Personalised Medicine – a Step Closer

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Doctors prescribing habits tend to be a hit or miss approach. But as our understanding of genetics increases it will be possible to pinpoint subpopulations that will respond better to certain drugs. Personalised medicine promises to improve the understanding of mechanisms of disease and permit more effective patient care.

One of the success stories in personalised medicine is Genentech’s breast cancer drug, Herceptin®, which only works in patients with high levels of protein HER2. To boost its presence in the diagnostics business, Roche acquired Ventana, the maker of the Her-2 test, used to determine which patients should receive Herceptin. Currently, diagnostic tests are also available to determine the effectiveness of Novartis’ Gleevec® (imatinib) and Bristol-Myers Squibb’s Sprycel® (dasatinib) both for cancer.

This brings into play the growth of companion diagnostic tests which pharma companies and drug regulators are increasingly turning to as a way to improve the odds that an expensive biotech drug will work in specific patients. Companion diagnostic tests are designed to guide prescribing of a specific drug by assessing a patient’s risk of adverse events or likelihood of therapeutic effectiveness when taking a drug.

A number of recent deals demonstrated big strides towards personalised medicine in the biopharm industry. Deals and alliances in diagnostic tests are the highest in the oncology therapy area, especially in the treatment of lung cancer, which is notoriously difficult to treat. Abbott has been elbowing its way to become a big player in the diagnostics arena. Recently, it entered into an agreement with Pfizer to develop a molecular diagnostic test intended to screen non-small cell lung cancer (NSCLC) tumours for one of Pfizer’s new anticancer agents. It has also done a deal with GlaxoSmithKline to develop a polymerase chain reaction-based test also intended to screen NSCLC tumours.

Last month, AstraZeneca linked up with DxS, a UK-based molecular diagnostics company, to develop a companion diagnostic, known as TheraScreen®: EGFR29 Mutation Kit to help determine which patients with NSCLC will benefit from receiving AstraZeneca’s Iressa® (gefitinib). AstraZeneca stopped selling Iressa in the US a few years back after it was found that it only helped 10-15% of patients. Recently, researchers demonstrated that Iressa works better in East Asian people who had specific mutations in the EGF receptor and for these patients it could be used as first line therapy.

Patient responses to medications vary hugely and diagnostic tests to figure out the genetic and biological particulars of a patient’s condition in order to provide a personalised drug regimen is fast becoming a reality. That way the treatment will be more effective in those patients and medical payors are likely to cover the costs.

This new treatment approach will require greater collaboration between biotechs, diagnostic and pharma companies and regulatory agencies when developing a new molecule for a particular disease. It is a shift in thinking from the traditional blockbuster model of drug development where companies tried to find the next drug that would be used by millions of patients. Therefore, it can be expected that we will see more alliances between pharma companies and diagnostic companies, such as those described above, in the coming years.