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Progress for Vivolux drug candidate VLX1570

Vivolux, a pharmaceutical company specialized in cancer treatment, announced today that the first patient in its ongoing Phase I/II study has successfully completed treatment at the third dose level of the drug candidate VLX1570.

Vivolux has developed a drug which through a newly discovered mechanism blocks the proteasome, the cell degradation 'machine' for defective proteins.

Large amounts of defective proteins form in tumor cells, making them vulnerable to disruption of proteasome function. The new mechanism of action by VLX1570 has been shown to inhibit tumor growth and prolong survival in various preclinical models of multiple myeloma, including those that exhibit resistance to other cancer treatments.

The clinical study is being conducted in collaboration with the Memorial Sloan-Kettering Cancer Center in New York and the Dana-Farber Cancer Institute at Harvard Medical School in Boston, MA. The phase I part of the study is designed to determine the safety and maximum tolerated dose of VLX1570 in patients with multiple myeloma who are no longer benefiting from conventional cancer treatment. The phase II part of the study is to investigate the clinical efficacy of VLX1570 in this patient population.

Proteasome inhibitors (e.g. bortezomib/Velcade®) have been available for the treatment of malignant diseases (e.g. multiple myeloma and mantle cell lymphoma) for some years although development of resistance to this therapy is a major clinical problem. As preclinical research has shown, the novel drug candidate VLX1570 acts on the proteasome through a new mechanism of action. By blocking the initiation process that regulates the breakdown of defective protein, the cancer cells are forced into apoptosis – programmed cell death. There is a significant medical need in multiple myeloma therapy, especially for patients who have become resistant to currently available cancer treatment such as bortezomib (Velcade®).

Preclinical research has generated considerable scientific interest and results have been published in renowned scientific journals such as *Nature Medicine* and *Blood*. This is the second drug candidate developed by Vivolux to proceed into the clinical phase. VLX600 is the company's first drug candidate to be evaluated at the clinical phase. The study is being conducted in collaboration with the Mayo Clinic Cancer Centers in the USA.

Hans Rosén, CEO and founder, said: "We are very excited about the progress in the VLX1570 study. We have a strong scientific basis for VLX1570 and the expectations

are high that this new approach to treating cancer will make a significant difference for cancer patients. We look forward to establishing the therapeutic dose and to evaluating VLX1570 on multiple myeloma patients.

Joachim Gullbo, MD, PhD and Chief Medical Officer at Vivolux, said: "VLX1570 is Vivolux's second drug candidate to reach first-in-human evaluation. VLX1570 represents a new molecular mechanism of action of an already proven pharmacologically important target for cancer treatment, the proteasome. We are very excited about the opportunity to cooperate with leading clinicians who are working to improve the treatment of critically ill patients. This is a new and promising concept for cancer treatment."

Vivolux was founded in Sweden in 2004 with a focus on the development of novel cancer drugs based on phenotypic models, where the unique behavior of malignant cells under specific conditions is utilized to identify new targets and molecules acting on these targets. Working in close collaboration with research groups at Uppsala University and the Karolinska Institute, Vivolux has developed a unique and comprehensive system for preclinical analysis of cancer drugs, including tests on primary cultures of human cancer cells, cells grown in three-dimensional aggregates and methods for molecular investigation of mechanism of action. Several drug candidates have been identified and optimized and the results from these investigations have been published in international scientific journals. Two novel drugs with new mechanisms of action for cancer treatment are currently undergoing clinical investigation in collaboration with leading cancer institutes in the USA. In 2014, the Vivolux head office was established in Ashburn, Virginia, USA. The Swedish office is located at the AZ BioVentureHub in Gothenburg.

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