Bioxodes presents BIOX-101 clinical data showing breakthrough potential for stroke in webcast with Prof Dr Robin Lemmens

- **Prof Lemmens underscores large unmet medical need in intracerebral hemorrhage**
- **"Very encouraging" data from Phase 2a trial with lead asset BIOX-101**
- **Bioxodes is preparing for a possibly registrational Phase 2b trial, could bring BIOX-101 to market by late 2030**

Gosselies, Belgium, 14 November 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 held a webcast on the breakthrough potential of its lead candidate BIOX101 to treat intracerebral hemorrhage (ICH) and discussed the data with Prof Dr Robin Lemmens, KU Leuven, the Principal Investigator of its Phase 2a BIRCH clinical trial. Prof Lemmens, a world-renowned stroke expert and head of the stroke unit at the University Hospital Leuven, underscored the urgent need to address the large unmet medical need in intracerebral hemorrhage, and provided his insights from the successful Phase 2a clinical study with BIOX-101. Bioxodes CEO Marc Dechamps presented the company's strategy in bringing BIOX-101 to market, possibly as early as late 2030.

"The trial results are very encouraging especially as it relates to safety. We need to take the next step and launch the Phase 2b trial to see if we find an effect of reducing the edema volume which is the main purpose of the drug," **said Prof Dr Robin Lemmens.** "BIOX-101 is a very important drug target to be evaluated in clinical trials. For ICH, unfortunately we don't have many alternatives to offer to patients. There is a high unmet medical need to try and identify better therapeutic solutions for patients who present ICH." To view a replay of the event with Prof Lemmens, please use this link.

In September, the Data Monitoring Committee unanimously endorsed proceeding to a Phase 2b/3 trial after the company stopped recruiting since the BIRCH Phase 2a trial had already achieved its objectives and announced strong second interim results. All patients treated with the candidate experienced a reduction in hematoma, a key clinical finding further supported by biomarker measurements, all of which trended in support of this and other clinical observations. Functional outcomes were also highly encouraging, with signals of recovery appearing more favorable than those seen in the standard-of-care control group. More patients regained independence on day 90 after BIOX-101 treatment than in the standard-of-care. Bioxodes is now preparing for a global multi-center Phase 2b trial in ICH. If successful, this could be sufficient to submit BIOX-101 for conditional marketing authorizations in the U.S. by late 2030 and in Europe in early 2031. The company will also develop BIOX-101 to treat ischemic stroke.

"The presentation by Prof Lemmens was a unique opportunity to learn about the clinical experience with stroke directly from an unrivalled expert. He made it very clear that intracerebral hemorrhage presents a large unmet medical need that could be addressed by BIOX-101 if further studies confirm the signals we have seen in our Phase 2a trial. I look forward to taking the next steps to bring BIOX-101 to patients, possibly as early as late 2030," **said Marc Dechamps, Chief Executive Officer at Bioxodes.**

Marketed anticoagulants cannot be used to treat ICH because they often increase bleeding. BIOX-101 is the first-in-class therapeutic candidate with anti-clotting effect that has not been shown to increase bleeding and has also been shown to exert potent synergistic anti-inflammatory effects in the BIRCH trial, which is expected to contribute to better outcomes for ICH patients.

Intracerebral hemorrhage (ICH) is a devastating condition with no approved therapies, accounting for 40% of all stroke-related deaths, despite making up just 15% of cases. Mortality approaches 50% at 30 days, and approximatively 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.

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 product also exerts anti-inflammatory effects by inhibiting activation of neutrophils and their release of extracellular DNA filaments (called NETs), which can cause excessive inflammation, exacerbating brain damage and disrupting the blood-brain barrier. Bioxodes has completed a positive Phase 2a clinical proof of concept trial of BIOX-101 to treat ICH and is currently planning a Phase 2b trial in ICH and 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 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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