WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[BT-ON013 trade name]*

Trastuzumab 150 mg powder for concentrate for solution for infusion

Abstract

[BT-ON013 trade name], manufactured at Biocon Ltd, Bengaluru, India, was included in the WHO list of prequalified medicinal products for the treatment of HER2 positive breast cancer on 23 February 2021.

[BT-ON013 trade name] is indicated for the treatment of HER2 positive breast cancer. Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The drug substance (DS) of [BT-ON013 trade name] is the antineoplastic monoclonal antibody, trastuzumab.

The efficacy and safety profile of trastuzumab is well established, based on extensive clinical experience in the treatment of HER2 positive breast cancer.

On the basis of data submitted and public information on the use of trastuzumab in the treatment of HER2 positive breast cancer, the team of assessors accepted [BT-ON013 trade name] for the list of prequalified medicinal products.

Summary of Prequalification Status for [BT-ON013 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 February 2021	listed
Quality	27 January 2021	MR
Non-clinical	July 2020	MR
Safety, efficacy	27 January 2021	MR
GMP (re-)inspection		
Drug substance	15 February 2021	MR*
Drug product	15 February 2021	MR*
GCP/GLP (re-)inspection	15 February 2021	NA

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.