**PRESS RELEASE** 



## Amoéba informs that the EPA cannot grant the registrations for the use of its active substance *Willaertia magna C2c Maky* in cooling towers

**Lyon (France), August 19th, 2019 - AMOEBA (FR0011051598 -AMEBA)**, producer of biological biocides capable of eliminating bacterial risks in water and human wounds, and a biocontrol product for plant protection, still in trial phase, announces that the US Environmental Protection Agency (EPA) cannot grant the registrations for the use of *Willaertia magna C2c Maky* in cooling towers.

The EPA has now completed the review of the biocide applications and has informed Amoéba that, at this stage, it cannot grant the registrations. Due to insufficient scientific data, the Agency has determined that it cannot conclude that the standards for registration are met. After the review of the dossiers, no hazard to human health or the environment has been determined by the EPA; however, based on the data submitted in support of the registrations, the EPA could not confirm that the biocidal products containing *Willaertia magna C2c Maky*, when used in accordance with commonly recognized practices, will not cause unreasonable adverse effects.

EPA has not denied the applications. Indeed, once the Agency informs the applicant that it cannot grant an application, the applicant has three options: request a denial, withdraw the application, or continue the application outside a legally-mandated timeframe (called the PRIA timeframe).

Based upon discussions with its US regulatory consultants and the EPA, the Company has decided that the appropriate option is a voluntary withdrawal of the applications. Indeed, a denial is an undesirable option for both the EPA and Amoéba. Furthermore, continuing the applications outside the legal timeframe is not favorable to Amoéba as the applications would fall within the Agency's non-priority reviews and the furtherance of the evaluations may last several years.

Amoéba is now evaluating the opportunity and timing to submit new applications to the EPA.

"We are, of course, not satisfied and are frustrated not to get an approval while no hazard has been determined. Nevertheless, EPA's constructive approach has made it possible to make progress in terms of assessing potential risks. We are confident that this pioneering work will be of benefit for our current and future dossiers. This situation does not change the progress we are currently making with regard to the biocontrol application, which registration dossiers will be submitted in Europe and the United States in the first quarter of 2020." said Fabrice PLASSON, President and CEO of Amoéba.



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  $\pounds$ 1.7Bn <sup>(1)</sup> on a global chemical biocide market for water treatment, evaluated at  $\pounds$ 21Bn <sup>(2)</sup> and on the biocontrol market for plant protection estimated globally at  $\pounds$ 1.6Bn <sup>(4)</sup>. In the future, the Company is looking at developing new applications such as chronic wound care, estimated at  $\pounds$  751 million <sup>(3)</sup> 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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