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Clinical Trial of Buccolam™ Treatment for Childhood Epilepsy

Auralis Limited ("Auralis"), a specialist pharmaceutical company, and Therakind Limited ("Therakind"), a paediatric healthcare company, are pleased to announce the start of a paediatric clinical trial of their first jointly developed new product, Buccolam™, designed for the rapid treatment of children suffering from acute epileptic seizures.

Buccolam™ is an oromucosal (buccal) solution of midazolam hydrochloride, which is placed in the space between the gums and the cheek to effect absorption directly into the bloodstream, enabling more rapid treatment of the patient. Buccal midazolam is already being used routinely in the treatment of acute seizures in children both in the UK and Europe but in an unlicensed form.

The European Medicines Agency ("EMA") agreed the Paediatric Investigation Plan for Buccolam™ earlier this year and the clinical trial, sponsored by Therakind, is being conducted in Germany. The study will involve up to 75 children aged between 3 months and 18 years and the objective is to gather the necessary clinical data for an application to the EMA for a paediatric licence across Europe.

Dr Clive Dix, Chairman of Auralis, said: "Acute epileptic seizures are very distressing episodes for children and those who care for them. Buccolam™ is designed to treat sufferers more rapidly and is another example of how niche SMEs can identify and deliver against unmet medical needs in line with patient requirements."

Nick Rodgers, Chairman of Therakind, said: "Buccolam™, our first joint product with Auralis, is an example of how effective co-development can be in an area of unmet need - paediatrics. The combination of Auralis's product development, manufacturing and distribution knowledge, and the regulatory and clinical development expertise of Therakind, has been extremely successful."

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NOTES TO EDITORS

BUCCOLAM™

Buccolam™ will be presented in four doses as pre-filled, ready to use, unit dose syringes. The four unit dose packs available will be:

2.5mg (yellow) for children aged 3 months to under 1 year

5mg (blue) for children aged 1 year to under 5 years

7.5mg (purple) for children aged 5 years to under 10 years

10mg (red/orange) for children aged 10 years to under 18 years

AURALIS LIMITED

Auralis is an innovative, specialist pharmaceutical company with strong development, technical and commercial capabilities.

The company was established in 2005 with the aim of developing a portfolio of innovative, technically complex, demand driven pharmaceuticals and has a specific focus on ensuring the availability and appropriate presentation of important medicinal products which will address unmet medical needs.

Auralis has a proven track record of successfully taking complex products from conception to commercialisation; having successfully gained a significant share in the key UK markets (Primary Care and Hospital sectors) with its lead injectable Diamorphine products.

Auralis has established a network of global partners who provide operational support to ensure that Auralis has a highly scalable operation and the ability to deliver to a high standard.

The company has a strong revenue stream, underpinned by long term supply contracts, enabling the business to establish an attractive commercial position and achieve ongoing sustainability.

To complement the current commercial products, Auralis has a clearly defined product development strategy with a key focus in the development of age-optimised paediatric formulations. The Auralis team are active within the Paediatric medical community with a well-established network of experts and globally recognised Key Opinion Leaders and advisors to ensure it has the best available advice supporting their decision making.

THERAKIND LIMITED

Therakind is a paediatric healthcare company with strong drug formulation, clinical development and regulatory capabilities. Focusing on paediatric medicine, the company has the expertise to develop a product from idea through to regulatory approval. The company identifies niche areas of unmet medical needs and works with other drug development companies on a collaborative basis.

Therakind was created in 2006 in collaboration between Intellectual Property (“IP”) commercialiser, IPSO Ventures, and the School of Pharmacy, London University to address the significant unmet need for paediatric drugs. The School of Pharmacy is the only research department in the UK focusing on this area.

Therakind's dedicated team brings a wealth of experience in:

- paediatric drug evaluation, formulation, and drug delivery;
- clinical and regulatory strategy;
- clinical study design, management, analysis, and reporting;
- interacting with Health Authorities and obtaining scientific advice; and
- securing agreements for Paediatric Investigation Plans ("PIPs"), and approvals for clinical trial and marketing authorisations.

In addition, Therakind has a network of highly competent and professional paediatric specialists in the UK and Europe with considerable experience of treating children.

Therakind has secured 'fast track' marketing approval status from the MHRA (UK Medicines and Healthcare products Regulatory Agency) for its second product, which is for paediatric pain control, and clinical trials are expected to be initiated in Quarter 1 2010. This is a collaborative project with another UK pharma company.

Therakind has a pipeline of further products which it is actively progressing with other partners with a view to securing regulatory approvals.

Why paediatrics?

The paediatric drug market has, in the past, been largely ignored by pharmaceutical companies since their products have been routinely used "off label" by clinicians treating children. Estimates vary, but the paediatric drug market would appear to represent between 15% and 25% of the overall drug market. EU and US regulators have sought to address the lack of licensed paediatric medicines through legislation which in the EU is both a "carrot" and "stick" offering added market protection for drugs, but with the threat of delays to adult approvals if there is no paediatric plan.

Shareholders

The shareholders of Therakind include the School of Pharmacy, UCL Business plc, Great Ormond Street Hospital, IPSO Ventures and Prof. Ian Wong.