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Licensing Opportunity

Di–Lithium Crystals. Novel Stable Soluble Li CoCrystals

(Di–Lithium)

Overview

Lithium has a long history in psychiatric medicine treating a broad spectrum of activity e.g., mania, mood disorders, depression, schizophrenia, disorders of impulse control (e.g., Bipolar disorder), mental illnesses in children, etc.

However, current Li formulations have toxic side effects. Because of the high dosing required to achieve the required concentration of Li in the brain, high levels (spikes) are also present in plasma. High plasma levels can result in toxicity and chronic use of Li requires regular monitoring of the drug concentration to avoid toxicity. Both the older immediate-release forms and the newer sustained-release forms exhibit toxicity. If toxic side effects are observed in patients, they stop taking Lithium and try combinations of other more expensive and often less efficacious drugs to treat symptoms.

Technology

Di-Lithium innovation and Competitive Advantage

1. Improved Safety Profile:

Unlike current lithium formulations, our PK data (from rats) shows that **Di-Lithium** does not result in the high plasma Li concentration spikes which cause the toxic side effects but still achieves the correct dose in the site of action, the brain.

2. Improved Bioavailability:

Effective brain concentrations of **Di-Lithium** (data in rats) without the dose-limiting high, plasma levels are typically found with immediate release commercially available Li prescription products.

3. Improved Stability:

Di-Lithium is a non-hygroscopic (does not absorb water) formulation which results in improved stability, ease of manufacture, and storage (stability testing on >50 co-crystals at 40°C, 70% relative humidity).

Molecule type: Small Molecule/NCE.

Benefits

Key Observations from Bioavailability Studies:

- Di-Lithium reaches peak concentration in the CNS 24 hrs later than Li. This could mean lower doses and less frequent dosing will be needed for Di-Lithium compared with current immediate-release Li formulations.
- Di-Lithium lasts longer in the brain, the therapeutic site of action, when compared to immediate release Li (Li-Carbonate) e.g., Eskalith.
- The Cmax for Di-Lithium Li (4.1 µg/gm) is 50% of that for immediate release Li, suggesting this drug at its effective dose level will have less propensity for side effects and toxicity.

Applications

Commercial Opportunity: Potential neuro-developmental disease targets for Di-Lithium include Fragile X Syndrome, Rett's Disease, and autism; while neurodegenerative disease targets include Alzheimer's Disease, Parkinson's Disease, Huntington's Disease, and traumatic brain injury.

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Commercial Opportunity

The University of Limerick is interested in seeking partners to exploit the commercial potential of these technologies by entering into licensing agreements.

Target Market for Innovation: Pharmaceutical companies

☐Development partner

☐Commercial partner

☒Licensing

☐University spin-out

☐Seeking investment

1. Patent Title: CRYSTAL FORM COMPRISING LITHIUM IONS, PHARMACEUTICAL COMPOSITIONS THEREOF, METHODS FOR PREPARATION AND THEIR USES FOR THE TREATMENT OF DEPRESSIVE DISEASE

   Type: Parent provisional

   Country: Europe

   Status: Filed

   Priority Date: 29 April 2016

   Application number: EP16167817

   Link: https://worldwide.espacenet.com/patent/search/family/056068650/publication/US2019382419A1?q=EP16167817

2. Patent Title: CRYSTAL FORM COMPRISING LITHIUM IONS, PHARMACEUTICAL COMPOSITIONS THEREOF, METHODS FOR PREPARATION AND THEIR USES FOR THE TREATMENT OF DEPRESSIVE DISEASE

   Type: Regional

   Country: Europe

   Status: Filed

   Priority Date: 29 April 2016

   Application number: 17720482.3

   Link: https://worldwide.espacenet.com/patent/search/family/056068650/publication/EP3430018A1?q=17720482.3

3. Patent Title: Stable Lithium Crystals

   Type: Regional

   Country: USA

   Status: Filed

   Priority Date:

   Application number: 16/097,444

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