

GENESIS Biomed drives the creation of PolyFIL Diagnostics, a spin-off from Hospital Universitario La Paz that detects polyps and colorectal cancer through blood-based liquid biopsy

- *The technology, developed at the Health Research Institute of Hospital Universitario La Paz (IdiPAZ), consists of a blood-based liquid biopsy using flow cytometry to identify and differentiate patients with polyps and colorectal cancer.*
- *In an initial evaluation using samples from 56 participants, PolyFIL achieved 100% sensitivity and 100% specificity in detecting polyps and colon cancer.*
- *The new test aims to improve the selection of patients who need a colonoscopy and help distinguish the presence of polyps from tumour lesions using technology that can be implemented in clinical diagnostic laboratories.*
- *The company, founded in 17 September 2026, was created after a year and a half of project valorisation, with a €50,000 seed investment from GENESIS Tech Transfer Boost, which, together with the Foundation for Biomedical Research of Hospital Universitario La Paz (FIBHULP), is part of the founding shareholding structure.*

Madrid, October 2026

GENESIS Biomed, through its investment vehicle GENESIS Tech Transfer Boost, announces the foundation of PolyFIL Diagnostics, S.L., a new spin-off from the Research Institute of Hospital Universitario La Paz (IdiPAZ) developing a pioneering in vitro diagnostic kit for the early detection of polyps and colorectal cancer through blood-based liquid biopsy.

The project was identified through the scouting activities that GENESIS Biomed regularly carries out at health research institutes and centres and has been supported for approximately a year and a half through to the incorporation of the company.

An immune signature in blood to determine who needs a colonoscopy

PolyFIL is based on a signature detected through liquid biopsy that makes it possible to identify patients progressing towards colorectal cancer across its different stages, from polyp to adenocarcinoma. Using a peripheral blood sample, the technology analyses immune system activation patterns by flow cytometry and generates a score that distinguishes between healthy individuals, people with polyps and patients with cancer.

The test is designed to address one of the main limitations of current screening. The faecal occult blood test (FOBT), used in population screening programmes, fails to detect around 30% of tumours and approximately 75% of polyps and also produces numerous false positives because of the low specificity of detecting blood in stool. These false positives result in avoidable colonoscopies, with significant associated human and economic costs.

PolyFIL can predict when a colonoscopy is genuinely necessary and when it is not, while also stratifying patients with benign polyps from patients with tumours, who require a different clinical approach. In a preliminary study involving 56 participants, the technology achieved 100% sensitivity and specificity in detecting polyps and colon cancer. The procedure and algorithm are protected by an international patent application (PCT/EP2025/052243), filed on 29 January 2025.

A pure venture-building model

GENESIS Tech Transfer Boost made an initial seed investment of €50,000 under a pure venture-building model. Part of the investment was allocated to proof-of-concept studies to valorise the project; another part to maintaining the intellectual property and a third part, in line with GENESIS Biomed's consultancy activity, to preparing PolyFIL's initial business plan.

During this period, the project has also completed the definition of its manufacturing and regulatory strategy (IVDR Class C), trademark registration, the design of the independent clinical validation with the UCICEC at Hospital La Paz, and the start of implementation of an ISO 13485 quality system. In total, the project has received €177,920 in cumulative investment, with support from the Instituto de Salud Carlos III, the Community of Madrid, the Pfizer Foundation, FIBHULP (Foundation for Biomedical Research of Hospital Universitario La Paz) and GENESIS Biomed.

As a result of this process, GENESIS Tech Transfer Boost holds 5% of the founding shares in PolyFIL Diagnostics, the same percentage as FIBHUL.

Founding team

The co-founding team is led by Dr Carlos del Fresno, principal investigator at IdiPAZ in the 'Innate Immune Response' group and the company's CEO-CSO, together with Dr Ramón Cantero, colorectal surgeon at Hospital Universitario La Paz (CMO), and Dr Eduardo López-Collazo, a cytometry expert and member of the same research group. During the project valorisation process, Carlos del Fresno took part in the GENESIS CEO Academy programme, designed to equip researchers with the entrepreneurial skills needed to lead a company in the healthcare sector.

Next steps

PolyFIL Diagnostics plans to open a €300,000 seed round to advance the quality system, kit manufacturing and engagement with the notified body and the AEMPS. Clinical validation, involving 508 patients at Hospital Universitario La Paz, is planned for 2027-2028, with the aim of obtaining CE-IVD marking in 2029. The kit will be marketed to private clinical analysis laboratories and to public and private hospitals, in a colorectal cancer screening market valued at €253 million in Spain and €1,591 million globally.

Carlos del Fresno, CEO and CSO of PolyFIL Diagnostics: 'PolyFIL is the result of years of research at IdiPAZ investigating the immune response to the development of lesions in the colon. With a

simple blood test, we can determine who needs a colonoscopy and who does not, representing a paradigm shift in colorectal cancer screening.'

Josep Lluís Falcó, CEO of GENESIS Biomed: 'PolyFIL exemplifies the type of project we seek through GENESIS Tech Transfer Boost: robust science, a committed clinical and research team, and a clear unmet medical need. It is a highly promising project in the field of liquid biopsy in oncology and is set to revolutionise patient stratification and the very early detection of colorectal cancer.'

ABOUT POLYFIL DIAGNOSTICS, S.L.

PolyFIL Diagnostics, S.L. is a spin-off from the Research Institute of Hospital Universitario La Paz (IdiPAZ), founded in September 2026, that is developing an in vitro diagnostic kit for the early detection of polyps and colorectal cancer through immune liquid biopsy in blood. More information: <https://immunomodulationlab-idipaz.es/>

ABOUT GENESIS Biomed

GENESIS Biomed is a consultancy specialising in the biomedical sector, founded in 2017 and headquartered at the Barcelona Science Park, with offices in Madrid and Valencia. It provides strategic business consulting services for early-stage biomedical projects at companies and research institutions.

ABOUT THE HEALTH RESEARCH INSTITUTE OF HOSPITAL UNIVERSITARIO LA PAZ (IdiPAZ)

The Health Research Institute of Hospital Universitario La Paz (IdiPAZ) is where the research supporting PolyFIL Diagnostics was carried out. The project is led by Carlos del Fresno and involves researchers and professionals affiliated with Hospital Universitario La Paz: <https://www.idipaz.es/>

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