

Addendum to the Office of Clinical Pharmacology Review

BLA number	761109
Link to EDR	\\CDSESUB1\evsprod\BLA761109\0372
Receipt date	12/14/2021
Submission type	Efficacy supplement
Supplement number	4
Brand name	LYUMJEV™
Generic name	LY900014 (Insulin lispro-aabc)
Dosage form, route of administration and strength	Multiple dose injection and Continuous Subcutaneous Infusion (Insulin Pump) for LYUMJEV 100 units/mL (U-100)
Proposed indication	Indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.
Applicant	Eli Lilly and Company
OCP Review Team	Snehal Samant MS, PhD, Xiaolei Pan PhD, Justin Earp PhD, Jaya Vaidyanathan, PhD
OCP Division	Division of Cardiometabolic and Endocrine Pharmacology

The is an addendum to the Office of Clinical Pharmacology (OCP) review for BLA 761109/ Supplement 4 for Lyumjev in DARRTS dated 9/23/2022.

The Office of Clinical Pharmacology/ Division of Cardiometabolic and Endocrine Pharmacology (OCP/ DCEP) has reviewed the information contained in BLA 761109/ Supplement 4 and finds it acceptable to support approval of Lyumjev to improve glycemic control in adults and pediatric patients with diabetes mellitus including administration of Lyumjev in pediatric patients by multiple daily injections and continuous subcutaneous insulin infusion (CSII).

The acceptability of administration of Lyumjev via CSII in pediatric patients is primarily supported by the pharmacokinetic (PK)/ pharmacodynamic (PD) study (I8B-MC_ITSA) for Lyumjev when administered as a single subcutaneous (SC) bolus administered via injection and via continuous subcutaneous insulin infusion (CSII) in children (≥ 6 years), adolescents and adults with Type 1 diabetes mellitus (T1DM). The application is primarily supported by the pivotal Phase 3 safety and efficacy trial (18BMC-ITSB) in pediatric patients which enrolled patients from ages 1 to < 18 years of age with T1DM. The Sponsor has also submitted PK/PD modeling and simulation to support the use of Lyumjev in pediatric patients with type 2 diabetes mellitus (T2DM).

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10/14/2022 10:33:36 AM

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