For Immediate Release

Bryn Pharma's UTULY™ 13.2mg Intranasal Epinephrine Spray Provides Higher and More Sustained PK Compared to Standard Reference Product, the 0.3mg Epinephrine Autoinjector and Inpatient Standard of Care, the 0.5mg Manual Injection

Late-Breaker Pivotal Data Presented at the 2023 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting

Raleigh, N.C. – February 24, 2023 – Bryn Pharma LLC, a privately held pharmaceutical company dedicated to finding a better way for patients and caregivers to treat anaphylaxis, today announced positive pharmacokinetic/pharmacodynamic (PK/PD) and safety data for its investigational 13.2mg intranasal (IN) epinephrine spray, UTULY™. The pivotal trial results were presented at the American Academy of Allergy, Asthma and Immunology (AAAAI) annual meeting in San Antonio, Tex. The poster can be found here.

UTULY is an investigational self-administered form of epinephrine being studied for the treatment of type 1 allergic reactions, including anaphylaxis.

Key data points include:

- UTULY 13.2mg administered to opposite and same nostrils showed rapid absorption comparable to the 0.3mg autoinjector and resulted in higher and more sustained therapeutic epinephrine plasma levels compared to the 0.3mg epinephrine IM autoinjector.
- The number and percentage of subjects reaching therapeutic plasma levels of epinephrine in the acute period post-dose with UTULY were comparable to or higher than seen with the 0.3mg IM autoinjector which is the outpatient standard of care, accounting for over 95% of prescriptions.
- When compared to the inpatient standard of care (0.5mg IM manual syringe), the study results showed that UTULY had a faster rate of absorption and a higher or comparable acute and overall exposure.
- These results demonstrate that UTULY provides an enhanced PK profile (higher and more sustained) compared to the standard reference product, the 0.3mg epinephrine autoinjector.

- These data support the ability of UTULY 13.2mg to achieve therapeutic levels of epinephrine rapidly and to maintain those levels essentially twice as long as those achieved using the 0.3mg IM autoinjector with a similar safety profile to IM epinephrine.
- There were no deaths, serious adverse events (SAEs), or laboratory-related events reported in this study. Overall, the safety results for UTULY and IM administration routes were comparable, demonstrating that UTULY was safe and well tolerated.

"We were extremely pleased with the results achieved in this pivotal study, demonstrating that therapeutic levels of epinephrine were achieved as quickly and maintained those levels for essentially twice as long as those achieved using the current standard of care, 0.3mg IM autoinjector, with a similar safety profile," said David Dworaczyk, Ph.D., CEO of Bryn Pharma. "The rapid attainment and sustained level of therapeutic levels of epinephrine are critical to optimize the successful treatment of anaphylaxis. This is an exciting advance for UTULY, and especially for the patient community that lives with severe food allergies and are seeking a needle-free alternative to autoinjectors."

Anaphylaxis is a serious and sometime life-threatening acute allergic reaction that requires immediate attention. IM autoinjector epinephrine (EpiPen) is the first-line therapy for anaphylaxis in an outpatient setting. Patient use of autoinjectors is suboptimal due to not carrying their devices routinely, reluctance to use a self-injector due to needle anxiety or fear, or application error, along with the additional risk of injection injuries. There is a clear need for a needle-free, compact alternative for patients, without sacrificing the need to quickly reach and maintain therapeutic levels of epinephrine.

"When it comes to treating anaphylaxis, time is of the essence. Delayed epinephrine administration or suboptimal exposure during anaphylactic events may increase the risk of hospitalizations and potentially fatal outcomes. There should be no hesitation in terms of treatment with rapid uptake," said Dworaczyk.

About the Study

This pivotal study was conducted to confirm the results observed in the dose-ranging study by comparing the pharmacokinetics (PK) of a single 13.2mg dose of UTULY to that of IM-administered epinephrine via autoinjector (0.3mg) the primary reference product, and prefilled manual syringe (0.5mg) as an additional point of reference. The study was designed to fully assess the comparability of the PK profiles of UTULY and the IM dosage forms as well as to assess the relative PD, safety and tolerability of IN epinephrine compared to epinephrine administered via an autoinjector in healthy adults.

Study results demonstrate that UTULY provides an enhanced PK profile (higher and more sustained) compared to the standard reference product, the 0.3mg epinephrine autoinjector.

Overall, the safety results for UTULY and IM administration routes were comparable, demonstrating that UTULY was well tolerated and that there were no new safety signals for the

IN route of administration. There were no deaths, SAEs, or laboratory related events reported in this study.

About Bryn Pharma
Bryn Pharma, established in 2017, is a privately held pharmaceutical company founded by patients for patients. Bryn is focused on positively disrupting the existing market for epinephrine autoinjectors by delivering an accessible, easy-to-use alternative that better meets the needs of patients. Bryn Pharma seeks to provide this growing population at risk for anaphylaxis with A Better Way to be prepared for a life-threatening allergic reaction. For more information visit www.brynpharma.com.

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