Basel, Switzerland
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Vaderis Receives FDA Fast Track Designation for VAD044 for the Treatment of Hereditary Hemorrhagic Telangiectasia

Basel, Switzerland, November 18th, 2024 – Vaderis Therapeutics AG (Vaderis), a clinical stage biotechnology company focusing on treatments for rare diseases associated with vascular malformations, today announces that the US Food and Drug Administration (FDA) has designated the allosteric AKT-inhibitor VAD044 a Fast Track product for the treatment of Hereditary Hemorrhagic Telangiectasia (HHT).

Fast Track is an FDA process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The FDA states the purpose of Fast Track to get important new drugs to the patient earlier.

Dr. Hanny Al-Samkari, the Peggy S. Blitz Endowed Chair in Hematology/Oncology at Massachusetts General Hospital and Associate Professor of Medicine at Harvard Medical School (USA) commented, "The FDA's decision to designate VAD044 as a Fast Track product for the treatment of HHT underscores its potential to be the first ever approved treatment for this debilitating genetic disease."

HHT, an Orphan Disease, is the second most common inherited bleeding disorder in the world frequently causing severe disease burden, reduced life expectancy and impaired Quality of Life. Despite this, there remains no approved treatment for HHT anywhere in the world. Vaderis is developing VAD044, an oral, once-daily allosteric AKT-inhibitor, the first novel therapy intended specifically for the treatment of HHT.

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About Vaderis

Vaderis is a clinical stage biotech company developing treatments for rare and orphan diseases associated with vascular malformations. There is a significant number of debilitating and largely untreated rare diseases, such as HHT (Hereditary Haemorrhagic Telangiectasia), in which patients have overactivation of AKT triggered by upstream genetic mutations resulting in vascular overgrowth. Vaderis is developing VAD044, a daily, oral allosteric AKT inhibitor, which has been investigated in a clinical proof of concept study in HHT patients and is currently in a 12-month Open

Label Extension. There are no drugs approved to treat HHT and Vaderis aims to be the first company to develop a medicine for the treatment of HHT and other diseases associated with vascular malformations.

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