

Press Release

Abliva AB (publ), 556595-6538
14 November 2023 20:15:00 CET - Lund,
Sweden



Abliva and Owl Therapeutics enter into licensing and collaboration agreement for NeuroSTAT® in Traumatic Brain Injury

Abliva AB ('Abliva' or the 'Company') and US-based Owl Therapeutics today announced the signing of a licensing and collaboration agreement for Abliva's NeuroSTAT® for the treatment of moderate to severe traumatic brain injury (TBI).

Under the agreement, Owl Therapeutics (San Antonio, Texas), a clinical-stage biopharmaceutical company focused on the development of diagnostic-powered therapeutics for traumatic brain injury (TBI) and brain health, will receive a global (excluding China and South Korea) license to develop, manufacture, and commercialize NeuroSTAT.

Under the terms of the agreement, Abliva is eligible to receive up to \$43.65 million in milestones (excluding royalties), \$1.15 million of which will be paid upon realization of specific clinical and regulatory milestones, with a further up to \$42.5 million payable on achievement of commercial related milestones. In addition, Abliva is eligible for mid-single digit royalties (based on net sales) upon commercialization. Owl Therapeutics will be responsible for all costs associated with the development, manufacture, and commercialization of NeuroSTAT. Given the collaborative nature of the agreement, the Abliva team will remain involved in the program and will contribute to the operational and strategic elements of the program. Abliva will contribute by way of an agreed and time-limited commitment with respect to certain Abliva team members.

"NeuroSTAT has been an important asset at Abliva for many years, and we are delighted to have found the right partner to take this program through development and to patients throughout the world who suffer from TBI. We are pleased that this agreement ensures Abliva expertise will be available as Owl drives the program forward, as well as has the potential to provide significant economics to Abliva," said Ellen Donnelly, CEO of Abliva.

"Abliva stands out as an exceptional partner for Owl Therapeutics, and we are excited to join forces in our collective commitment to advance NeuroSTAT," said William E. Haskins, Co-Founder and Chief Executive Officer of Gryphon Bio, which wholly owns Owl Therapeutics. "We are thrilled to focus our team's scientific, clinical, and business experience on this potentially game-changing treatment for military and civilian TBI patients."

TBI is a significant public health concern, affecting millions of individuals annually through accidents, falls, sports injuries and military combat. TBI occurs when a sudden external force or impact to the head disrupts normal brain function, leading to a wide range of cognitive, physical, and emotional symptoms. The far-reaching impact of TBI extends beyond the individual patient, exerting a substantial economic burden on healthcare systems and society. Additionally, the emotional and financial toll on affected individuals and their families underscores the pressing need for continued research and advancements in TBI prevention,

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diagnosis, and treatment. Efforts in this direction are crucial to not only improve patient outcomes but also alleviate the socioeconomic consequences of this complex and pervasive health issue.

This information is information that Abliva AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out below, at 2023-11-14 20:15 CET.

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About NeuroSTAT®

NeuroSTAT is a novel, ready-to-use, lipid-based intravenous formulation of cyclosporine that differentiates from currently available IV formulations due to a superior safety profile. NeuroSTAT is expected to counteract the emergence of neurological and functional secondary brain damage that occurs after a traumatic brain injury (TBI), and thereby preserve neurological functions, improving quality of life and increasing survival. NeuroSTAT has shown favorable properties in a Phase 1b/2a clinical study and is enabled by orphan drug designation (ODD) in Europe and the US, as well as an investigational new drug (IND) approval and Fast Track designation for clinical development for moderate and severe TBI in the US.

Abliva – Delivering mitochondrial health

Abliva discovers and develops medicines for the treatment of mitochondrial disease. This rare and often very severe disease occurs when the cell's energy provider, the mitochondria, do not function properly. The company has prioritized two projects. KL1333, a powerful regulator of the essential co-enzymes NAD⁺ and NADH, has entered late-stage development. NV354, an energy replacement therapy, has completed preclinical development. Abliva, based in Lund, Sweden, is listed on Nasdaq Stockholm, Sweden (ticker: ABLI).

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Owl Therapeutics – Unlocking Wisdom for Brain Health

US-based Owl Therapeutics, a wholly-owned subsidiary of Gryphon Bio, is a clinical-stage biopharmaceutical company created to develop diagnostic-powered therapeutics for traumatic brain injury (TBI) and brain health. The company has rapidly built a promising, diversified pipeline of small and large molecule medicines poised to address the highly unmet medical needs of patients with neurodegenerative disease. Owl is led by a proven, cohesive, interdisciplinary, and internationally recognized team with deep scientific, clinical, and business experience in drug development and commercialization.

Attachments

[Abliva and Owl Therapeutics enter into licensing and collaboration agreement for NeuroSTAT® in Traumatic Brain Injury](#)