



Press release – inside information

Biotalys Receives Regulatory Approval by U.S. EPA for EVOCA

U.S. Registration Marks a Significant Milestone as the First Protein-Based Biofungicide of its Kind to be Approved by the EPA

Ghent, BELGIUM – 2 December 2025, 07:00 CET – [Biotalys \(Euronext: BTLS\)](#) is excited to announce it has received regulatory approval from the U.S. Environmental Protection Agency (EPA) for its first biofungicide, EVOCA™*. This product was developed using Biotalys' AGROBODY™ technology platform and is the first protein-based biofungicide of its kind to be approved by the EPA.

EVOCA is a precision biocontrol solution with a new mode of action** that targets the fungal pathogens botrytis (grey mold) and powdery mildew in high-value fruits and vegetables while minimising the risk to beneficial organisms or the environment.

With this approval in hand, Biotalys can proceed with the dossiers for state registrations in California and Florida, two of the most important growing regions for fruit and vegetables in the United States***. In Europe, EVOCA has entered the peer review phase, and the Netherlands – as the rapporteur member state – has proposed approval in Europe, subject to the provision for certain additional data as requested during the peer review phase.

Additionally, the company can move forward with building up the U.S. regulatory submission for EVOCA NG – its next-generation product – currently in the final phases of development. The regulatory review process for EVOCA NG is expected to be significantly shorter, as the product contains the same active ingredient as EVOCA and features enhanced formulation and production methods. Biotalys envisages obtaining registration of EVOCA NG in the U.S. in 2028-29 and in the EU and Brazil in 2029-30, and subsequently launching it commercially in these markets worth around USD 1.2 billion combined¹.

“This approval marks a major regulatory milestone for EVOCA and moves us closer to delivering a new, sustainable tool for farmers to protect their crops,” **said Kevin Helash, CEO of Biotalys**. “The product has an entirely new mode of action to target fungal diseases, highlighting the uniqueness of Biotalys’ technology platform as a pathway to discovering many new modes of action in the coming years. The EPA’s decision reinforces the potential of our technology to help shape the future of agriculture and is a testament to the dedication of our entire team.”

EVOCA is developed to provide growers with a novel solution that bridges the efficacy and scale of commonly used chemistries with the environmental advantages of biological solutions. Benefits to growers include:

- Flexibility for use in both pre- and post-harvest applications across a wide range of food and non-food crops in both greenhouse and outdoor growing conditions;
- Compatibility with an array of application methods and easy integration into existing farm management practices; and

¹ Source: Kynetec 2020; Biotalys



- A new mode of action to manage resistance build up, when compared with existing fungicides.

End of October 2025, the EPA also posted a final rule exempting EVOCA's active ingredient residues on treated crops from tolerance requirements. No maximum residue limits will apply given EVOCA's exemplary safety profile.

To read the full EPA documents please visit: <https://www.regulations.gov/docket/EPA-HQ-OPP-2021-0165>

** EVOCA™: Registered by the Environmental Protection Agency (EPA) in the United States. This product candidate is not currently registered for sale or use in other jurisdictions such as the European Union and is not being offered for sale.*

*** This was recognised by the Fungicide Resistance Action Committee (FRAC), a panel of renown industry experts. EVOCA obtained FRAC-code F10, one of only 8 new codes granted in the last decade.*

**** Biotalys already submitted a dossier for approval in California, as this State performs its own in-depth review parallel to the EPA review.*

About EVOCA

EVOCA is a novel protein-based biofungicide that helps control the fungal diseases botrytis (grey mold) and powdery mildew in fruits and vegetables. EVOCA has demonstrated strong performance in trials across various regions, climates, soil types, production types, pathogen pressure and crops. EVOCA contains the same active ingredient as EVOCA NG, expected to be the first commercial product of the company.

About Biotalys

Biotalys is an Agricultural Technology (AgTech) company developing precision biocontrol solutions based on proteins for the protection of crops in both the pre- and post-harvest markets. The company provides novel solutions that bridge the efficacy and scale of chemistry with the environmental advantages of biological solutions. Based on its novel AGROBODY™ technology platform, Biotalys is developing a strong and diverse pipeline of effective product candidates with a favorable safety profile that aim to address key crop pests and diseases across the whole value chain, from soil to plate. Biotalys was founded in 2013 as a spin-off from the VIB (Flanders Institute for Biotechnology) and is listed on Euronext Brussels. The company is based in the biotech cluster in Ghent, Belgium. More information can be found on www.biotalys.com.



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Important Notice

Biotalys, its business, prospects and financial position remain exposed and subject to risks and uncertainties. A description of and reference to these risks and uncertainties can be found in the [annual report](#) on the consolidated annual accounts published on the [company's website](#).

This announcement contains statements which are "forward-looking statements" or could be considered as such. These forward-looking statements can be identified by the use of forward-looking terminology, including the words 'aim', 'believe', 'estimate', 'anticipate', 'expect', 'intend', "have the potential", 'may', 'will', 'plan', 'continue', 'ongoing', 'possible', 'predict', 'plans', 'target', 'seek', 'would' or 'should', and contain statements made by the company regarding the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are warned that none of these forward-looking statements offers any guarantee of future performance. Biotalys' actual results may differ materially from those predicted by the forward-looking statements. Biotalys makes no undertaking whatsoever to publish updates or adjustments to these forward-looking statements, unless required to do so by law.