



Public Assessment Report Scientific discussion

**Ruxolitinib Vivanta 5 mg, 10 mg, 15 mg and
20 mg tablets
(ruxolitinib hydrochloride)**

NL/H/6247/001-004/DC

Date: 27 July 2026

This module reflects the scientific discussion for the approval of Ruxolitinib Vivanta 5 mg, 10 mg, 15 mg and 20 mg tablets. The procedure was finalised on 19 January 2026. For information on changes after this date, please refer to section 'steps taken after finalisation' at the end of this PAR.

Table of Contents

I.	INTRODUCTION	4
II.	EXECUTIVE SUMMARY	4
II.1.	Rationale for the product	4
II.2.	About the product	5
II.3.	General comments on compliance with GMP, GLP, GCP and agreed ethical principles	5
III.	QUALITY ASPECTS	6
III.1.	Introduction	6
III.2.	Active substance	6
III.3.	Medicinal Product	7
III.4.	Discussion on chemical, pharmaceutical and biological aspects	8
IV.	NON-CLINICAL ASPECTS	8
IV.1.	Introduction	8
IV.2.	Ecotoxicity/environmental risk assessment (ERA)	8
IV.3.	Discussion on the non-clinical aspects	8
V.	CLINICAL ASPECTS	9
V.1.	Introduction	9
V.2.	Pharmacokinetics	9
V.3.	Summary Pharmacovigilance system	12
V.4.	Risk Management Plan	12
V.5.	Discussion on the clinical aspects	12
VI.	USER CONSULTATION	13
VII.	POST-APPROVAL COMMITMENTS (PAC's)	13
VIII.	OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION	13
IX.	RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION	13
IX.1.	List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC	13
IX.2.	List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC	14

List of abbreviations

AE	Adverse Event
AI	Acceptable Intake
ANOVA	Analysis of Variance
BCS	Biopharmaceutics Classification System (-based biowaiver)
BE	Bioequivalence
CBG /MEB	College ter Beoordeling van Geneesmiddelen / The Medicines Evaluation Board
CHMP	Committee for Medicinal Products for Human Use
CMD(h)	Coordination group for Mutual recognition and Decentralised procedure for human medicinal products
CMS	Concerned Member State(s)
DCP	Decentralised Procedure
EDMF	European Drug Master File
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
ERP	European Reference Product
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practice
GvHD	Graft versus host disease
ICH	International Conference of Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use)
LALA	Locally applied, locally acting products
MAH	Marketing Authorisation Holder
PAR	Public Assessment Report
PD	Pharmacodynamics
Ph.Eur.	European Pharmacopoeia
PK	Pharmacokinetics
PL	Package Leaflet
PPI	Proton Pump Inhibitor
PSURs	Periodic safety update reports
QC	Quality control
RH	Relative Humidity
RMP	Risk Management Plan
RMS	Reference Member State
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy
USP/NF	United States Pharmacopoeia/National Formulary

Note: Not all abbreviations may apply for this PAR.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Ruxolitinib Vivanta 5 mg, 10 mg, 15 mg and 20 mg tablets, from Vivanta Generics s.r.o.

The products are indicated for:

Myelofibrosis (MF)

- treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis

Polycythaemia vera (PV)

- treatment of adult patients with polycythaemia vera who are resistant or intolerant to hydroxyurea

Graft versus host disease (GvHD)

- Acute GvHD
treatment of adults and paediatric patients aged 28 days and older with acute graft versus host disease who have inadequate response to corticosteroids or other systemic therapies
- Chronic GvHD
treatment of adults and paediatric patients aged 6 months and older with chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies

A comprehensive description of the up-to-date indications and posology is given in the SmPC.

II. EXECUTIVE SUMMARY

II.1. Rationale for the product

The marketing authorisation has been granted pursuant to Article 10(1) Generic medicinal product application of Directive 2001/83/EC, which concerns a generic application.

To demonstrate bioequivalence with the reference medicinal product, the MAH has submitted data on two bioequivalence studies and has requested a biowaiver. See Section V. Clinical aspects.

In this decentralised procedure the reference medicinal product is Jakavi 5 mg, 10 mg, 15 mg and 20 mg, tablets, which has been authorised in the EEA via the centralised procedure EU/1/12/773 by Novartis Europharm Limited since 23 August 2012. The marketing authorisation of Jakavi is based on a full dossier (Art 8(3), Directive 2001/83/EC). The reference product has been authorised in the EU for more than eight years, thus the period of data exclusivity has expired.

This application has been assessed with The Netherlands as Reference Member State (RMS) and Denmark, Finland, Germany, Italy, Norway, Spain and Sweden as concerned Member States (CMS).

Assessment of similarity with authorised orphan medicinal product(s) under market exclusivity
According to Article 8(1) of Regulation (EC) No 141/2000, no marketing authorisation can be granted for a product similar to an orphan medicinal product for a period of ten years, when this concerns a similar medicinal product with the same therapeutic indication. Therefore, the MAH has provided a similarity assessment between Ruxolitinib Vivanta and the current orphan products authorised in the EU. These orphan products and their indications are Omjjara and Inrebic:

- Omjjara (mometotinib, EU/1/23/1782) is indicated for the treatment of post-polycythaemia vera myelofibrosis, the treatment of post-essential thrombocythaemia myelofibrosis and the treatment of primary myelofibrosis.
- Inrebic (fedratinib, EU/1/20/1514) is indicated for the treatment of primary myelofibrosis, the treatment of post-essential thrombocythaemia myelofibrosis and the treatment of post-polycythaemia vera myelofibrosis.

The assessment included the comparison of the therapeutic indication, mechanism of action and principal (molecular) structure. After consideration of the MAH arguments, Ruxolitinib Vivanta is considered similar to the orphan products based on therapeutic indication and **not** similar based on mechanism of action and principal molecular structure.

Therefore, the existence of any market exclusivity for Omjjara and Inrebic, with the current orphan indication, does not prevent the granting of the marketing authorisation for Ruxolitinib Vivanta.

II.2. About the product

Pharmaco-therapeutic group (ATC Code): Antineoplastic agents, protein kinase inhibitors, ATC code: L01EJ01

Dispensing status: prescription only

II.3. General comments on compliance with GMP, GLP, GCP and agreed ethical principles

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these product types at all sites responsible for the manufacture and assembly of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, 'close-out letters' or 'exchange of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

GMP active substance

Regarding the statement on GMP for the active substance, a statement/declaration is provided from the manufacturer(s) responsible for manufacture of the medicinal product and batch release situated in the EU.

III. QUALITY ASPECTS

III.1. Introduction

Ruxolitinib Vivanta are immediate release tablets containing 5 mg, 10 mg, 15 mg or 20 mg of the active substance ruxolitinib as ruxolitinib hydrochloride. The tablets of the different strengths can be distinguished by their shape, size and debossing and are as follows:

5 mg strength

Round biconvex white to almost white tablets, approximately 7.5 mm in diameter, debossed with “MR” on one side and “14” on other side.

10 mg strength

Round biconvex white to almost white tablets, approximately 9.4 mm in diameter, debossed with “MR” on one side and “11” on other side.

15 mg strength

Ovaloid biconvex white to almost white tablets, approximately 15 mm long and 7 mm wide, debossed with “MR” on one side and “12” on other side.

20 mg strength

Elongated biconvex white to almost white tablets, approximately 16.5 mm long and 7.5 mm wide, debossed with “MR” on one side and “13” on other side.

The excipients are: lactose monohydrate, microcrystalline cellulose (E460), sodium starch glycolate, hydroxypropyl cellulose (E463a), povidone K30 (E1201), colloidal anhydrous silica (E551) and magnesium stearate (E470b).

The four tablet strengths are dose proportional.

The tablets are packed in calendar blisters or perforated unit dose blisters, made of oriented polyamide (OPA), aluminium (Alu) and polyvinyl chloride (PVC): OPA/Alu/PVC-Alu.

III.2. Active substance

The structure of the active substance has been adequately proven and its physico-chemical properties are sufficiently described. The active substance is ruxolitinib hydrochloride, an established active substance not described in the European Pharmacopoeia (Ph.Eur.).

The active substance is a white to off-white crystalline powder and is insoluble in water (except at pH 1.2). The chirality (purity) and the polymorphic form of the active substance are routinely controlled.

Manufacturing process

The manufacture of the active substance has been adequately described. The used starting materials, solvents and reagents are considered acceptable. Adequate tests and acceptable specifications have been adopted for these.

Quality control of the active substance

The active substance specification includes relevant tests and the limits for impurities and degradation products have been justified in accordance with the applicable ICH Guidelines for impurities in new Drug Substances. The analytical methods applied are suitably described and non-compendial methods have adequately been validated. The active substance specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided for three batches.

Stability of the active substance

Stability data have been submitted for three batches of the active substances in accordance with the applicable European guidelines. Based on the data submitted, the re-test period for the active substance was confirmed for 18 months when stored under the stated conditions. This is acceptable.

III.3. Medicinal Product

Pharmaceutical development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. The choice of the excipients is justified, and their functions are explained. The main development studies were for the optimisation of the formulation and development of the dissolution method used to support the bioequivalence (BE) studies.

Manufacturing process

The manufacturing process has been sufficiently described and critical steps identified. The manufacturing process has been validated according to relevant European/ICH guidelines. Process validation data on the product have been presented for three batches per strength. The product is manufactured using conventional manufacturing techniques.

Control of excipients

The excipients comply with the current version of the Ph.Eur. monograph. With additional in-house specifications for lactose monohydrate and magnesium stearate. These specifications are acceptable.

Quality control of the medicinal product

The medicinal product specifications are adequate to control the relevant parameters for the dosage form. The specification includes tests for description (including, dimensions), identity, average mass, uniformity of dosage units (by content uniformity), dissolution, assay, related substances, microbiological quality and water content. Limits in the specification have been justified and are considered appropriate for the adequate quality control of the product.

An adequate risk evaluation report on nitrosamines has been submitted. No risk for the presence of nitrosamines in the medicinal product was identified. This justifies the absence of any further testing for nitrosamine impurity in the ruxolitinib hydrochloride and medicinal product.

Satisfactory validation data for the non-compendial analytical methods have been provided. Batch analytical data for three validation batches per strength from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of the medicinal product

Stability data on the product have been provided for three batches of each strength stored at 25°C/ 60% RH (18 months) and 40°C/75% RH (6 months). The stability was tested in accordance with applicable European guidelines. Photostability studies were performed in accordance with ICH recommendations. The results showed that the product is stable when exposed to light. Based on the data submitted, a shelf life of 24 months was granted. The labelled storage conditions are: "This medicinal product does not require any special storage conditions."

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

Scientific data and/or certificates of suitability issued by the EDQM for lactose monohydrate have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via medicinal products has been satisfactorily demonstrated.

III.4. Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the Member States consider that Ruxolitinib Vivanta has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the ruxolitinib hydrochloride and medicinal product.

IV. NON-CLINICAL ASPECTS

IV.1. Introduction

Pharmacodynamic, pharmacokinetic and toxicological properties of ruxolitinib hydrochloride are well known. As ruxolitinib hydrochloride is a widely used, well-known active substance, the MAH has not provided additional studies and further studies are not required. The submitted overview based on literature is appropriate.

IV.2. Ecotoxicity/environmental risk assessment (ERA)

At the time of the approval of this application, before 1 September 2024, the revised ERA guideline (EMA/CHMP/SWP/4447/00 Rev. 1- Corr.*) was not yet applicable. Then the conclusion for this medicinal product was: since Ruxolitinib Vivanta is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment was therefore not deemed necessary.

IV.3. Discussion on the non-clinical aspects

This product is a generic formulation of Jakavi which is available on the European market. Reference was made to the preclinical data obtained with the reference medicinal product. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which was based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology,

pharmacokinetics and toxicology data. Therefore, the Member States agreed that no further non-clinical studies are required.

V. CLINICAL ASPECTS

V.1. Introduction

Ruxolitinib hydrochloride is a well-known active substance with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The Member States agreed that no further clinical studies are required, besides the two bioequivalence studies discussed below. Bioequivalence has been investigated in line with the EMA Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**).

V.2. Pharmacokinetics

To support the application, the MAH has submitted two bioequivalence studies comparing the pharmacokinetic profiles of the test product Ruxolitinib Vivanta 20 mg tablets, Vivanta Generics s.r.o., Czechia and the reference medicinal product Jakavi 20 mg, tablets, Novartis Europharm Limited, Ireland. Because of the pH-dependent solubility of ruxolitinib, and the different salt in the test product (hydrochloride) compared to the reference product (phosphate), a second bioequivalence study with pre-treatment with a proton pump inhibitor (PPI) (pantoprazole) was performed to demonstrate bioequivalence in a gastric pH-altered environment. A biowaiver was requested for the lower strengths: 5 mg, 10 mg and 15 mg. The formula and manufacturing process of the bioequivalence batches was identical to the formula proposed for marketing.

Biowaiver

According to the EMA bioequivalence guideline, the following general requirements must be met where a waiver for additional strength is claimed:

- a. the pharmaceutical products are manufactured by the same manufacturing process,
- b. the qualitative composition of the different strengths is the same,
- c. the composition of the strengths are quantitatively proportional, i.e. the ratio between the amount of each excipient to the amount of ruxolitinib hydrochloride(s) is the same for all strengths (for immediate release products coating components, capsule shell, colour agents and flavours are not required to follow this rule),
- d. appropriate *in vitro* dissolution data should confirm the adequacy of waiving additional *in vivo* bioequivalence testing.

All requirements above were met.

The dissolution tests at pH 1.2, 4.5 and 6.8 show for the 5 mg strength of the medicinal product that more than 85% of the active is released within 15 minutes. For the 10 mg, 15 mg and 20 mg strengths, no 85% dissolution is achieved after 30 minutes for all three pH values for both the test and the reference product. According to the MAH ruxolitinib exhibits dose depending solubility, therefore dissolution studies were performed with an equivalent dose of 20 mg using four units of 5 mg tablets, which showed comparable dissolution. This is acceptable.

As the conditions for the biowaiver criteria are met, a biowaiver for the 5 mg, 10 mg and 15 mg strengths has been granted.

Bioequivalence studies C1B03175 and C1B05562

Design C1B03175 Study with 20 mg under fasted conditions, without pre-treatment with a PPI

A single-dose, randomised, open label, two-treatment, two-period, two-sequence, balanced, crossover bioequivalence study was carried out under fasted conditions in 26 healthy male subjects, aged 21-46 years. Each subject received a single dose (20 mg) of one of the two ruxolitinib formulations (hydrochloride or phosphate salt). The tablet was orally administered with 240 mL water after a fasting period of at least 10 hours. There were two dosing periods, separated by a washout period of three days.

The plasma concentration time curve was used to assess the rate and extent of absorption. Blood samples were collected pre-dose and at 0.17, 0.33, 0.5, 0.75, 1.0, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 6, 8, 10, 12, 16 and 24 hours after administration of the products.

The SmPC recommends administering the product orally, with or without food.

The design of the study was considered acceptable as according to the SmPC ruxolitinib may be administered without reference to food intake. The bioequivalence study under fasting conditions is in accordance with CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** Note for Guidance on the investigation of bioavailability and bioequivalence.

Bioanalytical/statistical methods

The bioanalytical method has been adequately validated according to current guidelines (ICH M10) and is considered acceptable for analysis of the plasma samples. The methods used in this study for the pharmacokinetic calculations and statistical evaluation are considered acceptable.

Results

All 26 subjects enrolled in the study were eligible for pharmacokinetic analysis.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean $\pm$ SD, $t_{\max}$ (median, range)) of ruxolitinib, 20 mg under fasted conditions without co-administration of PPI pantoprazole.

Treatment N=26	AUC_{0-t} (ng.h/mL)	AUC_{0-∞} (ng.h/mL)	C_{max} (ng/mL)	t_{max} (h)
Test	2123 $\pm$ 1127	2155 $\pm$ 1146	473 $\pm$ 186	0.88 (0.33-2.00)
Reference	2078 $\pm$ 989	2110 $\pm$ 1002	504 $\pm$ 166	0.75 (0.33-2.00)
*Ratio (90% CI)	0.99 (0.94-1.05)	--	0.92 (0.87-0.98)	--
AUC_{0-t} Area under the plasma concentration-time curve from time zero to t = 24 hours AUC_{0-∞} Area under the plasma concentration curve extrapolated to infinite time. C_{max} Maximum plasma concentration t_{max} Time after administration when maximum plasma concentration occurs CI Confidence interval * Back-transformed from ln-transformed least-squares mean values				

Design C1B05562 Study with 20 mg under fasted conditions, with pre-treatment with a PPI

A single-dose, randomised, open label, two-treatment, two-period, two-sequence, balanced crossover bioequivalence study, with co-administration of pantoprazole, was carried out under fasted conditions in 28 (24 male / 4 female) subjects, aged 24-51 years. Each subject received a single dose (20 mg) of one of the two ruxolitinib formulations (hydrochloride or phosphate salt). The tablet was orally administered with 240 mL water after a fasting period of at least 10 hours. There were two dosing periods, separated by a washout period of seven days.

As pre-treatment, one tablet Protium 40 mg gastro-resistant tablets (pantoprazole) was orally administered with 240 mL water twice daily at an interval of 12 hours and approximately 30 minutes before serving standardised breakfast or dinner, from Day -4 to Day -1. On Day 0, one tablet of Protium 40 mg Gastro-resistant Tablets (pantoprazole) was administered with 240 mL water 1 hour prior to dosing of the investigational product.

The plasma concentration time curve was used to assess the rate and extent of absorption. Blood samples were collected pre-dose and at 0.08, 0.17, 0.33, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 6, 8, 10, 12, 16 and 24 hours after administration of the products.

The SmPC recommends administering the product orally, with or without food.

The design of the study was considered acceptable as according to the SmPC ruxolitinib may be administered without reference to food intake. The bioequivalence study under fasting conditions is in accordance with CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** Note for Guidance on the investigation of bioavailability and bioequivalence.

Bioanalytical/statistical methods

The bioanalytical method has been adequately validated according to current guidelines (ICH M10) and is considered acceptable for analysis of the plasma samples. The methods used in this study for the pharmacokinetic calculations and statistical evaluation are considered acceptable.

Results

Out of 28 enrolled subjects, three subjects discontinued the study due to adverse events: one with an increased eosinophil count, one with pyrexia and one with increased white blood cells. A total of 25 subjects were eligible for pharmacokinetic analysis.

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean $\pm$ SD, $t_{\max}$ (median, range)) of ruxolitinib, 20 mg under fasted conditions with co-administration of PPI pantoprazole.

Treatment N=25	AUC_{0-t} (ng.h/mL)	AUC_{0-∞} (ng.h/mL)	C_{max} (ng/mL)	t_{max} (h)
Test	2895 $\pm$ 831	2992 $\pm$ 935	500 $\pm$ 98	1.75 (0.50 - 4.00)
Reference	2970 $\pm$ 990	3078 $\pm$ 1102	512 $\pm$ 111	1.25 (0.167 - 4.00)
*Ratio (90% CI)	0.98 (0.95 – 1.01)	--	0.98 (0.92 – 1.04)	

AUC_{0-t}	Area under the plasma concentration-time curve from time zero to t = 24 hours
AUC_{0-∞}	Area under the plasma concentration curve extrapolated to infinite time.
C_{max}	Maximum plasma concentration
t_{max}	Time after administration when maximum plasma concentration occurs
CI	Confidence interval
*	Back-transformed from ln-transformed least-squares mean values

Conclusion on bioequivalence studies:

The 90% confidence intervals calculated for AUC_{0-t} and C_{max} are within the conventional bioequivalence acceptance range of 80% – 125%. Based on the submitted bioequivalence studies Ruxolitinib Vivanta 20 mg is considered bioequivalent with Jakavi 20 mg under fasted conditions.

As a biowaiver has been granted, the results of studies C1B03175 and C1B05562 with the 20 mg formulation can be extrapolated to the lower strengths 5 mg, 10 mg and 15 mg, in accordance with the conditions in the ICH Guideline M13B on bioequivalence for immediate-release solid oral dosage forms - Scientific guideline.

V.3. Summary Pharmacovigilance system

The MAH has submitted a signed Summary of the MAH's and/or Proposed Future MAH's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the RMS considers the Summary acceptable.

V.4. Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Ruxolitinib Vivanta. At the time of approval, the accepted version of the RMP was version 0.2 with sign-off date 29 November 2025.

Table 3. Summary table of safety concerns as approved in the RMP

Important identified risks	• Serious infections
Important potential risks	• Developmental toxicity
Missing information	• Safety in the paediatric patients > 12 years (Graft versus Host Disease only)

The Member States agreed that routine pharmacovigilance activities and routine risk minimisation measures are sufficient for the risks and areas of missing information.

V.5. Discussion on the clinical aspects

For this authorisation, reference is made to the clinical studies and experience with the reference medicinal Jakavi. The MAH demonstrated through two bioequivalence studies that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of this

reference medicinal product. Risk management is adequately addressed. This generic medicinal product can be used instead of the reference medicinal product.

VI. USER CONSULTATION

The package leaflet (PL) has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PL was English.

A user consultation with target patient groups on the package leaflet (PL) has been performed based on a bridging report making reference to Jakavi 5 mg, 10 mg, 15 mg and 20 mg tablets, centralised procedure EMEA/H/C/002464, for the content and to Rosuvastatin Vivanta 5 mg, 10 mg, 20 mg and 40 mg, film-coated tablets, decentralised procedure NL/H/4158/001-004/DC for the layout. The bridging report submitted by the MAH has been found acceptable; bridging is justified for both content and layout of the leaflet.

VII. POST-APPROVAL COMMITMENTS (PAC's)

Post-approval commitments: not applicable.

VIII. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Ruxolitinib Vivanta 5 mg, 10 mg, 15 mg and 20 mg tablets have a proven chemical-pharmaceutical quality and are generic forms of Jakavi 5 mg, 10 mg, 15 mg and 20 mg, tablets. Jakavi is a well-known medicinal product with an established favourable efficacy and safety profile. Bioequivalence has been shown between the test and reference medicinal products, in line with the requirements of European guidance documents.

The Board followed the advice of the assessors.

There was no discussion in the CMD(h). Agreement between Member States was reached during a written procedure. The Member States, based on the data submitted, considered that essential similarity has been demonstrated for Ruxolitinib Vivanta with the reference medicinal product, and have therefore granted a marketing authorisation. The decentralised procedure was finalised with a positive outcome on 19 January 2026.

IX. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

IX.1. List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

N.A.

IX.2. List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

N.A

STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
N.A.	N.A.	N.A.	N.A.	N.A.	N.A.