

Merrion finalises its Phase III development program for Orazol™ in the USA

DUBLIN, IRELAND, 16 November 2010 - After recent consultation with the FDA in November 2010, Merrion is preparing for its Phase III study for Orazol™. If successful, the Phase III study will allow a new drug application for Orazol to be made under the FDA's abbreviated approval procedure section 505(b)(2) using a single Phase III study. The study will compare Orazol against placebo as an adjuvant breast cancer treatment with a primary endpoint of Disease Free Survival of patients with breast cancer.

If approved, this drug would provide a new treatment, which could improve prognosis, in combination with existing treatments, for early stage breast cancer patients. Merrion has been focused on an oral form of this drug (zoledronic acid) for the bone metastases indication. However this trial would expand Orazol's potential by allowing Orazol to be used for early treatment of breast cancer in addition to bone metastases for late stage cancer patients. Zoledronic acid has been shown to improve Disease Free Survival in large-scale Phase III clinical studies, involving thousands of breast cancer patients.

Commenting on the announcement, John Lynch, Chief Executive Officer said: "Merrion is still focused on licensing Orazol and believes this news will facilitate its discussions. Following the conclusion of its licensing discussions, Merrion would anticipate that, in conjunction with a licence partner, it would request a special protocol assessment (SPA), from the FDA, of the detailed protocol. Subject to approval from the FDA, the intention is to commence Phase III trials in 2011."

Merrion has previously received scientific advice from the Committee for Medicinal Products for Human Use (CHMP) agreeing the approval pathway for Orazol in Europe for the existing bone metastases indication. Following a licensing agreement, Merrion would seek agreement from the CHMP to expand the use of Orazol to earlier stage breast cancer treatment.

Orazol, Merrion's lead product, is a unique tablet formulation of zoledronic acid, made possible by Merrion's proprietary GIPET® technology, and for which there are issued US Orazol patents to 2027. Orazol provides an ideal product profile to address the market needs, as a well-tolerated tablet formulation with weekly dosing.

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About Orazol™

Orazol™ is a weekly tablet bisphosphonate (zoledronic acid) compound for the treatment of early stage breast cancer and metastatic bone disease. There is also excellent clinical data on zoledronic acid's efficacy as an adjuvant treatment in metastatic disease, particularly breast cancer.

Because of poor bioavailability, the bisphosphonate products available and indicated for oncology indications are usually administered by monthly intravenous infusion. The sales of zoledronic acid as an intravenous infusion were almost \$2.0Bn in 2009.

Merrion uses GIPET® technology to formulate a sufficiently bioavailable oral dosage form of the market leading bisphosphonate for bone metastases.

Orazol showed several benefits over current infusion therapy in Phase II:

- Orazol tablet taken weekly had equal efficacy after one week compared with the monthly infusion.
- Orazol had faster and greater magnitude of bone pain relief.
- Had no Acute Phase Reaction (APR) side effect, compared to 50% APR with the infusion.
- Orazol reduced the maximum drug concentration (Cmax) which offers improved profile for renal safety.

As well as these clinical advantages, Orazol offers advantages in patient quality of life, patient access, health economics and market expansion.

About Merrion:

Merrion Pharmaceuticals is a publicly listed product development company focused on delivering innovation to the market by:

- designing our own patented products and
- partnering with other pharmaceutical companies to develop patented products.

Established in 2003, Merrion are engaged in the development of oral forms (tablets/capsules) of drugs that have poor absorption and are generally given by injection. Merrion Pharmaceutical's patented drug delivery technologies (GIPET®) hugely increase bioavailability, by improving absorption in the gastrointestinal tract, of drugs that are otherwise poorly absorbed. As well as increasing absorption, Merrion's technologies also increase the consistency of absorption.

These new products can provide substantial benefits in enhanced drug efficacy, improved safety, toxicity and side effect profile, health economics, patient experience and quality of life.

Merrion has agreements with several pharmaceutical companies. Merrion has two license agreements with Novo Nordisk A/S to develop and commercialise oral Insulin and oral GLP-1 using Merrion's GIPET technology. Merrion also has an oral drug delivery research collaborative program with Ferring Pharmaceuticals, a Swiss based international pharmaceutical company. There are other, unannounced collaborations.

Merrion Pharmaceuticals is based in Dublin, in a state of the art, purpose built cGMP facility which allows rapid development and reduced risk in taking product ideas from conception to final product formulation. Merrion also has operations in Wilmington, North Carolina.

Merrion is listed on the Irish Stock Exchange (ESM) under the symbol MERR.

www.merrionpharma.com