# Press release

## Multiparametric screening: the only patented effective solution on the market, designed by ODPM to prevent possible serious side effects of 5-FU, used in the treatment of many cancers

Angers, March 27, 2018

As of 28 February 2018, the ANSM has been recommending the detection of dihydropyrimidine dehydrogenase (DPD) deficiency in cancer patients to be treated with 5-FU, a molecule used in approximately 60% of chemotherapies. The risk is well-documented: Patients with a partial or total DPD deficiency (the enzyme that allows the degradation of the 5-FU molecule) are exposed to a risk of serious or even fatal toxicity during treatment with 5-FU.

**This recommendation is considered insufficient by ODPM**, the innovative company founded and led by Michèle Boisdron-Celle, PharmD, at the Institute of Oncology of the West (ICO) in Angers, France.

Screening for DPD deficiency must not only become **mandatory and systematic**, but above all be carried out through a **multiparametric approach** and **fully reimbursed by the French health system**.

- **Multiparametric screening is the only effective method to avoid potential 5-FU toxicities**

Among the different screening methods available, only the patented multiparametric approach (CE IVD) implemented by ODPM, combining genotyping and phenotyping as well as the patient's physiological profile, is able to predict 100% of the lethal toxicities and 96% of serious toxicities (decrease in the number of blood cells, diarrhea, vomiting, dehydration or even coma). In addition, the PK-guided dose adjustment algorithm drops the percentage of serious side effects throughout treatment significantly, from 20-25% to 0.6%.

- **Genotyping is necessary but not enough on its own**. According to the ICO data, only 33% of patients with toxicity following treatment had one of the 4 genetic mutations responsible for DPD deficiency, which leaves the remaining patients (67%) at risk of serious toxicity.
- Conversely, **phenotyping is necessary but not sufficient**. According to the ICO data, phenotyping alone can detect 84% of patients with a risk of toxicity but leaves 16% of patients undetected, who therefore are at risk for serious toxicity.

- **ODPM, a proven screening method for over 15 years**

Michèle Boisdron-Celle, PharmD, Erick Gamelin, MD (oncologist) and Alain Morel, PhD, (geneticist), alerted the health authorities of the risk of toxicity to this anticancer drug as early as 1999. Based on their research in the oncopharmacology laboratory at ICO and the University of Angers, they have developed a multiparametric screening method allowing for the individualization of therapeutic treatments in oncology with the development of a DPD deficit screening device, 5-FU$^{\text{ODPM Tox™}}$ and a protocol to adjust the dose of 5-FU throughout treatment, 5-FU$^{\text{ODPM Protocol™}}$.

These 2 tests integrate calculators (CE IVD) making it possible to determine the risk of toxicity for patients deficient in 5-FU and to adjust the dose of 5-FU accordingly throughout the treatment. Patented in 2005, the calculators have been utilized by ODPM, the company which was created by Michèle Boisdron-Celle, Erick Gamelin and Alain Morel in 2010.

510 oncologists in 314 medical centers (public hospitals, university hospitals, private clinics, etc.) in France have chosen the ODPM multiparametric screening method. The analyses are currently processed by the laboratory at the ICO as well as the Eurofins Biomnis laboratory, covering the entire country, as well as other European countries. The method has already benefited more than 26,000 patients, over the past fifteen years.

- **Give the same opportunities to all patients**

According to the National Cancer Institute (INCa), 100,000 patients receive chemotherapy based on 5-FU in France each year. An estimated 200 patient deaths per year can be linked to overexposure to 5-FU, caused by undetected DPD deficiency. Performing a multiparametric screening systematically with a proven and patented protocol would make it possible to avoid these 200 deaths each year. This is especially poignant in the case of adjuvant therapies, prescribed for "potentially cured" patients, for whom chemotherapy is prescribed after resection to avoid recurrence. In addition, treatment optimisation throughout its duration with 5-FU dose adaptation enhances its effectiveness and improves the quality of life of patients.

The ODPM multiparametric screening method, at a cost of around €193, is mostly covered by the healthcare establishments under the complementary list (a provisional system of reimbursement in France). Only the cost of the calculators (27€), which are used in the screening for the proposed dose adjustments throughout treatment, is not yet reimbursed. According to a medico-economic study, if all patients in France were screened systematically, the average cost "avoided" per patient would be € 313 over the first two cycles of chemotherapy, corresponding to the costs of treating the toxicities avoided by the screening. This method guarantees optimal efficacy of 5-FU treatments while limiting early toxicities (avoiding multiple screens, limiting errors in the interpretation of results, limiting travel to hospitals, bed-days for treating toxicities, etc.).

**About ODPM:**
Founded in 2010, ODPM (Onco Drug Personalized Medicine) creates, develops and markets high-performance therapeutic oncology personalization solutions. 5-FU$^{\text{ODPM Tox™}}$ and 5-FU$^{\text{ODPM Protocol™}}$ mathematical scores enable healthcare professionals to improve the quality of their patients' care by pre-therapeutic screening for serious risk of toxicity associated with 5-FU, a major molecule in anti-cancer drugs, while increasing the effectiveness of chemotherapy by adapting doses to the metabolism of each patient. The validation and optimization of these solutions over more than 15 years and screening over 26,000 patients, place ODPM in a leading position in the market for personalization of 5-FU-based treatments.
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