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Compassionate Input to Phase III

A compassionate use program involving patients from melanoma clinics in Sydney, Brisbane and Adelaide is helping to develop the dosing regimen for a metastatic disease trial.

US drug developer Provectus Pharmaceuticals conducted the program for its melanoma drug PV-10. It enabled patients to undergo more frequent and extensive treatments over a longer period of time than was allowed under a previous phase II trial. It enrolled more than 40 patients, ten of whom were expanded access patients from the company's phase II trial of PV-10 for metastatic melanoma, as well as more than 30 new patients.

The dosing regime was a treatment of lesions with up to a total of 15 mg of PV-10 at any one time. Treatments were for any number of lesions up to the 15 mg limit. Treatments were allowed every 28 days for as long as necessary.

Australian trial sites included the Melanoma Institute Australia in Sydney, the Princess Alexandra Hospital in Brisbane and the Royal Adelaide Hospital. The Australian compassionate program was conducted under the guidelines of the TGA's Special Access Scheme.

The program was only available for cancer indications that did not involve treatment of visceral organs and were not subject to enrolment in ongoing clinical trials. These indications included certain breast cancers, basal cell carcinoma, squamous cell carcinoma, certain head and neck cancers and melanoma.

Dr Craig Dees, CEO of Provectus said the company was pleased the compassionate use program was providing patients with access to the therapy.

"The success of the program is in addition to the very positive results from our phase I and phase II melanoma trials. More recently, early results from our phase I liver cancer trial have also indicated that the treatment is well-tolerated with substantial evidence of potential efficacy. We intend to continue advancing PV-10 for both indications, and will continue providing access via the compassionate use program while we prepare for a pivotal phase III melanoma trial to expedite approval in the US and abroad," he said.

Recently, Provectus met with the TGA to seek clarity for the approval pathway of PV-10 in Australia and is gathering additional data from 125 to 150 patients.

PV-10 is a proprietary, injectable formulation of Rose Bengal, a small molecule agent that has been used for nearly thirty years by ophthalmologists to assess damage to the eye. It has also been used as an intravenous diagnostic to detect ailments of the liver. Provectus has discovered a novel use for Rose Bengal based on the observation that it is selectively toxic to cancer cells via a process called chemoablation.

The phase III trial is expected to begin in 2011.

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