



Press release – inside information*

Biotalys Provides Regulatory Review Update on EVOCA

- *Dutch Regulatory Authority CTGB Recommends European Approval*
- *U.S. Review Ongoing*

Ghent, BELGIUM – 14 January 2025, 07:00 CET – [Biotalys \(Euronext: BTLS\)](#), an Agricultural Technology (AgTech) company developing protein-based biocontrol solutions for sustainable crop protection, today provides an update on the regulatory review process of its first biofungicide, EVOCA™**, in Europe and the United States.

European Union

Biotalys is very pleased to announce that the Dutch regulatory authority, CTGB (*College voor de Toelating van Gewasbeschermingsmiddelen en Biociden*), provided the company with its initial Draft Assessment Report, recommending the approval of EVOCA's active ingredient throughout the European Union. The CTGB will now send its draft report to the Dutch Institute for Health and Environment (RIVM) for potential input regarding classification, labelling and packaging requirements, resulting in the closure of the first phase of the regulatory review of EVOCA in Europe.

Biotalys CEO Kevin Helash said: "This is a significant milestone in the regulatory journey for our first biocontrol, and we see this as a major win for our team. The CTGB has extensive expertise in the evaluation of biocontrols, and we are very pleased with their recommendation for approval as we believe this validates the potential of our innovative AGROBODY™ technology platform for the development of novel biocontrol solutions for growers. While the review process is lengthy and there's a lot of work still to be done, earning the support of the regulator in one of the largest exporting countries of fruits and vegetables worldwide is a sign of confidence in our technology. We look forward to receiving our first full regulatory approval in Europe."

In the next phase, the European Food Safety Authority (EFSA) and EU member states perform in-depth reviews of the dossier and provide feedback to the CTGB, while allowing Biotalys to deliver certain data requested by CTGB. This next phase is expected to take in total between 12 and 18 months and also includes a public consultation, ending with a vote by the European member states on the approval of the active ingredient at EU level.

The CTGB draft assessment report follows its [recent decision](#), whereby the authority approved large-scale demonstration trials of EVOCA in greenhouses while allowing the harvested fruits and vegetables to be sold for human consumption.

United States

The Environmental Protection Agency (EPA) continues its review of the regulatory dossier of EVOCA in the United States. Biotalys is working closely with the EPA to advance the dossier to a successful outcome and plans to provide an update on the EPA review in conjunction with the company's year-end results press release and investor webcast scheduled on 19 March 2025.



In parallel with the EPA, the California Department of Pesticide Regulation (CDPR) has been reviewing the regulatory dossier for EVOCA submitted by Biotalys. [As announced previously](#), the company understands that the CDPR has finalized its own in-depth review, opening a path to a swift approval at state level pending EPA approval of the product at the federal level

** This press release contains inside information to the extent it relates to the draft report of the CTGB.*

*** EVOCA™: Pending regulatory review. This product is not currently registered for sale or use in the European Union, the United States, or elsewhere and is not being offered for sale and no assurance can be given if and when registration will be obtained.*

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. If approved, EVOCA will pave the way for EVOCA NG which is expected to be the first commercial product out of the Biotalys' pipeline.

About Biotalys

Biotalys is an Agricultural Technology (AgTech) company developing protein-based biocontrol solutions for the protection of crops and aiming to provide alternatives to conventional chemical pesticides for a more sustainable and safer food supply. 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 since July 2021. 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', '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. Biotaly's actual results may differ materially from those predicted by the forward-looking statements. Biotaly's makes no undertaking whatsoever to publish updates or adjustments to these forward-looking statements, unless required to do so by law.