ONCOLOGY RESEARCH INTERNATIONAL LIMITED

NEWSLETTER

December 2014

2014 Annual General Meeting

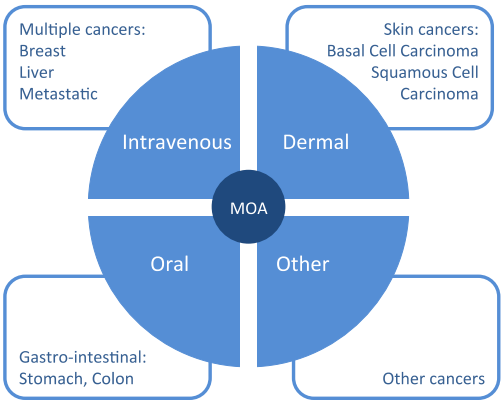
ORIL's AGM was held in our registered offices in Perth, WA on November 27, 2014. A copy of the CEO presentation to shareholders can be found in our website (www.oril.com.au). Key achievements for 2014 include:

- Proving the mode of action of ORIL007 which involves interactions with molecules of the cellular membrane that trigger a cascade of events leading to programmed cell death (or apoptosis). This confirms that ORIL007 is a first-in-class compound due to its novel mechanism of action. This work is also critical in supporting the application for an Investigational New Drug (IND) application with the US Food & Drug Administration (FDA).
- GMP scale-up of lead compound ORIL007 which secures compound supply for several Phase I clinical trials.
- Progress has been made with multiple drug delivery systems: parenteral, topical and oral. This point is discussed in more detail in the following section of this newsletter.
- More safety and toxicology data have been generated, which is required for regulatory and ethics submissions prior to clinical trials.
- Expansion of the pool of toxicology, clinical, scientific, statistical and regulatory compliance experts to support the preparation for the scheduled Phase I clinical trials.
- Strengthening the IP portfolio and knowledge base.

R&D Strategy

In our June 2014 newsletter we discussed how targeting several drug delivery systems on parallel helps to mitigate technical risks while broadening treatment opportunities and ultimately, maximising shareholder value. ORIL's research and development efforts were initially directed to the development of a parenteral (i.e. intravenous) formulation of its lead candidate ORIL007. Similar to many drugs

including anti-cancer drugs, ORIL007 is poorly soluble in aqueous solutions, a critical requirement for the physiological transport of drugs. Solubilisation of ORIL007 proved to be a hurdle that needed to be overcome in order to successfully incorporate ORIL compounds into a clinically relevant formulation. After a period of significant experimentation, solubilisation has been achieved utilising nano-technology. This is still under development, as consistent results in animal efficacy studies have not been achieved.



Results of an animal efficacy trial completed just prior to the AGM utilising an alternative method of solubilising the ORIL compounds showed no reduction of the tumours in the treated mice. In order to assist with the development of the nano-particle formulations, ORIL has partnered with a North American specialist CRO with a track record of delivering solutions for difficult to formulate oncology drugs. We are very excited with this partnership and testing of optimised nano-particle formulations is planned for early in 2015.

It is clear that the optimisation work required for the parenteral ORIL formulations has impacted our timelines for Phase I clinical trials in humans for this type of drug delivery system. However, and as discussed in our previous newsletter, ORIL has expanded the application of its platform technology to at least two other drug delivery systems: topical and oral. The characteristics and mechanism of action of compounds of the ORIL family enable multiple formulation types. The table below summarises the market size, technical, regulatory and commercial risks for topical, oral and parenteral routes of administration.

	Topical	Oral	Parenteral
Market (2014) US$BB	0.50 (NMSC)	0.75	3.24
Technical risk (will it work?)	low	medium	high
Safety & Toxicity Risk	low	Low-medium	Medium-high
Regulatory risk (of approval)	low	medium	high
Commercial risk (if approved)	medium	low	medium

Importantly, while still providing significant market opportunity, the topical and, to a lesser extent, oral formulations present reduced technical risk when compared with parenteral formulations. This reduced technical risk, together with a simpler regulatory process, should shorten the path to clinical trials for topical and oral formulations.

Formulation work for topical gel formulations has been completed and two prototype formulations will enter animal testing in December 2014. Provided that the initial safety studies are successful, efficacy data are expected by the end of February 2015 with toxicology studies to start in the second quarter of 2015. It is expected that the topical formulation will reach the clinical phase ahead of oral and parenteral formulations, later in 2015.

ORIL's CEO, Dr Philip Marshall has recently travelled to Hong Kong to meet with key opinion leaders and Clinical Trial Units (CTU) to evaluate their capabilities. Other world-class centres, including those in Australia continue to be investigated.