



Apeiron Announces Publication of Clinical Data with Anti-GD₂ Antibody Demonstrating Efficacy in Relapsed & Refractory High-Risk Neuroblastoma

Vienna, Austria Dec. 18, 2017– APEIRON Biologics AG, a company focused on cancer immunotherapy, today announced the publication of a successful clinical study in high-risk neuroblastoma patients in the December issue of *mAbs*, a prominent journal in the monoclonal antibody field. Dr. Holger Lode, Professor and Chair of the Department of General Pediatrics and Pediatric Hematology and Oncology of the Faculty of Medicine of the University of Greifswald, Germany, conducted the study as primary investigator, in collaboration with Apeiron Biologics.

Treatment with antibodies, directed against disialoganglioside GD₂, has emerged as an important therapeutic option for patients with neuroblastoma. The study successfully explored a GD₂ antibody administration schedule of 10 day continuous slow infusion, to limit treatment-associated neuropathic pain, while preserving efficacy. To date, neuropathic pain has been an obstacle to the wider adoption of GD₂ antibodies. The study results were a key component of Apeiron's Marketing Authorisation Application for the anti-GD₂ antibody dinutuximab beta to the European Medicines Agency, which was granted in May, 2017. Dinutuximab beta is marketed by Apeiron's global license partner EUSA Pharma under the brand name Qarziba[®]. It has orphan status in the EU, and orphan designation in the U.S.

Hans Loibner, Chief Executive Officer of Apeiron Biologics, said, "The study results confirm the importance of dinutuximab beta as a new standard of care for the treatment of relapsed & refractory neuroblastoma, and its potential as a cancer therapy in general. By substantially reducing neuropathic pain with this new anti-GD₂ dosing regimen, the investigators have shown a significant improvement in survival of the entire cohort, including the relapsed patients, compared to historical controls. Long-term infusion of our anti-GD₂ antibody thus shows an acceptable toxicity profile, objective clinical responses and a strong signal of clinical efficacy in relapsed & refractory neuroblastoma patients who have a rather poor prognosis."

Lee Morley, Chief Executive Officer at EUSA Pharma which acquired exclusive global commercialisation rights to dinutuximab beta from Apeiron in October 2016, said "We are delighted that the data concerning the efficacy and tolerability of the anti-GD₂ antibody continues to develop and publication of the results of dinutuximab beta given by long term infusion is an important step. These data will form a key part of the upcoming Biologics Licence Application (BLA) to the FDA in the U.S. which is expected during 2018."

The published paper, entitled “Tolerability, response and outcome of high-risk neuroblastoma patients treated with long-term infusion of anti-GD₂ antibody ch14.18/CHO,” evaluates the toxicity, clinical response and survival of anti-GD₂ antibody ch.14.18/CHO (dinutuximab beta). The data demonstrate that dinutuximab beta (together with IL-2) given by long-term infusion is associated with a substantially reduced pain and thus could be delivered in an outpatient setting. The single-center study, without a control group, showed a best response rate of 40% and a significantly prolonged survival compared to matched historical controls.

To access the study: <https://doi.org/10.1080/19420862.2017.1402997>

About neuroblastoma

Neuroblastoma is the second most common solid tumor in childhood, following brain tumors, and predominantly affects children under five years old. Every year in Europe, around 1,200 children are diagnosed with neuroblastoma, a rare cancer arising from neural crest cells, which are involved in the foetal development of the nervous system and other tissues. Almost half of children are initially diagnosed as 'high-risk' with a poor prognosis. Approval of dinutuximab beta brings new hope to these children with high risk neuroblastoma. Dinutuximab beta treatment is indicated in patients who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as those with a history of relapsed or refractory neuroblastoma, with or without residual disease (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003918/WC500227724.pdf).

About Apeiron Biologics AG

Apeiron Biologics, based in Vienna, Austria, is focused on innovative projects in cancer immunotherapy. Approved by the European Medicines Agency for the treatment of neuroblastoma, its lead program APN311 (dinutuximab beta) is partnered with EUSA Pharma (Hemel Hempstead, UK). The company is developing additional immunotherapies based either on targeted, tumor-specific approaches, or on the stimulation of the immune system via novel and proprietary modes of action, such as unique checkpoint blockade mechanisms, to fight cancer by engaging the human body's natural defence mechanisms.

For further information, see www.apeiron-biologics.com

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