

MITSUBISHI TANABE , Outperform - Invokana: Nice to Have A Clean Label, Yet A Long Way To Go Before Gaining Full Confidence!

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Abstracts

Invokana clean label thrills many on the street rising hopes that Invokana sales could cross \$2.5b+ at peak. However we think that CV issues (dose dependent increase in LDL, CV events observed in first 30 days in CANVAS study), associated genital/UTI infections, compromised efficacy in renally impaired patients and long term safety study requirements by FDA (Table 1), should be seen in conjunction with the 'clean label'. These issues will limit the initial uptake of Invokana to a small segment of diabetic patients - we think patients moving to triple OAD, on GLP-1 or Insulin (due to insufficient control from existing therapies, and escalating disease) are the broader target base of Invokana. Within this broader patient pool, ~40% patients with renal risks, >30% obese patients with co-morbid conditions and CV risks, and females at high UTI infection risk need to be restricted further – this leaves a merely ~263k (or ~2.1% of total OAD patients) patients in the US for SGLT-2 inhibitors

Taking All Factors into Account, We arrive the Following Target Patient Base for Invokana (Table 4, 5- Invokana Market Model):

We expect the market share to split between Invokana: Empagliflozin: Dapagliflozin by ~55:35:10 respectively as

Based on the available data comparison of Empagliflozin vs. Invokana, its efficacy looks better than Empagliflozin. While on safety front, based on PhIIb data empagliflozin reported less genital mycotic infections and equivalent UTI infection to Invokana when indirectly compared.

What to watch next in the SGLT2 class?

Key Tables:

Invokana- Post Marketing Study Required by FDA
SGLT2 inhibitors: Efficacy Comparision
SGLT2 inhibitors: Safety Comparision
Invokana- Assumption/Target Patient Population
Invokana – Market Model
SGLT2 Pipeline (Japan and Global Status)

Companies mentioned

Mitsubishi Tanabe, Johnson & Johnson, Eli Lilly, Lexicon

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