



ONCOLOGY RESEARCH INTERNATIONAL LIMITED
NEWSLETTER
April 2015

Announcement

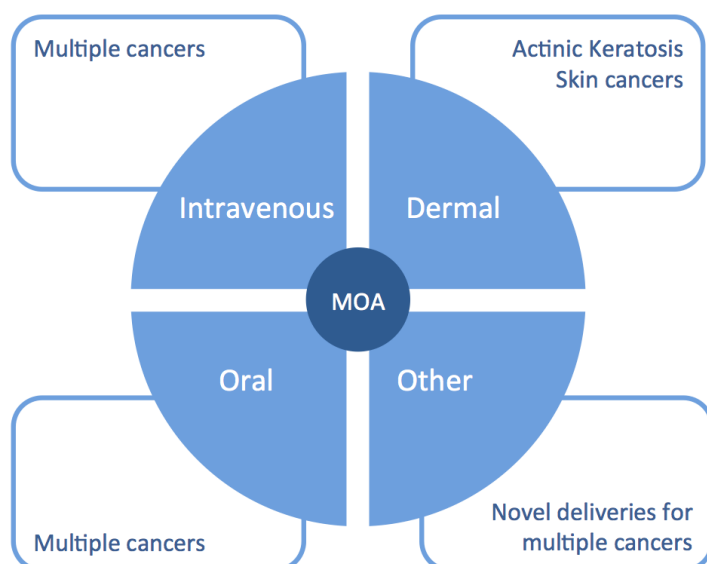
ORIL is delighted to announce it has entered into collaboration with a leading Medical Research Institute (MRI) for investigation of the application of ORIL007 in skin cancer. Details to follow in coming weeks.

We are also pleased to advise that Elizabeth (Liz) Wilkinson has been engaged as Clinical Project Manager. Liz brings a wealth of experience in managing Phase I-III clinical trials including oncology, in Australia and overseas.

R&D Strategy

In our December 2014 newsletter we discussed how targeting several drug delivery systems in parallel helps to mitigate technical risks while broadening treatment opportunities and ultimately, maximising shareholder value.

ORIL's research and development efforts were previously solely directed to the development of a parenteral (i.e. intravenous) formulation of its lead candidate ORIL007. Work is actively continuing on three delivery systems: topical, parenteral and oral while maintaining a watchful eye on opportunities for development of other novel delivery systems.



Topical

Laboratory formulation work for topical (dermal) gel formulations has been completed; the prototypes are stable, and have entered animal testing. The initial safety studies were successful, and skin penetration studies (human skin) showed penetration of ORIL007 at levels well above those required to kill cancer cells *in vitro*. Two animal efficacy trials have just been completed and the results, however, showed no reduction of the tumours in the treated mice. The reasons for this are unclear and may be related to: the species and cancer cell lines selected, formulation, schedule of application, dose, nuances of mouse skin, interaction of ORIL007 with skin components or the drug itself. Notwithstanding this setback ORIL plans to continue its investigation and development of ORIL007 in a topical product in collaboration with the MRI and other groups using various methodologies and in animal models that closely mimic the clinic situation.

Parenteral

As advised in December ORIL has partnered with a North American specialist CRO with a track record of delivering solutions for difficult to formulate oncology drugs using nanotechnology. This has progressed to the development of three prototypes which have been characterised and the pharmacokinetic profile determined. The lead prototype is about to undergo further animal testing.

Oral

Formulation work to improve solubility for application to oral formulations has provided encouraging results. Testing in animals in suitable cancer models will commence following the determination of the pharmacokinetic profile of several prototypes.

Corporate

ORIL has confirmed its strategy to concurrently pursue all three dosage forms of delivery. Regrettably the delay in topical development means that the topical formulation is unlikely to be ready for Phase I study in 2015 and a target date of early 2016 is more likely.