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Drawbridge initiates clinical trial for anaesthetic drug

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Singapore: Australia-based Drawbridge Pharmaceuticals has commenced a phase 1C clinical trial of alphaxalone dissolved in sulfobutyl ether beta cyclodextrin, Phaxan.

The project is a randomized double blind, dose-finding study using a Bayesian design. The purpose of the trial is to compare the anaesthetic properties of Phaxan with propofol, which is the current standard for intravenous anaesthesia.

The trial will be conducted at the Jessie McPherson Private Hospital under the guidance of investigator, Dr John Monagle, director of Monash Anaesthesia and Pain Management, at Monash Health.

"The aim of the trial is to reintroduce into clinical practice an intravenous anaesthetic which we believe has a higher safety profile than the drugs in current clinical practice," said Professor Colin Goodchild, chief medical officer at Drawbridge Pharmaceuticals.

Twenty-four subjects will take part in the trial, with 12 subjects to receive, propofol and 12 to receive the study drug, Phaxan. Pain on injection, which is a common problem with propofol, the quality of the anaesthesia and effects on cardiovascular and respiratory systems will be observed and compared between the drug treatments.

"The trial will be the first time that Phaxan has been tested clinically in a critical care setting; if ultimately shown to be safe and efficacious in humans, it could provide an alternative new treatment option for patients requiring intravenous anaesthesia," said Dr Anthony Filippis, CEO, Drawbridge Pharmaceuticals.

The need for a for a new anaesthetic that is both safe and effective continues to grow significantly with more than 80 million general anaesthesia procedures performed annually in the United States and Europe alone.

Although propofol is commonly used in anaesthesia, there are significant problems associated with its use including: a propensity to cause falls in blood pressure, depression of breathing, the lipid based preparation is easily contaminated and

supports bacterial growth; is incompatible with plastic containers and leads to lipid toxicity.

Phaxan has none of these problems when tested in preclinical studies. The active pharmaceutical ingredient in Phaxan, alphaxalone, has been administered previously to humans as Althesin, which was withdrawn from the market due to allergic reactions caused by the excipient. By changing the excipient in the formulation, Phaxan overcomes this issue and Drawbridge looks forward to re-introducing alphaxalone to the market as Phaxan.