Austrian Biotech Company "APEIRON" Announces Start of its First Clinical Trial for Neuroblastoma Patients in Japan

Japan a New Hotspot for International Pharma and Biotech Research?

Tokyo, Vienna, July 7th, 2014: Austrian biotech company APEIRON Biologics AG ("Apeiron") announced today that a phase I clinical trial with its neuroblastoma immunotherapy APN311 has received all necessary approvals to start recruiting patients.
The trial will be locally conducted by Nagoya University Hospital and is part of a long-term collaboration to make this therapy available to patients suffering from this severe type of children's cancer. In Japan, it won a grant by the Japanese government as an Investigator-initiated clinical trial that utilizes collaboration between the Department of Pediatrics and the Center for Advanced Medicine and Clinical Research (CAMCR) at Nagoya University Hospital.

"This is a great achievement for us as we have supported this joint effort from the very beginning. Two years ago the ground was prepared when the Austrian Embassy – Commercial Section in Tokyo hosted a scientific meeting for Japanese pediatric oncologists to learn about this innovative therapy of pediatric neuroblastoma developed by Apeiron ", says Dr. Martin Glatz, Commercial Counsellor of the Austrian Embassy. "The meeting two years ago was part of a focus program aiming to bring more Austrian medical research and biotech companies to the Japanese market. The market has seen tremendous changes recently with companies exploring new opportunities and the government addressing regulatory issues," he added.

Hans Loibner, PhD, CEO of Apeiron, commented, "We are very happy and proud to be rewarded with this milestone achievement after all the effort that was invested. I would like to particularly thank the physicians from Nagoya University, Dr. Seiji Kojima and Dr. Yoshiyuki Takahashi, as well as Dr. Masaaki Mizuno, Dr. Katsuyoshi Kato and Dr. Shinobu Shimizu at CAMCR, as we owe it to their dedication and tireless work that this trial can now start. We are confident that Japanese patients will benefit from the introduction of APN311 to Japan and look forward to making the next steps towards approval of this promising antibody therapy of neuroblastoma by the Japanese regulatory authorities."

About Neuroblastoma and APN311

Neuroblastoma is the most common extracranial solid cancer in infants and children with 50% of all cases being diagnosed within the first year after birth.
APN311 is a monoclonal chimeric antibody (ch14.18/CHO) targeting the GD2 antigen on neuroblastoma cells and is currently in preparation for submission for marketing authorization both in US and Europe.

About APEIRON Biologics AG (as of May 2014)
Apeiron is a mainly privately financed biotech company based in Vienna, Austria, developing immunologic therapies against cancer. Its portfolio consists of five clinical projects and some preclinical approaches.
Its lead project, APN311 (ch14.18/CHO), is a chimeric monoclonal antibody against the GD2 ganglioside abundandly expressed on neuroblastoma and other tumors. Together with the internationally active SIOPEN study group, APN311 is clinically investigated in high-risk neuroblastoma, with more than 600 patients treated to date. A novel treatment modality has been elaborated with substantially improved tolerability and marked clinical activity also in relapsed/refractory neuroblastoma patients. The project is close to submission for market authorization in the EU and US. Apeiron's project APN301 is an anti-GD2 antibody-IL2 fusion protein (immunocytokine) which is currently being tested in a phase II trial in the US and Canada in neuroblastoma (together with COG) and in a separate trial in melanoma. Furthermore, a broad program is pursued to develop therapies to selectively boost the immune system via checkpoint blockade to combat cancer: APN401 is a novel individualized adoptive cellular therapy based on the target cbl-b. A Phase I study in USA is presently being set up. The APN411 project aims for development of low molecular weight compounds to boost immune cells via novel checkpoint blockade mechanisms, and is performed in collaboration with Evotec. APN201 (human Superoxide Dismutase) is pursued to cope with oxidative stress and associated inflammation, with a focus on applications in oncology. The recombinant human Angiotensin Converting Enzyme 2 (GSK2586881, APN01) was developed by Apeiron until end of Phase I, licensed to GlaxoSmithKline (GSK) in 2010 and is presently being investigated by GSK in an ongoing phase II study in Acute Lung Injury.
(URL: www.apeiron-biologics.com)

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