

## UWA technology licensing/ partnering opportunity:

### Pediatric formulation to mask bitterness

Researchers at the University of Western Australia have developed a chocolate based, pharmaceutical formula that masks the taste of bitter drugs such as midazolam thereby ensuring therapeutic compliance with minimal distress in young children.

**Problem:** To achieve the benefits of a medicine, the patient must be willing to take it in the correct amount at the appropriate time. Most medicines are not formulated for use in children. For those that are, few are considered sufficiently palatable.

Each year, millions of infants and children require sedation for medical and dental procedures. Practitioners struggle to achieve "successful sedation" while preventing or avoiding adverse events, in particular from receiving incorrect dosage. The incidence of "failed sedation" is reported to be up to 50% of patients. Midazolam is particularly bitter tasting, there are no commercial paediatric formulations available in Australia (the syrup available in the US and EU is unpalatable) and extemporaneous formulations are untested and quite unstable.

**Solution:** We have developed a chocolate based, pharmaceutical formula for children that masks the taste of bitter drugs such as midazolam, providing for greater dosing accuracy. Clinical trial data have shown the UWA midazolam chewable tablet to be very effective at masking the bitter drug taste, and the familiarity of chocolate makes it more readily acceptable to the paediatric patients. Children, even those very young or with low coping abilities can finally receive the correct dose for sedation with minimal distress.

#### Stage of development:

Safety and bioequivalence information and Clinical trial data in paediatric patients.

Assessments of the product have included:

(i) Drug Content and Content Uniformity (ii) Stability Data to 18 months at room temperature (iii) In vitro drug dissolution profile (iv) Taste evaluation in a standard animal model (v) Taste evaluation in paediatric patients (vi) Pharmacokinetic and pharmacodynamic (& some safety) data in 90 paediatric patients to date.

This formulation does not affect the PK of the drug; is stable at room temperature, for at least 18 months, with no effect of drug content and has been demonstrated to effectively provide palatable formulations for bitter drugs to assist clinicians achieve the desired therapeutic outcomes in paediatric patients.

**Intellectual Property:** Market exclusivity is protected by a combination of the formulation platform, method claims and multiple therapeutic targets. A provisional patent application is ready for filing that relates to a composition and method for the preparation of taste-masked active pharmaceutical ingredients for oral delivery.

#### The Team:

Prof Lee Yong Lim is a formulation expert at the Pharmacy department UWA

Prof. Britta Regli-Von Ungern-Sternberg is a pediatric anesthesia specialist at Princess Margaret Hospital for Children.

**UWA is seeking a commercial partner to in-licence and develop this technology.**

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