ATTACHMENT B – Dear Healthcare Professional Letter – Pharmacist

IMPORTANT DRUG WARNING

Subject: Risk of Urinary Retention with POTIGA

Dear Pharmacist

The purpose of this letter is to inform you of important safety information for POTIGA™ (ezogabine) Tablets, approved by the Food and Drug Administration (FDA) for adjunctive treatment of partial onset seizures in patients 18 years of age and older. As a potassium channel opener, POTIGA can reduce the contractility of urinary bladder smooth muscle which can cause urinary retention.

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for POTIGA to ensure the benefits of the drug outweigh the risk of urinary retention and its associated morbidities.

As one element of the REMS, we are providing this letter to further communicate these risks.

Risk of Urinary Retention

POTIGA caused urinary retention in clinical trials. The Prescribing Information for POTIGA states in the Warnings and Precautions section that because of the increased risk of urinary retention on POTIGA, urologic symptoms should be carefully monitored. Closer monitoring is recommended for patients who have other risk factors for urinary retention (e.g., benign prostatic hyperplasia [BPH]), patients who are unable to communicate clinical symptoms (e.g., cognitively impaired patients), or patients who use concomitant medications that may affect voiding (e.g., anticholinergics).

Patients should be informed that POTIGA may cause urinary retention (including urinary hesitation and dysuria). If patients experience any symptoms of urinary retention, inability to urinate, and/or pain with urination, they should be instructed to seek immediate medical assistance, as these symptoms may indicate possible acute urinary retention.

As a Pharmacist, you have a key role in communicating these risks by providing the Medication Guide with every prescription filled for POTIGA and counselling patients as appropriate.

Medication Guide

A Medication Guide is available for POTIGA and contains important safety information for patients. Specifically, the Medication Guide includes information on symptoms of urinary retention described as being unable to start urinating, having