Nasus Pharma Announces Ground-Breaking Five Years Stability of its FMXIN002 Nasal Epinephrine Powder for Severe Allergy and Anaphylaxis

Nasus Powder Epinephrine offers long term stability as well as rapid and higher epinephrine absorption- changing the face of anaphylactic shock treatment

Tel Aviv, Israel August 6th 2024-- **Nasus Pharma Ltd** a clinical-stage biopharmaceutical company focused on developing needle-free, powder-based Intranasal (PBI) product portfolio, to address acute medical conditions announced the results of a 5 years stability study of its FMXIN002 drug candidate – nasal powder epinephrine for the treatment of severe allergy and anaphylactic shock.

FMXIN002 is an investigational intranasal epinephrine **powder** spray device that is noninvasive, needle-free, user-friendly, and reliable and could provide timely effective rescue for severe potentially life-threatening allergic reactions to food, medications, and insect bites.

FMXIN002 stored 5-year at room temperature (15-25° Celsius) showed full stability of the nasal powder and device. Epinephrine base was 97.5% at 5 years well within the defined limits (95-105% ICHQ1). The levels of degradation products were 0.37% which is significantly below the maximum level of 4 % defined for the low-dose (<10 mg) producta. In addition, the enantiomeric purity was found to be 100%,. These results are in line with prior results of FMXIN002 showing full stability after 6 months in accelerated conditions (40° Celsius and 75% humidity). These findings are also in line with a prior study that compared FMXIN002 with Epipen autoinjectors showing 100% Epinephrine enantiomeric purity in FMXIN002 vs 1.9% S-Epinephrine impurity found in Epipen injector (below allowed level of 3%) and 3.8 % of S-Epinephrine impurity found in Junior Epipen injectors (above allowed level). Both autoinjectors were still prior to their expiration date.

Epinephrine, the mainstay of immediate treatment for severe allergy and anaphylaxis is known to be unstable in liquid form requiring the addition of multiple excipients and stabilizers some of which may be associated with added safety concerns. Epinephrine in solution carries between 12-18 months expiration dates. FMXIN002 is a proprietary powder dosage form that requires no stabilizers and offers extremely long stability period and excellent safety profile.

The long stability of Epinephrine carries meaningful advantages both for patients (currently need to replace injectors on average every 12 months) and healthcare payors given the high costs of Epinephrine autoinjectors.
Additionally, the stability of FMXIN002 under extreme conditions of heat and humidity enables carrying the FMXIN002 inhaler during daily activities and avoiding the need to shield the inhaler from heat and humidity

Lately, Nasus Pharma published the results of its phase 2 clinical study demonstrating the clear advantage of its FMXIN002 inhaler in creating quicker and higher levels of Epinephrine in the blood compared to Epipen autoinjector, especially in the first 30 minutes – when prompt treatment in Epinephrine is critical.

Importantly the pharmacokinetics of the powder-based intranasal epinephrine were able to abate multiple concerns recently raised within the medical community as to the adequacy of other albeit solution-based nasal epinephrine products in development with regards to the protection in the immediate period following the development of anaphylactic shock: FMXIN002 demonstrated clear and meaningful advantage both in the pharmacokinetic profile of the first 20-30 minutes and in the number of patients reaching drug plasma clinical threshold of Epinephrine. (91% in the first 6 minutes).

"The results of our long-term stability study as well as the results from our phase 2 clinical study are further confirmation of the advantages of our proprietary powder intranasal epinephrine FMXIN002 in offering easy to use reliable small device that can be carried around in a small pocket and is a highly effective immediate treatment for anaphylactic shock" - Said Dr. Dalia Megiddo, Nasus Pharma CEO.

Udi Gilboa, Executive Chairman of the Board added:
" We are extremely encouraged by the data generated by the company up-until today including the latest outstanding results showing unheard of Epinephrine stability of 5 years.
The commercial potential of our Powder-Based Epinephrine product and its potential to become the fastest-acting simple-to-administer, needle-free nasal spray, provides patients and caregivers with the most promising alternative for this growing Type I allergic reaction market.
The stability of our FMX002 powder inhaler is financially meaningful as the current alternatives in the market of solution-based Epinephrine have only 12-18 month stability.

Powder-based products are also known to have better stability, as compared to solution-based products. Yet an additional advantage for powder-based formulation of epinephrine , a drug that undergoes rapid degradation in the currently-available short shelf-life liquid dosage forms."

About FMXIN002

FMXIN002 is a powder formulation of epinephrine nasal spray developed by Nasus Pharma based on its unique intranasal powder proprietary technology. The company believes that the FMXIN002 may enable people to deliver epinephrine in emergency situations easily, rapidly, and with less hesitation, at the onset of an allergic reaction, as compared to currently available epinephrine auto-injectors. FMXIN002 uses APTAR Nasal Unidose Powder device – an intuitive and easy-to-use device with 360° functionality and precise one-dose nasal drug delivery.

Anaphylaxis is a severe, life-threatening allergic reaction with a sudden onset that can occur within a few minutes —and unless treated promptly could be fatal . Some 5 million people in the United States are at risk of having an anaphylaxis reaction. Over 200,000 emergency room visits due to severe reactions from food allergies are reported annually.

About Nasus Pharma

Based on its unique microsphere technology, Nasus Pharma is developing a number of intranasal powder products aimed at assisting patients in several acute emergency situations such as opioid overdose and anaphylactic shock.
Intranasal administration is most suitable for those situations in which rapid drug delivery is required and offers multiple advantages such as rapid drug delivery, ease of use, non-invasiveness, and safety. Nasus portfolio comprises a number of programs: Intranasal Naloxone completed pivotal study and Intranasal Epinephrine (phase 2) as well as a number of preclinical POC programs.

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