



Press release

Biotalys Reports Progress in the Regulatory Review of EVOCA in both US and EU

US EPA projects taking a regulatory decision by end of September 2025

Dutch authorities finalise first phase of regulatory dossier for EVOCA in Europe

Ghent, BELGIUM – 11 June 2025, 07:00 CEST – Biotalys ([Euronext - BTLS](#)), an Agricultural Technology (AgTech) company developing protein-based biocontrols for sustainable crop protection, is pleased to announce progress in the regulatory approval procedures in both the United States and Europe of its first protein-based biocontrol product, EVOCA™*.

In the US, Biotalys received a communication from the Environmental Protection Agency (EPA) that the company has provided responses to all the agency's requests for additional information. The EPA currently projects it will complete the scientific review of the EVOCA dossier later this summer and make a regulatory decision by September 30th, 2025.

In Europe, Biotalys is pleased to confirm that both the Dutch Board for Authorisation of Plant Protection Products (CTGB) and the Dutch Institute for Health and Environment (RIVM) have now provided positive evaluations of EVOCA's regulatory dossier, paving the way for the peer review phase at the European level.

In their review, both Dutch authorities have classified EVOCA's active ingredient as low risk based on the current data. This classification is important as it recognizes the active ingredient's safety profile and aligns with Biotalys' commitment to delivering sustainable, effective solutions for crop protection. No critical areas of concern were identified and therefore the Netherlands, as rapporteur Member State, proposes that the active ingredient of EVOCA can be approved in Europe, subject to the provision of certain additional data during the peer review phase. Biotalys' current assessment is that a regulatory decision in the European Union can be expected in the second half of 2026.

Kevin Helash, Chief Executive Officer of Biotalys, said: "We are pleased with the regulatory progress in both the US and EU, and look forward to a favorable outcome. An approval decision would be a major milestone for our company and a validation for our unique AGROBODY™ technology platform. This platform has the potential to develop many more protein-based biocontrol solutions for growers to fight key pests and diseases in agriculture. I am very grateful for the thorough review and guidance by the regulatory agencies, and for the hard work by our team to generate and provide the required scientific data on our innovative product."

The first biocontrol developed on Biotalys' AGROBODY™ technology platform, EVOCA helps safely control fungal diseases Botrytis (grey mold) and powdery mildew for fruit and vegetable growers looking to add effective, biodegradable solutions to their integrated pest management (IPM) initiatives to reduce chemical applications.

** EVOCA™: Pending Registration. 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.*



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. 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.