ERELZI® PATIENT ALERT CARD

This Patient Alert Card contains important safety information that you need to be aware of before you are given Erelzi® and during treatment with Erelzi®. Please ask your doctor if you do not understand this information.

- Show this card to any doctor involved in treating you.
- See also Erelzi® package leaflet for more information.

Use in Children and adolescents (weighing less than 62.5kg)

Erelzi® should not be used in children and adolescents weighing less than 62.5kg. Please ask your doctor if you have any questions about this.

Infections

Erelzi® may increase the risk of getting infections, which could be serious.

- You should not be treated with Erelzi® if you have an infection. If you are not sure, ask your doctor.
- If you develop symptoms suggestive of infection, such as fever, persistent cough, weight loss or listlessness, seek medical attention immediately
- You should be evaluated for tuberculosis (TB). Ask your doctor to record the dates and results of your last screening for TB below:

Test: _____

Date: _____

Results: _____

Test: _____

Date: _____

Results: _____

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• Please ask your doctor to list your other medications that may increase your risk of infection.

Congestive Heart Failure

If you develop symptoms **suggestive of congestive heart failure or worsening of existing congestive heart failure** such as shortness of breath, swelling of ankles, persistent cough or fatigue, seek medical attention immediately.

Other information (please complete):

• Patient's name: _____
• Doctor's name: _____
• Doctor's phone number: _____

Keep this card with you during your treatment with Erelzi® and for 2 months after the last Erelzi® dose, since side effects may occur after your last dose of Erelzi®.

It is important that you and your doctor record the brand name and batch number of your medication.

Call for reporting

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to:

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann, SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of **Erelzi®** to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Sandoz GmbH Biochemiestr. 10 A-6250 Kundl Austria

Local Distributor: V.J. Salomone Pharma Limited - Upper Cross Road, Marsa, MRS 1542, Malta

For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - http://www.medicinesauthority.gov.mt/rmm **- and download the required material with the latest date.**

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SANDOZ A Novartis Division