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In this issue

EU legislation: safe new drugs available faster to patients?

In the European Union, oncology drugs are currently authorised by two routes: the Mutual Recognition Procedure (MRP) and Centralised Procedure (CP). Due to changes in drug legislation, from November of 2005, all oncology drugs will now be authorised by CP. Drug development and marketing can currently be authorised under three different criteria and mechanisms: orphan drug legislation; exceptional circumstances provision; and accelerated evaluation procedure. In this issue of *EJC*, Dr. Netzer from Merck KGaA Regulatory Strategy Division, Germany, has evaluated the efficiency of these available regulatory mechanisms to facilitate the marketing authorisation of cancer agents. He concludes his review by speculating that new EU legislation implementing drug authorisation via CP only, offers the chance to reduce the time innovative oncology agents take to reach the market, although – based on experience with current procedures – more effort is likely to be required to achieve this goal.

Caring for childhood cancer survivors

Approximately 70% of children diagnosed with cancer now have long-term survival prospects resulting from advances in chemotherapy, paediatric surgery, radiotherapy, supportive care, and treatment at specialist paediatric oncology centres with inclusion in clinical trials. Many survivors of childhood cancer however, have significant health problems due to their former illness or treatment. In this issue of *EJC*, Curry and colleagues present a population-based study of children aged 0–14 years, diagnosed from 1960 to 1999, in the West Midlands Health Region, UK. The study examined the number of long-term survivors (defined as those alive at 5 years after diagnosis), their disabilities and consequent long-term needs. During the study period, the number of long-term survivors in the West Midlands Region increased from 98 (23%) to 2100 (70%) with most (at least 61%) having one or more chronic medical problems, possibly requiring multi-disciplinary care. The authors conclude that the remarkable improvements in survival rates of children with cancer in the last 40 years need to be matched by equally rigorous protocol-driven follow-up, in specialised, age-appropriate clinics dealing with late effects of cancer therapy. Importantly, adequate financial provisions must be provided to deliver cost-effective care for this increasing population, allowing audit of follow-up methods, to ensure that survivors enjoy the best possible quality and quantity of care.

Targeted therapies for solid tumours

Novel targeted agents that interfere with either EGF/VEGF-receptor interactions, or the downstream Raf/MEK/ERK signalling pathway, have shown promising clinical activity against several advanced solid tumour types. In contrast to standard chemotherapies, targeted agents are also generally well tolerated. In this issue of *EJC*, Strumberg and colleagues have analysed the safety and efficacy of the novel agent BAY 43-9006 (sorafenib) by pooling data from four phase I dose-escalation trials. Sorafenib effects tumour growth and vasculature, most probably, by inhibiting Raf, and pro-angiogenic VEGF and PDGF receptor tyrosine kinases in vivo. In the study reported here, sorafenib monotherapy induced stable disease for $\geq$6 months in 12% of patients (6% stabilized for $\geq$1 year) with untreatable advanced and/or metastatic solid tumours. Sorafenib was well tolerated, and interestingly, those who experienced skin toxicity/diarrhoea, had a significantly increased time to progression compared with patients without such toxicity (P <0.05). Similar to sorafenib, improved clinical activity of other EGF pathway-targeting agents has also been reported to correlate with the appearance of skin rash. However, this association requires further validation from appropriately designed clinical trials.

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