



## PRESS RELEASE

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### Oncology Alliance:

#### Apeiron, CCRI and SIOPEN Join Forces Against Neuroblastoma

**Vienna (Austria), June 22nd 2011 –Vienna based biotech company APEIRON Biologics AG (Apeiron) strengthens its oncology pipeline: The company will support the clinical development of an immune therapy against high-risk neuroblastoma that is being conducted by the Children’s Cancer Research Institute (CCRI) and the European Neuroblastoma Research Network (SIOPEN). It is presently under investigation in a phase III trial across various European clinical centers. In return, Apeiron obtains the rights to file for regulatory approval and to market the final product. The approach is based on a monoclonal antibody (ch14.18) and constitutes Apeiron’s most advanced project. It also marks another milestone for the company and its development strategy to treat neuroblastoma. This strategy was initiated earlier this year with the licensing of a clinical phase II project from Merck KGaA.**

Today, the Vienna based APEIRON Biologics AG (Apeiron) announced the conclusion of an agreement with the Children’s Cancer Research Institute (CCRI) and the European Neuroblastoma Research Network (SIOPEN). Thereby, Apeiron obtains the rights to further develop, file for regulatory approval and market the antibody ch14.18. This monoclonal antibody exhibits therapeutic effect against high-risk neuroblastoma, an aggressive form of infant cancer. The antibody specifically targets the antigen GD2, a feature on the surface of neuroblastoma cells and thereby initiates an immune reaction against these cells.

As part of the agreement, Apeiron will provide substantial support for an ongoing European clinical phase III trial with ch14.18. Due to the limited number of clinical centers specializing in the treatment of high-risk neuroblastoma, Apeiron is considering marketing the therapy on its own.

The Austrian company Polymun Scientific, a long-time business partner of Apeiron, has already been producing clinical supplies for the CCRI/SIOPEN sponsored clinical studies. Apeiron has now commissioned Polymun to continue production and to prepare for manufacture of material at market standard.

Dr. Hans Loibner, CEO of Apeiron, commented on the successful completion of the agreement: „This novel form of collaboration with CCRI and SIOPEN is a milestone for Apeiron. These non-profit organizations have accomplished remarkable clinical development achievements which we can now complement with our industrial know-how. With this collaboration, we add a project to our portfolio that is both innovative and close to the market.“

Professor Ruth Ladenstein, head of the coordination center for clinical studies at CCRI, senior physician at St. Anna Kinderspital and European president of SIOPEN said: „We are convinced to have found an ideal partner in Apeiron for our project. Together, we will take the final steps of development for an urgently needed therapy against high-risk neuroblastoma. By applying immune therapy and other treatment improvements, we hope to increase the chances of survival for children with high-risk neuroblastoma by 30%, thereby rendering future survival rates of 60-70% realistic“

Financial details were not disclosed.

Photographs of the press conference will be available from 12.30am EST onwards at:  
[http://www.apeiron-biologics.com/news/pk\\_20110622/pk\\_20110622.html](http://www.apeiron-biologics.com/news/pk_20110622/pk_20110622.html)

About Apeiron (as of June 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 agreement for the antibody ch14.18, Apeiron's project portfolio includes five projects that are under clinical evaluation. This includes the immunocytokine hu14.18-IL2 that is about to enter a phase II/III (for certain neuroblastoma patients) shortly and is also being clinically tested against melanoma. Also in a clinical stage is a liposomal formulation of recombinant human Superoxide Dismutase to prevent or treat skin damage due to radiation treatment in cancer. A further clinical project, recombinant human Angiotensin Converting Enzyme 2, 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. 20 people.

About ch14.18:

Ch14.18 is a mouse-human chimeric monoclonal antibody against the antigen GD2 (a disialoganglioside) that is strongly expressed on the surface of neuroblastoma cells. The antibody is produced in Chinese Hamster Ovary cells, the most common cell type for the commercial production of monoclonal antibodies, and purified from the supernatant. The anti-tumor effect of ch14.18 is first and foremost based on the triggering of the body's own immunological mechanisms to destroy tumor cells to which the antibody binds due to its specificity for GD2. Ch14.18 has already shown clinical efficacy in form of remissions in children with high-risk neuroblastoma in a phase I study conducted by

SIOPEN. It is currently being tested in a broad multicentric phase III trial and other studies in many European countries. This phase III study also evaluates whether the concomitant subcutaneous administration of interleukin-2 improves the efficacy of ch14.18. Interleukin-2 is a commercially available protein that activates the body's immune cells. Positive results of this phase III may be used for registration of the product.

**About CCRI:**

The CCRI (Children's Cancer Research Institute) started its activities in 1988 under the leadership of Professor Helmut Gadner. In the last 23 years, the CCRI has accomplished pioneering work in many areas to improve the treatment quality and the chances for cure of children and adolescents suffering from cancer. Today, an internationally renowned multi-disciplinary scientific team of physicians, molecular biologists and technicians is successfully working in ten cooperating groups in the fields of tumor cytogenetics, immunology, molecular and cell biology of children cancer cells as well as clinical research. Every three years, an international expert commission reviews the CCRI to assess its scientific achievements and to give advice on further development. Since inception, the institute works on lean administration and is primarily financed by donations and competitively raised external funds.

**About SIOPEN:**

SIOPEN (Society of Paediatric Oncology European Neuroblastoma Network) is a European research network for clinical studies and integrated research with the goal to improve the survival of high-risk patients and to introduce risk-adjusted treatments to increase quality of survival. Harmonized procedures and quality management systems have paved the way towards new insights in tumor biology of neuroblastoma. A web-based database and communication system enables the joint performance of clinical studies in 18 European countries and to link them with relevant research data. This concept is currently being successfully applied to the European phase III study in high-risk neuroblastoma patients with minimal residual disease. This trial evaluates the efficacy of an immune therapy with the antibody ch14.18 with or without interleukin-2.

Vienna, June 22nd, 2011

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