INTRODUCTION

• **Asthma**2 Human insulin inhaled powder, commonly cited as Techtosphere®
  inhaled insulin (TI), is a powder formulation of rapid-acting insulin
  developed for treatment of patients with type 1 diabetes (T1D) or
  type 2 diabetes (T2D). TI consists of microparticles of fumaryl diketopiperazine to which insulin
  is attached, then formulated as a dry powder and administered via the Genk inhaler device (Figure 1).1

- Compared with subcutaneous regular human insulin, and contemporary
  rapid-acting insulin analogs, TI has been shown to have a rapid
  absorption, reaching maximum plasma concentration within 15 minutes,
  with a short duration of action of 2–3 hours due to its dry powder
  inhalation delivery system (Figure 2 and Table 1).

- The PK/PD profile of TI is more similar to the physiological profile of insulin
  than currently available standard rapid-acting insulins.2

- Uncomplicated URTIs, on safety, in particular the risk of hyperglycemia,
  hypoglycemia, and any adverse events (AEs) they experienced were included in the
  analysis. Table 2 lists the symptoms (runny nose, nasal stuffiness, sneezing, sore throat,
  scratchy throat, hoarseness, new-onset cough, sinus pain/pressure, headache,
  sinus congestion, and any adverse events (AEs) they experienced during a period of
  URTI were included in the analysis. The incidence of AEs was estimated by the percentage of
  patients using TI and the annualized rate of overall AEs was significantly greater in patients
  with URTIs compared with those without URTIs (Figure 4).

- Patients in the URTI group were less likely to experience hypoglycemia
  compared with those in the no-URTI group (Figure 4).

- The annualized rate of hyperglycemia/ketoacidosis was significantly
  lower in patients with URTIs compared with those without URTIs (Figure 4).

- The annualized rates of hypoglycemia were comparable between groups
  (Figure 4).

- The incidence of hyperglycemia/ketoacidosis and the decreased frequency of hypoglycemia associated with TI use during URTIs
  may be related to the strong stress hormone response, leading to higher overall glycemia, which is associated with a greater risk of hyperglycemia and possibly a greater risk of ketoacidosis.

- Additional insulin during or immediately following patients with URTIs, which
  is used to replace the rapid-acting insulin inhaled powder, or TI, may mitigate the
  increased risk of hypoglycemia during URTIs. 

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  URTIs. The incidence of hyperglycemia/ketoacidosis and the decreased
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- Other studies focused on the impact of upper respiratory tract infections (URTIs)
  on safety, in particular the risk of hyperglycemia, hypoglycemia, and any adverse events (AEs) they experienced during a period of URTI were included in the analysis.

- The incidence of AEs was estimated by the percentage of patients using TI and the annualized rate of overall AEs was significantly greater in patients with URTIs compared with those without URTIs.

- Patients in the URTI group were less likely to experience hypoglycemia compared with those in the no-URTI group.

- The annualized rate of hyperglycemia/ketoacidosis was significantly lower in patients with URTIs compared with those without URTIs.

- The incidence of hypoglycemia was comparable between groups.

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  used to replace the rapid-acting insulin inhaled powder, or TI, may mitigate the increased
  risk of hypoglycemia during URTIs.

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- The incidence of hyperglycemia/ketoacidosis and the decreased frequency of hypoglycemia associated with TI use during URTIs may be related to the stress hormone response, leading to higher overall glycemia, which is associated with a greater risk of hyperglycemia and possibly a greater risk of ketoacidosis.

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