PRESS RELEASE

AMOEBA announces that Austria has agreed to be the Rapporteur Member State to start the evaluation of its biocontrol active substance in Europe in the first quarter of 2020 with a view to a potential commercialisation in 2025.

Lyon (France), February 12th, 2019 - **AMOEBA (FR0011051598 - AMEBA)**, producer of a biological biocide capable of eliminating bacterial risk in water and human wounds, and a biocontrol product for plant protection, announces that Austria has agreed to be the Rapporteur Member State for the evaluation of its active biocontrol substance and specifies the regulatory timetable for Europe.

In Europe, the marketing of a plant protection product is subject to the prior granting of a marketing authorisation in accordance with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. The evaluation is divided into two major steps:

1) Evaluation of the active substance at European level followed by
2) Evaluation of the commercial preparations (products) carried out by the Member States.

Before submitting an application for approval of an active substance, the applicant must first obtain the acceptance of one of the Member States to be the rapporteur of the application.

The Company has therefore requested three Member States - among the most experienced in the evaluation of plant protection active substances - to evaluate its application for approval of the active substance, the powdered lysate of *Willaertia magna C2c Maky* amoebae.

Austria has agreed to be the Rapporteur Member State, with a submission of the application expected during the first quarter of 2020 to the Austrian Agency for Health and Food Safety (*AGES, Agentur für Gesundheit und Ernährungssicherheit*).

Before the application is submitted, a pre-submission meeting will be held with AGES in the 2nd quarter of 2019 to answer any outstanding questions and receive an estimate of the quality of the application.

In 2019, the Company will also generate the required regulatory data, including physicochemical data on the substance, its toxicity, ecotoxicity, behaviour and fate in the environment, as well as field test results.

The Company below recalls the main regulatory steps for the approval of a plant protection active substance in Europe, once the dossier has been submitted and the evaluation initiated by the Rapporteur Member State:

1) *Assessment phase by the rapporteur Member State*: This phase lasts approximately 14 months, with a possible 6-month clock-stop if additional information is requested. The rapporteur Member State shall forward the draft assessment report to the European Food Safety Authority (EFSA), the applicant and the other Member States. **The Company expects that the draft assessment report will be available in the first quarter of 2022.**

2) *Risk assessment phase*: EFSA carries out the risk assessment and sets-up a 3-month peer review consultation involving the Member States. Following the expert consultation, EFSA

publishes a peer-review report containing its conclusions within 4 to 8 months, with a possible clock-stop in the event of a request for additional information.

3) *Risk management phase*: Within 6 months after EFSA conclusions, the European Commission shall submit a review report and a draft regulation to the Standing Committee on the Food Chain and Animal Health, which shall vote on the approval or non-approval of the active substance. The approval of an active substance implies that it is eligible for use in a plant protection product on EU territory. The decision is ultimately adopted by the European Commission.

Under the EU rules, it takes 2.5 to 3.5 years from the date of admissibility of the application to the publication of a Regulation approving a new active substance. The regulatory deadlines for the evaluation of applications for approval of active substances vary according to the novelty, complexity, completeness and type of application, but also according to the workload of the competent authorities: these deadlines are not systematically respected as indicated in the research article *A comparison of the EU and US regulatory frameworks for the active substance registration of microbial biological control agents*[a]. Thus, **the company estimates that the active substance could be approved in the 2nd quarter of 2024, provided that approval criteria are met.**

Once the active substance has been approved by the European Commission, EU Member States have a legal period of 6 months to determine whether the plant protection products (commercial products) containing this active substance meet the approval criteria and to issue their marketing authorisation decision. **The Company estimates that the marketing authorisation for the plant protection product(s) containing the active substance could be granted in 2025, provided that approval criteria are met.**

As a reminder, to date, the Company is in the trial phase for biocidal and plant protection applications and does not market any products.

AMEBA
LISTED
EURONEXT

About AMOEBA:
Amoéba's ambition is to become a major player in the treatment of bacterial risk in the fields of water, healthcare and plant protection. Our biological solution is an alternative to chemical products widely used today. Amoéba is currently focusing on the market of industrial cooling towers estimated at €1.7Bn (1) on a global chemical biocide market for water treatment, evaluated at €21Bn (2) and on the biocontrol market for plant protection estimated globally at €1.6Bn (4). In the future, the Company is looking at developing new applications such as chronic wound care, estimated at € 751 million (3) in the USA. Sales of associated products with healthcare, biocides and crop protection are subject to the Company being granted local regulatory market authorizations. The Company is currently in a trial phase for biocidal and plant protection applications and does not market any products. Created in 2010, based in Chassieu (Lyon, France) with a subsidiary in Canada and in the United States, Amoéba is quoted on the compartment C of Euronext Paris. The Company is a member of the BPIfrance Excellence network and is eligible for the PEA-PME SME equity savings plan setup. More information on www.amoeba-biocide.com.
(1): Amoéba data combined from sources: DRIRE 2013, Eurostat, ARHIA 2013

[a] https://onlinelibrary.wiley.com/doi/epdf/10.1002/ps.5133

(2): Sources combined by Amoéba from water treaters, Freedonia, Eurostat et MarketsandMarkets
(3): BCC Research, "Markets for Advanced Wound Management Technologies," Wellesley, MA, 2017
(4): Biopesticides Worldwide Market 2013, CPL, Wallingford, UK

Contacts :

Amoéba
Valérie FILIATRE
Directeur administratif et Financier
04 26 69 16 00
valerie.filiatre@amoeba-biocide.com

Actifin
Ghislaine GASPARETTO
Communication financière
01 56 88 11 11
ggasparetto@actifin.fr

Disclaimer

This press release contains certain forward-looking statements concerning AMOEBA which are based on its own assumptions and hypothesis and on information that are available to us. However, AMOEBA gives no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of AMOEBA filed with the French Financial Markets Authority (*Autorité des Marchés Financiers*) on April 27, 2018 (a copy of which is available on www.amoeba-biocide.com). The forward-looking statements contained in this press release are also subject to risks not yet known to AMOEBA or not currently considered material by AMOEBA. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of AMOEBA to be materially different from such forward-looking statements.