PRESS RELEASE

Bioxodes presents positive final Phase 2a intracerebral hemorrhage results at ESOC affirming breakthrough potential of BIOX-101

- **Final results confirm and build on interim BIRCH results in 23 ICH patients**
- **Primary safety endpoint met with no mortality observed**
- **Encouraging efficacy signals on all clinical and biomarker endpoints**
- **New adaptive pivotal Phase 2b/3 trial design meets EMA and FDA registration requirements – potentially upon positive Phase 2b data**
- **Poster presentation at European Stroke Organisation Conference (ESOC) 2026**

Gosselies, Belgium, 6 MAY 2026 (14:30 CET) – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, today announced positive final results from its Phase 2a clinical trial of its investigational therapy, BIOX-101, in 23 patients with intracerebral hemorrhage (ICH). The data and regulatory discussions support progression into a single pivotal adaptive Phase 2b/3 trial.

The open-label randomized 3:1 Phase 2a proof-of-concept study showed favorable safety and tolerability, no mortality and no microhemorrhages at Day 7. Furthermore, encouraging signals were observed across multiple measures, including hemorrhage volume, edema growth, several key inflammation biomarkers, and a trend towards functional improvement in patients treated with BIOX-101 compared to standard of care (SoC).

"These final BIRCH data are highly encouraging in a disease where there are no approved therapeutic options. The directional findings on hemorrhage volume, edema growth and functional recovery, together with a clean safety profile in patients who typically face very poor outcomes, provide a strong basis for advancing BIOX-101 into the planned pivotal adaptive Phase 2b/3 trial," said **Prof. Robin Lemmens, MD, PhD, Principal Investigator of the BIRCH trial and head of the stroke unit at University Hospitals Leuven**.

“These final clinical proof of concept results provide strong evidence supporting our biological therapeutic candidate’s mechanism of action as the first disease modifying breakthrough therapy for ICH patients. Recent discussions and feedback from regulators and our regulatory consultants in the U.S. and Europe have validated our new adaptive Phase 2b/3 pivotal trial design, which we will initiate upon accessing sufficient funding,” said **Marc Dechamps, Chief Executive Officer at Bioxodes**. “We believe that positive Phase 2b data could enable us to register BIOX-101 for accelerated approval around the end of 2029 and launch this breakthrough therapy towards the end of 2030 in the U.S. and

in 2031 in Europe. We are in advanced discussions with both potential partners and investors and expect to have the resources required to advance this urgently needed candidate to patients without delay."

Among the findings disclosed at ESOC 2026:

- **Reduced hemorrhage volume.** At Day 3, hemorrhage volume in the BIOX-101 arm had decreased by 2.19 mL vs a 3.85 mL increase in the SoC arm.
- **Limited edema growth.** At Day 3, perihematomal edema (PHE) growth in the BIOX-101 arm was 6.44 mL, versus 10.46 mL in the SoC arm. This finding is critical, as growth in perihematomal edema (PHE) is a biomarker that has been shown to be associated with poor functional outcomes in patients with ICH[1]; PHE will serve as a key secondary endpoint in the planned pivotal trial.
- **Fewer secondary lesions with BIOX-101.** In patients treated with BIOX-101, 5.9% (1/17) showed secondary ischemic lesions on day 7, vs 16.7% (1/6) in the SoC arm.
- **More stable inflammatory profile.** BIOX-101 was associated with a more stable neutrophil-to-lymphocyte ratio over time compared with SoC, suggesting diminishing of the acute systemic inflammatory response following ICH.
- **Trend towards functional improvement.** At Day 90, 7 of 16 BIOX-101 patients achieved a modified Rankin Scale (mRS) score of 0–2, indicating functional independence, compared to 0 of 5 patients in the SoC arm.
- **Clear target engagement.** BIOX-101 demonstrated controlled exposure during 48-hour infusion (mean t½β: 31.45 h) with a fast and reversible antithrombotic effect lasting up to 72 hours, confirming inhibition of FXIa and FXIIa coagulation factors.
- **Favorable safety.** No mortality and no microhemorrhages at Day 7 were observed in either arm. Three SAEs in two BIOX-101 patients (11.8%) were considered unlikely drug-related or unrelated; three SAEs were observed in two SoC patients (33.3%)

Poster presentation details

Abstract title: *BIRCH: A Phase IIa proof-of-concept study of BIOX-101 in spontaneous intracerebral haemorrhage* Abstract number: ESOC2026LB16 Poster number: P143 Date and time: Wednesday, 6 May 2026, 13:00–14:00 CEST Location: Poster area, MECC Maastricht, the Netherlands.

[1] Peer-reviewed analysis in press, authors include members of Bioxodes' Clinical Advisory Board

About the BIRCH trial - BIRCH (NCT05970224) is a multicenter, open-label, randomized 3:1 Phase 2a proof-of-concept trial conducted at 8 stroke units in Belgium. The trial evaluated BIOX-101 administered as a 48-hour intravenous infusion within 24 hours of symptom onset in 23 patients with first-ever spontaneous ICH (5–60 mL hemorrhage volume) compared to standard of care.

Bioxodes is currently planning a pivotal adaptive Phase 2b/3 trial with up to 500 patients with functional outcomes as primary endpoint [2]. PHE volume will serve as a key secondary efficacy endpoint, following the results from the Phase 2a trial. The company is of the view that compelling Phase 2b interim efficacy data would be sufficient to support an accelerated approval pathway, and that BIOX-101 could be granted U.S. approval in late 2030, and 2031 in the EU. The company is actively engaged in a €70 million Series B fundraising to finance the trial, manufacturing, and registration of BIOX-101.

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.

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[2] Measured by the modified Ranking Scale (mRS), which gives a single score ranging from 1 to 6 reflecting a patient's level of functional independence.