



To Whom It May Concern:

13 June 2024

Regulatory Compliance Confirmation

Xofluza® Film coated Tablets 20 mg (Ro 719-1686/F04-01) The Chancellor Masters and Scholars of the University of Oxford's Clinical Trial MV45225 (EU CT number: 2023-507441-29-00)

We herewith declare that we will supply the Chancellor Masters and Scholars of the University of Oxford, University Offices, Wellington Square, Oxford, OX1 2JD, United Kingdom with Xofluza film-coated tablets 20 mg (Ro 719-1686/F04-01) 'bulk product' before trial-specific operation (trial specific packaging and labeling) in compliance with the Xofluza® EU Marketing Authorization number EU/1/20/1500/001, with following modifications:

(P.3.1) Differences to the marketing authorization

Clinical supply tablets:

- Release and stability testing sites: Shionogi Pharma Co. Ltd. 2 Chome 1-3, Kuise Terajima Amagasaki, Hyogo 660-0813, Japan
- Primary packaging sites: F. Hoffmann-La Roche AG, Wurmisweg, 4303 Kaiseraugst, Switzerland
- Secondary packaging sites:
 - F. Hoffmann-La Roche AG, Wurmisweg, 4303 Kaiseraugst, Switzerland
 - 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

Marketing Authorized tablets:

- Release testing sites: SGS Institut Fresenius GmbH, Tegeler Weg 33, 10589 Berlin, Germany and SGS Institut Fresenius GmbH, Im Maisel 14, 65232 Taunusstein, Germany
- Stability testing sites: Shionogi Pharma Co. Ltd, 2 Chome 5-1, Mishima, Settsu, Osaka, 566-0022 Japan, F. Hoffmann-La Roche AG, Wurmisweg, 4303 Kaiseraugst, Switzerland and F. Hoffmann-La Roche AG, Grenzacherstrasse 124, 4070 Basel, Switzerland
- Primary and secondary Packaging sites: Sharp Packaging Services, LLC, 22-23 Carland Road, Conshohocken, PA 19428 USA

(P.5.1) Specifications:

- Clinical supply tablets are without embossment for blinding reason while Marketing Authorized Product is debossed with “772” on one side and “20” on the other side.
- Related substances limits: S-033447: Clinical supply tablets have NMT 2.0% while Marketing Authorized Product has NMT 1.0%; Total except S-033447: Clinical supply tablets have NMT 2.0% while Marketing Authorized Product has NMT 1.5%.
- Dissolution: Clinical supply tablets have Q 75% in 30min while Marketing Authorized Product has Q 80% in 30min.

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

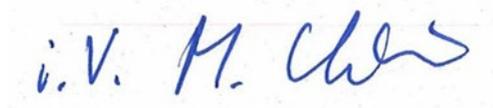
We herewith authorize the Sponsor (The Chancellor Masters and Scholars of the University of Oxford) to submit this declaration with his Clinical Trial Applications for the above mentioned study protocol number to any EU Competent Authority.

Sincerely,

F. Hoffmann-La Roche AG



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