Clinical Pharmacology Memo	
NDA	022350 Supplement 022
Submission Date:	12/12/2023
PDUFA Date:	10/11/2024
Brand Name:	Onglyza
Generic Name:	Saxagliptin
Sponsor:	AstraZeneca
Dosing regimen:	2.5 mg or 5 mg once daily
Dosage Form	Tablets
Proposed Indication:	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
OCP Reviewer:	Dong Guo, PhD
OCP Team Leader:	Edwin Chiu Yuen Chow, PhD
OCP Division:	Division of Cardiometabolic and Endocrine Pharmacology (DCEP)
OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)

The supplement NDA (sNDA) submission is an efficacy supplement with data from the pediatric study (D1680c00019). The Applicant did not conduct additional PK/PD study in pediatric patients. The Applicant is not seeking a pediatric indication for saxagliptin, as efficacy was not demonstrated in the 10-17 years old pediatric subjects with type 2 diabetes mellitus (T2DM). At Week 26, the adjusted mean change from baseline (SE) in HbA1c was 0.06% (0.198%) in the saxagliptin group and 0.50% (0.202%) in the placebo group, resulting in a difference of -0.44% (95% CI -0.93, 0.05; p =0.078). The label related to clinical pharmacology was not substantially changed. Therefore, a detailed clinical pharmacology review was not conducted.

The clinical pharmacology team considers PMR 3199-1 to be fulfilled.

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/s/

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06/17/2024 11:27:14 AM

EDWIN C CHOW
06/21/2024 02:40:54 AM