ONCOLOGY RESEARCH INTERNATIONAL LIMITED

NEWSLETTER

June 2015

Announcement

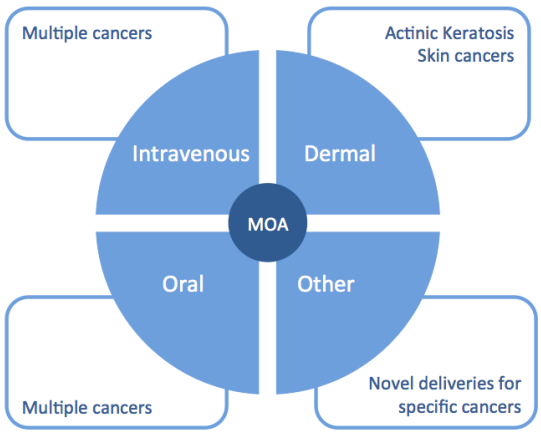
ORIL is delighted to announce it has entered into collaboration with the Translational Research Institute at the University of Queensland (https://www.tri.edu.au/) in the investigation of the application of ORIL007 in skin diseases including cancer and actinic keratosis (a precursor to some skin cancers). Professor Peter Soyer and Associate Professor Helmut Schaider, both based within the Department of Dermatology at the University of Queensland are world recognised experts in the field of dermatology and oncology.

Given the earlier two efficacy trials did not show a reduction of the tumours in the treated mice, as reported in the April 2015 Newsletter, the TRI were approached to consider alternative models to demonstrate efficacy. As part of this resultant collaboration, the efficacy of topical (dermal) application of ORIL007 will be investigated in clinically relevant melanoma and actinic keratosis models. The impact of these studies is that results will take around 9-10 months to generate. These models are highly clinically relevant and ORIL believes provide the best testing platform for its lead topical candidate, albeit means deferring the Phase I clinical entry into 2016 (and of course subject to supporting data).

R&D Strategy

In our April 2015 newsletter we discussed how targeting several drug delivery systems in parallel helps to mitigate technical risks while broadening treatment opportunities, noting the goal of every drug delivery system is to deliver an effective quantity of drug to its target.

Until mid-2014 ORIL's research and development efforts were directed to the development of a parenteral (i.e. intravenous) injectable formulation of its lead candidate ORIL007. Work is continuing on the three major delivery systems: topical, parenteral and oral while studying opportunities using other novel delivery systems, with the aim to develop at least one system to "IND[1]-ready" regulatory status.



[1] IND is Investigational New Drug – a US FDA process to obtain approval for a Phase I of a new drug entity.

Topical

Trials with TRI are about to commence shortly and will take around 9-10 months to complete. A reformulated topical product showing higher drug content and skin penetration will be tested in the TRI studies. In addition, a study of the delivery of the ORIL007 into the skin using radiolabelled ORIL007 is underway to determine precisely where within the skin structure the drug is delivered. Previous *ex vivo* test results using human skin show the drug penetrates the epidermis into the dermis

Parenteral

Progress with a North American specialist CRO has advanced to the development of three prototypes which have been characterised and the pharmacokinetic (PK) profile determined, that is how much and to what extent is the drug distributed in the body. The PK profile of the newly developed formulation is similar to previous unsuccessful formulations and is therefore undergoing further internal assessment with the CRO on whether to vary the formulation before a decision is made to proceed further. It should be noted that while solubilisation of the drug into an injectable dosage form (formulation) can be achieved a number of ways it is the delivery of effective amounts of the drug to the tumour that is the challenge.

Oral

Formulation work to improve solubility for application to oral formulations is well advanced and has provided encouraging results. Testing in animals to determine the pharmacokinetic profile (how much and to what extent is the drug absorbed) of two prototypes will commence shortly. Subject to suitable data the prototype(s) will undergo efficacy testing in tumour-bearing rodents. The technology (devised by ORIL) used in the formulation prototypes not only provides an opportunity to strengthen the ORIL IP portfolio through patents but also has the potential for application to other drug delivery systems.

Pipeline

The June 2014 Newsletter reported the company strategy includes building a product pipeline by application of its platform technology to other cancer-related diseases and conditions, for example those in which angiogenesis plays a role and which are covered in the ORIL patent. Such conditions include psoriasis, diabetic retinopathy, and others that remain confidential. Background investigations and discussions with CROs to design *in vitro* and *in vivo* studies to support additional "proof-of-concept" stage have commenced.

Corporate

As previously advised it was planned to enter into clinical trials by the end of 2015. However, due to the setback with the topical efficacy trials, this will be now deferred until 2016, given that the current topical trial with TRI will take 9-10 months to produce results. While this is being implemented the oral formulation continues to be developed with the anticipation efficacy results will be available in late 2015.