PRESS RELEASE

Bioxodes expands Clinical Advisory Board, shares pivotal trial design for BIOX-101 in intracerebral hemorrhage

- **Three world-leading key opinion leaders, researchers and clinicians, join Clinical Advisory Board, reinforcing Bioxodes' global registrational clinical strategy**
- **Positive ongoing discussions with regulators on pivotal clinical trial design**
- **Planned adaptive Phase 2b/3 trial for BIOX-101 will have functional outcomes as primary endpoint, with potential approval upon positive Phase 2b data**
- **The company is now fully focused on ICH and has deprioritized additional indications**
- **Raising €70 million Series B to finance trial, manufacturing and regulatory**
- **Active discussions ongoing with strategic partners and potential investors**

Gosselies, Belgium, 17 APRIL 2026 (08:30 CET) – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, has appointed three additional internationally respected neurovascular experts to its Clinical Advisory Board. The nominations come as Bioxodes is in dialogue with regulators to design the pivotal clinical trial of BIOX-101 to treat intracerebral hemorrhage (ICH), an urgent unmet medical need.

Neshika Samarasekera from the University of Edinburgh, Karin Klijn from the Radboud University Medical Center in Nijmegen, and Else Charlotte Sandset from the Oslo University hospital have newly been appointed. The expanded Clinical Advisory Board now comprises 11 world-leading stroke specialists from across the world.

"Assembling this breadth of ICH expertise spanning epidemiology, trial design, acute care and regulatory science across Europe and North America reflects widespread conviction amongst the leading clinical experts in our field, as we prepare to launch a landmark pivotal trial of BIOX-101 to treat hemorrhagic stroke," said **Marc Dechamps, Chief Executive Officer of Bioxodes.** "Guidance from these experts, along with our ongoing dialogue with regulators in U.S. and EU, will be central to our trial design and execution, and highly relevant to our advanced fundraising and partnering discussions, as we aim to bring BIOX-101 to patients in late-2030 in the U.S., and 2031 in the EU."

A recent FDA pre-IND meeting led Bioxodes to conclude that a single registrational study using functional outcomes as the primary endpoint [1] could be sufficient for U.S. and EU marketing authorizations. Change in perihematomal edema (PHE), a biomarker associated with poor functional outcomes in ICH [2], will serve as a key secondary efficacy endpoint, following results from Bioxodes' Phase 2a trial suggesting that BIOX-101 reduced hematoma volume and slowed PHE growth compared to standard of care arm.

Bioxodes has developed an adaptive Phase 2b/3 study with up to 500 patients, of which the Phase 2b portion will require about 265 patients. Interim analysis from the Phase 2b portion will enable sample size re-estimation and provide early assessment of significance or probability of success. The company is currently conducting discussions with the FDA and EMA to confirm Bioxodes' view that compelling Phase 2b interim efficacy data would be sufficient to support an accelerated approval pathway.

Bioxodes intends to seek U.S. Fast Track and EU PRIME designations and estimates that BIOX-101 could be granted U.S. approval in late 2030, and 2031 in the EU. Bioxodes is actively raising a Series B round in the range of €70 million to finance the trial, manufacturing and registration. The target amount is reduced from a previously announced €100 million, based on the costing for the new adaptive trial design and reduced investment in developing BIOX-101 in additional indications.

Neshika Samarasekera, PhD, joins the Clinical Advisory Board as a consultant neurologist at the NHS Lothian and NRS Research Fellow at the University of Edinburgh's Centre for Clinical Brain Sciences. A member of the Edinburgh RUSH (Research to Understand Stroke due to Hemorrhage) program, her research focuses on epidemiology, causes and long-term consequences of ICH, including neuroinflammation and perihematomal edema, the key endpoints in BIOX-101's Phase 2b/3 trial.

Prof. Karin Klijn is Chair of the department of Neurology at the Radboud University Medical Center in Nijmegen, the Netherlands. Her research focuses on neurovascular disease, particularly ICH. Recognized as one of Europe's leading authorities on intracerebral hemorrhage, she has authored numerous peer-reviewed publications and has led or co-led multiple (inter)national studies aimed at improving outcomes after brain hemorrhage, thereby bringing crucial expertise in the design and conduct of clinical trials in ICH to Bioxodes' Phase 2b/3 program.

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[1] As measured in the modified Ranking Scale, or mRS, which gives a single score ranging from 1 to 6 reflecting a patient's level of functional independence after a stroke.

[2] Peer-reviewed analysis in press, authors include Bioxodes CAB members.

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Else Charlotte Sandset, MD, PhD, is Chair of Stroke and General Neurology at the Oslo University Hospital and chairs the Oslo Clinical Stroke Research Group. Her research focuses on acute stroke care, particularly blood pressure management and prehospital stroke pathways, and she is an active contributor to international clinical trials. As former Secretary General of the European Stroke Organisation, she brings extensive pan-European stroke network experience to Bioxodes' international Phase 2b/3 program.

Intracerebral hemorrhage (ICH) is the deadliest form of stroke, a devastating condition with no approved therapy that accounts for up to 40% of all stroke-related deaths. Fewer than 20% of survivors achieve functional independence after six months, with secondary damage from untreated bleeding and inflammation causing secondary ischemia, neuroinflammation and neuronal damage.

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 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/3 adaptive 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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