



Bioxodes meets first Phase 2a patient enrollment milestone with BIOX-101 in intracerebral hemorrhagic stroke

- **First-in-class drug candidate evaluated in first eight patients**

Gosselies (Belgium), June 27, 2024 – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, announces today that it has enrolled the first eight of 32 patients in a Phase 2a clinical study of its lead asset BIOX-101 (Ir-CPI). The study is evaluating BIOX-101 in intracerebral hemorrhagic stroke (ICH), a devastating condition for which there is currently no available treatment. Reaching this first milestone allows Bioxodes to conduct an initial analysis of pharmacokinetic and pharmacodynamic data to evaluate the dose-response and preliminary clinical proof-of concept of the therapeutic candidate, as well as safety in this patient population.

“For the first time, we are able to assess the preliminary results of BIOX-101 in ICH patients, who up until now have had very few treatment options. Analysis of these first 8 patients will yield preliminary proof-of-concept data for BIOX-101, a first-in-class drug candidate derived from a protein found in the saliva of the tick ¹, designed to prevent the harmful secondary brain injuries that occur after a hemorrhagic stroke,” said Marc Dechamps, Chief Executive Officer at Bioxodes.

The study, conducted in 10 stroke units in Belgium and led by Prof Robin Lemmens, a world-leading stroke authority and head of the clinic at the University Hospital Leuven, aims to enroll 32 patients aged 18 and above, with 24 receiving BIOX-101, and 8 standard-of-care treatment. The trial is a randomized, open-label proof-of-concept study, and will evaluate the safety and tolerability of BIOX-101 in patients with spontaneous ICH, while also generating preliminary data on secondary efficacy objectives. All patients will be monitored for at least one year to evaluate the impact of the treatment on long-term functional outcomes. Interim results for the first 16 patients are expected by the fourth quarter of 2024.

BIOX-101 prevents blood clot formation without increasing the risk of further bleeding. Moreover, by inhibiting the activation of neutrophils, a type of white blood cell that often act as the first responders of the inflammatory system, it also prevents the acute neuroinflammatory events associated with ICH. BIOX-101 is also in early development as a platform for a series of other indications, including ischemic stroke and other thrombo-inflammatory diseases.

KEY FACTS ABOUT STROKE:

- * 15 million people worldwide suffer from a stroke each year,
- * Of those, 5 million die, another 5 million are left severely disabled
- * Stroke is the leading cause of disability among neurological conditions worldwide, according to the Global Burden of Disease Study 2021 ([Lancet Neurology May 2024](#)).
- * Two types: ischemic stroke (caused by a blood clot) and hemorrhagic stroke (ruptured vessel)

¹ Ixodes ricinus



- * Hemorrhagic stroke makes up 13% of all cases, but causes 40% of deaths
- * Intracerebral hemorrhagic stroke (ICH) is by far the most common type of hemorrhagic stroke
- * For hemorrhagic stroke, there is little other to do than surgery, with poor outcomes
- * Bioxodes has applied for an orphan disease designation for BIOX-101 in the US and EU. Being awarded the designation could accelerate the regulatory approval process.

About Bioxodes

Bioxodes is a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases. Since its founding in 2013, Bioxodes has developed its lead asset BIOX-101, a first-in-class drug candidate aimed at patients with thrombo-inflammatory 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. The company, which is based in the biopark of Gosselies near Brussels in Belgium, has so far secured €34 million in funding from Belgian investment funds and business angels, including €12 million in non-dilutive funding from the Wallonia region. Worldwide, Bioxodes holds both granted and pending patents associated with BIOX-101. <http://www.bioxodes.com/>

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