Positive Results from Pivotal Study for Bryn Pharma's Investigational Epinephrine Nasal Spray Published in the Journal of Allergy and Clinical Immunology: Global

~ First study to demonstrate rapid and sustained absorption of NDS1C epinephrine nasal spray compared to epinephrine intramuscular autoinjector, while offering higher and more sustained therapeutic plasma levels ~

~ Study also found that NDS1C was safe and generally well-tolerated, showing the enhanced pharmacokinetic profile of NDS1C does not compromise pharmacodynamic parameters such as heart rate and blood pressure ~

~ If approved, NDS1C may offer patients at risk of anaphylaxis a novel and practical alternative to needle-based administration routes ~

Lebanon, NJ – December 12, 2023 – Bryn Pharma, LLC, a privately held pharmaceutical company dedicated to finding a novel and convenient way for patients and caregivers to treat anaphylaxis, today announced data from the Company's pivotal clinical study for its investigational epinephrine nasal spray (ENS), NDS1C, have been published online by the *Journal of Allergy and Clinical Immunology (JACI): Global*.

The results showed that NDS1C provides comparable rates of absorption, with overall higher and more sustained epinephrine plasma concentrations, compared to two intramuscular (IM) treatments (0.3 mg epinephrine autoinjector and 0.5 mg manual syringe).

The data support the ability of NDS1C to achieve a rate of absorption comparable to the 0.3 mg IM autoinjector, with a higher therapeutic level of epinephrine (i.e., >100 pg/mL) for essentially twice as long and with a similar safety profile.

"The results of this study are highly encouraging as an important alternative to the autoinjector in the real-world outpatient setting remains a significant unmet medical need. Recent treatment guideline updates discuss the potential need for alternative, safe, and effective epinephrine delivery devices to alleviate their symptoms quickly and efficiently," said Matt Greenhawt, M.D., Professor of Pediatrics, Section of Allergy and Immunology at Children's Hospital Colorado and the University of Colorado School of Medicine. "Currently, challenges with needle-phobia, which can delay treatment and exacerbate symptoms requiring a second dose, and reluctance to carry a potentially bulky device with them, remain a key challenge in effectively managing anaphylaxis for patients and their families."

Pharmacokinetic parameters for NDS1C exceeded those of the 0.3mg intramuscular autoinjector with a rapid and higher Cmax, (intranasal 429.4, autoinjector 328.6), and greater systemic exposure (AUC0-360 intranasal 539,060g*min/mL than autoinjector 517,440g*min/mL).

Safety results from the study found that NDS1C was safe and generally well-tolerated with no new safety signals observed for the intranasal route of administration. Similar blood pressure and heart rate effects were observed for intranasal and autoinjector administration. The most common AEs were headache (Cohort 1) and mild vomiting (Cohort 2).

"The publication of our pivotal NDS1C data in JACI Global further validates our ambition to develop an epinephrine product that is comparable to the outpatient standard of care, the EpiPen® autoinjector. We are pleased that the published results from our clinical development program are able to provide that peace of mind to the anaphylaxis community, in addition to supporting the potential of a needle-free, small, easy-to-use and affordable option," said Sandy Loreaux, chief executive officer at Bryn Pharma. "We are confident that, if approved, NDS1C will offer a novel, practical and convenient alternative to needle-based administration routes to help overcome some of the persisting barriers that cause patients and caregivers experiencing an anaphylactic attack to delay or avoid treatment."

Additional details can be found in the manuscript, which is available in the "Articles in Press" section of the *JACI* website, located at: https://www.jaci-global.org. *JACI* is an official journal of the American Academy of Allergy, Asthma, and Immunology.

Study Design
The pivotal study was an open-label, three-period, crossover study was conducted in 116 healthy adult volunteers to assess the bioavailability of a single intranasal dose of epinephrine, 13.2 mg compared to an intramuscular 0.3 mg autoinjector, and a 0.5 mg manual syringe. Patients achieving epinephrine concentrations of 50, 100, and 200 pg/mL at 10-, 20-, 30-, and 60-minutes post-dose were also evaluated.

About NDS1C
If approved, NDS1C will offer patients a novel delivery system for emergency epinephrine, an area that hasn't seen significant innovation in fifty years. In 1987, the FDA approved the first epinephrine autoinjector, which has since become the standard of care in outpatient settings. Today, Bryn is working to continue the path of innovation by advancing a development program focused on pharmacokinetic/pharmacodynamic and safety comparisons of NDS1C to the current standard of care treatment, the 0.3 mg IM autoinjector, in accordance with clinical practice guidelines. Bryn is dedicated to creating a novel and practical solution to help this community address these challenges and better manage their daily lives with severe allergies.

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 novel and practical way to be prepared for a life-threatening allergic reaction. For more information visit www.brynpharma.com.

Media Contact:
Elixir Health Public Relations
Lindsay Rocco
+1 862-596-1304
lrocco@elixirhealthpr.com