

Amoéba submits its biocide application in the USA

Information of the timetable for the other regulatory dossiers

Chassieu (France), April 6, 2021 – 5.45 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 a development phase, has submitted today the application for approval of the biocidal active substance, the living amoeba *Willaertia magna* C2c Maky, and the biocidal products containing it, to the U.S. Environmental Protection Agency (U.S. EPA).

Amoéba reminds that in August 2019, it had decided to voluntarily withdraw its application for approval of the biocidal active substance, the living amoeba *Willaertia magna* C2c Maky, and biocidal products containing it, and to submit a new application for approval at a later stage.

During a pre-submission meeting in November 2019 between Amoéba and the U.S. EPA, requests for clarification were raised about the scientific elements that led to the withdrawal of the dossier and the way in which Amoéba planned to respond.

Amoéba was therefore able to submit a new application today, with the additional studies required by the U.S. EPA.

Once the active substance and biocidal product registrations are obtained, expected by mid-2022 subject to approval by the US EPA, registration (notification and payment of fees) will be required at the state level, which will take about two months (except for California, which requires a full dossier evaluation of about 12 months). Once registration is obtained at the local level, marketing may be possible in the State.

Amoéba thus envisages the first sales of its biocide product in the United States from the **second half of 2022**, subject to a positive decision by the U.S. EPA.

Information on the timetable for other biocidal and phytosanitary regulatory dossiers:

Amoéba also provides information on the regulatory timetable for the various regulatory dossiers:

- **Biocide application (biocidal active substance, living *Willaertia magna* C2c Maky):**
 - Europe: the application for approval of the active substance, submitted in 2019 (see *Press Release of 12 August 2019*), is currently being evaluated by the Maltese authority. Amoéba considers that the evaluation report of the authority could be available mid-2021.
 - Canada: the application for registration of the active substance and biocidal products containing it, submitted in 2019 (see *Press Release of 1 February 2019*) is currently being evaluated. The extension of the evaluation period (initially estimated at 24 months) is due to a request for additional information from the Canadian agency to which the company has responded. Amoéba estimates that the decision of the Canadian agency could occur before the end of 2021.
- **Phytosanitary application (biocontrol active substance, lysate of *Willaertia magna* C2c Maky):**
 - Europe: the application for approval of the active substance, submitted in 2020 (see *Press Release of 29 May 2020*), is currently being evaluated by the Austrian authority. Amoéba considers that the evaluation report of the authority could be available at the end of 2021.
 - United States: the application for registration of the active substance and products containing it, submitted in 2020 (see *Press Release of 1 October 2020*) is currently being evaluated. The decision of the American agency should occur during 2022.
 - Brazil: an experimental permit was obtained in February 2021, allowing the Company to initiate field trials on soybean, coffee and banana. Such trials in Brazil are required for an application file.

Details of the procedures are available in the Universal Registration Document (URD) filed with the French Financial Markets Authority (Autorité des Marchés Financiers) on 30 April 2020 under number D20-0416, in particular in sub-section 5.4.3. The URD is available on the company's website and its update, including the above information, will be published in April 2021.

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. 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*

(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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