2011