Press release
Lyon, 17 October 2019

Personalised medicine in onco-haematology: what our genes tell us about ourselves!

New genetic tests as a tool in diagnosis, prognosis and therapeutic management

Personalised medicine is based on a new approach in which the analysis of molecular biomarkers allows health professionals to make or confirm a diagnosis or prognosis and thus to select the best treatment regimen for a patient. Eurofins Biomnis, a driver of innovation in the field of in medical biology, applies NGS (*Next Generation Sequencing*) high-throughput sequencing in several innovative genetic tests in onco-haematology to analyse panels of genes implicated in haematological malignancies ... and in the near future also in solid tumours.

High throughput sequencing for personalised medicine

"The challenge for Eurofins Biomnis is to support high precision medicine by offering innovative tests. The complexity of the genetic tests to be performed for each patient means that gene analysis using panels, which can be realised now with NGS, is the obvious solution. These analyses save time in both diagnosis and treatment for patients," says François Cornu, CEO of Eurofins Biomnis.

Technological progress is the main driver of medical advances. Eurofins Biomnis, which introduced high-throughput sequencing in 2015 for the non-invasive prenatal testing (NIPT) of trisomies 13, 18 and 21, now uses it routinely for other constitutional conditions such as renal pathologies, infertility ... In 2019, Eurofins Biomnis wished to extend the technique to haematological malignancies in order to provide health professionals with aids for diagnosis, prognosis or therapy decisions. This panel-based approach makes it possible to optimise the turnaround time for results to clinicians.

Specific NGS panels for optimised management of haematological malignancies

45,000 new cases of haematological malignancy are reported in France per year (figures for 2018 - *Santé Publique France*), accounting for about 12% of new cancer cases in France.
The diagnosis, prognosis and monitoring of malignant haemopathies are based on lab tests comparing cell haematology, histological, cytogenetic and molecular biology data.

With its technical expertise and experience in high throughput sequencing, since April 2019 Eurofins Biomnis has been offering NGS targeted gene panels for MyeloProliferative Neoplasias (MPN's), Chronic MyeloMonocytic Leukemia (CMML), MyeloDysplastic Syndromes (MDS's) and Acute Myeloid Leukemias (AML's). These panels are based on the WHO's classification of the haematological malignancies issued in 2017. The list of molecular biomarkers is likely to continue to grow in view of the work presently being done in the field of targeted therapies and the ongoing identification of new diagnostic or prognostic markers.
NGS technique will thus create the basis for more personalised patient care.

In relation, for example, to MDS's, the gene profile for a patient obtained with our NGS panel makes it possible to determine whether the prognosis for a haematological disease is favourable (e.g. an SF3B1 mutation) or unfavourable (e.g. a mutation of ASXL1), thus enabling the clinician to optimise the therapeutic management (for example to decide whether or not to proceed with allograft), especially in young patients. The same is true for MPN's in the context of therapeutic management of primary myelofibrosis," says Dr. Benoit Quilichini, Head of Cellular Haematology and Cytogenetics at Eurofins Biomnis.

For Dr. Katell Le Dû, a haematologist at the Victor Hugo Clinic, Le Mans, "*clinical biology now allows creation of clear decision trees. Gene analysis can accurately diagnose diseases and adapt treatment to optimise response and avoid*

unnecessary toxicities. This will facilitate our interactions with patients, saving time and increasing quality of life for the patient himself."

"It should be realised that the medical community only studies the main genes involved in Myeloproliferative Syndromes (MPS's) but there are more than 20 secondary genes that make it possible to assess the severity of the disease. The NGS technique is a major breakthrough for both onco-haematologists and patients," points out Serge Giraudier, Chairman of ALTE-SMP (association of MPS patients in French-speaking countries).

For personalised medicine available to all

The NGS panels are innovative services and are therefore not covered by French statutory health insurance (Assurance Maladie) as of 2019. The panels cost between € 500 and € 1500. However, if the molecular biology service is included in the RIHN price schedule (List of Non-Reimbursable Innovative Treatments), health establishments can make application to their ARS (Regional Health Authority) to access funds from budgets assigned by the French Health Ministry. If they are covered by this RIHN budget, Eurofins Biomnis will apply the RIHN rate.

Eurofins Biomnis, in order to facilitate reimbursement and thus maximise access to new innovative tests for each patient, is in permanent consultation with the public authorities, which ultimately have the sole power to decide whether these services should be classified as reimbursable by *Assurance Maladie*.

"There is an anomaly in France in terms of the reimbursability of clinical biology services. *In the case of haematological malignancies, molecular biology analyses are not included in the NABM (List of Reimbursable Medical Biology Services). And we are the only country in Europe that operates in this way!"* adds Dr. Benoit Quilichini.

"The technique is there but protocols are not evolving fast enough in France to make the technique available to all patients ... The goal should be however to give a better chance to the greatest number of patients! Moreover, health professionals are unfortunately not sufficiently informed about these techniques and regrettably they do not systematically offer them to patients," adds Serge Giraudier.

"In order to be increase the awareness of healthcare professionals like me, it would be a good idea to set up platforms for clinical biology laboratories offering these innovative tests. The problem today is that nothing is centralised. It would also facilitate exchanges between health professionals and clinical biologists," says Dr Katell Le Dû.

Coming soon! NGS panels in solid tumours

Molecular biology techniques are essential for therapeutic management of certain solid tumours, in combination with immunohistochemistry and fluorescence in situ hybridisation or FISH. Eurofins Biomnis has been offering selective stand-alone and complementary tests for about ten years which are of decisive importance in therapeutic management (e.g. colorectal cancer and KRAS-NRAS status, non-small cell lung cancer and EGFR-ALK-ROS1 status, breast cancer and HER2 status).

Advances in molecular knowledge have made it possible in recent years to determine:
- the prognostic value of certain biomarkers (e.g. BRAF in colorectal cancer: a mutation in this gene is associated with a poor prognosis irrespective of the treatments administered)
- the resistance to targeted therapies (e.g. KRAS whose mutation is associated with resistance to treatment of colon cancer).

In future, the prescription of a targeted therapy will therefore involve looking for a "panel" of biomarker mutations. Next Generation Sequencing (NGS) techniques will enable more sensitive and faster analysis.
It is for these reasons that Eurofins Biomnis will propose in 2020 new organ-specific gene panels (e.g. for lung cancer, colon cancer, melanoma, glioma, etc.) using the NGS technique.

Other Eurofins Biomnis press releases

22/01/2019	*Optimising the treatment of depression through genetic screening*
16/01/2019	*1 in 2 women do not know about NIPT (non-invasive prenatal testing)*
14/09/2018	*Preventive medicine: Juvenalis®, a new range of biological assessments*
10/07/2018	*Toxicity to 5-FU:The Eurofins Biomnis pre-therapeutic screening test is available at the same price as those carried out in hospitals*

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About Eurofins Biomnis

European leader in the sector of specialised clinical pathology, Eurofins Biomnis carries out over 32,000 analyses per day from a range of over 2,500 available tests, including specialised tests for which the company has the appropriate authorisations. Founded in 1897 by Marcel Mérieux, Eurofins Biomnis is the leader in specialised clinical pathology in France. It has maintained this leading position through continuous technological innovation and investment, particularly in areas such as female biology, oncology and personalised medicine, as well as chromosomal and molecular genetics. With 120 years of expertise and innovation in the service of clinical pathology, Eurofins Biomnis forms the core of the Clinical Diagnostics division of the Eurofins Group in Europe and is actively expanding in worldwide markets. www.eurofins-biomnis.com

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