PRESS RELEASE

AMOEBA announces the result of the European vote on the non-approval and informs on the medium-term prospect of submitting an updated dossier.

Lyon (France), November 29, 2018 - **AMOEBA (FR0011051598 - AMEBA)**, producer of a biological biocide capable of eliminating bacterial risk in water, plant protection and wound care applications, announces the publication of the result of the vote on the non-approval of the biocidal active substance *Willaertia magna C2c Maky* and informs on the medium-term prospect of submitting an updated dossier.

1 - Results of the vote on the non-approval of the biocidal active substance

The vote took place during the session of the European Commission Standing Committee on Biocidal Products on November 23rd, 2018 ; Amoéba became aware of the result on November 28th, 2018.

Following the opinion adopted by the Biocidal Products Committee (see April 26th, 2018 press release), the 28 Member States have voted for the non-approval of the biocidal active substance *Willaertia magna C2c Maky* for use as product type 11 (TP 11 - Liquid protection products used in cooling and manufacturing systems).

The Commission's implementing decision on non-approval will be published and will enter into force in the coming weeks.

2 - Prospect of submitting an updated dossier

Following discussions between the European institutions and the Company on the issues faced by Amoéba during the review of its dossier, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) confirmed that it had "*already encouraged ANSES to continue the dialogue in case* [Amoéba] *would like to submit a new application for approval*" and "*if needed, ANSES can also consult ECHA and the relevant working group(s) of the Biocidal Products Committee (BPC)* ***in order to ensure a harmonised view*** **[at European level]** ***on the type or level of data needed***".

On the basis of DG SANTE's recommendations, and following an official request by Amoéba, ANSES has agreed to examine a new application dossier for approval of the active substance *Willaertia magna C2c Maky,* completed with elements to address the safety and efficacy concerns raised during the examination of the first dossier.

However, in view of the Agency's current workload plan for examining dossiers for biocidal and plant-protection substances and products, ANSES will only be able to accept the submission of the dossier from the first quarter of 2021. As such a deadline is not acceptable to the Company, Amoéba has requested that ANSES reviews the proposed submission date. In parallel, Amoéba, in agreement with ANSES, is looking for another evaluating Member State that could initiate the evaluation in a shorter period of time.

As soon as the final schedule is known, Amoéba will transmit 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: a necessary condition for its use in a biocidal product.
2) The authorisation to place the biocidal product on the market, delivered either by the European Commission (Union authorisation) or by each Member State (national authorisation), depending on the procedure chosen by the applicant.

(See Chapter 6.8.1. of the 2017 company reference document filed with the French Financial Markets Authority on April 27, 2018).

"We expected that the European Commission would follow Biocidal Products Committee opinion. A constructive work with the European Commission and Member States, including France, will allow an updated dossier to be resubmitted. One of the important points to highlight is the European Commission's request to guarantee a harmonized view of the data needed for the dossier. In this way, the requirements will be clearly defined before the evaluation. We hope that this clearly established roadmap can lead to the approval of our substance", declares Fabrice PLASSON, Chairman of AMOEBA.

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.
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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