INHALATION OF INSULIN: EFFECT OF SYMPTOMATIC UPPER RESPIRATORY TRACT INFECTIONS ON PHARMACOKINETIC/PHARMACODYNAMIC (PK/PD) PROPERTIES

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ABSTRACT

We investigated the effect of symptomatic upper respiratory tract infections (URTIs) on pharmacokinetic/pharmacodynamic (PK/PD) properties of Technosphere® Insulin Inhalation Powder (TI). In patients with type 1 or type 2 diabetes, we evaluated the PK/PD properties of TI following the 4-hour meal challenges (during URTI and post-URTI) in patients with type 1 diabetes (T1DM) and type 2 diabetes (T2DM) receiving TI or usual care.

OBJECTIVES

• To evaluate the effect of symptomatic upper respiratory tract infections (URTIs) on the PK/PD properties of TI in patients with type 1 or type 2 diabetes.

INTRODUCTION

Technosphere® Insulin Inhalation Powder (TI) has a drug product formulation that consists of insulin suspended in very fine, nonagglutinating microparticles of inert material. The microparticles are composed of a hydrophobic polymer and are designed to achieve rapid and sustained absorption from the airway epithelium.

METHODS

Study Design and Patients

This was a randomized, open-label, double-blind, placebo-controlled study of 20 patients with type 1 or type 2 diabetes, who received TI or usual care. The study was conducted at the Model Clinical Research facility in Baltimore, MD, USA.

RESULTS

Efficacy Analyses

• Natural log transformation was performed on AUC0-240 min and paired t-tests were used to assess the between-period differences; the ratio (SD) of FDKP AUC0-240 min during URTI to post-URTI was 1.1 (0.6) ng·min/mL (P = 0.3105).

PK/PD Parameters

• Descriptive statistics of the PK/PD and safety parameters were calculated both during URTI and post-URTI.

Safety

• All 20 patients completed the study; there were no premature discontinuations and no deaths, and no AEs (including hypoglycemia).

DISCLOSURES

• This study was supported by Sanofi. Philip A. Levin reports research support, consulting fees, and other remuneration from Amgen, Amylin Pharmaceuticals, Inc., Boehringer Ingelheim, Biodel, Daiichi Sankyo, Eli Lilly, Halozyme, Mannkind, Merck, Orexigen, Pfizer, and Novo Nordisk.

REFERENCES


ECONOMIC IMPLICATIONS

The authors declared that they have no competing interests.

CONCLUSIONS

• No statistically significant differences were noted during URTI and post-URTI.

• In terms of safety and tolerability, there were no deaths, no premature discontinuations, and no AEs (including hypoglycemia).

• The PK profile of insulin measured by AUC0-240 min, Cmax, and Cmin, and the PK profile of FDKP measured by AUC0-240 min, Cmax, and Cmin, were not different during URTI and post-URTI.

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