

Press release

## Amoéba: final phase for marketing authorisation of AXPERA

- The ANSES evaluation process for the application submitted in March 2025 is currently in its final stage.
- At the same time, French and Italian agricultural sectors have begun procedures to obtain derogatory marketing authorisations for the use of AXPERA to combat fungal diseases from the start of their production season.
- At this stage, there is nothing to prevent the marketing authorisation of the product in 2026.

Chassieu (France), 23 February 2026 – 6:00 pm - Amoéba (FR0011051598 - ALMIB), industrial greentech specialised in the development of natural microbiological solutions based on the patented use of amoebae, **announces that the ANSES** (French Agency for Food, Environmental and Occupational Health & Safety) **has initiated the final phase of its assessment of the marketing authorisation application for the biocontrol product AXPERA, submitted in March 2025.**

### One final step before obtaining marketing authorisation on the French market

In 2025, Amoéba initiated the procedure in Europe to apply for marketing authorisation for its AXPERA biocontrol product in priority Member States. France agreed to act as the rapporteur Member State (zRMS) for all of these countries (see press releases dated [15 January 2025](#) and [22 April 2025](#)). As such, the **ANSES**, the French competent authority, **is currently finalising its assessment of the authorisation application submitted in March 2025.**

The procedure includes a final stage for comments on the draft assessment report ("*draft Registration Report*"), open to both the applicant (Amoéba) and the other Member States concerned. This comment phase, which began in February, will end on 6 March 2026. It will be followed by the final phase of signing and official publication of the marketing authorisation in France. This administrative phase may take several weeks.

At this stage of the *draft Registration Report*, Amoéba considers that **there are no obstacles to the marketing authorisation of the product.** The requested uses (culture/disease combinations) have all been deemed acceptable, and the product's safety profile has been confirmed.

On the basis of the ANSES final assessment report and the French authorisation, the other Member States concerned will then initiate the national authorisation procedure for AXPERA in their territories.

## New derogatory marketing authorisations to come in order to meet demand from the agricultural sectors for AXPERA

Given the uncertainty regarding the timing of this final phase, **the agricultural sectors in France and Italy have initiated procedures to obtain exceptional marketing authorisations for the use of AXPERA in certain situations presenting phytosanitary emergencies**, similar to the authorisation granted in 2025 for the use of AXPERA against downy mildew in vineyards in France ([see press release of 22 April 2025](#)). **The aim is therefore to enable agricultural producers to use AXPERA from the start of the production season.**

Furthermore, following on from the exceptional authorisation granted in 2025 by the Dutch authorities, **Amoéba has submitted a new application for exceptional authorisation for large-scale trials in the Netherlands to use AXPERA on several crops**, including the possibility of consuming the harvests.

Provided they are granted, which was the case in 2025, these derogatory authorisations would allow AXPERA to be marketed for the uses concerned, regardless of the final timetable for obtaining marketing authorisation.

### **About Amoéba:**

Founded in 2010, Amoéba is a green tech company based in Chassieu (Lyon, France) that aims to become a major player in microbiological risk treatment through the patented use of amoebae in the plant protection and cosmetics sectors.

With unique expertise protected by numerous patents, Amoéba is currently the only company authorised to use the *Willaertia amoeba* industrially for biocontrol and cosmetic applications. To the Company's knowledge, it is also the only company capable of producing it on an industrial scale in volumes compatible with commercial applications, in order to offer a viable alternative to the chemical products widely used today.

Amoéba is currently focusing on the global biocontrol market for plant protection and the cosmetics market. As the marketing of plant protection products is subject to obtaining local regulatory approvals, the Company has taken the necessary regulatory steps and submitted applications for approval in Europe and the United States. The active substance has already been approved in the United States in 2022 and received a positive and final report from the EFSA in Europe. Product registration was obtained in 2025 for the United States and is expected in 2026 in France and then in other targeted European countries.

The cosmetic application does not require prior approval from a competent authority in Europe or the United States. The cosmetic ingredient is already listed on the INCI (International Nomenclature of Cosmetic Ingredients) list, paving the way for its commercialisation worldwide, except in China, where local approval is required.

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

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