

For Immediate Release

## Bryn Pharma's UTULY<sup>™</sup> 13.2mg Intranasal Epinephrine Spray Provides Enhanced PK Profile (higher and more sustained) Compared to 0.3mg Epinephrine Autoinjector (EpiPen) in Subjects with and without Nasal Congestion

## New Data Presented at the American Society for Clinical Pharmacology & Therapeutics (ASCPT) Annual Meeting

Raleigh, N.C. – March 28, 2023 – Bryn Pharma LLC, a privately held pharmaceutical company dedicated to finding a better way for patients and caregivers to treat anaphylaxis, announced positive results from a study designed to assess the impact of nasal congestion on the absorption of its investigational 13.2mg intranasal epinephrine spray, UTULY<sup>™</sup>. The new research presented at the American Society for Clinical Pharmacology & Therapeutics (ASCPT) annual meeting in Atlanta, Ga., showed that nasal congestion enhanced peak levels of epinephrine after intranasal administration of UTULY. The poster, "The Effect of Nasal Congestion on the Bioavailability of Intranasally Administered Epinephrine in Healthy Adult Subjects with Seasonal Allergies," can be found <u>here</u>.

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

The study showed:

- A statistically significant increase in the intranasal absorption of epinephrine with congestion when compared to levels attained when dosed without congestion
- Higher and more sustained therapeutic plasma levels of epinephrine (i.e., >100pg/mL) when compared to the 0.3mg intramuscular autoinjector (EpiPen), the standard of care for anaphylaxis in an outpatient setting, and an overall higher exposure (AUC<sub>0-360</sub>) compared to the 0.5mg intramuscular manual syringe
- Intranasal administration of epinephrine was safe and well tolerated

"We are encouraged by these results, as congestion is a common symptom during anaphylaxis. These data show that UTULY is absorbed as fast as with an autoinjector, but also offers a higher and more sustained exposure of epinephrine. This potentially negates the need for a second dose of epinephrine and gives patients more time to seek emergency medical attention," said David Dworaczyk, Ph.D., Head of R&D, Regulatory and Production at Bryn Pharma. "The rapid attainment and sustained 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."

"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.

This part of the open-label study was conducted in 26 healthy adults with seasonal allergies who achieved a target level of congestion with allergen challenge, and assessed safety, pharmacokinetics, blood pressure and heart rate. Four treatments were assessed, including: intranasal 13.2mg of epinephrine (UTULY) as two sprays in opposite nostrils, with and without nasal congestion via allergy challenge; intramuscular 0.3mg epinephrine injection (EpiPen); and intramuscular 0.5mg epinephrine injection by manual syringe. The study showed that all treatments were well tolerated.

## 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 <u>www.brynpharma.com</u>.

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