



## **Bioxodes meets enrollment milestone in Phase 2a intracerebral hemorrhagic stroke trial**

- **Bioxodes has enrolled first 16 patients in trial with BIOX-101**
- **Completing treatment of first cohort of patients will trigger interim analysis**
- **BIOX-101 is a first-in-class drug candidate, a peptide developed from tick saliva**

**Gosselies (Belgium), 19 December 2024 (08:30 CET)** – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, has enrolled the first 16 of 32 patients in the open-label, randomized and controlled Phase 2a clinical trial of its lead asset BIOX-101 in patients with intracerebral hemorrhagic stroke (ICH). Treatment of the first 16 patients will trigger an interim analysis, according to the trial protocol. Data of these patients will be available for investors under condition of confidentiality, as is already the case with currently available patient data. BIOX-101 is a proprietary novel therapeutic candidate, a peptide which Bioxodes has developed from a protein discovered in tick saliva.

“We’ve reached a crucial point in the development of BIOX-101, which we believe can save lives, and improve quality of life, by preventing the harmful secondary damage in patients hit by intracerebral hemorrhagic stroke, a devastating condition for which there is no currently available treatment. I am looking forward to the full interim analysis report from the first 16 patients in March of next year,” said Marc Dechamps, Chief Executive Officer at Bioxodes.

The BIRCH trial will enroll a total of 32 patients, with 24 receiving BIOX-101, and 8 standard-of-care treatment. In the study, BIOX-101 is administered intravenously within the first hours from onset. It is being conducted in 10 stroke units in Belgium, led by Prof Robin Lemmens, a world-leading stroke authority and head of clinic at the University Hospital Leuven.

Only 13% of strokes are classified as ICH, yet these account for 40% of all stroke-related deaths, leaving many survivors with permanent or long-term disability. Standard of care consists largely of monitoring and stabilizing patients, without using anticoagulant medication, which can worsen bleeding.

ICH is an orphan disease in U.S. and Europe. Drugs developed for orphan indications often have relatively rapid and cost-effective paths to market compared to drugs for other indications. Bioxodes filed for orphan drug status in the U.S. and Europe this month, which could lead to a response from regulatory agencies in both territories in the first quarter of 2025. At the same time, the company is preparing to ramp up production of BIOX-101 for a potential registrational international Phase 2b trial, for which it plans to start recruitment in the first quarter of 2027.

BIOX-101, developed from a protein found in the saliva of the tick <sup>1</sup>, is designed to reduce the harmful secondary brain injuries that occur after a hemorrhagic stroke. It works by preventing blood clot formation

---

<sup>1</sup> Ixodes ricinus



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

#### **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. Worldwide, Bioxodes holds both granted and pending patents associated with BIOX-101.

**For more information please visit [www.bioxodes.com](http://www.bioxodes.com) or contact:**

#### **HEAD OFFICES**

BioPark Charleroi-Bruxelles Sud  
Rue Santos-Dumont, 1  
6041 Gosselies, Belgium  
+32 496 590354  
[investment@bioxodes.com](mailto:investment@bioxodes.com)

#### **MEDIA RELATIONS**

Alexandra Schiettekatte  
[communication@bioxodes.com](mailto:communication@bioxodes.com)  
+32 476 65 04 38

#### **COHESION BUREAU**

EU MEDIA RELATIONS  
Sophie Baumont  
[sophie.baumont@cohesionbureau.com](mailto:sophie.baumont@cohesionbureau.com)

#### **INVESTOR RELATIONS**

Giovanni Ca' Zorzi  
[giovanni.cazorzi@cohesionbureau.com](mailto:giovanni.cazorzi@cohesionbureau.com)