Date: 11 October 2021

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**TUKYSA ▼ (tucatinib) 50 mg and 150 mg film-coated tablets:**
**Interim Supply of French or German/Austrian Stock**

Dear Healthcare Professional,

## Summary: TUKYSA ▼ (tucatinib) 50 mg and 150 mg film-coated tablets packaged for use in Northern Ireland are not yet available.

To enable supply to Northern Ireland, Seagen has obtained approval from the MHRA to supply packs of TUKYSA labelled in German or French, which are expected to be available in Northern Ireland from October 2021 to April 2022.

Please note the following:

- This product is considered licensed in the United Kingdom, including Northern Ireland.
- The product has the same formulation as the Northern Ireland product.
- The product is manufactured according to the same manufacturing process and quality controls as the Northern Ireland product.
- Please ensure the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are followed.
    - The combined product information for TUKYSA (including the SmPC and PIL) in English is available from the EMA website[1].
- Copies of the English PIL are enclosed with this letter. Discard the German or French language PIL in the pack and provide the English PIL to the patients being dispensed the product
- To request additional printed copies of the leaflet, please contact medinfoEU@seagen.com.
- The expiry date and batch number are expressed on the carton and blister after “EXP” and “Lot” on French cartons and blisters, and “verwendbar bis” and “Ch.B” on German/Austrian packs, respectively
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of TUKYSA and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

**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 to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

**Company contact point**

If you have any questions about this letter, please contact Seagen at: medinfoEU@seagen.com.

Many thanks for your attention to this matter.

Yours faithfully,

Mr. Peter Martin,

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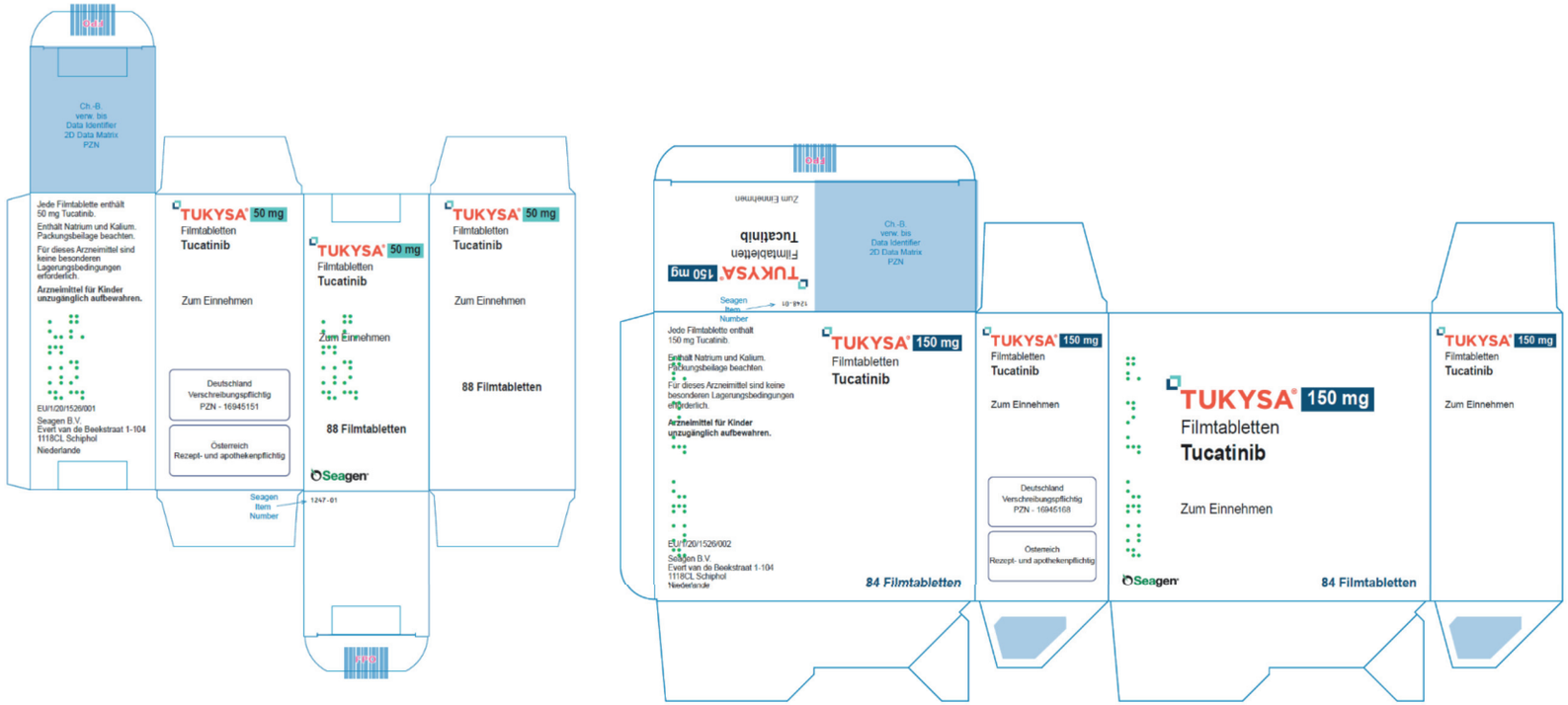
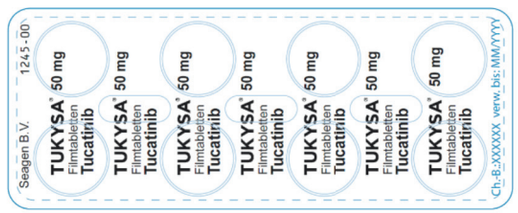
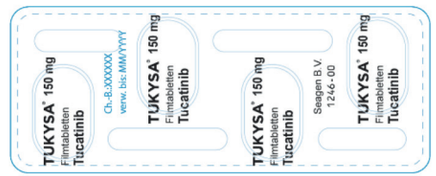
[1] https://www.ema.europa.eu/en/documents/product-information/tukysa-epar-product-information_en.pdf

## Appendix 1: German pack



## Appendix 1: French pack