Bioxodes reports positive DMC meeting for BIOX-101 Phase 2a trial in intracerebral hemorrhagic stroke

- Planned Data Monitoring Committee (DMC) meeting recommended continuation of the study after reviewing data from the first 8 patients
- Interim data from 16 patients scheduled around the end of 2024

Gosselies (Belgium), August 21, 2024 – Bioxodes SA, a clinical stage biopharmaceutical company developing novel therapies to prevent and treat thrombotic and inflammatory diseases, announces today that the DMC reviewed the data from the first 8 patients in a planned review of the ongoing BIRCH Phase 2a trial of BIOX-101 to prevent secondary damage after intracerebral hemorrhagic stroke (ICH).

The randomized, open-label, controlled Phase 2a clinical study is designed to enroll 32 patients. In the study, intravenous BIOX-101 treatment is initiated within the first hours from onset. To date, no serious adverse events related to BIOX-101 have been reported and none of the patients have died.

Although only 13% of strokes are classified as ICH, it is a devastating condition and accounts for 40% of all stroke-related deaths, leaving many survivors with permanent or long-term disability. There is currently no approved treatment for these patients.

“We are highly encouraged by the DMC’s decision and the fact that there have been no safety issues” said Marc Dechamps, Chief Executive Officer at Bioxodes. BIOX-101 is a first-in-class drug candidate derived from a protein found in tick saliva[1]. “It is well known that the saliva of the tick has the ability to modulate the immune response and the defence mechanisms of the host” pointed out Edmond Godfroid, PhD, co-founder and Chief Scientific Officer of Bioxodes.

“Because BIOX-101 has shown strong anti-inflammatory and antithrombotic properties but does not increase the risk of bleeding, we are testing its ability to prevent the harmful secondary brain injuries that occur in most ICH patients. While we are eager to test BIOX-101 in ischemic stroke and other diseases, ICH is considered an orphan disease in U.S. and Europe, offering a relatively rapid and more cost-effective path to market” adds Marc Dechamps.

After treating the first 8 patients in the open-label trial, the company is conducting a preliminary analysis of pharmacokinetic and pharmacodynamic data to evaluate the dose-response and efficacy of BIOX-101. Bioxodes may make the data available to select potential partners or investors under confidentiality.

The recommendation by the DMC, an independent group of experts overseeing the study, allows the company to enroll the next 24 patients. The company expects an interim data read-out based on the first 16 patients around the end of the year.

The study, conducted in 10 stroke units in Belgium and led by Prof Robin Lemmens, a world-leading stroke authority and head of clinic at the University Hospital Leuven, aims to enroll up to 32 ICH patients aged 18

[1] Ixodes ricinus

or older, with 24 receiving BIOX-101, and 8 standard-of-care treatment. Standard-of-care consists largely of monitoring and stabilizing the patient without the use of anticoagulant medication, which increases the risk of secondary damage, a major threat that often causes death or long-term disability.
The study will evaluate the safety and tolerability of BIOX-101 in patients with spontaneous ICH, while also generating preliminary data on efficacy. All patients will be monitored for at least one year to evaluate the impact of the treatment on long-term functional outcomes.

BIOX-101 works by preventing blood clot formation without increasing the risk of further bleeding, the way anticoagulants do. 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.

About Bioxodes
Bioxodes (www.bioxodes.com) 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.

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