

# Bioxodes raises €5.5 million Series A extension to continue preparations for pivotal trial of breakthrough stroke candidate

- Newton Biocapital enters as new investor, strong participation of existing investors
- Pivotal Phase 2b trial initiation in 2027 of BIOX-101 to treat intracerebral hemorrhage
- BIOX-101 may be commercialized as early as H2 2030

Gosselies, Belgium, 10 December 2025 (08:30 am CET) — Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, has raised €5.5 million in a Series A extension funding round, enabling the company to continue preparations to launch a potentially registrational Phase 2b trial of its lead candidate BIOX-101 to treat intracerebral hemorrhage (ICH) in 2027. Newton Biocapital, a specialist life science venture capital firm focusing on early-stage companies in Europe and Japan, entered as a new investor, together with other new and existing shareholders, bringing the total Series A financing to about €17.5 million.

"Bioxodes is grateful for the renewed trust in the company's ability to develop our groundbreaking treatment for hemorrhagic stroke. Our Phase 2a data clinical results in ICH patients are very promising and the principal investigator is encouraging us to push forward rapidly with registrational studies. I am particularly excited to see the respected specialist fund, Newton Biocapital, join our group of shareholders. The funding advances preparations for the pivotal Phase 2b trial and may enable us to bring BIOX-101 to patients as early as the second half of 2030," said Marc Dechamps, CEO at Bioxodes.

Bioxodes in September <u>announced strong interim results</u> for its BIRCH Phase 2a trial in ICH, meeting the safety endpoint, and achieving highly encouraging efficacy signals across clinical and biomarker measures. The unanimous recommendation of the DMC at that time was to launch a larger Phase 2b trial. Starting the study in 2027 could allow Bioxodes to submit BIOX-101 for conditional marketing authorizations for a Go-to-Market in the U.S. by late 2030 and in Europe by early 2031. The company also plans to develop BIOX-101 to treat ischemic stroke. To fund these future clinical trials, Bioxodes has launched a €80 million Series B fundraising. The company is also in active discussions with potential partners.

"Bioxodes looks to be a rare example of a success story in stroke. The BIOX-101 Phase 2a trial yielded very convincing data in intracerebral hemorrhage, an often deadly disease that presents an important unmet medical need. While the company is breaking new ground in this indication, we believe the path to registration is clear, with objective endpoints that look achievable based on the data at hand. BIOX-101 is exactly the kind of innovative drug that we at Newton like to have in our portfolio, also given our previous experience supporting companies in neurological and neurovascular diseases, including stroke," said Alain Parthoens, Chief Executive Officer at Newton Biocapital.

**Intracerebral hemorrhage** (ICH) is a devastating condition with no approved therapies, accounting for up to 40% of all stroke-related deaths, despite making up just 15% of cases. Mortality approaches 50% at 30 days, and approximately half of all ICH-related deaths happen within the first 24 hours. Fewer than 20% of survivors achieve functional independence after six months, often due to secondary damage



resulting from the untreatable bleeding and associated inflammation, which causes secondary ischemia, neuroinflammation and neuronal damage, amongst others.

Marketed anticoagulants cannot be used to prevent secondary ischemic lesions after ICH because they invariably carry a risk of exacerbating bleeding. BIOX-101 is the first-in-class therapeutic candidate with an anticoagulant effect that has been shown not to increase bleeding. Separately, the drug candidate also has been shown to exert potent anti-inflammatory effects through its impact on the neutrophils, which can worsen the damage of the initial stroke by triggering inflammation and swelling. This dual anticoagulant and anti-inflammatory mode of action is expected to improve survival and contribute to faster and better outcomes for patients with ICH.

**BIOX-101** is a proprietary recombinant version of a small protein found in the saliva of the tick (*Ixodes ricinus*). It is designed to inhibit the harmful secondary effects of hemorrhagic stroke such as secondary ischemia, neuroinflammation and neuronal damage. Unlike currently marketed anticoagulants, BIOX-101 is an investigational anticoagulant that reduces clotting without increasing bleeding. It does this by targeting Factors XIa and XIIa of the intrinsic coagulation pathway. The candidate product also exerts anti-inflammatory effects through a second mechanism, inhibiting activation of neutrophils and their release of extracellular DNA filaments (also called neutrophil extracellular traps or NETs), which can cause excessive inflammation, contributing to edema expansion and exacerbating brain damage and disrupting the blood-brain barrier. Bioxodes reported positive BIOX-101 Phase 2a clinical proof of concept data in ICH patients and is currently preparing to initiate a Phase 2b trial in ICH and as well as Phase 2 trials of BIOX-101 to treat acute ischemic stroke and an undisclosed indication.

**Bioxodes SA (www.bioxodes.com)** is a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases. The company's lead asset, BIOX-101, is a first-in-class drug candidate being developed to treat stroke. BIOX-101's unique dual mechanism of action is the foundation of an innovative pipeline of drug candidates for treatment and prevention of thromboinflammatory diseases. Worldwide, Bioxodes holds both granted and pending patents associated with BIOX-101. Bioxodes research is supported by the Walloon Region (*SPW Recherche*), and the company is registered in Belgium under number 825.151.779.

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