

The journey for Vonjo®

19 July 2023



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Agenda and presenters



Opening remarks



Guido Oelkers, Chief Executive Officer
Swedish Orphan Biovitrum

Overview of Myelofibrosis and Vonjo



John Mascarenhas, Professor of Medicine
Icahn School of Medicine at Mount Sinai

Emerging Insights & Future Potential of Pacritinib



Sarah Buckley, Medicine Development Lead Swedish Orphan Biovitrum

Summary and Q&A

Vonjo is part of our journey to build the leading rare haematology portfolio



Leading products in Haemophilia A and B Only oral TPO-RA
with no food
restrictions and
clean safety
profile

First in class C3 inhibitor and only sub-cutaneous therapy in PNH

Safe and
efficacious CD-19
ADC in severe
DLBCL

First and only
JAK1-sparing
inhibitor that
targets both
JAK2 and IRAK1*











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ALPROLIX

^{*} Approved under accelerated approval in the US for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythaemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10⁹/L.

Well-prepared CTI integration capturing Vonjo's value





Positive and smooth first two weeks focused on seamless continuation of Vonjo operations



Life-cycle management planning initiated for geographic expansion and extended indications



Thoughtful strategy to maximize Vonjo's potential and synergies beyond cost savings

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Emerging Insights & Future Potential of Pacritinib



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Summary and Q&A

Myelofibrosis is a blood cancer with clinical features including splenomegaly and abnormal blood counts



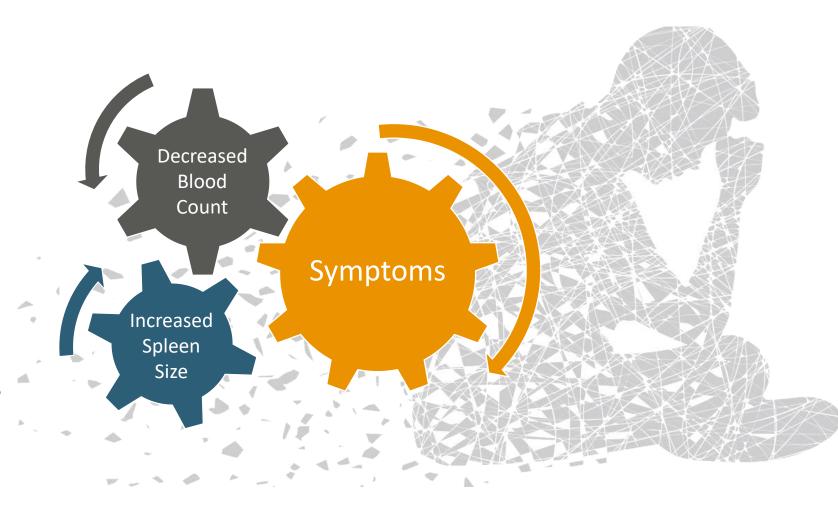
Abnormal haematopoiesis:

driven by mutations affecting the JAK/STAT pathway¹

Splenomegaly: resulting from bone marrow fibrosis and extramedullary hematopoiesis²

Myelofibrosis symptoms:

resulting from aberrant cytokine production and splenomegaly²



Symptoms and associated disease complications impact QoL and prognosis of myelofibrosis patients



Symptoms

Symptoms of MF may go unrecognized in early disease, but with **progression** they can lead to **reduced QoL**, **functional status**, and **activities of daily living**¹⁻³



Haematology-Driven Symptoms

e.g., fatigue/inactivity experienced by nearly all patients⁴



Cytokine-Driven Constitutional Symptoms

e.g., night sweats, itching, bone pain, fever, weight loss, and cough⁴



Splenomegaly-Related Symptoms

e.g., early satiety and abdominal pain/discomfort⁴

Complications

risk of leukemic transformation within 10 years⁵

have thrombosis or thromboembolism, and 10% have bleeding events^{6,7}

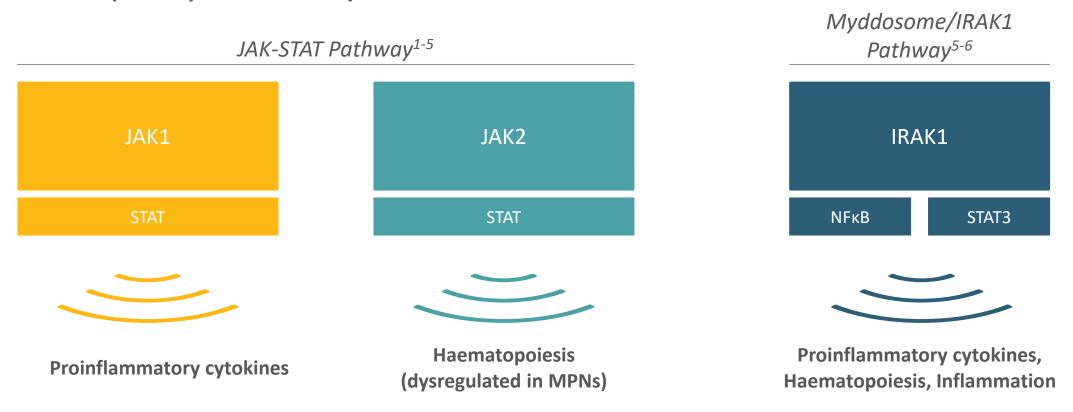
5-6 years median overall survival8

QoL=quality of life.

Myelofibrosis is characterised by activated JAK-STAT signalling and inflammation



Different pathways involved in myelofibrosis



IRAK1=interleukin 1 receptor-associated kinase; JAK=Janus kinase; MPN=myeloproliferative neoplasms; NFkB=Nuclear factor kappa-light-chain-enhancer of activated B cells; STAT=signal transducer and activator of transcription. **References: 1.** O'Sullivan JM, Harrison CN. Mol Cell Endocrinol. 2017;451:71-79. **2.** Tefferi A. Am J Hematol. 2021;96(1):145-162. **3.** Tefferi A, et al. Am J Hematol. 2018;93(3):348-355. **4.** Kleppe M, et al. Cell Stem Cell. 2017;5:21(4):489-501. **5.** Mascarenhas J, et al. Leukaemia. 2023;37:255-264. **6.** Singer JW, et al. Oncotarget. 2018;9(70):33416-33439.

Proliferative and cytopenic MF are clinically and biologically different and present across a spectrum



The Phenotypic Spectrum of Myelofibrosis^{1,2}

Proliferative Myelofibrosis		Cytopenic Myelofibrosis
Normal or elevated blood counts	Lab values (clinical presentation) ^{1,2}	Lower blood counts, increased circulating blasts
JAK2 mutations present more often, other mutations less common	Gene mutations ^{1,3}	JAK2 mutations present less often, other mutations more common
Better prognosis/Lower AML risk ^{1,2,4} (112 months median survival, per retrospective analysis, N=685)	Prognosis ^{1,2}	Poor prognosis/Higher AML risk ^{1,2,5} (69 months median survival, per retrospective analysis, N=1,054)

Cytopenias are a common feature of MF progression and a frequent side effect of JAK1/2 inhibitors

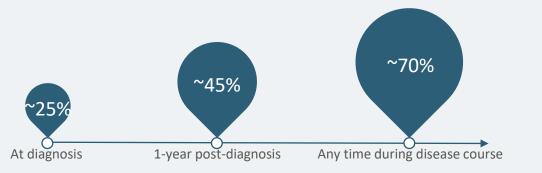


Thrombocytopenia

Prevalence of moderate-to-severe thrombocytopenia in patients with MF rises over time 1-3 †



Time from diagnosis



Anaemia

Prevalence of anaemia^b in patients with MF rises over time and is often an anticipated downside of current therapies^{4-6‡}



^a Moderate-and-severe thrombocytopenia is defined as platelet counts <100 x 10⁹/L. ^b Anaemia is defined as haemoglobin <10 g/dL. [†] Prevalence at presentation from a retrospective cohort analysis of 1281 patients with thrombocytopenia presented at a single centre between Jan 1984 and Dec 2015; prevalence at 1-year post-diagnosis from TriNetX; prevalence any time during course of the disease from a recent survey of >800 haematologists/oncologists from 12 countries. [‡] Prevalence at diagnosis and within 1 year of diagnosis among 1000 Mayo Clinic patients with primary MF. JAK=Janus associated kinase; MF=myelofibrosis References: 1. Masarova L, et al. Leuk Res. 2020;91:106338. 2. Masarova L, et al. Eur J Haematol. 2018;100(3):257-263. 3. TriNetX. Dataworks US EMR Database. Accessed March 2021. https://trinetx.com/. 4. Tefferi A, et al. Mayo Clin Proc. 2012;87(1):25-33. 5. Naymagon L, et al. HemaSphere. 2017;1(1):e1. 6. Tefferi A, et al. Clin Ther. 2014;36(4):560-566.

Myelofibrosis patients with severe cytopenias have significantly shorter overall survival



Worst survival in cytopenic myelofibrosis patients^{1,2}

Patients frequently have more than one cytopenia

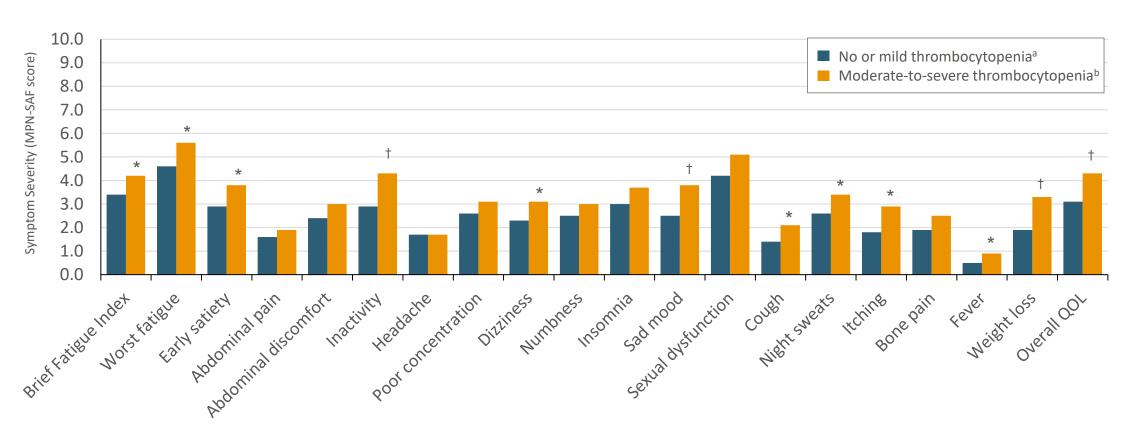
~70% of thrombocytopenic patients also have anaemia^{3,4}

Thrombocytopenia Anaemia OS in patients with MF by platelet count¹ OS in patients with MF by degree of anaemia² atelets 51-100, N=176, died 98 latelets >100, N=948, died 479 **Cumulative Survival** P<.001 0.8 No anemia - median survival 7.9 years 8 Mild anemia - median survival 4.9 years 0.6 Survival Moderate anemia - median survival 3.4 years Severe anemia - median survival 2.1 years OS=57 mo OS=15 mo P<.0001 (12-18)OS=44 mo 0.0 (34-54)10 15 20 25 30 0.00 50.00 100.00 150.00 200.00 250.00 Years Time (mo) 1.25 2.1 Median OS (PLT<50 x 10⁹/L) Median OS (HB <8 g/dL or TD) vears vears

Symptom burden is also worse in myelofibrosis patients with thrombocytopenia



Symptom burden in myelofibrosis patients with thrombocytopenia¹



^a No or mild thrombocytopenia is defined as platelet counts >100 x 10⁹/L. * P<0.05. † P<0.001. MPN-SAF=Myeloproliferative Neoplasm Symptom Assessment Form; QOL=Quality of life. **Reference: 1.** Scotch A, et al. Leuk Res. 2017;63:34-40.

Pacritinib is the only approved JAK inhibitor studied in MF patients with platelet counts <50 x 10⁹/L at baseline

Sobi

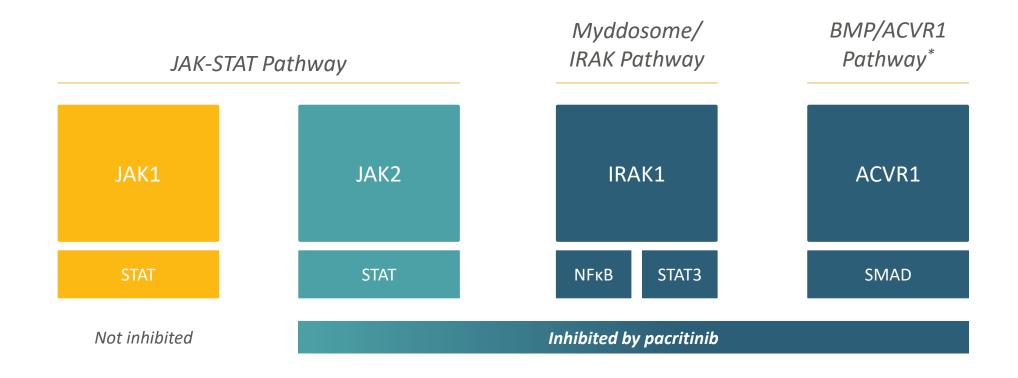
Pacritinib

Pacritinib is indicated in the US for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythaemia vera or post-essential thrombocythemia) myelofibrosis with severe thrombocytopenia (platelet counts <50 x 10⁹/L).¹

This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Pacritinib is a JAK1-sparing JAK2 inhibitor that acts on multiple pathways involved in myelofibrosis





^{*} Published data on file. This pathway is not currently referenced in the USPI.

ACVR1=activin receptor-like kinase-2; IRAK1=interleukin 1 receptor—associated kinase; JAK=Janus associated kinase; NFkB=nuclear factor kappa light chain enhancer of activated B cells; STAT=signal transducer and activator of transcription.

Pacritinib received accelerated FDA approval in February 2022 based on data from PERSIST-2



PERSIST-2 study design¹

Patient Population

- PMF, PET-MF, PPV-MF
- DIPSS intermediate- or high-risk disease
- Platelets ≤100 x 10⁹/L
- Prior JAK inhibitors permitted



Co-Primary Endpoints[†]:

- ≥35% spleen volume reduction at Week 24
- Reduction of ≥50% total symptom score (TSS) at

Efficacy was established on spleen volume reduction in patients who received pacritinib 200 mg twice daily and had a platelet count $<50 \times 10^9 (N=31)^2$

Safety data are based off the 106 patients who were treated with pacritinib 200 mg twice daily²

Note: Accelerated approval is based on efficacy data from PERSIST-2 and safety data from PERSIST-2 and PAC203 (a phase 2 dose-finding study). Continued approval may be contingent upon verification and description of clinical benefit in Phase 3 PACIFICA confirmatory study. * The 400 mg once daily dose could not be established to be safe, so further information on this arm is not provided. † The efficacy population included patients who received pacritinib 200 mg BID (n=31) or BAT (n=32) and had baseline platelet counts <50 x 109/L. ‡ Limitation: No conclusions regarding the benefits or risks of pacritinib can be established based on the TSS data from PERSIST-2. These data are not included in the VONJO® Prescribing Information. BID=twice daily; DIPSS=Dynamic International Prognostic Scoring System; MF=myelofibrosis; PET-MF=post-essential thrombocythemia MF; PMF=primary MF; PPV-MF=post-polycythaemia vera MF; QD=once daily.

Baseline demographics

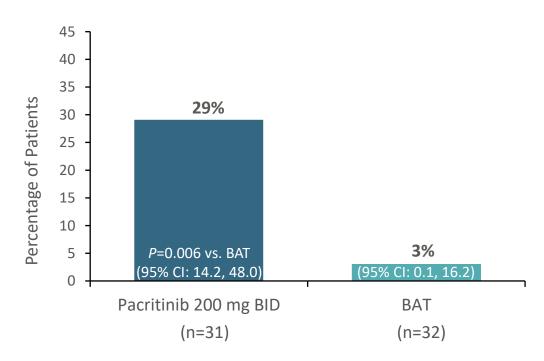


Characteristics	PERSIST-2 patient demographics (ITT population; N=311) ¹		
Median age	68 years (range 32 to 91)		
Gender	55% male, 45% female		
Ethnicity	86% Caucasian, 14% non-Caucasian		
Median baseline platelet count	 55 x 10⁹/L 45% of patients had Grade ≥3 thrombocytopenia (platelet count <50 x 10⁹/L) 		
Median baseline haemoglobin	 9.5 g/dL 23% of patients were red blood cell transfusion dependent at study entry 		
Prior ruxolitinib therapy	Vonjo arm (n=211): 46%	BAT arm (n=100	0): 51%
Disease history	Primary MF: 68%	PPV-MF: 20%	PET-MF: 12%
Baseline median spleen length	14 cm assessed by magnetic resonance imaging or computerized axial tomography		

Pacritinib approval was based on spleen volume reduction in severely thrombocytopenic MF patients

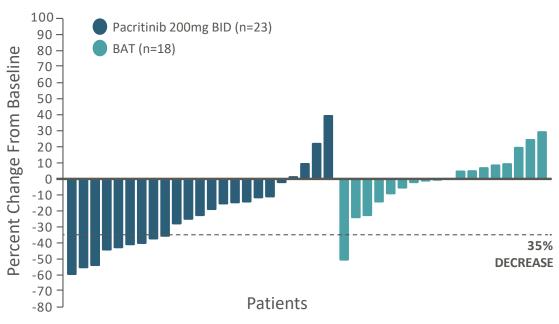


Percentage of patients with platelet counts <50 x 10⁹/L achieving ≥35% SVR from baseline to Week 24 (ITT Efficacy Population)¹



Patients on pacritinib were ~10x more likely to achieve ≥35% SVR vs BAT (29% vs 3%)

Median percent change from baseline in spleen volume at Week 24 in patients with platelet counts <50 x10⁹/L (ITT Efficacy Population)^{1*†}



^{*} Dropout rates in pacritinib and BAT arms were 26% and 44%, respectively.

83% of patients on pacritinib experienced any SVR compared to 56% of patients on BAT in the efficacy population (platelet count $<50 \times 10^9/L$)[†]

[†] Only patients with an available SVR percent change value at Week 24 were included in the waterfall plot.

Pacritinib was observed to be generally well tolerated



Key safety overview from PERSIST-21

Most common adverse events of any grade occurring in ≥20% of patients (N=106) treated with PAC 200mg BID were diarrhoea (45%), thrombocytopenia (32%), nausea (30%), anaemia (23%) and peripheral oedema (19%)

• Most cases of diarrhoea were low-grade, manageable with loperamide and resolved within 1-2 weeks^{1,2}

Serious adverse reactions occurred in 47% of patients treated with PAC 200 mg BID and in 31% of patients treated with BAT

• The most frequent serious adverse reactions occurring ≥3% in patients receiving PAC 200 mg BID were anaemia (8%), thrombocytopenia (6%), pneumonia (6%), cardiac failure (4%), disease progression (3%), pyrexia (3%), and squamous cell carcinoma of skin (3%)

Fatal adverse reactions occurred in 8% of patients receiving PAC 200 mg BID and in 9% of patients treated with BAT

A post hoc risk-adjusted safety analysis showed favourable safety profile for pacritinib 200 mg BID



Events per 100 patient-years are calculated as 100 times the number of patients with an event divided by the cumulative time on treatment for each patient until the first adverse event for patients with an event otherwise the last dose of treatment

Patients with Events Per 100 Patient-Years at Risk¹

	Pooled PAC (PERSIST-2/PAC203*) (n=160)	BAT (n=98)	BAT=RUX (n=44)
Cardiac event ^a	62	81	67
Bleeding event ^a	98	129	127
Thrombosis ^b	4	2	6
Non-melanoma skin cancer events ^c	5	7	11
Infection event ^d	116	88	80
Zoster reactivation ^e	0	2	6
Fungal infection ^f	6	12	6
Deaths	12	22	27

- Rates of fatal events, thrombosis, major adverse cardiac events, non-melanoma skin cancer numerically higher on ruxolitinib than pacritinib¹
- No excess risk of bleeding, on pacritinib, including in patients with severe thrombocytopenia¹
- Infection more frequent on pacritinib vs BAT but no increased risk of zoster or fungal infection¹

Limitation: These data are not included in the Pacritinib Prescribing Information. Results should be interpreted with caution. * PAC203 study: a phase 2, open-label, randomized, dose-finding study of pacritinib in adult patients with intermediate or high-risk primary or secondary myelofibrosis who were intolerant of, or failed to benefit from ruxolitinib. a Cardiac and bleeding events determined by Standardised MedDRA Query. Includes arterial thrombosis, venous thrombosis, thromboembolism, ischemic stroke, and type 1 myocardial infarction. Includes basal cell and squamous cell carcinoma of the skin, as determined by medical review. Includes all events within the Systems Order Class 'Infection'. Includes any infection with the term 'zoster' or 'shingles'. Determined by medical review. BAT=best available therapy; BID=twice daily; PAC=pacritinib; RUX=ruxolitinib Reference: 1. Pemmaraju N, et al. EJHaem. 2022;3(4):1346-1351.

The confirmatory Phase 3 PACIFICA trial is ongoing



PACIFICA Study Design¹⁻³

Key Eligibility Criteria

- PMF, PET-MF, PPV-MF
- DIPSS Intermediate- or highrisk disease
- Severe thrombocytopenia at baseline (<50 x 10⁹/L)
- JAK1/2 inhibitor-naïve or limited duration of prior JAK1/2 inhibitor^{a,b}

2:1 Randomization N=399

Stratification at randomization:

- Prior JAK1/2 inhibitor therapy
- Physician's choice proposed

Pacritinib 200 mg BID

Physician's Choice

- Low-dose ruxolitinib (5 mg QD or BID)
- Hydroxyurea
- Danazol
- Corticosteroids

Co-primary endpoints at 24 weeks:

- SVR ≥35%
- Reduction in TSS ≥50%

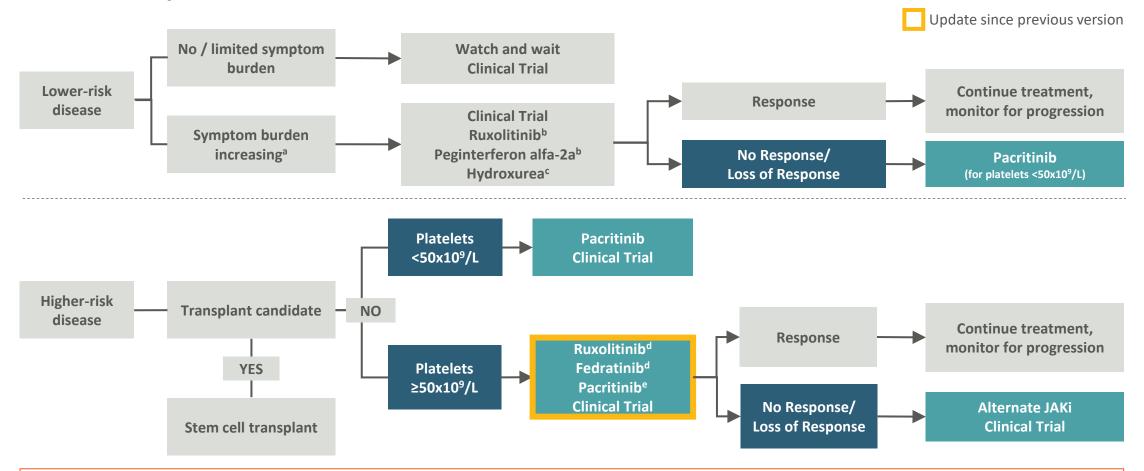
Key secondary endpoints

- Overall survival
- PGIC
- Safety

Recruitment is currently ongoing across 83 sites and 16 countries.

The NCCN guidelines have been recently updated to include pacritinib as a first and second line treatment





Disclaimer: The recommendations provided by the NCCN Guidelines are not contained in the FDA-approved pacritinib (VONJO®) US Prescribing Information and were not part of FDA's evaluation to grant accelerated approval for pacritinib.

^a Supportive Care. ^b Useful in certain circumstances. ^c Hydroxyurea, if cytoreduction would be symptomatically beneficial. ^d Category 1. ^e Category 2B, all other recommendations are category 2A. **Reference:** NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myeloproliferative Neoplasms. V1.2023

Agenda and presenters



Opening remarks



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Emerging Insights & Future Potential of Pacritinib

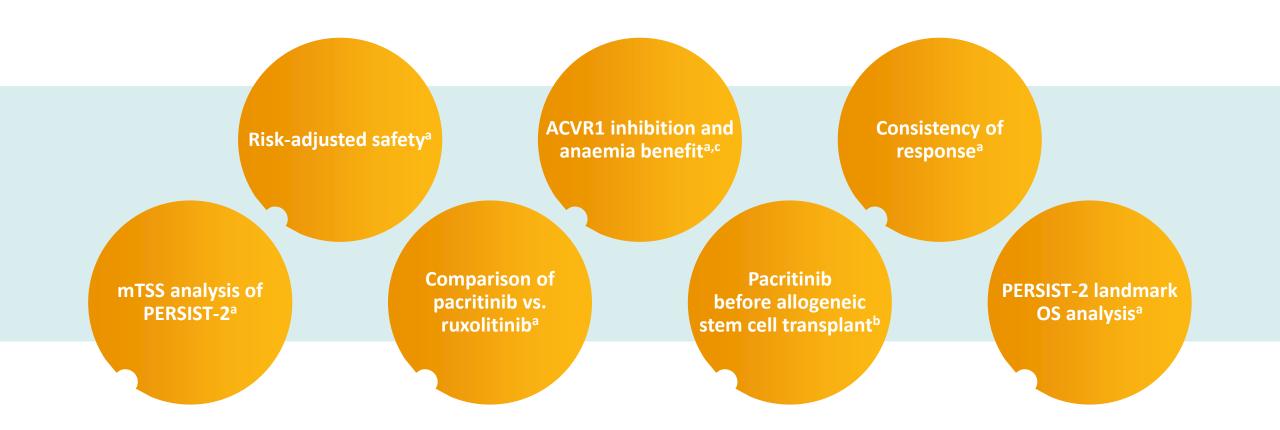


Sarah Buckley, Medicine Development Lead Swedish Orphan Biovitrum

Summary and Q&A

Additional insights have been emerging on the benefit of pacritinib for myelofibrosis patients



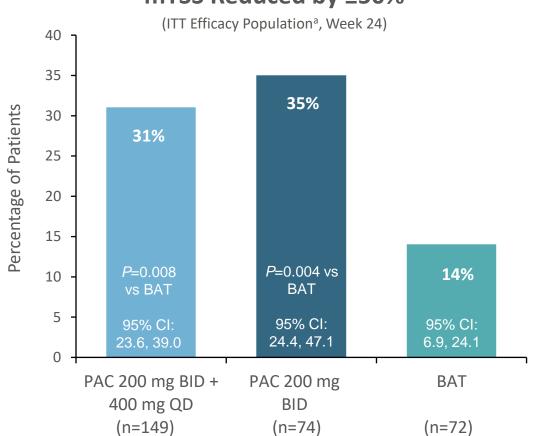


^a Retrospective analysis. ^b Investigator sponsored study (HOVON-134) by Van Dijck, R et al. Oral session (S249) presented at EHA 2023, Frankfurt, Germany. ^c In vitro data. ACVR1=activin receptor-like kinase-2; mTSS=modified total symptom score; OS=overall survival.

mTSS: A retrospective analysis based on mTSS shows PERSIST-2 would have met the primary endpoint



mTSS Reduced by ≥50%^{1,2}



PERSIST-2 included tiredness as part of the total symptom score (TSS) endpoint.

A retrospective analysis of PERSIST-2 based on modified TSS^b, which excludes tiredness, found PERSIST-2 would have achieved the primary endpoint with symptom benefit seen with pacritinib vs. BAT.

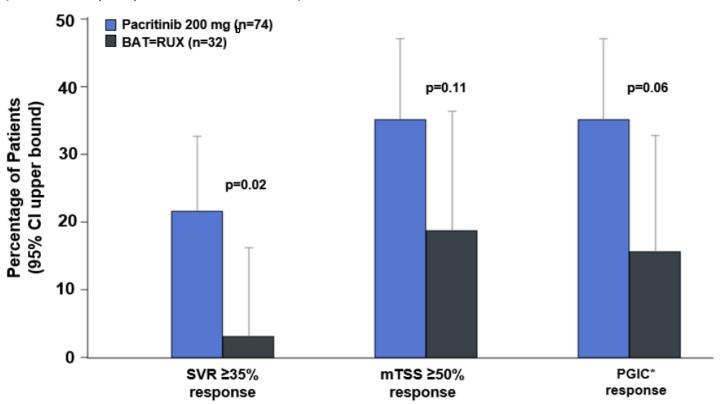
Limitation: No conclusions regarding the benefits or risks of PAC can be established based on the TSS data from PERSIST-2. These data are not included in the Pacritinib Prescribing Information. Results should be interpreted with caution. ^a ITT-efficacy population includes those patients who were randomized ≥22 weeks prior to study termination. ^b mTSS was used for regulatory approval by other JAK inhibitors in myelofibrosis. BAT=best available therapy; BID=twice daily; CI=confidence interval; ITT=intention-to-treat; MF=myelofibrosis; mTSS=modified total symptom score; PAC=pacritinib; QD=once daily. **References: 1.** Palmer J. et al. Poster (#3628) presented at ASH 2021. Atlanta. GA. **2.** FDA Integrated Review. Pacritinib. Version 2.0 (04/23/2020). Reference ID: 4944832.

PAC vs. RUX: Pacritinib 200 mg BID showed larger response compared to ruxolitinib in PERSIST-2



Retrospective Analysis - Efficacy endpoints¹

(ITT Efficacy Population^a, Week 24)

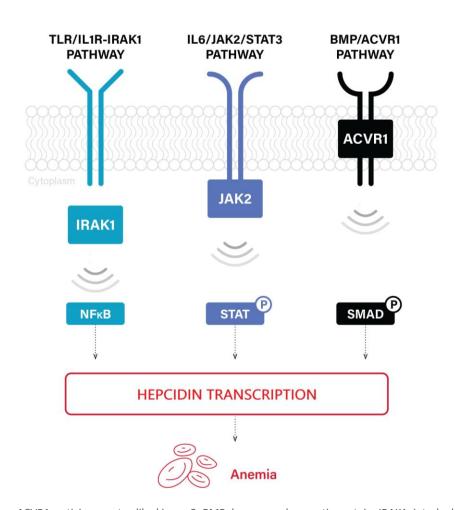


Patients treated with pacritinib versus ruxolitinib achieved higher rates of spleen volume reduction and total symptom score (v2.0, excluding tiredness) at Week 24

PGIC response including "very much improved" and "much improved" was higher with pacritinib than ruxolitinib

ACVR1: Multiple pathways in myelofibrosis can contribute to anaemia





ACVR1 is a receptor kinase that controls the expression of the peptide hormone hepcidin

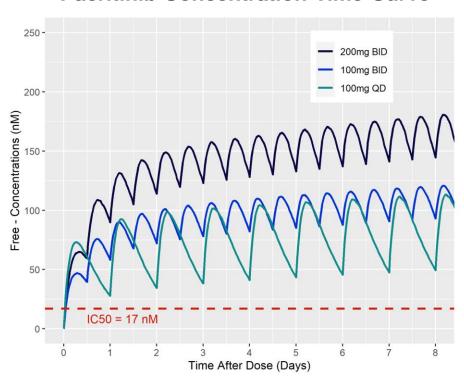
Inhibition of ACVR1 reduces production of hepcidin, which leads to increased iron availability for erythropoiesis

In parallel, inhibition of IRAK1 contributes to the reduction of downstream cytokines, particularly interleukin-6, which also impacts hepcidin expression

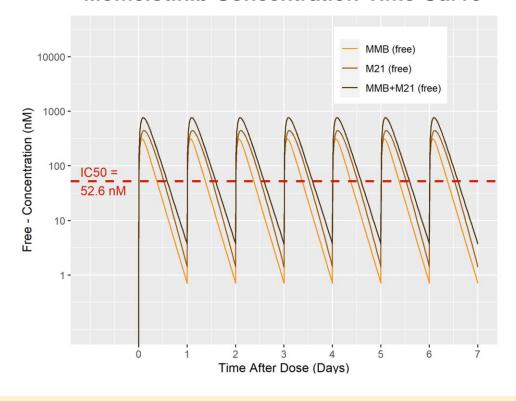
ACVR1: Pacritinib is a potent ACVR1 inhibitor *in vitro*, with predicted 24-hour on-target inhibition



Pacritinib Concentration-Time Curve¹



Momelotinib Concentration-Time Curve¹



Pacritinib is a highly potent, 24-hour inhibitor of ACVR1

Anaemia: Pacritinib increases transfusion independence (PERSIST-2 retrospective analysis)



TI conversion rate (Gale criteria*)¹

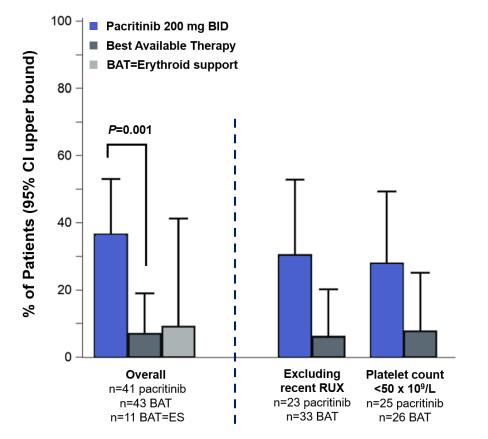
Among patients requiring RBC transfusion at baseline

PAC 200 mg BID N=41	BAT N=43	<i>P</i> -value
37%	7%	0.001

TI conversion was more common on pacritinib than BAT

Rate of Transfusion Independence¹

Over 12-week interval through Week 24 (Gale criteria)



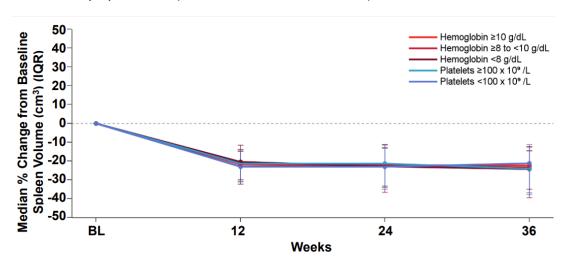
Consistency of response: Pacritinib has similar efficacy regardless of baseline cytopenias



Retrospective Analysis

Spleen Reduction Over Time by Subgroups¹

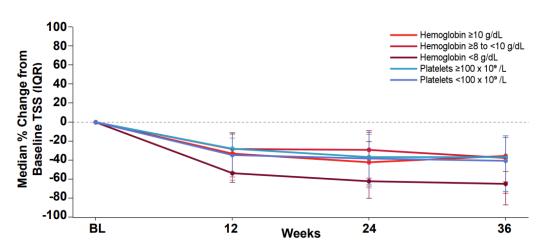
Evaluable population (PERSIST-1 and PERSIST-2)



- The depth of Week 24 spleen reduction was consistent across all analysed platelet and haemoglobin subgroups
- Spleen reduction occurred by Week 12 across all subgroups and remained consistent over time

TSS Reduction Over Time by Subgroups¹

Evaluable population (PERSIST-1 and PERSIST-2)



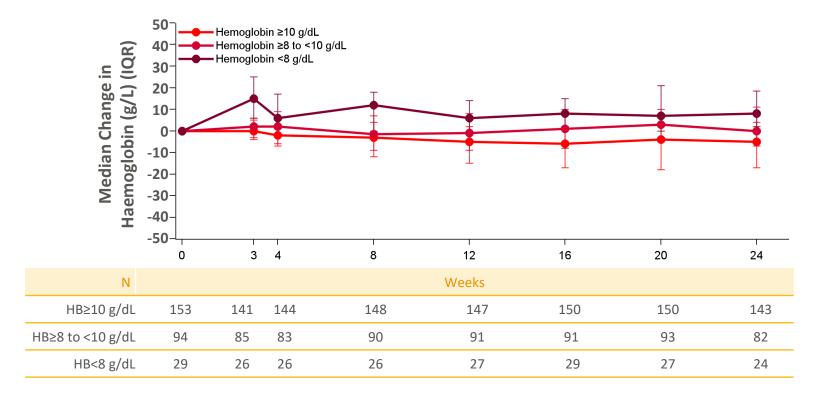
- Symptom improvement occurred consistently across subgroups, with greatest improvement in patients with baseline haemoglobin <8 g/dL
- Some ongoing improvement seen beyond Week 12

Consistency of response: Haemoglobin stability/improvement with pacritinib



Median Change in Haemoglobin Over Time by Baseline Haemoglobin Subgroups¹

Evaluable population (PERSIST-1 and PERSIST-2); retrospective analysis



Median haemoglobin remains stable through Week 24

Improvements in haemoglobin observed in subgroup with baseline haemoglobin <8 g/dL

The future potential of pacritinib





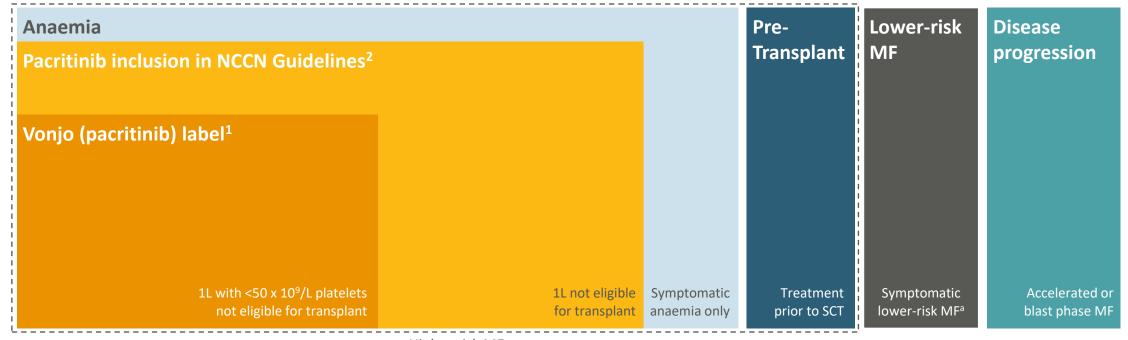
We are committed to exploring the potential of pacritinib to benefit patients in myelofibrosis and beyond

Pacritinib has the potential to address unmet needs in additional patient populations in myelofibrosis



Illustration of myelofibrosis patient populations

Approx. 20k myelofibrosis patients in the US

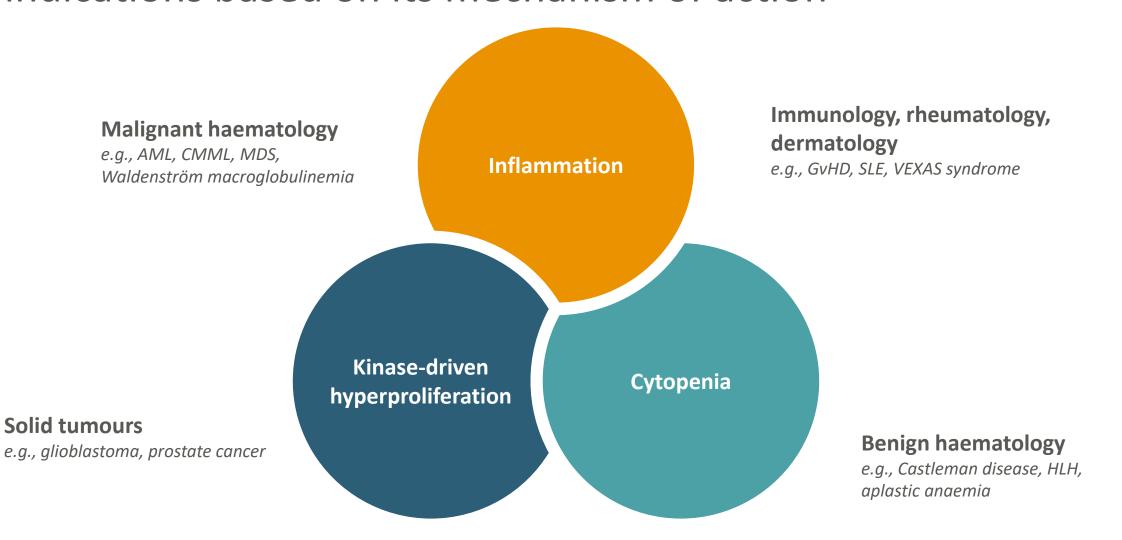


Higher-risk MF

Pacritinib alone or combination with novel agents currently in development may be able to address unmet needs in myelofibrosis patient populations beyond its current label

Treatment with pacritinib could be beneficial in other indications based on its mechanism of action





Pacritinib is well positioned for further exploration of its benefits in myelofibrosis and beyond







Additional data generation into the benefit of pacritinib in different patient populations to understand its potential and enable wider patient access



Strong scientific rationale for benefit of pacritinib as combination partner of choice in myelofibrosis as well as in other diseases with underlying inflammation-driven pathophysiology



Regulatory submissions in international markets based on current label and supported by additional data from PACIFICA trial

Agenda and presenters



Opening remarks



Guido Oelkers, Chief Executive Officer Swedish Orphan Biovitrum

Overview of Myelofibrosis and Vonjo



John Mascarenhas, Professor of Medicine
Icahn School of Medicine at Mount Sinai

Emerging Insights & Future Potential of Pacritinib



Sarah Buckley, Medicine Development Lead Swedish Orphan Biovitrum

Summary and Q&A

Combined leadership in haematology





Vonjo has a differentiated profile in myelofibrosis





Severe thrombocytopenic MF represents an **unmet** clinical need



Complementary haematology reach and expertise



Expectation: highly accretive to Sobi's revenue and margins

