PRESS RELEASE

AMOEBA announces that Malta has agreed to be the reviewer of the new application for approval of its active substance for biocidal application in Europe.
The start of the evaluation, formerly planned for the first quarter of 2021, will take place in 2019.

Lyon (France), February 25th, 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 Malta has agreed to be the Member State that will evaluate the new application for approval of its biocidal active substance in Europe.

Following the non-approval of its biocidal active substance *Willaertia magna C2c Maky* in 2018, Amoéba had expressed its willingness to submit a new application for approval, on the basis of an updated dossier addressing the safety and efficacy concerns raised during the first dossier examination (see press release dated 26 April 2018). Although the French authority ANSES accepted the submission of a new dossier from the first quarter of 2021, the Company sought another Member State to initiate the evaluation of the active substance within a shorter period (see press release dated 29 November 2018).

Malta Competition and Consumer Affairs Authority (MCCAA) has agreed to be the evaluating competent authority for the new application for approval. The active substance to be evaluated is the amoeba *Willaertia magna C2c Maky* in its living form, intended for use in cooling towers to prevent legionella growth (Product Type 11 - Preservatives for liquid-cooling and processing systems) and to control the biofilm (Product Type 12 - Slimicides).

As part of the acceptance process by the evaluating competent authority, open and constructive exchanges have already occurred between the MCCAA and Amoéba. A meeting will be held in the 2nd quarter of 2019 between the MCCAA, its non-governmental experts based in the Netherlands and Amoéba. The main objectives of this pre-submission meeting prior to the application submission are to discuss the technology and intended use of the biocide, to validate the data required for this new submission and to agree on the submission date and evaluation stages.

The MCCAA indicated that it was in favour of consulting the European Chemicals Agency (ECHA) to ensure a harmonised view at European level on the type and level of data required, and in particular on the non-sufficiently demonstrated efficacy and the hypothetical risk associated with a 'Trojan Horse' effect. Such a consultation, which should take place in 2019, had been proposed by the European Commission during discussions with Amoéba. This proposal for a prior consultation followed the issues Amoéba had faced during the previous evaluation.

Amoéba is considering the submission of the application before the end of 2019. As soon as the date of submission and the estimated timetable are known, Amoéba will publish this information by means of a press release.

As a reminder, two regulatory steps are required before any biocidal product can be marketed in the European Union:

1) The approval of the biocidal active substance by the European Commission, following the evaluation by a Member State and the peer-review. The approval of the active substance is a necessary condition for its use in a biocidal product.

2) The authorisation to put the biocidal product on the market, issued either by the European Commission (EU authorisation) or by each Member State (national authorisation and mutual recognition), depending on the procedure chosen by the applicant.

Considering a submission of the application for the active substance approval before the end of 2019, and subject to an assessment report by the MCCAA recommending the active substance approval and issuance of provisional authorisations (valid for 3 years, converted into definitive authorisations once the active substance has been approved), the Company could consider the first placing on the market of biocidal products containing the active substance from the 2nd half of 2022 in Europe, for use in the prevention of biofilm and legionella growth in cooling towers. Details of the procedure will be specified in the future press release specifying the submission date and the provisional timetable.

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
(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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