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**An open-label, clinical study to evaluate the safety and tolerability of Treprostinil Inhalation Powder (TreT) in patients with pulmonary arterial hypertension (BREEZE Study)**

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**Background:** United Therapeutics is developing a new drug-device product comprised of a dry powder formulation of treprostinil inhalation powder (TreT) and a small, portable, dry powder inhaler, to treat pulmonary arterial hypertension (PAH). An open-label, single ascending dose (SAD) study in healthy volunteers, MKC 475 001, was conducted to assess the safety and tolerability of TreT. A total of 36 healthy volunteers were sequentially assigned to 6 cohorts (6 subjects per cohort) receiving single doses of TreT. Overall, TreT was safe and well tolerated as oral inhalation doses up to 150 µg in healthy volunteers. The primary objective of this study (BREEZE) is to evaluate the safety and tolerability of TreT in patients with PAH currently treated with inhaled treprostinil (Tyvaso®).

**Methods:** BREEZE is a single-sequence safety and tolerability study in which 45 patients on a stable regimen of Tyvaso® will switch to an equivalent dose of TreT. At Baseline, patients currently taking stable doses of Tyvaso® (6 to 12 breaths 4 times daily) will undergo pharmacokinetic and safety assessments and complete a 6-Minute Walk Test. Following these in-clinic assessments and inhalation training using a proprietary BluHale® technology, patients will be assigned a corresponding dose of TreT and treated for 3 weeks. Patients will return to the clinic and undergo the same assessments performed at the Baseline Visit. Patients who complete 3-weeks of treatment with TreT may elect to participate in an Optional Extension Phase (OEP). During the OEP, higher dose titration will be permitted and evaluated on an ongoing basis.

**Results:** Enrollment in the BREEZE study is anticipated to begin in 2019.

**Conclusions:** This study hypothesizes that TreT will achieve similar systemic exposure and tolerability as Tyvaso, but delivered as a small, portable, dry powder inhaled form of treprostinil.



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