

Press Release: Promise Proteomics



Promise Proteomics announces CE-IVD marking of its mAbXmise kits for therapeutic drug monitoring by mass spectrometry



In recent years, the number of biotherapies available has taken off, and they now represent almost a third of the worldwide pharmaceutical market. Within this new generation of drugs, the majority correspond to monoclonal antibodies used to treat cancer and auto-immune diseases. These products contribute to the therapeutic options available for patients with serious diseases, which have often been untreatable up to now.

However, each patient and their individual metabolism is unique, and consequently dose or frequency of administration may need to be adapted to optimise therapeutic efficacy while minimising the risk of adverse events. With this intention, therapeutic drug monitoring consists in measuring the concentration of a drug in a biological sample to provide clinicians with the information required to personalise treatment.

For a few years now, mass spectrometry-based assay techniques have occupied a significant position in the tools used to monitor numerous therapeutic molecules. The two main advantages of this technology are its very high specificity and its multiplexing capability - the capacity to simultaneously assay several distinct molecules. Up to now, this technology was unavailable for the assay of therapeutic monoclonal antibodies.

After 10 years of research and development, Promise Proteomics is bringing to market the first commercial solution allowing quantification of these innovative therapies by mass spectrometry, and has been granted CE-IVD marking for the first two products in the range.

"mAbXmise kits are a unique patented solution combining labelled monoclonal antibodies, reagents and laboratory supplies to quantify therapeutic monoclonal antibodies. This multiplexed method outperforms other analytical methods, thus providing scientific, clinical and economic perspectives that fully meet the constraints of routine therapeutic drug monitoring" indicates Dorothée LEBERT, CSO of Promise Proteomics.

The range developed and commercialised by Promise Proteomics today comprises two products: an mAbXmise Inflammation kit designed to monitor therapeutic antibodies prescribed to treat inflammatory diseases; and a second kit, mAbXmise Oncology, that targets antibodies prescribed in cancer treatment.

The kit for inflammatory diseases allows quantification of two therapeutic antibodies, Infliximab and Adalimumab, the two molecules most widely used to treat inflammation. Meanwhile, the oncology kit can be used to monitor the seven therapeutic antibodies most commonly used today: Bevacizumab, Cetuximab, Ipilimumab, Nivolumab, Pembrolizumab, Rituximab and Trastuzumab.

The mAbXmise Oncology kit was assessed in a study undertaken by a group of experts in clinical and oncological pharmacology (GPCO-UNICANCER) working in five French hospitals. The conclusions of their study reflect the robustness of the approach and the interest in this innovation. [1]

Eric ROUGEMOND, CEO of Promise Proteomics explains: *"The CE-IVD marking of the mAbXmise kits confirms Promise Proteomics' capacity to respond to the quality and regulatory requirements relating to medical devices for in vitro diagnostics. This recognition is the accomplishment of work started several years ago, and confirms that we can transform major scientific innovations into saleable products that are available to laboratories. The CE-IVD marking enshrines the company's evolution towards commercialisation and production activities at a larger scale. Numerous other developments are ongoing and will be proposed to healthcare professionals in the near future".*

The commercial launch of the two mAbXmise kits is planned from November 2021 for the European market, and availability will be extended to the rest of the world in the coming months.

About Promise Proteomics

Promise Proteomics is a spin-off of CEA Grenoble, created in 2010. This MedTech is currently wholly owned by the Aguettant group and is directed by Dr Eric ROUGEMOND. Its business model is based on a range of services in bioproduction and on the development of products to label and quantify proteins in biological samples. Since 2013, Promise Proteomics has been a partner in an innovative and ambitious R&D programme which has allowed it to develop its technology, emerging today as diagnostic kits for personalised medical applications. Capitalising on its unique know-how in the production of internal standards for protein assays and its recognised expertise in mass spectrometry-based quantification methods, today Promise Proteomics is making its skills available to aid health care professionals and patients through its mAbXmise kits.

[1] Marin, C.; et al. Cross-Validation of a Multiplex LC-MS/MS Method for Assaying mAbs Plasma Levels in Patients with Cancer: A GPCO-UNICANCER Study. *Pharmaceuticals* 2021, 14, 796. <https://doi.org/10.3390/ph14080796>