

## **Apeiron announces start of a phase I trial with a unique cellular anti cancer therapy triggering immunological checkpoint blockade**

Apeiron's project APN401, based on the collection, stimulation and subsequent re-administration of a patient's immune cells, is being investigated in a clinical phase I trial performed at a renowned, academic medical center in the United States.

Vienna, Winston-Salem, February 26<sup>th</sup>, 2015: Austrian biotech company APEIRON Biologics AG ("Apeiron") announced today that a first patient has been treated as part of a phase I clinical trial with Apeiron's individual cellular therapy APN401. The investigator-initiated trial is performed at Wake Forest Baptist Medical Center (WFBMC) led by Pierre L. Triozzi, professor of internal medicine at WFBMC's Comprehensive Cancer Center, North Carolina, USA.

The trial studies the safety, tolerability and optimal dose of autologous, peripheral immune cells silenced ex-vivo for the Cbl-b gene, a completely novel approach to support the immune system's ability to fight cancer via checkpoint blockade.

"There are factors in immune cells that hamper their ability to efficiently kill cancer cells. Achieving so-called 'checkpoint blockade' by treating certain blood derived immune cells ex-vivo with a small interfering ribonucleic acid (siRNA) to silence the Cbl-b gene helps those cells to more efficiently kill cancer cells after re-infusion," said Pierre L. Triozzi. "Such activation of the immune system could in principle be applied for treatment of any type of cancer, and also in combination with other immunotherapies such as other checkpoint blockades or cancer vaccination approaches," he added.

Hans Loibner, CEO of Apeiron, commented, "The project is based on groundbreaking research by Apeiron's founder Josef Penninger, and the start of this trial is an important milestone for Apeiron as it marks the advancement of another one of our proprietary projects into clinical development. At the same time, we are able to demonstrate once again that Apeiron has an outstanding set of capabilities for bringing breakthrough discoveries closer to real-life applications."

### **About APN401 and the phase I study at WFBMC**

APN401 is an individual adoptive cell therapy in which human peripheral blood mononuclear cells are silenced ex-vivo for Cbl-b (an E3 ubiquitin ligase) using small interfering ribonucleic acid (siRNA), thereby activating them to fight cancer more efficiently. They are subsequently re-administered to the patient, with the entire procedure taking place on the bedside in one day, avoiding any additional handling and shipment.

This phase I trial studies safety, tolerability and optimal dose of APN401 in patients with melanoma, pancreatic cancer, or other solid tumors that have spread to other parts of the body or that cannot be removed by surgery.

### **About Wake Forest Baptist Medical Center**

Wake Forest Baptist Medical Center ([wakehealth.edu](http://wakehealth.edu)) is a fully integrated academic medical center located in Winston-Salem, N.C. The institution comprises [Wake Forest](#)

[School of Medicine](#), a leading center for medical education and research; [Wake Forest Baptist Health](#), the integrated clinical structure that includes nationally ranked [Brenner Children's Hospital](#); [Wake Forest Innovations](#), which promotes the commercialization of research discoveries and operates [Wake Forest Innovation Quarter](#), an urban research and technology park; plus a network of affiliated community hospitals, physician practices, outpatient services and other medical facilities. Wake Forest Baptist clinical programs and the School of Medicine are regularly ranked among the best in the country by U.S. News & World Report.

### **About APEIRON Biologics AG (as of February 2015)**

Apeiron is a private biotech company based in Vienna, Austria, developing immunologic therapies against cancer. Its lead project, APN311 (ch14.18/CHO), is a chimeric monoclonal antibody against the GD2 ganglioside abundantly expressed on neuroblastoma and other tumors. Together with the internationally active SIOPEN study group, APN311 is clinically investigated in neuroblastoma, with more than 700 patients treated to date. The project is close to submission for marketing authorization in the EU and US. Apeiron's project APN301 is an anti-GD2 antibody-IL2 fusion protein (immunocytokine) which is currently in phase II in the US and Canada in neuroblastoma (together with the Children's Oncology Group) and is also pursued in melanoma. Furthermore, a broad program is pursued to develop therapies to selectively boost the immune system via checkpoint blockade to fight cancer: besides APN401 (described above), Apeiron pursues APN411, an early-stage project which aims for development of low molecular weight compounds to boost immune cells via novel checkpoint blockade mechanisms, and which is performed in collaboration with Evotec.

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