Manufacturing Authorization Number: 1582 IMP

ELECTS
Eli Lilly European Clinical Trial Services S.A.
Rue Emile Francqui, 3 (Site Axis Parc),
B-1435 Mont-Saint-Guibert, Belgium
Phone +32 (0)10 83 50 00

QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES

EU CT number / Trial Alias	Name of the IMP(s)
2024-515689-15-00 / J2N-MC-JZNX	Drug Product Pirtobrutinib (LY3527727, LOXO-305) T2 Tablets

MANUFACTURING AND/OR IMPORTATION AUTHORISATION (MIA) NUMBER UNDER WHICH THIS DECLARATION IS MADE:

Authorization # 1.582 IMP, Eli Lilly European Clinical Trial Services S.A. (ELECTS), Rue Emile Francqui, 3 (site Axis Parc) B-1435 Mont-Saint-Guibert, Belgium

Part A

Name of the IMP(s)	Manufacturing site(s) (name & address where the activity is performed)	Activity performed at this site (including packaging, labeling & testing)
Drug Product Pirtobrutinib (LY3527727, LOXO-305) T2 Tablets	Lilly del Caribe, Inc. 12.6 KM 65th Infantry Road (PR01) Carolina, Puerto Rico (PR) 00985, USA	Drug Product Manufacturing
	Eurofins Lancaster Laboratories, Inc 2425 New Holland Pike Lancaster, PA 17601, USA	Drug Product Analytical Testing
	Bend Research Inc., 20503 Builders Street Bend, OR 97701, USA	Drug Product Manufacturing and Packaging & Labelling
	Bend Research Inc., 64550 Research Road Bend, OR 97701, USA	Drug Product Analytical Testing
	Almac Clinical Services 25 Fretz Road,Souderton, PA 18964, USA	Drug Product Packaging & Labelling
	Almac Clinical Services Limited 9 Charlestown Road Seagoe Industrial Estate, Craigavon,BT63 5PW United Kingdom	Drug Product Packaging & Labelling
	Catalent CTS, LLC 10245 Hickman Mills Drive Kansas City, MO 64137, USA	Drug Product Packaging & Labelling
	Catalent CTS Edinburg Limited 1 Inchwood Park, Bathgate, EH48 2FY United Kingdom	Drug Product Packaging & Labelling
	Catalent Pharma Solutions, LLC 10381 Decatur Road, Philadelphia, PA 19154, USA	Drug Product Packaging & Labelling
	Fisher Clinical Services, Inc. ("FISHER") Lilly Technology Center 1221 West Morris, Indianapolis, Indiana 46221 USA	Drug Product Packaging & Labelling

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	Fisher Clinical Services GmbH Steinbühlweg 69, CH-4123, Allschwil Switzerland	Drug Product Packaging & Labelling
	Fisher Clinical Services UK Limited Langhurstwood Road, Horsham West Sussex RH12 4QD, United Kingdom	Drug Product Packaging & Labelling
	Catalent (Shanghai) Clinical Trial Supplies Co, Ltd. 353 Riying Bei Road, Unit 10C Waigaoqiao Free Trade Zone Shanghai PRC, China 200131	Drug Product Packaging & Labelling

Part B

☒ I confirm that I am a QP and am authorized to make this declaration.
☒ I declare that compliance with GMP at least equivalent to EU GMP has been verified on the basis of:

(i) Audit

Manufacturing site(s) (name & address where the activity is performed)	Auditing party	Date of the last audit (completion)
Lilly del Caribe, Inc. 12.6 KM 65th Infantry Road (PR01) Carolina, Puerto Rico (PR) 00985, USA	GQAAC (Global Quality Auditing & Compliance)	12-15 Apr 2021
Eurofins Lancaster Laboratories, Inc 2425 New Holland Pike Lancaster, PA 17601, USA	GQAAC (Global Quality Auditing & Compliance)	02-04 Aug 2022
Bend Research Inc., 20503 Builders Street Bend, OR 97701, USA	GQAAC (Global Quality Auditing & Compliance)	15-17 Feb 2022
Bend Research Inc., 64550 Research Road Bend, OR 97701, USA	GQAAC (Global Quality Auditing & Compliance)	15-17 Feb 2022
Almac Clinical Services 25 Fretz Road,Souderton, PA 18964, USA	GQAAC (Global Quality Auditing & Compliance)	16-17 Aug 2022
Almac Clinical Services Limited 9 Charlestown Road Seagoe Industrial Estate, Craigavon, BT63 5PW United Kingdom	GQAAC (Global Quality Auditing & Compliance)	14-15 Dec 2022
Catalent CTS, LLC 10245 Hickman Mills Drive Kansas City, MO 64137, USA	GQAAC (Global Quality Auditing & Compliance)	19-20 Jul 2022

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Catalent CTS Edinburg Limited 1 Inchwood Park, Bathgate, EH48 2FY United Kingdom	GQAAC (Global Quality Auditing & Compliance)	15-17 Aug 2022
Catalent Pharma Solutions, LLC 10381 Decatur Road, Philadelphia, PA 19154, USA	GQAAC (Global Quality Auditing & Compliance)	07-08 Mar 2023
Fisher Clinical Services, Inc. ("FISHER") Lilly Technology Center 1221 West Morris, Indianapolis, Indiana 46221, USA	GQAAC (Global Quality Auditing & Compliance)	08-09 Jun 2021
Fisher Clinical Services GmbH Steinbühlweg 69, CH-4123, Allschwil Switzerland	GQAAC (Global Quality Auditing & Compliance)	13-15 Dec 2021
Fisher Clinical Services UK Limited Langhurstwood Road, Horsham West Sussex RH12 4QD, United Kingdom	GQAAC (Global Quality Auditing & Compliance)	22-23 Apr 2024
Catalent (Shanghai) Clinical Trial Supplies Co, Ltd. 353 Riying Bei Road, Unit 10C Waigaoqiao Free Trade Zone Shanghai PRC, China 200131	GQAAC (Global Quality Auditing & Compliance)	05-06 Feb 2024

(ii) If an audit of the site has not been performed, please provide a brief justification and explanation on how the QP knows that standards at least equivalent to EU GMP are being followed at the site.

Manufacturing site(s) (name & address where the activity is performed)	**Justification**
N/A	N/A

This declaration is submitted by:

Signature:.....
Print name: Suzelle Magalie Gombe
Title: ELECTS Qualified Person

Date: 03 SEP 2024

History Version

Version number	Reason
V01	Initial version to match EU-Pirtobrutinib-IMPD-JZNX-Initial-2024-08