

## **Innovations that outpace cancer**

### ***A call for urgent healthcare system reform to benefit patients***

An unprecedented wave of new cancer treatments is expanding the arsenal of pharmaceutical products available to improve cancer treatment and attack forms of cancer for which no therapeutic options were previously available. More than 70 new cancer drugs have been granted authorisation over the last 5 years, a large proportion of which have been targeted therapies, and a further 1,800 molecules are currently under development.

This accelerated rate of innovation in cancer research offers patients a huge opportunity to benefit from new and more effective treatments, at the same time as challenging our healthcare system. That is precisely the aim of the proposals platform unveiled today by Leem: to defend the pioneering role of France in research, and promote the widespread introduction of new treatments and patient access to them by bringing all cancer research stakeholders together in a partnership approach.

The treatment revolution is already here, and the mind-changing revolution is underway. The new cancer immunotherapy treatments are profoundly revolutionising the therapeutic and cognitive landscape of oncology. It is now clear that cancer is not just an anarchic process of cellular degeneration, but also a failure of the immune system in its task of monitoring and protecting the body. Medicine is becoming increasingly personalised, because it is now focusing much more closely on the immune system of the host rather than the characteristics of the tumour.

In this phase where innovations are coming thick and fast, with the emergence of immunotherapies, gene therapies and cell therapies, drugs must be made available quickly to patient groups that are becoming increasingly targeted. The seamless clinical development of a drug right through to its integration into the patient care pathway is now a more relevant and pressing challenge than ever before. The goal of the pharmaceutical companies platform is therefore to enable this wave of innovations to become a therapeutic reality for patients by delivering on a series of key proposals:

- Supporting new models of research by shortening clinical trial approval and startup lead times, and by promoting research programmes based on public/private partnerships
- Promoting early-stage patient access to innovative therapies, some of which may be identified at the end of Phase 2, by reforming the Temporary Authorisations for Use (ATU) system as the basis for moving towards an indication-based fast-track mechanism
- Adapting reimbursement assessment methods on the basis of data generated under real-life conditions of use to rate treatment efficacy within a given patient population
- Using horizon scanning tools to anticipate the emergence of innovations and their impact in terms of drugs market access and the structuring of patient care
- Using the arrival of new therapeutic approaches within the patient care pathway to develop new models for coordination between healthcare professionals

*“We must review every aspect of the processes of assessment and access to the drugs market. It's something with which France must engage fully if it is to consolidate its leadership in oncology and its research and treatment ecosystem, and within which we, as manufacturers, are proactive contributors and facilitators of concerted action”,* says Leem Chairman Patrick Errard.

Innovation in oncological therapy is a model engaged in profound transformation, and one that must rapidly embrace the complexity of diseases, action mechanisms, genetic profiles and data in order to respond to the individual needs of patients. *“This is one of those issues we will be focusing on at the meeting of the Strategic Council for the Healthcare Industries (CSIS) next July”. It is also of vital importance to patients to advance this issue as we look forward to the prospect of a future Cancer Plan”,* concludes Patrick Errard.

## **New drugs are shifting the position lines.**

As we learn to understand the mechanisms involved in the transformation of a healthy cell into a cancerous cell through a series of successive genetic mutations, cancer research is becoming less and less organ-specific as it moves towards the development of therapies that specifically target molecular anomalies or changes in malignant cells. The arrival of targeted therapies in the early 2000s marked the entry of cancer research into the era of precision medicine, with the following consequences:

- the introduction of new clinical trial approaches based on identifying changes at the molecular level
- an increasing concentration on screening for causal genetic and/or molecular mechanical changes (biomarkers) to identify patients likely to benefit from targeted treatments

The very latest therapeutic strategies – the immunotherapies – use another target, the body's immune system, to help it destroy cancerous cells by stimulating the patient's natural defences and circumventing the strategies of malignant cells, with the following consequences:

- therapeutic solutions for patients in whom the receptor of the immunological response has been identified, thereby enabling advances in treating those cancers for which no effective treatment was previously available
- treatments that are easier for patients to tolerate
- a transition towards cancer becoming a chronic illness

Immunotherapy is a step-change innovation that disrupts the traditional care protocols built around radiotherapy, surgery, chemotherapy and hormone therapy by enabling an alternative combination of treatments:

- an increased number of therapeutic sequences that are adapted to the individual situation of each patient
- therapeutic strategies are developing at the same rate as new discoveries and the hope that these approaches now hold out for patients
- the possibilities of combination treatments are expanding: of the thousand clinical trials now underway worldwide, a very large proportion are devoted to combination treatments based on different clinical trial designs

The conjugation of two trends - dynamic progression of upstream research and increase in clinical trials involving target groups - is profoundly changing the overall system for developing, evaluating and adopting treatments; a system that is no longer compatible with the revolution in therapy now underway:

- marketing authorisations are being applied for in respect of treatments that incorporate multiple alternative potential indications (clinically trialled as and when the biological mechanisms associated with a particular tumour are identified)
- at the same time, the options for combinations/sequences of multiple treatments are raising question marks about clinical developments and treatment trends

*Full details of the platform and its breakdown into individual files are available to download from [www.leem.org](http://www.leem.org)*

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