

## **AMOEBA FILES THE APPLICATION FOR THE AUTHORIZATION OF ITS BIOCONTROL SOLUTION IN THE U.S.A.**

**Chassieu, October 1, 2020, 6.00 pm**, AMOEBA (FR0011051598-ALMIB) - producer of a biological biocide capable of eliminating the risk in water and human wounds, and of a biocontrol product for plant protection, still in the testing phase, informs that the application for approval of its biocontrol active substance "lysate of *Willaertia magna* C2c Maky" and products containing it was submitted today to the competent authority of the United States, the Environmental Protection Agency (EPA). The biocontrol solution, developed by Amoéba, is intended for use as a fungicide in agriculture.

### **A dossier meeting regulatory requirements**

This application for approval is partly based on the studies carried out for the European dossier (see Press Release of May 29, 2020). Additional toxicity studies, required by the U.S. pesticide regulation, have been conducted and have confirmed the absence of hazard to human and animal health.

### **A possible approval in 2022**

Being a naturally occurring substance, the biocontrol active ingredient is a biopesticide and the application for approval will be evaluated by the Biopesticides and Pollution Prevention Division (BPPD). The approval process will take between 18 and 24 months, with a decision expected in 2022. The main steps are as follows:

- 1) *Initial 21-day Content Screen* : the EPA verifies whether the application is sufficiently complete, which takes 21 days.
- 2) *Preliminary Technical Screen* : a preliminary technical review is conducted within 90 days of Step 1) to determine if the data is accurate and complete, consistent with the proposed labelling and if, subject to a full review, could lead to the acceptance of the application. If the information is considered insufficient by the EPA at this stage, the applicant has 10 business days to provide the required information.
- 3) *In-Depth Review of Data* : Upon successful completion of the Preliminary Technical Screen stage, the application is subject to a thorough review. If, during this in-depth review, the EPA determines that there are data gaps or that additional data are required to complete the review, the EPA will notify the applicant. The applicant will be given 75 days to make corrections or to provide additional data.

Ultimately, if the EPA considers that the substance can be used in a plant protection product without posing unreasonable risks to human health and the environment, then it issues a federal marketing authorization. Once registration of the product is obtained at the federal level, registration (notification and payment of fees) is required by local regulations in most states and takes approximately one to two months (except in California, which requires an evaluation of the complete file in approximately 12 months). Once registration has been obtained at the local level, marketing is possible in the state.



The Company is therefore considering a marketing approval in the United States for products containing the biocontrol active substance "lysate of *Willaertia magna* C2c Maky" in 2022.

### **Research partnerships on biocontrol applications**

Amoéba is currently and until mid-October exchanging with each partner having signed a material transfer contract (see press release of April 29, 2020) all the respective technical results of their field trials. The analysis of product performance will be used as a basis for discussions on future commercial collaborations. For obvious reasons of competition, the partners should not release their results publicly.

### **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 Euronext Growth 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](http://www.amoeba-biocide.com).

(1): Amoéba data combined from sources: DRIRE 2013, Eurostat, ARHIA 2013

(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

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