Mikrobiomik obtains approval for EUTEGRA (MBK-01), the first biological therapy based on gut microbiota for *Clostridioides difficile infection*

- The Spanish company is the first to obtain authorization under the new European SoHO Regulation, approved in June 2024, in a process coordinated in Spain by the National Transplant Organization, which is responsible for its implementation.
- EUTEGRA (MBK-01) is the first innovative therapy approved as an alternative to the antibiotic-based standard for *Clostridioides difficile* infection (CDI), the leading cause of antibiotic-associated diarrhea in developed countries.
- Mikrobiomik has begun negotiations with the Autonomous Communities for the distribution of EUTEGRA (MBK-01) in Spanish hospitals.

Derio, 17 February 2026 – Mikrobiomik, a Basque biopharmaceutical company founded in 2018, a pioneer in Spain and Europe, promoting an innovative therapeutic approach based on the microbiota to improve people's health and well-being, has obtained authorization for its biological therapy in oral capsules EUTEGRA (MBK-01) oral capsules using FSPIM® (Full Spectrum Purified Intestinal Microbiota) technology as an alternative to standard antibiotic-based treatment for *Clostridioides difficile infection* (CDI).

With this approval, Mikrobiomik becomes the first establishment in Spain authorized to prepare and process fecal microbiota for this therapeutic indication, in accordance with the requirements established by the new European Regulation on Substances of Human Origin (SoHO). For its part, EUTEGRA (MBK-01) is the first microbiota transplant-based therapy to be authorized in our country under this reinforced regulatory framework, which guarantees standards of quality, traceability, safety and clinical efficacy for patients.

The authorization has been processed through the Basque Country's Regional Transplant Coordination and has undergone technical evaluation by the National Transplant Organization (ONT) and the SoHO Innovation Evaluation Committee (CEI-SoHO), established by the Transplant Commission of the Interterritorial Council of the National Health System and coordinated by the ONT.
Mikrobiomik has initiated discussions with the Autonomous Communities for the launch of EUTEGRA (MBK-01) in Spain and to enable access to this therapy in hospitals across the country.

'The European authorization of EUTEGRA is a major boost for Mikrobiomik and, above all, for the thousands of patients who currently have no alternatives to standard antibiotic-based treatment for CDI,' explains Dr Patricia del Río, executive director of Mikrobiomik. 'Being the first Spanish and European company to obtain authorization under the new SoHO Regulation will also help to drive the future development of innovative microbiota-based therapies,' she adds.

EUTEGRA, the first microbiota-based biological therapy approved under the European SoHO Regulation

EUTEGRA (MBK-01) is the first fecal microbiota-based biological therapy authorized in Spain in accordance with the requirements of the European SoHO Regulation as an alternative to standard antibiotic-based treatment for CDI.

Mikrobiomik has developed EUTEGRA (MBK-01) using FSPIM® (Full Spectrum & Purified Intestinal Microbiota) technology, which allows the complete bacterial ecosystem of a validated healthy donor to be

incorporated, with the aim of restoring functional microbiota in patients with recurrent *Clostridioides difficile* infections.
The treatment comes in 250 mg oral capsules, with purified gut microbiota and a gastro-resistant formulation, which facilitates standardized and convenient administration compared to traditional fecal transplants.

Available data show that EUTEGRA (MBK-01) reduces ICD recurrences by more than 50% compared to antibiotic treatment, which translates into savings of approximately £1,271 per patient in direct costs and up to £12,000 per recurrence avoided for the healthcare system.

An innovative response to a growing problem

Although Mikrobiomik has recently received authorization for EUTEGRA (MBK-01) under the new European SoHO Regulation, it had previously been available in Spain for compassionate use since 2022, when it received authorisation from the Spanish Agency for Medicines and Health Products (AEMPS) for the treatment of DFI. This has allowed more than 200 patients to be treated in more than 35 hospitals throughout the country to date. Mikrobiomik has had to adapt to the demands of regulatory change (from being considered a medicine to SoHO), a transition that has been facilitated by cooperation between the AEMPS and the ONT, as well as the Autonomous Community of the Basque Country.

ONT Director Beatriz Domínguez-Gil acknowledges 'the effort made by Mikrobiomik to adapt to this regulatory transition' and applauds 'the contribution of EUTEGRA (MBK-01) in addressing *Clostridioides difficile* infection, with a significant impact on morbidity and mortality and on the sustainability of the healthcare system'.

CDI is the leading cause of antibiotic-associated diarrhea in developed countries and one of the hospital infections with the greatest clinical and economic impact. In Spain, the incidence of CDI stands at 171 cases per 100,000 admissions and 13.4 cases per 100,000 inhabitants, according to multicenter studies. Thus, an estimated 7,601 episodes of ACD occur annually (17.1 per 10,000 hospital discharges). Mortality ranges from 2% to 7%, reaching up to 30% in fulminant colitis. The estimated annual cost to the National Health System is €32.1 million.

The patients most affected are those over 65 years of age treated with antibiotics, hospitalized or institutionalised patients, immunocompromised patients, and those with a history of previous episodes of SSI. In Europe, the disease increases hospital costs by between 33% and 54% compared to comparable patients without infection, in a context of sustained increase in its incidence in both hospitals and the community. EUTEGRA (MBK-01) inaugurates a new therapeutic category within microbiota-based therapies, with the potential to reduce recurrences, decrease dependence on antibiotics, and improve clinical outcomes in particularly vulnerable patients.

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About Mikrobiomik

Founded in 2018 and based in the Derio Technology Park (Vizcaya, Spain), Mikrobiomik is a pioneering company in Spain and Europe that promotes an innovative therapeutic approach based on the microbiota to improve people's health and well-being.

Its activity focuses on the research, development and production of a new generation of biological treatments based on the human microbiome for serious diseases with no effective therapeutic alternative.

The first of these is EUTEGRA, a unique biological therapy approved for the treatment of primary and recurrent *Clostridioides difficile* infection (CDI), which does not require prior antibiotic treatment and is administered in a single dose of four 250 mg oral capsules.

Mikrobiomik has also initiated a Phase II trial for the treatment of uncomplicated acute diverticulitis with EUTEGRA and has an ongoing Phase III trial for the treatment of decompensated liver cirrhosis.

Mikrobiomik has a team of leading professionals and shareholders who are strongly committed to the project and have extensive experience in biopharmaceutical innovation, biomedicine and entrepreneurship. These include investment instruments serving entrepreneurship, such as Seed Capital Bizkaia and the venture capital firm Orza, as well as various family offices.