

Neuroblastoma:

APEIRON Grants EUSA Pharma Global Rights to Immunotherapy

Vienna, Austria: 04 October 2016 – APEIRON Biologics AG grants EUSA Pharma, UK exclusive global commercialization rights to the oncology product ISQETTE®. ISQETTE® is an antibody-based immunotherapy with orphan drug designation for the treatment of pediatric neuroblastoma. The therapy has been developed by APEIRON together with an academic network including the St. Anna Children's Cancer Research Institute in Vienna.

APEIRON Biologics AG, a private biotech company based in Vienna, Austria, developing immunological therapies against cancer, today announced that it grants EUSA Pharma, UK exclusive global commercialization rights to the immuno-oncology product ISQETTE® (APN311, dinutuximab beta). In Europe, dinutuximab beta is widely used in clinical trials as part of the regimen for the treatment of high risk neuroblastoma with approx. one thousand patients treated and is available under a managed access program. The immunotherapy has orphan drug designation in the US and EU and is currently under review for marketing approval by the European Medicines Agency (EMA). Under the terms of the agreement, APEIRON receives an upfront fee, regulatory milestone payments upon marketing approval in key territories and royalties on future product sales.

Dr. Hans Loibner, Apeiron Biologics' Chief Executive Officer comments: "The global license for commercialization of our most advanced project APN311 is a major step forward in the successful development of the company. It validates our strength in advanced clinical development of cancer immunotherapies. ISQETTE® may get European marketing approval soon and deserves a competent partner for future commercialization. With its strong focus on oncology and specialty commercial expertise in Europe, the US and further afield, EUSA Pharma is an excellent partner to bring ISQETTE® to the market."

"We are delighted to acquire the global rights to ISQETTE®, which is a perfect fit with our strategic focus in the specialty oncology field and will allow us to leverage our commercial infrastructure in the EU and expand our presence in the US. We look forward to working with the experienced APEIRON team", adds Lee Morley, EUSA Pharma's Chief Executive Officer.

ISQETTE® is a monoclonal antibody that specifically targets the GD2 antigen expressed on the surface of neuroblastoma cells and thereby initiates a selective immunological attack against these tumor cells. Clinically relevant activity has been widely observed upon treatment, also in advanced stages of the disease. Neuroblastoma is an orphan oncology indication that accounts for up to 10% of childhood tumors and affects approximately 1,200 children in the EU and US each year. APEIRON developed ISQETTE® together with academic partners, in particular with the Children's Cancer Research Institute (CCRI), associated with the St. Anna Children's Hospital, Vienna and SIOPEN (Society of Paediatric Oncology European Neuroblastoma Network). SIOPEN is a European academic network for clinical studies and integrated research with the goal to improve the survival of neuroblastoma patients.

EUSA Pharma intends to continue ISQETTE®'s managed access program, and once approved in Europe will promote the immunotherapy to oncologists through its specialty sales team. In the United States, EUSA plans to submit a regulatory filing in 2017, and once approved will commercialize the product directly through its established US infrastructure. In other territories, including Japan, EUSA plans to bring the product to market through its international network of partners.

About APEIRON Biologics AG (as of October 2016)

Apeiron is a private biotech company based in Vienna, Austria, engaged in various innovative projects in applied immuno-oncology (cancer immunotherapy): Its most advanced project, **APN311** (ch14.18/CHO, ISQETTE®), has been submitted to the EMA for European marketing authorization in May 2015; the approval process now is in an advanced stage. APN311 was licensed from SIOOPEN and the CCRI, Vienna, and development then continued as a joint effort between Apeiron, SIOOPEN and associated institutions. **APN301** is an anti-GD2 antibody-IL-2 fusion protein in clinical stage. The focus of 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 our partners Sanofi and Evotec. **APN401** is a unique individual cellular immunotherapy targeting the 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

About EUSA Pharma

Founded in March 2015, EUSA Pharma is a specialty pharmaceutical company with commercial operations in the US and Europe, and a wider distribution network in approximately 40 further countries. Currently, EUSA has a broad portfolio of approved and named-patient specialty hospital products, which the company has ambitious plans to expand through acquisition and in-licensing. EUSA is led by an experienced management team with a strong record of building successful specialty pharmaceutical companies, and is supported by significant funding raised from leading life science investor Essex Woodlands.

For more information visit www.eusapharma.com

Contact APEIRON Biologics AG:

Dr. Hans Loibner, CEO
Campus-Vienna-Biocenter 5
1030 Vienna, Austria
T +43 / (0) 664 / 926 3820
E hans.loibner@apeiron-biologics.com
W www.apeiron-biologics.com

Copy Editing & Distribution:

PR&D - Public Relations for Research & Education
Mariannengasse 8
1090 Vienna, Austria
T +43 / (0)1 / 505 70 44
E contact@prd.at
W www.prd.at