Bioxodes obtains Orphan Drug Designation for hemorrhagic stroke therapeutic candidate in US and Europe

- **FDA, EMA grant BIOX-101 ODD status to treat intracerebral hemorrhagic stroke (ICH)**
- **ODD status may expedite drug candidate development and approvals**
- **BIOX-101 interim Phase 2a data in ICH imminent**

Gosselies (Belgium), 5 March 2025 (08:30 am CET) – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies for the prevention and treatment of thrombotic and inflammatory diseases, has received Orphan Drug Designation (ODD) for its first-in-class BIOX-101 therapeutic candidate to treat intracerebral hemorrhagic stroke (ICH) from both the U.S. Food and Drug Administration (FDA) and the E.U.'s European Medicines Agency (EMA).

"The granting of Orphan Drug Designation in these two jurisdictions confirms that we are on a relatively rapid and cost-effective path to market for BIOX-101. We are working hard to offer a disruptive new therapy for patients suffering from Intracerebral Hemorrhagic Stroke, an often deadly condition with a poor prognosis, for which no therapeutic is currently available," said Marc Dechamps, CEO at Bioxodes.

"I am looking forward to achieving our next milestones, including the upcoming interim results from our Phase 2a study of BIOX-101 and the launch of our Series B financing," he said.

The FDA and EMA grant ODD to diseases that are rare, and receive little research funding as a result. Only 13% of strokes are classified as ICH, yet these account for 40% of all stroke-related deaths, with many survivors suffering permanent or long-term disability. The standard of care consists largely of monitoring and stabilizing patients, without using anticoagulant medication, as this can increase bleeding.

BIOX-101 is designed to inhibit the harmful secondary effects of a hemorrhagic stroke - such as secondary brain ischemia, neuroinflammation and neuronal damage – through a dual mechanism exerting both anti-inflammatory and anti-clotting effects, yet without increasing the risk of bleeding.

Bioxodes is planning to release interim results from the first 16 patients in its Phase 2a BIRCH trial of BIOX-101 to treat ICH imminently. The study is taking place 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.

Bioxodes plans to launch a Series B financing round in the second quarter of 2025 to support a potentially registrational Phase 2b trial with BIOX-101 for ICH. The Chemistry, Manufacturing and Controls (CMC) process required to produce BIOX-101 for Phase 2b will take approximately a year to complete, and the company is currently ramping up production to this end. Patient recruitment is planned to start in 2027.

The trial could be sufficient to register BIOX-101 for marketing authorizations in the U.S. and Europe before the end of this decade. Bioxodes is planning to file for PRIME status with the EMA this year, and for Fast Track approval at the FDA later during development of the product.

BIOX-101 is a recombinant version of a small protein found in tick saliva[1]. It has demonstrated striking benefits in preclinical proof-of-concept studies, such as the prevention of blood clot formation and a reduction in detrimental neuroinflammation after ICH. Unlike currently marketed anticoagulants, BIOX-101 reduces clotting without increasing the risk of bleeding, by targeting Factors XIa and XIIa of the intrinsic coagulation pathway. The product exerts its anti-inflammatory effects by inhibiting activation of neutrophils and their release of extracellular DNA filaments (called NETs), which can cause excessive inflammation, exacerbating brain damage and disrupting the blood-brain barrier.

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 thrombo-inflammatory disease. Bioxodes is working to characterize and develop additional drug candidates from its groundbreaking research into tick saliva, including novel anti-inflammatory drug candidates. Worldwide, Bioxodes holds both granted and pending patents associated with BIOX-101. Bioxodes research is supported by the Walloon Region, and the company is registered in Belgium under number 825.151.779.

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[1] *Ixodes ricinus*