Bioxodes announces positive Phase 2a interim data for BIOX-101 in intracerebral hemorrhagic stroke patients

- **Primary endpoint met, no drug-related serious adverse events**
- **Positive hematoma and edema volume evolution**
- **Recruitment stopped early due to positive exploratory and efficacy outcomes**
- **Preparations underway to initiate Phase 2b study**

Gosselies, Belgium, 24 April 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, today announces promising interim results from the BIRCH Phase 2a clinical trial of its lead asset, BIOX-101, to treat intracerebral hemorrhagic stroke (ICH). Interim analysis from the first 16 patients in the standard-of-care controlled, randomized trial showed that primary safety and secondary efficacy endpoints were met. The Data Monitoring Committee (DMC) identified no safety concerns related to changes in ICH volumes, serious adverse events, neurological outcomes, or mortality.

Bioxodes will release a second interim report in the second half of 2025, and a final analysis of the study in 2026. The company has stopped recruitment for the trial, as it believes that adding more data would not alter the conclusions based on the available findings. Bioxodes will now start preparing the launch of a potentially registrational Phase 2b trial of BIOX-101 in ICH.

“While preliminary, the data from this study all point in the right direction. This excellent result has given us the confidence to start the Phase 2b trial as soon as possible,” said **Hans Warrinnier, Chief Medical Officer** at Bioxodes. “Although hemorrhagic stroke often has debilitating consequences, it is a neglected disease, and the prospect of offering these patients hope is a strong motivating factor for our team.”

“These encouraging results are an important milestone, which enables us to start looking ahead. We will now launch a Series B funding round, and start the CMC process required to produce sufficient BIOX-101 for the Phase 2b trial. This will take approximately a year to complete, so that we hope to start recruitment in the first half of 2027,” said **Marc Dechamps, Chief Executive Officer** at Bioxodes.

No deaths have so far been recorded in the patient population, a surprisingly positive outcome, and no serious adverse events were attributed to treatment over the course of the trial. Treatment was well-tolerated, with no signs of increased bleeding. Data showed a consistent exposure to the drug during infusion, while pharmacodynamic data aligned well with pharmacokinetic findings. Imaging data suggested a favorable evolution of hematoma and edema volumes, while exploratory outcomes on inflammation biomarkers measurements were very encouraging.

ICH is a devastating condition, which while accounting for only 13% of all cases of stroke, is behind 40% of all stroke-related deaths. There is currently no approved treatment, and many survivors are left with permanent or long-term disability. Bioxodes received Orphan Drug Designation for BIOX-101 in both the U.S. and in Europe in March 2025. The company is planning to file for PRIME status with the EMA later in 2025, and for Fast Track designation with the FDA later during development of the product. The planned

Phase 2b trial could be sufficient to submit BIOX-101 for conditional marketing authorizations in the U.S. and Europe before 2030.

BIOX-101 is a 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. The product exerts its 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. Unlike currently marketed anticoagulants, BIOX-101 reduces clotting without increasing bleeding, by targeting Factors XIa and XIIa of the intrinsic coagulation pathway. Bioxodes is currently investigating the possibilities of a Phase 2 trial with BIOX-101 in acute ischemic stroke.

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 thromboinflammatory disease. BIOX-101's unique mechanism of action is the foundation of an innovative pipeline of drug candidates for the prevention of (thrombo)inflammatory diseases. Worldwide, Bioxodes holds both granted and pending patents associated with BIOX-101. Bioxodes research is supported by the Walloon Region, and the company is registered in Belgium under number 825.151.779.

HEAD OFFICES
BioPark Charleroi-Bruxelles Sud
Rue Santos-Dumont, 1
6041 Gosselies, Belgium
+32 496 590354
investment@bioxodes.com

MEDIA RELATIONS, BELGIUM
Alexandra Schiettekatte
communication@bioxodes.com
+32 476 65 04 38

MEDIA RELATIONS, INTERNATIONAL
Douwe Miedema
Cohesion Bureau
douwe.miedema@cohesionbureau.com

INVESTOR RELATIONS
Giovanni Ca' Zorzi
Cohesion Bureau
giovanni.cazorzi@cohesionbureau.com