

Vidac Pharma secures approval for next phase of clinical study of lead asset in Cutaneous T-Cell Lymphoma

London (UK), March 12, 2024 (07:30 CET) – Vidac Pharma Holdings Plc. (Hamburg and Stuttgart: T9G; ISIN:GB00BM9XQ619; WKN: A3DTUQ), a clinical-stage oncology biopharmaceutical company pioneering a novel class of cancer treatments, today announced it has received approval from the Helsinki Committee of the Beilinson Hospital in Israel to proceed with the second stage of a Phase 2a clinical trial of its lead drug candidate VDA-1102 in Mycosis Fungoides (MF), a form of Cutaneous T-Cell Lymphoma (CTCL). Having reported positive interim results based on 50% of subjects in January, the company now expects the second stage of the trial to take 3 to 4 months, and to be able to report final results in the fourth quarter of the year.

"The go-ahead by the Helsinki Committee is a crucial step for us to continue the search for a cure of CTCL, a rare and painful disease that might command fast-track regulatory processing as an orphan disease," said Prof. Max Herzberg, Chief Executive Officer of Vidac. "Our work so far suggests that VDA-1102, and its sister drug candidate VDA-1275, are both safe and efficacious in a wide variety of cancers, offering hope for an entirely novel way of treating these diseases."

The Helsinki Committee is an ethics committee whose procedures are in line with Israel's Public Health Regulations (Medical Experiments in Human Subject) and the regulations for conducting Medical Trials on Humans. The Committee operates in accordance with the Harmonized International Guidelines for Good Clinical Practice (ICH-GCP), which are renewed each year.

In January, Vidac <u>reported interim results of the Phase 2a trial</u>, which compared favorably to the standard care of mechlorethamine from more than 50% of patients – 9 out of 16 – in an openlabel within-subject placebo-controlled study into the efficacy and safety of VDA-1102 as a topical ointment treatment for 12 weeks, in adult subjects with relapsed stage-1 MF.

Both VDA-1275 and the more advanced VDA-1102, now in Phase 2b testing of advanced actinic keratosis and Phase 2 testing of cutaneous T cell lymphoma, disrupt the interaction between hexokinase 2 (HK2) and the voltage-dependent anion channels (VDACs) in mitochondria. Cancer cells overexpress HK2, which catalyzes the first step of the glucose metabolism necessary to fuel tumor growth. HK2 blocks VDACs, which prevents apoptosis, supports cancer cell proliferation, and suppresses immune responses. Clinical data for Vidac's first-generation metabolic checkpoint modulator candidates have shown powerful effects in halting cancer cell proliferation and restoring immune-sensitivity and apoptosis.

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Vidac Pharma is a clinical-stage biopharmaceutical company dedicated to discovering and developing first-in-class medicines to help people suffering from a range of oncologic and oncodermatologic diseases. Vidac develops first-in-class anti-cancer drugs by modifying the hyper glycolytic tumor microenvironment, targeting the overexpression and wrong anchoring of the Hexokinase 2 metabolic checkpoint (HK2) in cancer cells, to renormalize tumor microenvironment and selectively provoke their programmed death without affecting surrounding normal tissue. VDA-1102, a first drug candidate of Vidac Pharma has shown to be effective against advanced Actinic Keratosis (AK) and interim results in Cutaneous T-cell Lymphoma (CTCL) positive effect Phase 2 trials in humans. gave in www.vidacpharma.com

Important

information

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