APEIRON BIOLOGICS

PRESS RELEASE

Marketing Approval for Children's Cancer Immunotherapy in the EU: Outstanding Success for privately financed Austrian Biotech Company Apeiron

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On May 8, 2017, The European Commission has granted marketing authorization for "Dinutuximab beta Apeiron", an antibody-based immunotherapy the rare pediatric cancer neuroblastoma. Thanks to the Vienna-based Biotech company Apeiron Biologics AG ("Apeiron") patients in Europe are now offered an additional treatment option with a promising therapy – a result of a collaborative effort of management and employees, academic institutions, Austrian private investors, business angels as well as public and private research initiatives.

The drug "Dinutuximab beta Apeiron" improves the survival and chances for cure in the severe pediatric cancer neuroblastoma. The biological agent, an antibody, causes clinically relevant effects in both early and advanced stages of this aggressive disease. Based on the European Commission's marketing authorization Apeiron and its marketing partner EUSA Pharma will now be able to provide an immunotherapy for neuroblastoma in Europe and subsequently worldwide.

Chief Executive Officer Hans Loibner, who set up and managed the company since 2005 and is considered the "father" of this success notes: "After years of hard work we have achieved an extraordinary medical and commercial success with this marketing approval, which is a rare event with only very few comparable biotech companies in Europe having achieved such a milestone over the past 10 years. 'We' refers to a remarkably small team of fewer than 20 employees who, together with excellent external partners, have shown what is possible with the right spirit, entrepreneurship and experience. I would like to mention some: Oliver Mutschlechner has led the team for all regulatory activities at Apeiron. Without Prof. Ruth Ladenstein from the St. Anna Children's Hospital in Vienna, the entire project would not exist. Prof. Holger Lode from the University Hospital Greifswald in Germany has provided key clinical contributions. Ulrich Granzer and his team in Munich have fundamentally supported us with their expertise in the regulatory process. Thanks to all."

Apeiron was founded in 2003 by Josef Penninger, an internationally renowned Austrian researcher, scientific director of the Institute for Molecular Biotechnology Austria (IMBA) and member of the Supervisory Board of Apeiron. He added: "The most beautiful thing first: We save lives of children with this product! On top, it is now apparent that the Austrian biotech research scene is competitive in the global market place. The future tax revenue originating from this success should justify public investment into this future technology."

The chairman of the Supervisory Board, Manfred Reichl, who acted as lead investor for the first time in 2007, emphasizes, "Apeiron is probably the only European biotech company having achieved such an outstanding success based exclusively private funding. Finding the required double-digit million Euro capital from private investors in Austria requires a high credibility of all persons involved." Reichl adds, "The worldwide annual sales of this product, which Apeiron will participate in significantly, are expected to reach triple digit million Euro amounts, demonstrating that the local entrepreneurial start-up culture can also be scientifically and commercially successful on an international level. "

The development of the antibody in Europe was initiated by Prof. Ruth Ladenstein at the St. Anna Children's Hospital and Children's Cancer Research Institute in Vienna. For more than

15 years, relevant academic clinical studies were conducted by her and by Prof. Holger Lode (University of Greifswald). She comments, "We recognised the potential of this antibody for neuroblastoma therapy at an early stage and have been working on its development together with the pan-European academic consortium SIOPEN and associated hospitals for many years. In Apeiron we have found a congenial industry partner. "

About "Dinutuximab beta Apeiron" and neuroblastoma

Neuroblastoma is an orphan oncology condition with significant unmet medical need. It accounts for up to 10% of childhood tumours and affects approximately 1,200 children in the EU5 and US each year. Dinutuximab beta was already widely used across Europe and abroad under a managed access program and was included in a number of treatment protocols for high risk neuroblastoma.

Dinutuximab beta Apeiron (ch14.18/CHO; APN311) is a mouse-human chimeric anti-GD2 monoclonal antibody produced in a state-of-the art process in Chinese Hamster Ovary (CHO) cells that significantly improves event-free and overall survival in children with high risk neuroblastoma, with a favourable safety profile compared to other antibody-based neuroblastoma immunotherapies. The antibody forms an important part of treatment regimens for high risk neuroblastoma. Furthermore, its features offer the potential for further development in other malignancies to expand its current role. It has orphan drug designation for neuroblastoma treatment in the US and EU, and EUSA plans to file the product for approval in the United States in 2017.

About APEIRON Biologics AG

Apeiron is a private biotech company based in Vienna, Austria, engaged in innovative projects in immuno-oncology. In addition to "Dinutuximab beta Apeiron (**APN311**, ch14.18/CHO) the company is developing additional cancer immunotherapy projects: **APN301** is a humanized anti-GD2 antibody-IL-2 fusion protein in clinical stage. Focus of clinical development presently is on melanoma by unique intratumoral application. A broad program is pursued to develop therapies aiming at stimulation of the immune system via novel checkpoint blockade mechanisms to fight cancer: **APN411** is a preclinical project for orally available drugs, performed together with Sanofi and Evotec. **APN401** is a novel individual cellular immunotherapy targeting the intracellular checkpoint cbl-b. A Phase I study in advanced cancer patients was successfully performed in the US (Wake Forest University, NC), Phase II is in planning stage.

For more information visit www.apeiron-biologics.com

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