Renown Pharma

Renown Pharma Announces Successful Results of Apomorphine Sub-lingual Spray Pharmacokinetic Study to Treat "OFF" Episodes in Parkinson's Patients

- Sub-lingual apomorphine spray closely replicates sub-cutaneous apomorphine injection

London, United Kingdom, March 7, 2017, Renown Pharma Limited ("Renown") today announced the results of a pharmacokinetic study intended to compare the plasma concentrations of Renown's sub-lingual apomorphine spray against the currently approved formulation of injectable apomorphine used to treat motor fluctuations, or "OFF" episodes, in Parkinson's disease patients. The pharmacokinetics and safety/tolerability of Renown's sub-lingual apomorphine spray were demonstrated in a Phase I pilot study in 12 healthy volunteers with all subjects receiving a 2.5mg sub-cutaneous injection of apomorphine on day 1 followed by escalating 10, 15, 20 & 25mg doses of sub-lingual apomorphine spray on the subsequent four days.

The 25mg apomorphine spray dose closely replicated the characteristics of the sub-cutaneous injectable with very fast absorption (peak plasma concentration at 15-20 minutes) and similar peak plasma concentrations. Based on these data, the estimated time to "ON" in patients with Parkinson's disease is expected to be 5-10 minutes which is similar to the injectable. Renown believes that the therapeutic dose for the sub-lingual apomorphine spray to treat "OFF" episodes in Parkinson's patients will be in the range of 15mg-25mg for the majority of patients.

Dr. Anthony Clarke, Chief Scientific Officer of Renown, commented, "Patients report that "OFF" episodes in Parkinson's disease are particularly debilitating with motor impairment often associated with non-motor symptoms such as anxiety, depression, pain and fatigue. Renown's sub-lingual apomorphine spray should address all the important factors that patients want in a treatment for "OFF" episodes."

Dr. Clarke continued, "Renown's rapidly-absorbed apomorphine spray should result in a fast "ON" time of 5-10 minutes. It can also be used to treat **all** daily "OFF" episodes including morning "OFF", which is often the hardest for patients with Parkinson's disease to cope with. The profile also suggests a reduced risk of troublesome dyskinesia caused by pharmacodynamic interaction with standard Parkinson's disease medications. The product was designed to be easy to use, is resident in the mouth for only seconds and it has a near-neutral pH in order to avoid mouth irritation."

Renown's sub-lingual apomorphine spray appeared to be safe and well-tolerated. Adverse events were generally mild in intensity.

Apomorphine, a potent dopamine agonist, is currently the only drug approved specifically for the treatment of acute motor fluctuations/hypomobility (freezing or "OFF" episodes) in patients

with Parkinson's disease. Presently, apomorphine is administered by intermittent sub-cutaneous injection, usually via a pre-filled injection pen. Drawbacks associated with sub-cutaneous injection therapy for patients and caregivers include the need for multiple injections each day, which can be painful, and lead to the development of painful injection site nodules. The injectable product also requires a degree of manual dexterity to use, which some patients with Parkinson's disease find difficult.

Renown's sub-lingual apomorphine spray has a near-neutral pH, the drug is very rapidly absorbed under the tongue directly into the blood stream and reproduces the blood levels typically only obtained by injection. The sub-lingual spray allows for easy self-administration without the risk of injection site side effects. The results of this study are consistent with the use of sub-lingual spray as an acute rescue treatment of hypomobility in Parkinson's disease and illustrate the product's potential to replace the use of repeated apomorphine injections and use in a wider group of patients.

About Renown and Apomorphine

Renown Pharma is a U.K. based specialty pharmaceutical company developing a sub-lingual spray formulation of apomorphine to treat "OFF" episodes in Parkinson's disease patients. The company's management has significant experience in developing Parkinson's disease drugs addressing unmet medical needs.

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