PRESS RELEASE

Bioxodes' BIOX-101 accelerated recovery and reduced secondary brain injury after intracerebral hemorrhage in newly published preclinical data

- **Publication in *CNS Neuroscience & Therapeutics* shows BIOX-101's anti-inflammatory effects and their association with faster functional recovery**
- **BIOX-101 significantly accelerated neurological and motor recovery**
- **BIOX-101 significantly reduced local infiltration of neutrophils and their release of neutrophil extracellular traps (NETs), sources of harmful inflammation**
- **BOX-101 significantly reduced neuronal damage at the hemorrhage site**
- **BIOX-101 did not increase brain bleeding or lesion volume, demonstrating a favorable preclinical profile**
- **Published findings are consistent with the Phase 2a BIRCH results presented at the World Stroke Congress in October 2026**

Gosselies, Belgium, November 2, 2026 – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, today announced the publication in the peer-reviewed journal *CNS Neuroscience & Therapeutics* of preclinical data on its lead drug candidate BIOX-101 (Ir-CPI) in an established rodent model of intracerebral hemorrhage (ICH).

Following an ICH, brain damage is not limited to the initial bleeding; inflammation contributes to further brain injury over the following days, with neutrophils playing an important role. Marketed anticoagulants are not indicated to treat ICH as they can increase bleeding and secondary damage. There is no approved therapy for ICH.

The newly published data shows that BIOX-101 significantly accelerated functional recovery in an experimental model of ICH. The improvement was associated with reduced neutrophil infiltration, decreased release of neutrophil extracellulaire traps (NETs), and less secondary brain injury. Importantly, these beneficial effects were observed without any increase in bleeding.

"Our findings show that BIOX-101 reduced neutrophil infiltration and the formation of neutrophil extracellular traps and this was associated with less neuronal damage. Furthermore, and most importantly, these effects were combined with faster functional recovery," said **Stéphanie Demoulin, PhD, corresponding author of the study and Medical Writer & Intellectual Property Manager at Bioxodes**.

The study (DOI:10.1002/cns.71227) was conducted with ETAP-Lab and Professor Denis Vivien, an internationally recognized expert in stroke and neurovascular research at Caen University Hospital (CHU Caen Normandie), France. Some of the findings were first presented as a poster at the International Stroke Conference 2025.

“This study supports the positive BIRCH Phase 2a BIOX-101 clinical data and further strengthens the overall evidence supporting BIOX-101 as a potential treatment for intracerebral hemorrhage,” said **Marc Dechamps, Chief Executive Officer of Bioxodes**. “Even before we had the BIRCH data, these preclinical data were critical to our success in securing Orphan Drug Designation for BIOX-101 from both the U.S. FDA and the EMA. Taken together with the BIRCH data and strong KOL support, the opportunity for investors and partners to support BIRCH2, the planned Phase 2b trial, is as strong as we could have hoped to achieve at this stage of development.”

BIRCH Phase 2a final clinical results were presented at the World Stroke Congress on October 21, 2026. The results showed that BIOX-101 was well tolerated, with no increased bleeding; hematoma expansion and perihematomal edema (PHE) growth at 72 hours were statistically significantly lower than with standard of care, and inflammatory biomarkers followed a more favorable trajectory. The data package supporting BIRCH 2, the proposed placebo-controlled Phase 2b trial of BIOX-101, is complete. The company is in discussions with potential partners and investors to finance the study.

Key data in the publication

In a collagenase-induced mouse model of ICH, BIOX-101 was given as an intravenous bolus followed by a 69-hour infusion, started immediately after ICH induction. Vehicle-treated animals served as controls and the low-molecular-weight heparin enoxaparin as an anticoagulant comparator. Inflammation, neuronal degeneration and MRI volumes were assessed through Day 3 (6 to 7 animals per group); safety and functional recovery were assessed through Day 14 (20 animals per group).

- **Functional recovery:** at Day 5, the neurological score (Bederson) was 1.55 with BIOX-101 compared with 2.21 with vehicle (p=0.04), and sensorimotor asymmetry on the corner test was 69.5% compared with 83.5% (p=0.04). By Day 14, corner test performance with BIOX-101 had returned to baseline, while vehicle-treated animals remained impaired. The benefit persisted after the end of the three-day infusion.
- **Neutrophils and NETs:** at Day 3, BIOX-101 reduced the number of infiltrating neutrophils (p=0.01 at the rostral level) and the number of neutrophils releasing NETs at the hemorrhage site (p=0.03). Enoxaparin had no significant effect on either.

- **Neuronal degeneration:** BIOX-101 reduced the proportion of degenerating neurons at the hemorrhage site (p=0.043) and at the caudal level (p=0.040).
- **Bleeding:** hemorrhage and lesion volumes on MRI did not differ between BIOX-101 and vehicle at Day 1, 3, 5 and 14. Enoxaparin showed a higher hemorrhage volume than BIOX-101 at Day 1 (p=0.004).
- **Human neutrophils:** in vitro, BIOX-101 associated with more than 98% of neutrophils from three healthy donors, supporting a direct effect on the cells that drive secondary brain injury after ICH.

Next step: BIRCH 2

Bioxodes is preparing BIRCH 2, a randomized, double-blind, placebo-controlled global Phase 2b trial of BIOX-101 in about 230 ICH patients. The planned primary endpoint is PHE volume at 72 hours adjusted for baseline; functional outcome on the modified Rankin Scale (mRS) at Day 90 and Day 180 and all-cause mortality are planned secondary endpoints. The trial will use the same patient criteria and the same regimen as BIRCH, as recommended by the independent Data Monitoring Committee and leading key opinion leaders. Recent research has shown that greater PHE growth within the first 72 hours after ICH is associated with death or dependence at 90 days, as assessed using the mRS[1]. Bioxodes is also preparing the BIRCH Phase 2a results for publication.

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 intracerebral hemorrhage (ICH), the deadliest and most disabling form of stroke, for which no approved therapy exists. BIOX-101's unique dual mechanism of action has the potential to address a broad range of thromboinflammatory diseases beyond ICH. 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.

[1] Samarasekera N, et al. Perihematomal Edema and Functional Outcome After Intracerebral Hemorrhage: A Meta-Analysis of Individual Participant Data. *Stroke*. 2026;57(5):1310–1324. doi:10.1161/STROKEAHA.125.053991.

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