New approaches to testing cancer drugs needed

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Research institutes, regulators and the pharmaceutical industry are urged to cooperate to develop new approaches to testing cancer drugs, in order to bring the revolution in personalised medicine to patients across Europe, says the European Society for Medical Oncology.

It has become clear in recent years that each patient's cancer has individual characteristics that are potentially amenable to "personalised" treatments that target those characteristics. But there is still a great deal of work to be done to ensure patients benefit from these developments as quickly as possible.

"We are approaching a time when it will be possible to analyse the tumours of many patients to help us select the most appropriate treatment and to personalize treatment," said ESMO spokesperson Marina Garassino of the Division of Medical Oncology at the Italian National Institute of Cancer.

Selecting drugs for individual patients helps avoid useless treatments, minimise toxicity and reduce costs for society. In an ideal situation, oncologists would like to be able to use such methods to ensure every single patient is treated with the best possible drugs, Garassino said.

A major challenge facing researchers is that it is not always feasible to perform the kind of large clinical trials that regulators have demanded in the past to prove the value of new treatments.

"We are used to comparing different treatments using large phase III trials, where thousands of patients are randomized," Garassino explained.

"This is feasible when the disease is frequent but not when we are working with small groups of patients who have particular tumour characteristics. In those cases, we need to work closely with statisticians to develop new methodological approaches."

"Regulatory agencies must take into consideration that these kinds of studies can provide important, reliable information about these new drugs," Garassino said. "ESMO would like to encourage regulatory agencies and governments to implement better strategies in research and drug development. Secondly, we feel it is vital that more educational events are created for patients, to increase their awareness that in 2013 it is possible to personalize treatment for many tumors."

At the European Cancer Congress 2013 today, researchers presented data from an early stage phase II study that illustrated one such approach. In the trial, scientists compared targeted therapy based on molecular profiling against conventional therapy in patients with any type of refractory cancer1.

Patients in the trial have their tumours tested using three different methods, including the assessment of hot spot mutations, gene copy number alterations and expression of oestrogen, progesterone and androgen receptors. Their treatments will be based on these tests, and the primary endpoint will be progression-free survival.

So far, 143 patients have been included in the study, with early results showing that comprehensively profiling the tumour in this way was safe, feasible and compatible with clinical practice. The study authors also found that many tumours carried mutations that made their cancer

susceptible to drugs that are already available, Garassino noted.

"This is an important study," Garassino said. "At a time when there are an increasing number of molecular profiling studies being performed, what makes this one particularly noteworthy is that they were able to identify candidate genes when there was already a drug for the selected target."

More information: 1. C. Le Tourneau, E. Mitry, A. Goncalves, N. Isambert, C. Gavoille, O. Tredan, J.P. Delord, M. Campone, X. Paoletti, M. Kamal. Randomised phase II trial comparing therapy based on tumour molecular profiling versus conventional therapy in patients with refractory cancer: results of the feasibility part of the SHIVA trial [European Cancer Congress, ECC2013, Saturday 28 September 2013, 14:30-16:30, Hall 4, Poster Session: Diagnostics/Biomarkers – Expression Profiling]

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