promise
ADVANCED PROTEOMICS

THE FIRST MONOCLONAL ANTIBODY MONITORING DEVICES BASED ON MASS SPECTROMETRY TECHNOLOGY OBTAIN CE-IVDR MARKING

- Knowledge about therapeutic antibodies and feedback from clinicians on the use of these drugs highlight a need for optimization. Therapeutic pharmacological monitoring is one of the diagnostic options making it possible to optimize the use of antibodies, for the benefit of patients as a priority.

- mAbXmise kits are a patented solution[1] combining labeled monoclonal antibodies, reagents and consumables to perform the quantification of monoclonal antibodies by mass spectrometry. This multiplex method has high analytical performances[2,3] thus offering scientific, clinical and economic perspectives fully meeting the requirements for implementing routine pharmacological monitoring.

- The range developed and marketed by Promise Proteomics now includes 7 CE-IVD products making it possible to monitor 19 antibodies, which address clinical needs in 6 therapeutic areas, chronic inflammatory diseases, oncology, hematology, transplantation, autoimmune diseases and hemophilia.

Grenoble, France, November 4, 2024

Promise Proteomics, a medtech company specializing in the development of therapeutic protein and monoclonal antibody quantitative assays by mass spectrometry for medical applications, announces that it has obtained CE-IVDR certification, issued by the BSI (The British Standards Institution) for 4 of the new kits from its mAbXmise range.

"Obtaining the CE marking according to the requirements of the new European regulation 2017/746 is an important milestone for Promise and for the team. It materializes our positioning as an integrated diagnostic company, capable of leading projects to develop innovative solutions, from the very early phases of development right through to market launch, in compliance with high standards" indicates Dorothée LEBERT, Scientific Director of Promise Proteomics.

Therapeutic monoclonal antibodies

So-called "monoclonal" antibodies are antibodies made by cells in culture to treat specific diseases. More than 80 monoclonal antibodies are marketed in France today and are prescribed in the treatment of a wide variety of pathologies: chronic inflammatory diseases (such as Crohn's disease, rheumatoid arthritis, psoriasis, etc.), cancers, prevention of transplant rejection, treatment of hemophilia... Monoclonal antibodies have revolutionized the management of numerous diseases, and today represent an increasingly large part of the therapeutic arsenal used by doctors for the treatment of their patients. The knowledge and feedback that has increased over the years on the use of these medications highlight the need to resort to pharmacological therapeutic monitoring as a priority, in order to optimize their usefor the benefit of patients.

Therapeutic pharmacological monitoring of mAbs

Indeed, the pharmacological monitoring of antibodies is a subject which has been of growing interest to health professionals in recent years. The rationale which points towards this type of approach is the inter-individual variability observed in treated patients, which is strong and which is observed for all monoclonal antibodies and whatever the pathology or therapeutic regimen[4-6] . This variability leads to variable efficiencies and unpredictable adverse effects/toxicity which can in particular be explained by underexposure or overexposure to treatments. The need for optimization is described in a certain number of scientific publications with the objectives of optimizing effectiveness, better management of toxicity and also cost control, since monoclonal antibodies are very expensive drugs[7-10]. Pharmacological monitoring is a response to these challenges, and a solution now accessible, thanks in part to the mAbXmise technology offered by Promise Proteomics.

"We were fortunate to be able to collaborate very early on with healthcare professionals who were interested in our technology. With them, our project matured, the design of our products is the fruit of these collaborations," explains Dorothée Lebert.

About mAbXmise

The mAbXmise approach is based on the use of mass spectrometry, a technology already widely used in specialized laboratories for the monitoring of traditional drugs. Mass spectrometry has many advantages, notably that of being highly specific, with direct identification of the molecule, and that of being multiplex, that is to say that it is possible to analyze several molecules simultaneously. These two advantages, associated with the use of an internal standd, position it favorably compared to immunological techniques, and give the approach and the results obtained unparalleled reliability and robustness [2,3] . The preparation of samples prior to analysis, on the other hand, is complex and it is precisely at this stage that the mAbXmise kits provide considerable benefit because they make it possible to simplify this stage as much as possible for the technical staff of hospital platforms.

"The technological innovation behind mAbXmise revolutionizes the monitoring of therapeutic antibodies by making cutting-edge technology-accessible to clinical-practice" explains Eric Rougemond, CEO of Promise Proteomics and the Aguettant group.

The technology has already been successfully deployed in several dozen European hospitals. The first results of clinical studies using monitoring of the concentration of monoclonal antibodies are beginning to be published and highlight the clinical relevance. Interest from the medical community is growing for multiple pathologies. For some, it is really a question of maximizing the patient's chances by monitoring the concentration of the therapeutic antibody as closely as possible, adjusting the doses if necessary, to guarantee optimal effectiveness for the necessary time. For others, it is a matter of placing the patient in the appropriate therapeutic window and anticipating the risks that could arise in the event of underexposure or overexposure [5,6,8,9,10,11] .

About Proteomics Proteomics

Promise Proteomics, a French company based in Grenoble, has developed a range of in vitro diagnostic medical devices which make it possible to monitor the concentration of therapeutic monoclonal antibodies in patients. Promise Proteomics thus capitalizes on its unique know-how in the production of internal standards for protein assay and its recognized expertise in mass spectrometry assay methods, which it now puts at the service of healthcare professionals and patients with mAbXmise kits. These devices were developed in collaboration and intended for hospital pharmacology and toxicology laboratories in order to enable the pharmacological monitoring of these new classes of "biological" drugs which are increasingly used by clinicians to treat their patients, whatever the nature of the drugor the therapeutic area. Promise Proteomics currently has 7 of these devices in its portfolio, 3 of which are which are self-certified with the CE-IVD mark, and 4 have just obtained CE-IVDR marking. 4 new kits are also in development.

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