

EMPERRA® submitted the Digital Diabetes Management Platform ESYSTA® for approval as DiGA (DTx) to the German BfArM

Emperra has submitted ESYSTA for permanent listing as a Digital Health Application (DTx) to the Federal Institute for Drugs and Medical Devices (BfArM Germany)

POTSDAM, BRANDENBURG, GERMANY, October 6, 2024 /EINPresswire.com/ -- [EMPERRA®](#) E-Health Technologies is a pioneer in the development of innovative digital health products in the field of diabetes mellitus and to improve the care of these patients.

Three studies with more than 1,200 patients have been successfully completed. A final Clinical Study Report (CSR) was prepared by the Principal Investigator, Prof. Dr. med. Peter H. Schwarz, University of Dresden and President of the International Diabetes Federation ([IDF](#)).

EMPERRA® has submitted the [ESYSTA](#) platform and the ESYSTA DiGA (DiHA/DTx) to the BfArM for approval on September 30, 2024. The company expects to receive unlimited marketing authorization in early 2025. This approval is the key regulatory requirement for EMPERRA® to make the ESYSTA® platform and ESYSTA® DiGA (DiHA/DTx) available to physicians dealing with diabetes mellitus for



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ESYSTA®
• Digital Diabetes Care

ESYSTA - Digital Diabetes Management made in Germany

nationwide prescription. Thus, all health care professionals (HCPs) can use the ESYSTA® platform with the ESYSTA® DTx component as an add-on approach for all diabetes patients treated with insulin.

The ESYSTA® platform and ESYSTA® DiGA (DiHA/DTx) thus significantly optimize long-term diabetes therapy.

Following BfArM approval - and taking over the costs by the German health

insurance funds - EMPERRA will begin targeted marketing of the ESYSTA platform and the ESYSTA® DiGA in Germany. EMPERRA® is also seeking specific discount agreements with German health insurance companies for the ESYSTA® platform and the ESYSTA® DiGA to optimize the treatment of patients with diabetes mellitus (T1DM/T2DM) treated with Insulin.

Emperra®

E-Health Technologies

EMPERRA GmbH -E-Health Technologies (Potsdam, Germany)



I am delighted that we initiated the approval process. Thus, our digital device-independent platform ESYSTA® can be used with a high level of medical evidence for the benefit of patients and HCPs."

*Dr. med. Janko Schildt
(Founder & CEO)*

EMPERRA® has focused primarily on medical efficacy, combined with the involvement of patients and doctors through efficient digital networking.

Immediately after approval for the German market, EMPERRA is planning further approval activities in selected EU countries as well as additional, focused pilot projects in relevant international markets with a high proportion of diabetes in the population.

Dr. med. Janko Schildt (CEO and founder): "I am delighted that we have now been able to provide comprehensive scientific proof and to execute the approval process. This means that our digital device-independent platform

ESYSTA® can be used with a high level of medical evidence for the benefit of patients and to relieve the burden on diabetes treatment teams in our core market of Germany in the long term. This also makes ESYSTA® an attractive system for all health insurance companies in terms of health economics."

Prof. Dr. med. Peter Schwarz (head of the three consecutive study projects of ESYSTA® and President of the International Diabetes Federation - IDF) explains: "Due to its uniqueness, ESYSTA® has many starting points for improving treatment, especially for insulin-treated patients in the diabetes mellitus therapy segment. I consider the available positive scientific results to be decisive in the further process toward the extensive prescribability of ESYSTA®. The current data show a faster reduction in the long-term marker HbA1c in poorly controlled patients, even in people with diabetes who are included in the so-called disease management programs (DMPs).

ESYSTA® also has a reinforcing effect when used with GLP-1 analogues (so-called “weight loss injections”). I am confident that these medical effects will also be recognized by experts outside Germany. In a few years' time, we should therefore see ESYSTA® as part of the digital standard procedures for the treatment of specific diabetes patient groups, and not just in Germany."

Dr. med. Horst Mertens (COO/CBDO) adds: "The ESYSTA® platform has shown that diabetes management can be easily, safely, and digitally integrated into treatment processes. As part of the planned German market launch in Germany, EMPERRA® has set itself the goal of generating further scientific data through a large-scale non-interventional study (NIS). The renowned FIDAM (Diabetes Research Institute, Bad Mergentheim) will be involved in this process. Based on this, ESYSTA® will also be used in other international projects."

A current financing round is still open for interested investors. For further interaction, please contact:

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