

## 7.2 Our opinion on oral drug delivery technologies in cancer

### ***Where the technology is now, its evolution, achievements and pitfalls***

At the present time we do not believe that improving patient compliance through the development of orally administered products is as high up on the wish list in cancer therapies in terms of unmet clinical need compared with the reduction in systemic toxicities and improvements in the therapeutic index. This has been and will remain a major driver for drug delivery companies and pharmaceutical companies as more "me too" chemotherapy agents enter clinical development.

### ***Competition***

While many hundreds of companies are developing oral drug delivery only a handful are specifically evaluating oral drug delivery platforms in the cancer arena. Each has adopted novel approaches to improve the delivery of agents across the intestinal wall ranging from nanoparticle polymers and liposomal micelles to vitamin-mediated polymer transport. Each has its strengths and weaknesses and may be specifically designed to deliver macromolecules, small molecules as well as active and inactive prodrugs. However many of these technologies are still being assessed in the laboratory and are yet to be fully validated in the clinic.

### ***Potential future applications***

In the longer term, the chronic use of many anticancer agents could shift the balance in favor of orally active agents and may provide niche opportunities for drug delivery specialists particularly if they lend themselves to the delivery of macromolecules, an area which has attracted considerable interest from the pharmaceutical sector.

### ***Activity in the market***

Until recently, most work in oral delivery has been in the optimization of water-insoluble agents or improvement of pharmacokinetics of orally active drugs to improve delivery to the intestinal wall through novel formulations. Activity in the cancer market has been limited as the majority of agents are given acutely and parenterally and have not lent themselves to oral delivery. The majority of activity has been in the periphery of the cancer market such as in post-operative pain and emesis where headway has been made.

We anticipate that oral technology platforms are most likely to be explored in other therapy areas where the need for oral convenience may be greater, and once tested may be transferred to the oncology arena. However, as the newer orally active, small molecule oncology agents emerge and gain acceptance in the market we anticipate this could stimulate further interest for novel oral drug delivery platforms.

### ***Major players***

Through our research we have identified that there are a vast number of companies which have developed oral drug delivery platforms particularly in controlled released formulation, but there are relatively few which specialize in the delivery of cancer agents. This report has covered a number of major players in this arena and includes: Access Pharmaceuticals, Emisphere, LaboPharm and Supratek which are applying polymer/liposome technologies to overcome the issues of oral drug delivery in cancer.

### ***Winners***

Three of these companies, Access Pharmaceuticals, LaboPharm and Supratek are evaluating cancer agents in their proprietary oral delivery system. Over the next five years we anticipate a number of products will enter proof-of-concept trials in the clinic to assess the feasibility and commercialization of these platforms.