Children's Oncology Group and Apeiron to Jointly Conduct Phase II Study in Neuroblastoma with hu14.18-IL2 (APN301)

Philadelphia, Vienna, Madison: 29 September 2011 - Children's Oncology Group (COG) and APEIRON Biologics AG (Apeiron) announced today that they will jointly investigate Apeiron's APN301 in a clinical phase II study in pediatric neuroblastoma patients.

APEIRON Biologics AG (Apeiron) and the Children's Oncology Group (COG) today announced a collaboration on conducting a clinical phase II study in neuroblastoma patients. Neuroblastoma, a cancer of the nervous system, can be one of the most difficult to treat childhood cancers with about 650 to 750 children diagnosed each year in the U.S. and the E.U., respectively.

In the course of this new clinical trial, Apeiron's APN301, a recombinant fusion protein consisting of the humanized anti-GD2 monoclonal antibody hu14.18 fused to the cytokine interleukin-2 (IL2), will be administered together with GM-CSF and isotretinoin to children with refractory or relapsed neuroblastoma. The design of this trial is based on a recently concluded study with an anti-GD2 monoclonal antibody, performed by COG, in which clinical activity was shown.

The study is scheduled to start in the third quarter of 2011 and will be conducted in multiple hospitals throughout the United States and Canada.

"We are excited to be working with Apeiron to continue to develop this important new approach to treating children with neuroblastoma," said Peter C. Adamson MD, Chair of the Children's Oncology Group. "Being able to leverage immunotherapy is a primary strategic initiative in our efforts to improve the outcome for patients with high-risk neuroblastoma."

Dr. Paul Sondel, Principal Investigator and Study Co-Chair (with Dr. Suzanne Shusterman): "This agent has demonstrated potent antitumor effects in preclinical work and has shown clinical antitumor activity in our recently completed clinical phase II trial. This next study is designed to provide even greater antitumor activity, to better understand the mechanisms of this activity and identify the characteristics of children most likely to respond."

Dr. Hans Loibner, CEO of Apeiron: "We are proud to collaborate with this renowned co-operative group. COG's expertise and the quality of their clinical network in the U.S. and Canada are most impressive. The study will give important insights into the efficacy of APN301 in high-risk neuroblastoma patients and the results may serve as an important component for the registration of this innovative immunotherapy."

*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 The Children's Oncology Group:
The Children's Oncology Group (childrensoncologygroup.org), a National Cancer Institute supported clinical trials group, is the world's largest organization devoted exclusively to childhood and adolescent cancer research. The Children's Oncology Group (COG) unites more than 7.500 experts in childhood cancer at more than 200 leading children's hospitals, universities, and cancer centers across North America, Australia, New Zealand, and Europe in the fight against childhood cancer. COG research has turned children's cancer from a virtually incurable disease 50 years ago into one with an overall cure rate approaching 80 percent today. Research conducted by the COG is also supported through the generosity of individuals, corporations and private foundations working with The Children's Oncology Group Foundation (TheCOGFoundation.org), which enables philanthropic resources to go directly to COG's worldwide team of researchers committed to turning new discoveries into better treatments.

About Apeiron (as of September 2011):
Apeiron is a privately financed biotech based in Vienna, Austria. Apeiron focuses on biological and immunological treatments against cancer and related conditions. Including the recently closed licence agreement for the phase III project Mab ch14.18/CHO (APN311), Apeiron's project portfolio consists of five projects under clinical evaluation, and four preclinical projects. Clinical projects include the immunocytokine hu14.18-IL2 (APN301) that is about to enter a phase II (for certain neuroblastoma patients) shortly and is also being clinically tested against melanoma. Also in clinical stage is a liposomal formulation of recombinant human Superoxide Dismutase (APN201) to prevent or treat skin damage due to radiation treatment in cancer. A further clinical project, recombinant human Angiotensin Converting Enzyme 2 (APN01), was licensed to GlaxoSmithKline early 2010. It is expected to commence a phase II study for the treatment of Acute Respiratory Distress Syndrome in the near future and has considerable potential in other disease areas. Apeiron is operational since 2006 and employs approx. 25 people.

About APN301:
APN301 (hu14.18-IL2) is a recombinant fusion protein that consists of the humanized 14.18 monoclonal antibody, which recognizes the GD2 disialoganglioside, strongly expressed on virtually all cases of human neuroblastoma, as well as on several other human cancer types (including melanoma, small cell lung carcinoma, osteosarcoma, and soft-tissue sarcoma), linked genetically to human recombinant interleukin-2 (IL2) lymphokine. IL2 has been tested extensively in clinical cancer trials and is approved as an immune activator with documented anti-tumor effects in certain cancers (melanoma and renal cell cancer).
In patients, hu14.18-IL2 localizes to GD2-positive tumor cells via the antibody component. The fused IL2 is designed to stimulate the patient's immune system against the 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). Hu14.18-IL2 has shown 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. Apeiron has obtained a world-wide exclusive licence for hu14.18-IL2 earlier this year from Merck KGaA.

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