

The third cohort of patients receive a higher 175mcg dose of microplasin, while the fourth cohort receive repeated monthly injections of 125mcg of microplasin.

All 60 patients have now been enrolled into the trial. The results from these two additional cohorts of patients will be presented at major ophthalmological meetings during the course of the second half of 2008.

### **Hy BioPharma enters Phase III with topical phototherapy of skin lymphoma**

Hy BioPharma is developing and commercialising a drug technology focused on the treatment of cancer, autoimmune disorders and inflammation. The company is entering Phase III development, with its lead product hypericin for topical phototherapy of CTCL.

The company has successfully completed its end of Phase II meeting with the FDA and is moving into Phase III development for topical phototherapy of the blood cell skin lymphoma, cutaneous T-cell lymphoma (CTCL) which forms cancer lesions in the skin. The FDA has accorded hypericin orphan drug status for the CTCL indication, thereby providing Hy BioPharma with the opportunity to rapidly complete Phase III requirements for filing an NDA to gain marketing approval.

Hy BioPharma's hypericin is also being developed as an oral brain cancer product for the treatment of malignant brain gliomas. Hypericin represents a novel form of anti-cancer therapy. The drug targets Heat-Shock Protein 90 (HSP 90), which controls multiple cell signalling pathways, thereby controlling cell replication and preventing development of tumour metastases.

### **Access presents ProLindac and Cobalamin data at Spanish conference**

Access Pharmaceuticals has given an oral presentation on its lead anticancer compound, ProLindac, at the International Symposium on Polymer Therapeutics: Laboratory to Clinical Practice in May 2008 in Valencia, Spain.

The presentation was entitled "Promising Safety and Efficacy Results from an Ongoing Clinical Study of ProLindac in Recurrent Ovarian Cancer." ProLindac is Access' novel DACH platinum-polymer prodrug, which has been shown to be active in a wide variety of solid tumours in both preclinical models and in human trials.

The presentation was given by Professor Esteban Cvitkovic, Access' Senior Director, Clinical Oncology R&D. Cvitkovic presented data from the ongoing Phase II monotherapy study of ProLindac in patients with recurrent ovarian cancer. In two dosing regimens, ProLindac was given once every two weeks and once every three weeks. During the last and highest dose levels explored, sustained and significant reductions in the specific serum market Ca-125 were seen over multiple dosings in several patients. ProLindac was well-tolerated with minimal side-effects.

ProLindac is currently in a Phase II dose-escalating monotherapy trial in recurrent ovarian cancer. Access believes that ProLindac's molecular design could potentially eliminate some of the toxic side-effects seen in the currently marketed DACH platinum, Eloxatin or oxaliplatin.

The company has also given presentations on its Cobalamin technology. The presentations are entitled "Vitamin B12-Polymer Conjugates as Constructs for Targeted Tumour Delivery and for Oral Drug Delivery."

Cobalamin is Access' proprietary technology based upon the use of vitamin B12 for targeted delivery of drugs to disease sites and for oral drug delivery of drugs that otherwise have poor oral bioavailability. The presentations provide new data showing that Cobalamin-coated nanoparticles can provide a substantial lowering of blood glucose levels in an animal model of diabetes when compared with unformulated insulin given orally, and glucose-lowering effect which has much greater duration when compared with using insulin given subcutaneously. In addition, data were presented which shows that Cobalamin-targeted polymer-linked daunorubicin reduces tumour volume following intravenous administration in an animal model, providing 'superior' efficacy when compared with polymer-daunorubicin without the targeting group, and substantially 'superior' efficacy to daunorubicin alone.

### **Graceway buoyed by positive Atopiclair data**

Graceway Pharmaceuticals has revealed the results of a multicentre, randomised, vehicle-controlled study published in the June 2008 issue of the Journal of Pediatrics. The study demonstrated that Atopiclair (MAS063DP) cream is effective and safe as a monotherapy for the treatment of symptoms of mild-to-moderate atopic dermatitis (eczema or AD) in infants and children.

The 43-day study was conducted in multiple US centres and involved 142 patients (age six months to 12 years), treated three times a day with either Atopiclair or vehicle base cream.