

To Whom It May Concern:

22 August 2024

Regulatory Compliance Confirmation

Xofluza® Film coated Tablets 20 mg (Ro 719-1686/F04-01) University Medical Center Utrecht's Clinical Trial MV43976 (EU CT number: 2023-5078889-89-00)

We herewith declare that we will supply University Medical Center Utrecht, Heidelberglaan 100, 3584 CX Utrecht, The Netherlands, with Xofluza granules for oral suspension 2 mg/ml (Ro 719-1686/F08-01) 'bulk product' before trial-specific operation (trial specific packaging and labeling) in compliance with the Xofluza® EU Marketing Authorization number EU/1/20/1500/005, with following modifications:

(P.3.1) In addition to Marketing Authorization, Secondary packaging and labeling may be performed at the following sites:

- F. Hoffmann-La Roche AG, Wurmisweg, 4303 Kaiseraugst, Switzerland
- DHL Supply Chain Singapore PTE. LTD, 1 Greenwich Drive #02-03, DHL Supply Chain Advanced Regional Centre, Warehouse Block 2 ,Singapore 533865, Singapore,
- Genentech Inc. 1 DNA Way South San Francisco CA 94080 USA
- Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 and 2, 73614 Schorndorf Germany
- Fisher Clinical Services GmbH, Steinbuehlweg 69, 4123 Allschwill, Switzerland
- Fisher Clinical Services, Inc, 7554 Schantz Road, Allentown, PA 18106, USA
- Almac Clinical Services Ltd., 9 Charlestown Road, Seagoe Industrial Estate, Craigavon BT63 5PW, UK
- DHL Supply Chain Operations GmbH, In der Au 9, 61197 Florstadt, Germany
- Almac Clinical Services (US), Inc. ,25 Fretz Road, Souderton, PA 18964, USA

Note:

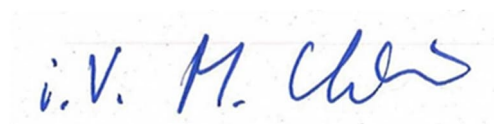
The same material or batches may be used throughout the entire clinical trial as used to initiate the trial. Therefore, upcoming technical variations submitted to the Marketing Authorization may not be implemented for the Investigational Medicinal Products mentioned above, or at a different point in time than for the EU market supplies

We herewith authorize the Sponsor (University Medical Center Utrecht) to submit this declaration with his Clinical Trial Applications for the above mentioned study protocol number to any EU Competent Authority.

Sincerely,
F. Hoffmann-La Roche AG

A handwritten signature in blue ink, appearing to read "ppa R. Gamboni".

Dr. Rina Gamboni
Pharma Technical Regulatory
F. Hoffmann-La Roche Ltd
CH-4058 Basel
Switzerland

A handwritten signature in blue ink, appearing to read "i.v. M. Usteri".

Dr. Mathias Usteri
Pharma Technical Regulatory
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