

Driving anti-cancer drug development

The race is on for the speedy translation of the rich harvest of new molecules from the laboratory to the bedside, which will meet the needs of cancer patients and oncology companies alike.

There has never been such a challenging time in the fight against cancer. There are around 1500 new molecules in the pipeline – each different, each targeted and each needing speedy and efficient evaluation. This rich harvest has its origins in the new technology that has facilitated finding and characterising new molecular targets, and in the synthesis of ‘clever’ matching compounds in industrial screening for good candidates. The era of ‘omics’ is upon us, including the most advanced pair: genomics and proteomics. The intracellular map of signal transduction is unravelling as is the biological understanding of key malignant processes such as angiogenesis and metastasis.

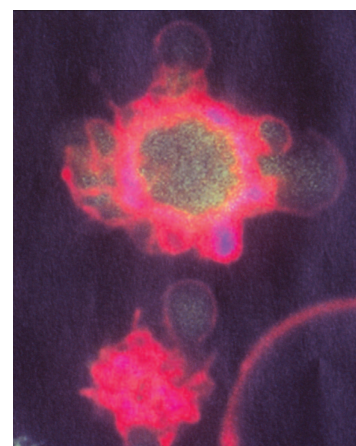
Many of the new drugs are specifically designed to a cancer-associated target, and could therefore be used on patients selected for that target. Given that toxicity is a minority issue in these new drugs, the old rules of dose scheduling based on myelotoxicity and gut toxicity are no longer relevant, and have been replaced by attainment of alteration of relevant ‘biomarkers’. Interdigitating pre-clinical drug development with early trials has become compulsory. Thus, as a drug is developed through pre-clinical pharmacology and toxicology stages, careful thought should be given to identification of assays for the relevant biomarkers. These could be bioassays and/or imaging methodologies, so that the transition from pre-clinical to clinical tests can be streamlined efficiently.

Selecting the ‘best of breed’

Imaging employing nuclear magnetic resonance and positron emission tomography is increasingly applied pre-clinically to select the ‘best of breed’ from a family of analogues, and to check on biotargeting of the molecule in the intact mouse or rat. When the target to be saturated by the novel compound is not measurable or visible, a surrogate intermediate biomarker will be required to act as a meaningful endpoint in early-phase clinical trials. So cross-talk at the pre-clinical/clinical interface is now a necessity. This is just one area in which Inveresk’s Oncology Therapeutic Team, with members from both pre-clinical and clinical divisions, can help clients by providing them with the expertise they need.

Contract research organisations need to think outside the box in order to address the needs of clients and patients in this demanding environment. With this in mind, Inveresk has entered a partnership with the world-renowned Harley Street Cancer Centre to provide clients with an enhanced resource to conduct efficient clinical trials in oncology. UK patients will, for the first time, be able to access new anti-cancer treatments in the private sector. This venture is supported by Inveresk’s rich tradition of toxicology and pharmacology, together with its cross-functional Oncology Therapeutic Team which harnesses extensive internal and external oncology drug development expertise. This seamless join enables the company to be competitive in meeting the demand of cancer patients and oncology companies alike, for speedy translation of these novel molecules from the laboratory to the bedside.

Many new challenges await, as new biomarkers and imaging tools develop and as regulatory bodies awake to the new dawn. There is optimism in the air for the first time in a century. ■



Cell talk (Photo courtesy of Professor Margaret Frame, Beatson Institute, University of Glasgow)

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