

## ALK to become sole manufacturer and distributor of skin antigen test for penicillin allergy

– PRE-PEN® (benzylpenicilloyl polylysine injection USP) is the only FDA-approved diagnostic skin test for the evaluation of penicillin allergy<sup>i,ii</sup> –

The Danish, pharmaceutical company ALK (*ALKB:DC / OMX: ALK B / AKBLF*), today announced it has successfully completed its acquisition of the business assets of AllerQuest, a U.S.-based company dedicated to manufacturing PRE-PEN® (benzylpenicilloyl polylysine injection USP) Skin Antigen Test. This acquisition makes ALK the sole manufacturer and distributor of PRE-PEN in the U.S. and Canada, with global ownership rights to all assets of AllerQuest.

PRE-PEN is the only FDA-approved diagnostic skin test for the evaluation of penicillin allergy and is indicated for the assessment of sensitization to penicillin (benzylpenicillin or penicillin G) in patients suspected to have clinical penicillin hypersensitivity.<sup>i,ii</sup> (Please see Important Safety Information below.)

Hans Lindeberg, senior vice president of ALK in North America, says: “*This transaction reaffirms ALK’s commitment to penicillin allergy testing and antimicrobial stewardship as well as supporting action plans, including that of the [World Health Organization \(WHO\)](#), in response to the growing threat of antibiotic resistance and infectious diseases. We are proud to ensure continued delivery of quality products and services to healthcare providers and their patients to ultimately help improve outcomes for those who might be affected by a penicillin allergy, and we thank AllerQuest for trusting us on this matter.*”

In the U.S., 10% of people report that they have a penicillin allergy yet, according to the Centers for Disease Control and Prevention (CDC), less than 1% of the population is actually allergic.<sup>iii,iv</sup> Correctly identifying patients who are not allergic to penicillin can help them receive first-line antibiotic therapy recommended by guidelines, and decrease exposure to broad-spectrum antibiotics, which can reduce incidence of adverse events and antibiotic resistance.<sup>v</sup> Antibiotic resistance is a growing concern worldwide, with the CDC estimating that more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 resulting deaths.<sup>vi</sup> By ensuring continued availability of skin antigen tests for penicillin, and through its deep allergy expertise, ALK aims to be part of the solution to help address this public health concern.

James Wolfe, M.D., President of AllerQuest says: “*We are proud of our partnership with ALK for over 14 years to distribute PRE-PEN in the U.S. and Canada. ALK is well-positioned to assume manufacturing capabilities for PRE-PEN and will continue to provide this important test to the millions of patients who are labelled as penicillin allergic.*”

ALK expects the acquisition to strengthen its American business, but it will not have a material financial impact on the company’s financial results for 2024.

### For further information, please contact ALK Headquarters in Denmark (CET):

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### **About PRE-PEN**

*PRE-PEN is indicated for the assessment of sensitization to penicillin (benzylpenicillin or penicillin G) in patients suspected to have clinical penicillin hypersensitivity. A negative skin test to PRE-PEN is associated with an incidence of immediate allergic reactions of less than 5% after the administration of therapeutic penicillin, whereas the incidence may be more than 50% in a history-positive patient with a positive skin test to PRE-PEN. These allergic reactions are predominantly dermatologic. Whether a negative skin test to PRE-PEN predicts a lower risk of anaphylaxis is not established. Similarly, when deciding the risk of proposed penicillin treatment, there are not enough data at present to permit relative weighing in individual cases of a history of clinical penicillin hypersensitivity as compared to positive skin tests to PRE-PEN and/or minor penicillin determinants.*

### **About ALK**

*ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,700 people worldwide and is listed on Nasdaq Copenhagen. Find more information at [www.alk.net](http://www.alk.net)*

## **IMPORTANT SAFETY INFORMATION**

The risk of sensitisation to repeated skin testing with PRE-PEN is not established. Rarely, a systemic allergic reaction including anaphylaxis (see below) may follow a skin test with PRE-PEN. To decrease the risk of a systemic allergic reaction, puncture skin testing should be performed first. Intradermal skin testing should be performed only if the puncture test is entirely negative.

PRE-PEN is contraindicated in those patients who have exhibited either a systemic or marked local reaction to its previous administration. Patients known to be extremely hypersensitive to penicillin should not be skin tested.

No reagent, test, or combination of tests will completely assure that a reaction to penicillin therapy will not occur. The value of the PRE-PEN skin test alone as a means of assessing the risk of administering therapeutic penicillin (when penicillin is the preferred drug of choice) in the following situations is not established:

- Adult patients who give no history of clinical penicillin hypersensitivity.
- Paediatric patients.

In addition, the clinical value of PRE-PEN where exposure to penicillin is suspected as a cause of a current drug reaction or in patients who are undergoing routine allergy evaluation is not known. Likewise, the clinical value of PRE-PEN skin tests alone in determining the risk of administering semisynthetic penicillins (phenoxymethylpenicillin, ampicillin, carbenicillin, dicloxacillin, methicillin, nafcillin, oxacillin, amoxicillin), cephalosporin-derived antibiotics, and penem antibiotics is not known.

In addition to the results of the PRE-PEN skin test, the decision to administer or not administer penicillin should take into account individual patient factors. Healthcare professionals should keep in mind the following:

- A serious allergic reaction to therapeutic penicillin may occur in a patient with a negative skin test to PRE-PEN.
- It is possible for a patient to have an anaphylactic reaction to therapeutic penicillin in the presence of a negative PRE-PEN skin test and a negative history of clinical penicillin hypersensitivity.
- If penicillin is the drug of choice for a life-threatening infection, successful desensitization with therapeutic penicillin may be possible irrespective of a positive skin test and/or a positive history of clinical penicillin hypersensitivity.

Occasionally, patients may develop an intense local inflammatory response at the skin test site. Rarely, patients will develop a systemic allergic reaction, manifested by generalized erythema, pruritus, angioedema, urticaria, dyspnea, hypotension, and anaphylaxis. The usual methods of treating a skin test antigen-induced reaction—the applications of a venous occlusion tourniquet proximal to the skin test site and administration of epinephrine—are recommended. The patient should be kept under observation for several hours.

Pregnancy Category C: Animal reproduction studies have not been conducted with PRE-PEN. It is not known whether PRE-PEN can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The hazards of skin testing in such patients should be weighed against the hazard of penicillin therapy without skin testing.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see full [Prescribing Information](#) for additional Important Safety Information.**

## References

<sup>i</sup> Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. US Food and Drug Administration. Accessed December 2023.

[https://www.accessdata.fda.gov/scripts/cder/ob/search\\_product.cfm](https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm).

<sup>ii</sup> PRE-PEN. Prescribing information. ALK-Abelló, Inc.;2013.

<sup>iii</sup> Evaluation and diagnosis of penicillin allergy for healthcare professionals. Centers for Disease Control and Prevention. Updated October 31, 2017. Accessed December 2023. <https://www.cdc.gov/antibiotic-use/clinicians/penicillin-allergy.html>.

<sup>iv</sup> U.S. and world population clock. Accessed December 2023. <https://www.census.gov/popclock>.

<sup>v</sup> Blumenthal KG, Peter JG, Trubiano JA, Phillips EJ. Antibiotic allergy. *Lancet*. 2019;393(10167):183-198. doi:10.1016/S0140-6736(18)32218-9.

<sup>vi</sup> About U.S. Antibiotic Awareness Week (USAAW). Centers for Disease Control. Accessed December 2023. <https://www.cdc.gov/drugresistance/usaaw/index.html#:~:text=Antimicrobial%20resistance%20happens%20when%20germs,people%20die%20as%20a%20result>.