

## AMOÉBA prepares for the commercial launch of the AXPERA Product Line in the USA with approval expected by 2025

**Chassieu (France), August 28, 2024 – 5:45pm - Amoéba (FR0011051598 - ALMIB), an industrial greentech specialising in the development of natural microbiological solutions based on the patented use of amoebae, announces that the US Environmental Protection Agency (US EPA) has confirmed the admissibility and completeness of the registration dossier for its biocontrol products in the United States.**

On the basis of the approval already obtained in the United States for its biocontrol active substance, and in order to accelerate its industrial and commercial development, Amoéba announces that in July 2024 it successfully submitted an application for federal market authorization application (MAA) for its biofungicide products AXPERA GREEN and AXPERA NOA to the US EPA, the US environmental protection agency.

The US EPA has confirmed the admissibility and completeness of the registration dossier for these products. The pre-approval assessment has now begun and the authorization decision is expected within a theoretical timeframe of 7 months. However, as a precaution and taking into account the generally observed evaluation periods, the conclusions from the US EPA are therefore expected in mid-2025. These conclusions will apply to the entire US territory, excluding California, where the registration procedure is separate. The US registration application for the plant protection products, AXPERA GREEN and AXPERA NOA, is based on the required regulatory studies, over 38 field trials conducted in the United States, in addition to more than 300 trials conducted on this version of the product outside the US.

In parallel with the evaluation, Amoéba is working in collaboration with Dunham Trimmer, a leading American consultancy in the biological products market, to prepare the commercial launch of AXPERA-based solutions, including the selection of commercial partners. If the registration timelines are met, the market authorization would allow the first distribution contracts could be signed by the end of 2025.

This information is in addition to that from the approval authorities in Europe. Now that the collective review of the active substance dossier by the Member States and the European Food Safety Authority (EFSA) has been completed, the EFSA must finalize its report concluding the evaluation, and has confirmed that it should be published by December 2024 at the latest.

## **About Amoéba:**

Founded in 2010, Amoéba is a greentech based in Chassieu (Lyon, France) with the ambition to become a major player for the treatment of microbiological risk in the crop protection and cosmetic sectors.

Based on the natural properties of a unique, exclusively patented, microorganism, the only one of its kind in the world, our biological solutions offer a viable alternative to the chemical products that are widely used in the industry today. Amoéba is currently focused on the global biocontrol market for plant protection and the cosmetics market. As the market release of phytosanitary products is subject to local regulatory approvals, the Company has completed the regulatory processes required and in 2022 obtained approval for its active substance in the United States and its recommendation for approval in Europe, issued by the Austrian authority. As the cosmetic application does not require prior approval from a relevant authority in Europe and the United States, the party responsible for bringing the formulated cosmetic product to market must carry out a self-assessment of its safety.

Amoéba is listed on Euronext Growth. The Company is a member of the BPI Excellence network and is eligible for the PEA-PME scheme. For more information, please visit [www.amoeba-nature.com](http://www.amoeba-nature.com).

## **Contacts:**

### **Amoéba**

Jean-François DOUCET  
Chief Executive Officer

+33 (0)4 26 69 16 00

 [jf.doucet@amoeba-nature.com](mailto:jf.doucet@amoeba-nature.com)

### **Actus finance & communication**

#### *Investors relations*

Pierre JACQUEMIN-GUILLAUME

+33 (0)1 53 67 36 79

 [amoeba@actus.fr](mailto:amoeba@actus.fr)

#### *Press relations*

Serena BONI

+33 (0)4 72 18 04 92

 [sboni@actus.fr](mailto:sboni@actus.fr)

## **Disclaimer**

*This press release contains certain forward-looking statements concerning Amoéba which are based on its own assumptions and estimates and on information that is currently available to us. However, Amoéba gives no assurance that the estimates contained in such forward-looking statements will be verified, with these estimates subject to numerous risks, including the risks set forth in Amoéba's universal registration document filed with the French Financial Markets Authority (Autorité des Marchés Financiers) on April 29, 2024 under number D24-0352 and available on the Amoéba website ([www.amoeba-nature.com](http://www.amoeba-nature.com)). The forward-looking statements contained in this press release are also subject to risks not yet known to Amoéba or not currently considered material by Amoéba. The occurrence of all or part of such risks could cause Amoéba's actual results, financial conditions, performance, or achievements to be materially different from such forward-looking statements.*