



**Contact:** Lora Grassilli  
Kovak-Likly Communications  
203-762-8833, lgrassilli@klcpr.com

**FOR IMMEDIATE RELEASE**

**BRYN PHARMA ANNOUNCES PRESENTATION OF POSITIVE CLINICAL RESULTS FROM MULTI-DOSE STUDY OF BI-DOSE EPINEPHRINE NASAL SPRAY FOR THE TREATMENT OF ANAPHYLAXIS AT AAAAI VIRTUAL ANNUAL MEETING**

**Findings Demonstrate Bi-Dose Nasal Spray Device Delivered Epinephrine Levels with a Release Profile Comparable to or Greater than Epinephrine Auto-Injector**

Raleigh, NC – February 27, 2021 – [Bryn Pharma, LLC](#) (“Bryn” or the “Company”), a privately held pharmaceutical company dedicated to finding a better way for patients and caregivers to treat anaphylaxis, today announced positive clinical results from its multi-dose study of BRYN-NDS1C (bi-dose epinephrine nasal spray). Results from the study demonstrated that administration of epinephrine with one spray/dosing from Bryn’s two-dose nasal spray device resulted in a favorable release profile with both short- and long-term pharmacokinetic (PK) outcomes that were comparable to or greater than those seen with administration by a single 0.3 mg epinephrine auto-injector. No safety issues were seen and there were no serious or unexpected adverse events with either intranasal (IN) or intramuscular (IM) dosing.

Full results from the late-breaking poster were presented today at the 2021 American Academy of Allergy, Asthma and Immunology (AAAAI) virtual annual meeting. The study [abstract](#) is published in the February 2021 online supplement to *The Journal of Allergy and Clinical Immunology*, and the [poster](#) presentation is available online.

“These clinical results show that a single spray from our bi-dose nasal spray device delivered epinephrine at levels equaling or exceeding those administered with a single 0.3 mg epinephrine auto-injector, potentially allowing patients to replace two auto-injectors with a single nasal device,” said David Dworaczyk, Ph.D., CEO of Bryn Pharma. “Up to 30% of patients experiencing an anaphylactic event require a second dose of epinephrine, and our bi-dose nasal spray device meets this critical need along with other advantages including needle-free delivery, ease of use and portability. We will continue to work diligently to complete the required steps remaining to gain FDA approval.”

## **About the Study**

The open-label, randomized, 5-treatment, 5-way crossover study compared the pharmacokinetics of intranasal (IN) and intramuscular (IM) epinephrine administration in 25 healthy adults 19-45 years of age. Epinephrine administrations were as follows: 6.6 mg IN (1 x 6.6 mg), 4.4 mg IN (2 x 2.2 mg), 8.8 mg IN (2 x 4.4 mg), 13.2 mg IN (2 x 6.6 mg), and 0.3 mg IM (1 x 0.3 mg). Epinephrine concentrations and cardiovascular effects were measured (-30-360 minutes). PK parameters ( $AUC_{0-10}$ ,  $AUC_{0-20}$ ,  $AUC_{0-30}$ ,  $AUC_{0-60}$ ,  $AUC_{0-360}$ ,  $C_{max(10\ min)}$ ,  $C_{max}$ ; ANOVA analysis) and safety were assessed. Epinephrine bioavailability and cumulative PK data showed that the single 6.6 mg IN epinephrine was comparable to or greater than 0.3 mg IM epinephrine auto-injector, with similar epinephrine related pharmacodynamic effects. Other key results of the study were as follows:

- At most times points, a comparable percentage of participants reached epinephrine plasma concentrations of 100 and 200 pg/mL at key time point intervals after administration of Bryn's IN as compared to IM administration.
- There were no clinically significant differences in heart rate or blood pressure after administration of epinephrine IN or IM

Researchers in the study concluded that Bryn's bi-dose nasal spray is a novel therapeutic option in anaphylaxis treatment which allows patients to administer a second dose readily if the first dose does not abate symptoms.

## **BRYN-NDS1C Bi-Dose Epinephrine Nasal Spray**

Bryn Pharma's Bi-dose Epinephrine Nasal Spray (BRYN-NDS1C) is a single, portable, needle-free device capable of delivering two therapeutic doses of epinephrine, ensuring compliance with clinical guidance while replacing the need to carry two epinephrine auto-injectors. The two therapeutic doses contained in each bi-dose IN device provides assurance that a second dose is readily available if another dose is needed for symptom control, a critical need that occurs in 30% of patients experiencing an anaphylactic event. In early 2019, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to BRYN-NDS1C. The Company has completed three human clinical studies of BRYN-NDS1C and has put in place a commercial-scale, high-speed manufacturing line in preparation for the anticipated market launch. BRYN-NDS1C is not currently approved for sale by the FDA or any international regulatory authority.

## **About Anaphylaxis**

Anaphylaxis is a serious, life-threatening allergic reaction. The most common anaphylactic reactions are to foods, insect stings, medication and latex.<sup>1</sup> A major difference between anaphylaxis and other allergic reactions is that anaphylaxis typically involves more than one system of the body.<sup>2</sup> Anaphylaxis requires immediate medical treatment, driving approximately 100,000 emergency room visits in the U.S. each year.<sup>1,3</sup> Because 30% of patients who develop anaphylaxis will require a second dose of epinephrine to control symptoms, practice parameters recommend that physicians provide patients with two auto-injectors.<sup>4</sup> If not treated properly, anaphylaxis can be fatal.<sup>2</sup> However, studies have shown that the majority of people at risk for anaphylaxis often do not carry two epinephrine auto-injectors due in part to size and cost of the products, putting patients at greater risk of severe complications during an allergic reaction.

## **About Bryn Pharma**

Bryn Pharma is a privately held pharmaceutical company founded by patients for patients. Bryn is focused on positively disrupting the existing market for epinephrine auto-injectors 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](http://www.brynpharma.com).

###

## **Forward Looking Statements**

Statements made in this press release that look forward in time or that express beliefs, expectations or hopes regarding future occurrences or anticipated outcomes or benefits are forward-looking statements. A number of risks and uncertainties, such as risks related to product development and commercialization efforts, results of clinical trials, ultimate clinical outcomes and benefit of the Company's products to patients, market and physician acceptance of the Company's products, intellectual property protection and competitive product offerings, could cause actual events to differ from the expectations indicated in these forward-looking statements. You are cautioned not to put any undue reliance on any forward-looking statement. This press release is neither an offer to sell nor a solicitation of an offer to purchase any particular securities. Any such offer or solicitation will be made only pursuant to definitive legal agreements prepared specifically for such purpose. An investment in the Company's securities entails significant risks and is suitable only for sophisticated investors who can afford a loss of

their entire investment; no assurance can be given that investment objectives will be achieved. In considering the performance information contained herein, you should bear in mind that past performance is not necessarily indicative of future results; there can be no assurance that the Company will achieve comparable results or that any projected returns will be met. The Company does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

1. American Academy of Allergy, Asthma & Immunology. Available at <https://www.aaaai.org/conditions-and-treatments/allergies/anaphylaxis>. Accessed on December 21, 2020.
2. American Academy of Allergy, Asthma & Immunology. Available at: <https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/anaphylaxis>. Accessed on December 21, 2020.
3. Fromer L. Prevention of Anaphylaxis: The Role of the Epinephrine Auto-Injector. *Am J Med.* 2016 Dec; 129(12): 1244-1250.
4. Anaphylaxis – a practice parameter update 2015; Lieberman, Phillip et al.; *Annals of Allergy, Asthma & Immunology*, Volume 115, Issue 5, 341-384