



## Equity Raising Presentation

Gary Phillips, CEO

December 2024

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# Investment Highlights



Australian-founded **clinical stage drug developer**.



Backed by **specialist healthcare investors** – 52% institutional.



Focus on first-in-class and best-in-class drugs backed by **in house long-life patent portfolio**.



Currently funded to mid-2025 with **near term data to drive value** over 12-18 months.



**Multiple shots on goal** from additional Phase 2, Phase 1 and preclinical assets.



Experienced team with **proven track record** in licensing deals – \$100m raised.



Three Phase 2 studies in **blood cancer indications** with addressable market value >\$4.5 bn.



**\$8.5m in non-dilutive** grant funding awarded in last 3 years.



## **December 2024 Trial Update:**

Positive interim data from Phase 2 clinical trial evaluating SNT-5505 in combination with ruxolitinib for the treatment of myelofibrosis suggest that SNT-5505 has potential as a breakthrough therapy

# Syntara Board

## Significant international pharmaceutical experience



**Dr Kathleen Metters**  
Chair

- Former Senior Vice President and Head of Worldwide Basic Research for Merck & Co. with oversight of the company's global research projects.
- In a subsequent role at Merck & Co she led work on External Discovery and Preclinical Sciences (1a).
- Former CEO of biopharmaceutical company Lycera Corp.



**Dr Simon Green**  
Non-Executive Director

- Experienced senior global pharma executive with 30 years' of experience in the biotechnology industry.
- Actively involved in CSL's global expansion over a 17-year period where he held roles as Senior Vice President, Global Plasma R&D and General Manager of CSL's manufacturing plants in Germany and Australia.
- Prior to joining CSL he worked in the USA at leading biotechnology companies Genentech Inc and Chiron Corporation.



**Gary Phillips**  
Chief Executive Officer

- 30+ years' of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia.
- Joined Syntara in 2003 and was appointed Chief Executive Officer in March 2013 at which time he was Chief Operating Officer.
- Previously held country and regional management roles at Novartis – Hungary, Asia Pacific and Australia.



**Hashan De Silva**  
Non-Executive Director

- Experienced life sciences investment professional with extensive knowledge of the biotech, pharmaceutical and medical technology sectors.
- Currently the Founder and Managing Partner of KP Rx, an ANZ focused healthcare VC firm. KP Rx is seeded and supported by Karst Peak Capital where Mr De Silva was the Head of Healthcare Research until December 2022. Previous roles include associate healthcare analyst at Macquarie Group covering ASX-listed healthcare companies and lead healthcare analyst at CLSA Australia.
- Prior to moving into life science investment he worked at Eli Lilly in various roles focused on the commercialisation of new and existing pharmaceuticals.

# Experienced senior management team

Significant global experience in drug development, commercialisation and partnering



**Gary Phillips**  
Chief Executive Officer

- 30+ years' of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia.
- Previously held country and regional management roles at Novartis – Hungary, Asia Pacific and Australia.



**Jana Baskar**  
Chief Medical Officer

- 20+ years' experience both in clinical medicine and the biopharmaceutical industry.
- Former Medical Director at Novartis Oncology in Australia; former Medical Director for IQVIA in Australia and New Zealand.



**Wolfgang Jarolimek**  
Head of Drug Discovery

- 20+ years' experience in pharmaceutical drug discovery and published more than 40 peer reviewed articles.
- Previously Director of Assay Development and Compound Profiling at the GlaxoSmithKline Centre of Excellence in Drug Discovery in Verona, Italy.



**Tim Luscombe**  
Chief Financial Officer

- 10+ years' experience as a Chartered Accountant both locally and abroad, Tim is a Director of Bio101, a professional services firm specialising in the Healthcare sector. Tim currently acts as outsourced CFO for a number of ASX listed healthcare companies, private University spin out companies and Venture Capital investee companies.



**Kristen Morgan**  
Head of Medical & Regulatory Affairs

- 20+ years' experience in the pharmaceutical industry.
- Previously held a senior role in medical affairs at Sanofi-Aventis, and a commercial sales role at GlaxoSmithKline.



**Dieter Hamprecht**  
Head of Chemistry

- 20+ years' experience with small molecule and peptide drug discovery, contributed to greater than 10 drug candidates brought to development and co-inventor of 50 patent families, co-author of 30+ scientific publications.
- Previously Managing Director – Boehringer Ingelheim's research group in Milan.

## Scientific excellence

- Global leaders in amine oxidase chemistry and biology – key to inflammatory and fibrotic diseases
- 3 Nature publications with collaborators in last 2 years

## Drug development expertise

- 6 drugs through preclinical and phase 1 / IND eligible since 2015
- 5 of these drugs went on to successfully clear phase 1
- 3 drugs completed Phase 1c/2 patient clinical proof of concept studies with acceptable safety and signs of efficacy

## Commercial acumen

- Three licensing / asset sale deals worth ~\$100m in cash receipts
- Extensive Pharma industry networks



# SNT-5505; Lead asset and a key driver of value

The interim results were presented at the 66th American Society of Hematology annual meeting (ASH). Further interim data to be released in 1H 2025 and final data in 2H 2025.



- FDA IND and orphan drug designation in myelofibrosis
- First and best in class pan-LOX inhibitor
- Long patent life
- Multiple Nature publications
- Phase 2 trial data as a monotherapy and interim data in combination with ruxolitinib presented at ASH
- Potential breakthrough therapy for sub-optimal myelofibrosis patients
- Contingent on success of the current trial, potential to commence a pivotal registration trial in 2025 and/or partnering



# Multicenter, Open-Label Phase 1/2a Study of PXS-5505 and Ruxolitinib in Patients With Primary, Post-Polycythemia Vera (PV) or Post-Essential Thrombocythemia (ET) Myelofibrosis

(NCT04676529)

## Oral Presentation #1001

presented on Monday 9<sup>th</sup> December at ASH 2024

### Contributing Investigators:

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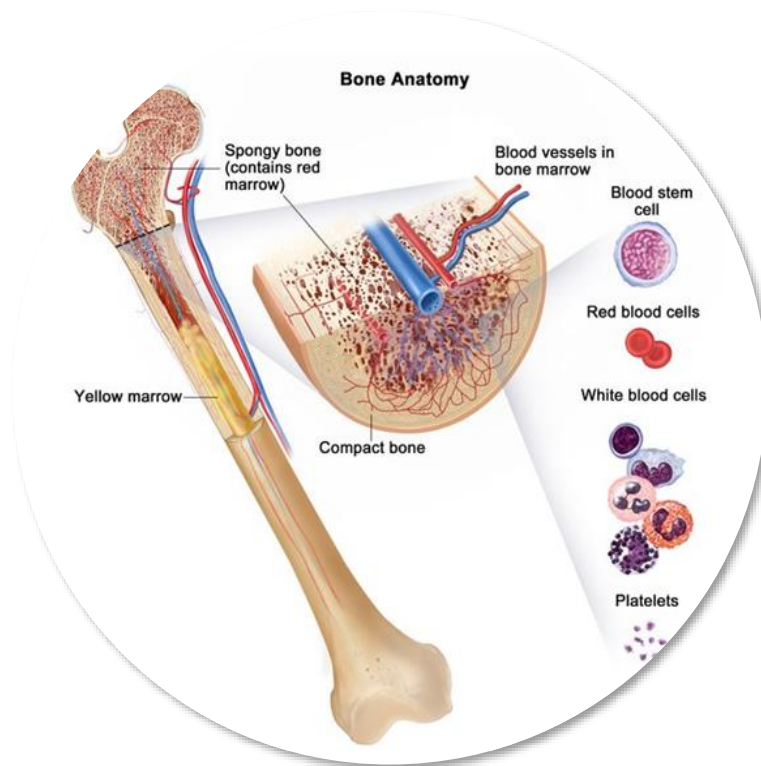
# Myelofibrosis

A rare type of bone marrow cancer that disrupts the body's normal production of blood cells

## Key Facts

- Affects ~15 in 1m people worldwide
- Age of onset typically from age 50; 5 years median survival
- 11% transformation to leukemia
- Reduced red blood cells can cause extreme tiredness (fatigue) or shortness of breath
- Reduced white blood cells can lead to an increased number of infections
- Reduced platelets can promote bleeding and/or bruising
- Enlarged spleen due to insufficient healthy blood cell production from the bone marrow
- Other common symptoms include fever, night sweats, and bone pain.

**Primary Myelofibrosis is characterised by a build up of scar tissue (fibrosis) in bone marrow reducing the production of blood cells.**



## Current standard of care (SoC): JAK inhibition

- Symptomatic relief plus some limited survival improvement.
- 75% discontinuation at 5 years
- Median overall survival is 14 – 16 months after discontinuation

## SNT-5505

In contrast to SoC SNT-5505 intervenes at the source, clearing fibrosis from the bone marrow and reducing growth factor activity; thus enabling increased production of healthy blood cells

## Clinical positioning

- Distinct mode of action, improved tolerability and a profile suitable for combination with SoC
- In addition to symptomatic relief, potential for disease modification.

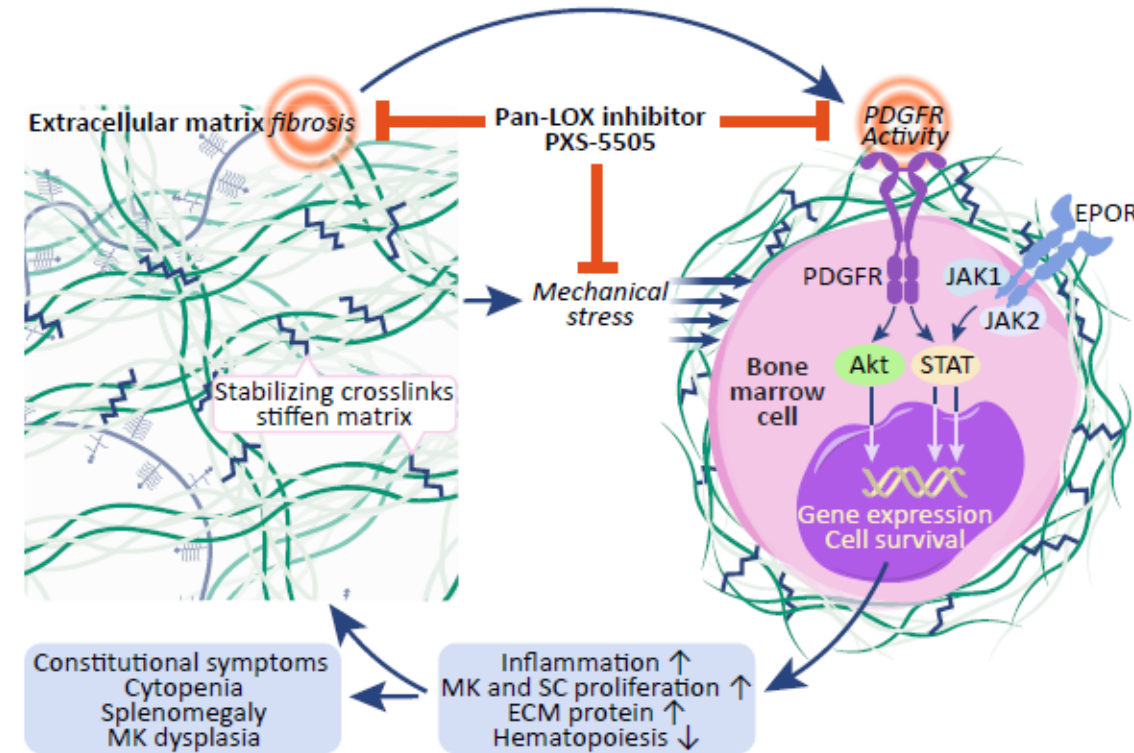
## Commercial Opportunity

- Current SoC; revenue ~US\$1b per annum
- Recent history of biotech exits in excess of US\$1.7b

# The role of lysyl oxidases in myelofibrosis

## SNT-5505 designed to improve the bone marrow microenvironment

- Lysyl oxidase gene family upregulated in the bone marrow (BM) of myelofibrosis patients<sup>1</sup>
- Increased lysyl oxidase activity<sup>1</sup>:
  - Catalyzes the formation of stabilizing crosslinks leading to a stiff BM microenvironment that exerts mechanical stress
  - Builds a fibrotic matrix that fosters abnormal megakaryocyte and stem cell development
  - Boosts PDGFR- $\beta$ -initiated mitotic proliferation in BM cells
- In preclinical models of MF, lysyl oxidase inhibitors (pan-LOX) reduce<sup>1</sup>:
  - BM fibrosis
  - Spleen size
  - Megakaryocyte count

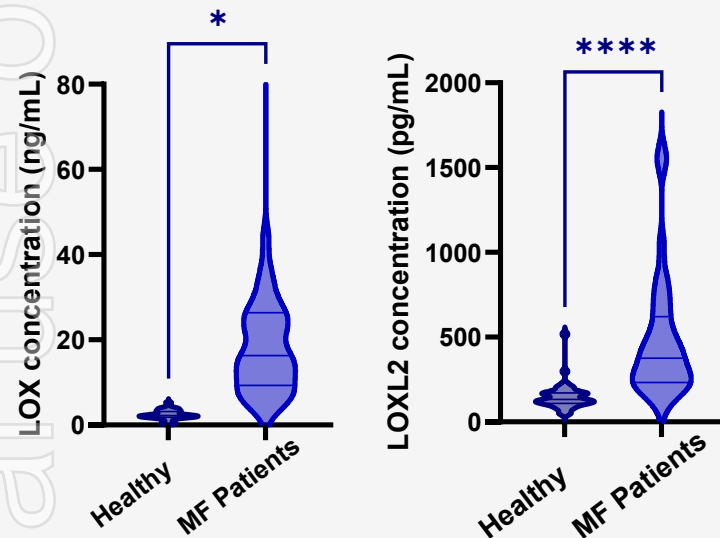


<sup>1</sup> The role of lysyl oxidases in MF reviewed by Leiva et al. *Am. J. Hematol.* 2018 DOI: 10.1002/ajh.25008

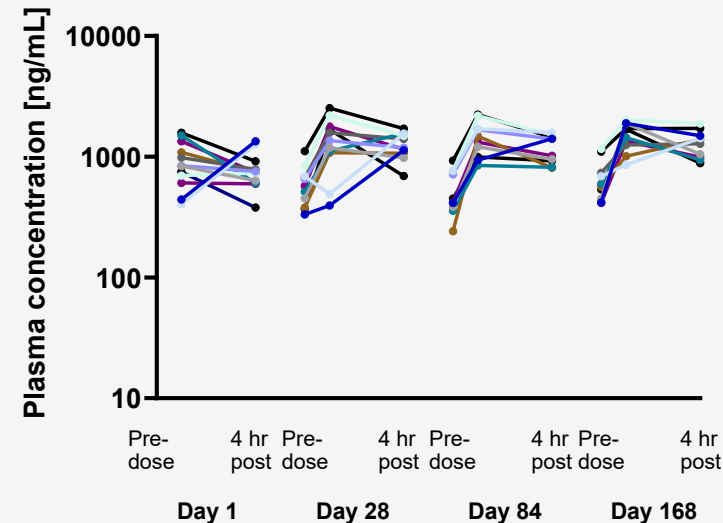
# Elevated LOX in MF targeted by SNT-5505

**SNT-5505 demonstrates >90% target inhibition<sup>1</sup>**

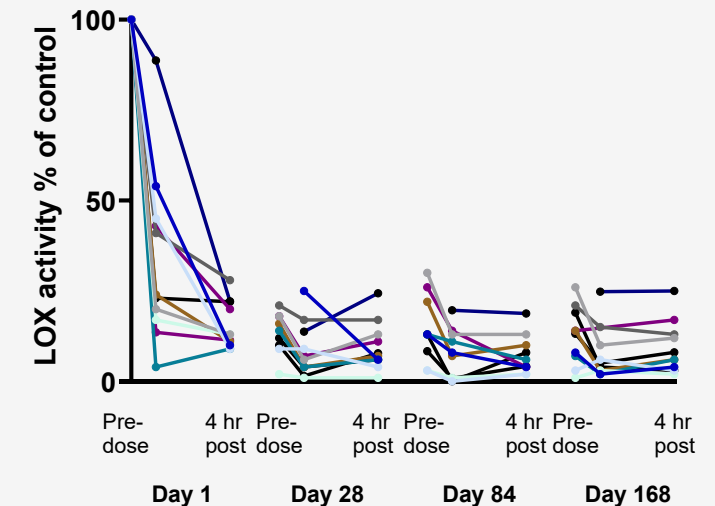
LOX and LOXL2 are upregulated in MF patients (plasma)



Very consistent SNT-5505 plasma levels across patients



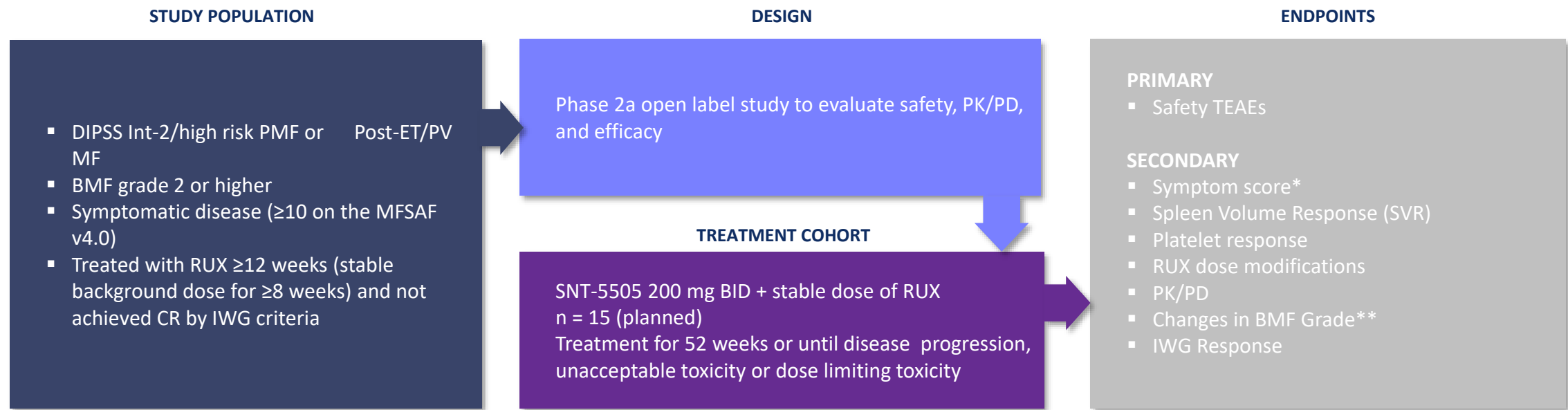
High target engagement even at trough (pre-dose)



**SNT-5505 monotherapy study in relapsed/refractory patients showed 200 mg BID was well tolerated. Excellent target engagement with preliminary indications of clinical activity.<sup>1</sup>**

SNT-5505-MF-101 Add-on to RUX (study in progress)<sup>1</sup>

- This add-on phase aims to further evaluate the safety and efficacy of SNT-5505 (200 mg BID) in patients with MF on **stable background regimens of ruxolitinib** (RUX) over a 52-week period



\*MFSAF v4.0 (Myelofibrosis Symptom Assessment Form v4.0; 7-day recall)

\*\*Bone marrow biopsy within 3 months prior to Day 1 treatment; bone marrow biopsies scheduled at baseline, weeks 12, 24 and 52

<sup>1</sup> Tan et al ASH 2024

# Baseline characteristics

## Heterogenous population with a high disease burden<sup>1</sup>

- Study is ongoing – data extracted 14 Nov 2024
  - 13 patients (pts) reached 12 week visit
  - 8 pts reached 24 week visit
  - 5 pts reached 38 week visit
- 12/16 pts continue on SNT-5505
- 4 pts have discontinued
  - 2 due to physician decision
  - 1 due to patient decision
  - 1 due to unrelated SAE, pneumonia
- Total exposure in the add-on phase to date is 390 weeks, median 24 weeks (range 5–48)

Characteristic	N=16
Age, median (range), years	71 (46-82)
Sex, male, n (%)	7 (44)
Time since MF diagnosis, median (range), months	60 (7–134)
Diagnosis, n (%)	
Primary MF	7 (44)
Post-PV MF	7 (44)
Post-ET MF	2 (13)
<b>Prior RUX therapy (months), median (range)</b>	<b>38 (5–89)</b>
Daily RUX dose (mg), median (range)	20 (5–40)
<b>MF-SAF v4.0 TSS score, median (range)</b>	<b>23 (10–52)</b>
IPSS, n (%)	
Intermediate-2	12 (75)
High-risk	4 (25)
JAK2 V617F mutation, n(%)	10 (63)
<b>≥1 High Molecular Risk (HMR) mutation, n (%)</b>	<b>7 (44)</b>
Transfusion dependent (TD), n (%)	2 (13)
Hb, median g/L (range)	93 (66-132)
Platelet count, x10 <sup>9</sup> /L, median (range)	116 (18 - 355)

Of the 16 enrolled patients, 12 patients were continuing to receive treatment as of the ASH data cut off. Subsequent to the data cut off, a further three patients discontinued after receiving 6 months of therapy. No discontinuations for adverse events were considered related to SNT-5505 treatment. This level of discontinuations in clinical trials is consistent with a patient group with a high disease burden.

<sup>1</sup> Tan et al ASH 2024



SNT-5505 has been well tolerated with no treatment related SAEs<sup>1</sup>

- Majority of AEs were mild, 44/61 (72%) ≤ Grade 2
- 82% of AEs considered not related to treatment
- 11 possibly related AEs\*
- 1 death due to unrelated SAE (congestive heart failure)
- 7 other non-hematological SAEs reported (all unrelated to SNT-5505\*)

\* Investigator’s assessment of relatedness

Pts with Grade 3/4 AEs Regardless of Causality<sup>#</sup>

Adverse Event	Grade 3 N=16	Grade 4 N=16
Anemia	4	
Platelet decrease		1
Urinary Tract Infection	2	
Ear Nose & Throat infection	1	
Odema Peripheral	1	
Pneumonia	1	
Sialoadenitis	1	

<sup>#</sup>Number of patients with events shown; for patients with multiple events of same Preferred Term, worst grade is shown

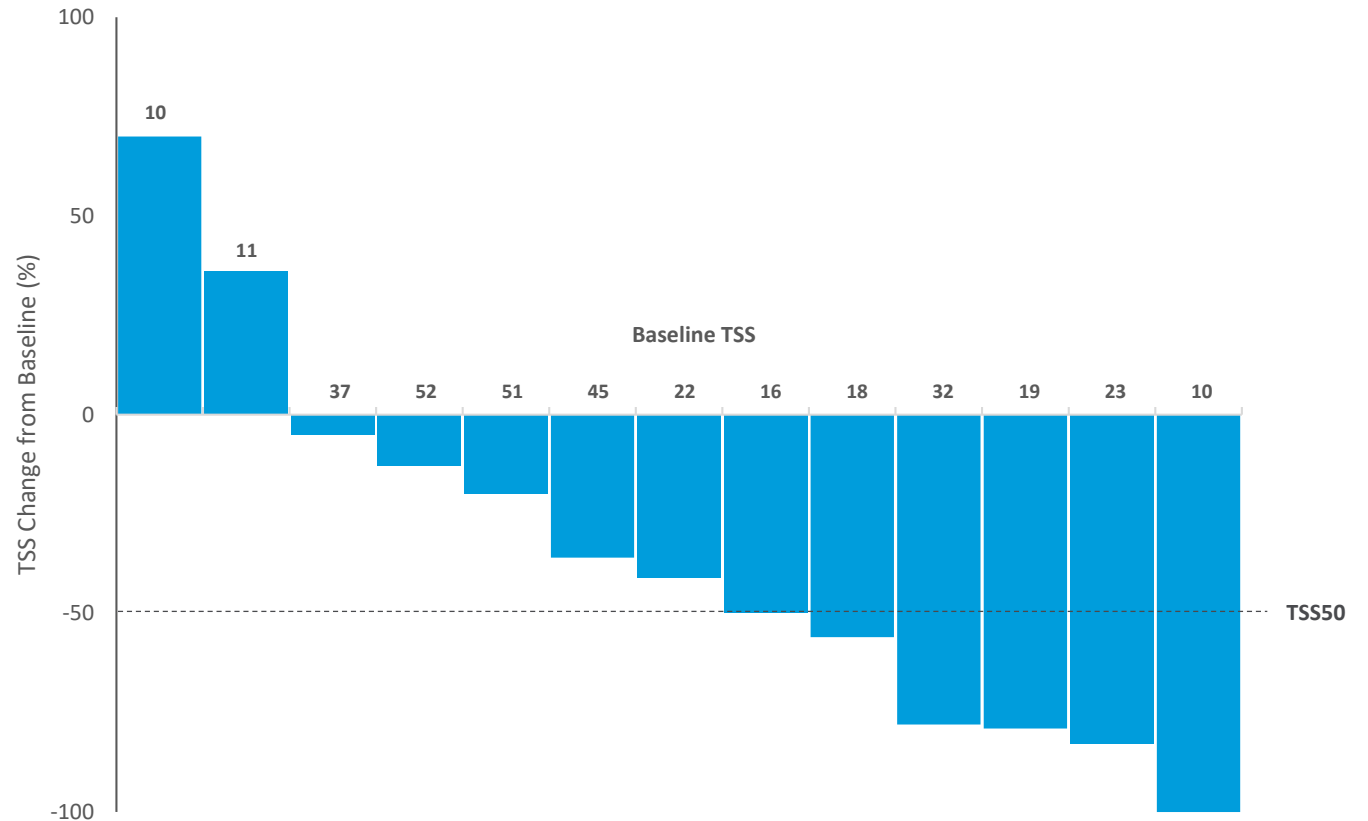
Good safety and tolerability is a highly valued quality in MF drugs and a key differentiator for SNT-5505

<sup>1</sup> Tan et al ASH 2024

# Total symptom score

## Improvements seen in TSS from Baseline to Week 12<sup>1</sup>

- 6/13 pts (46%) achieved TSS50
- Median absolute change was -10
- Median % change was -41%



**TSS50 is widely used in clinical trials and by regulators as a threshold for a meaningful response to treatment**

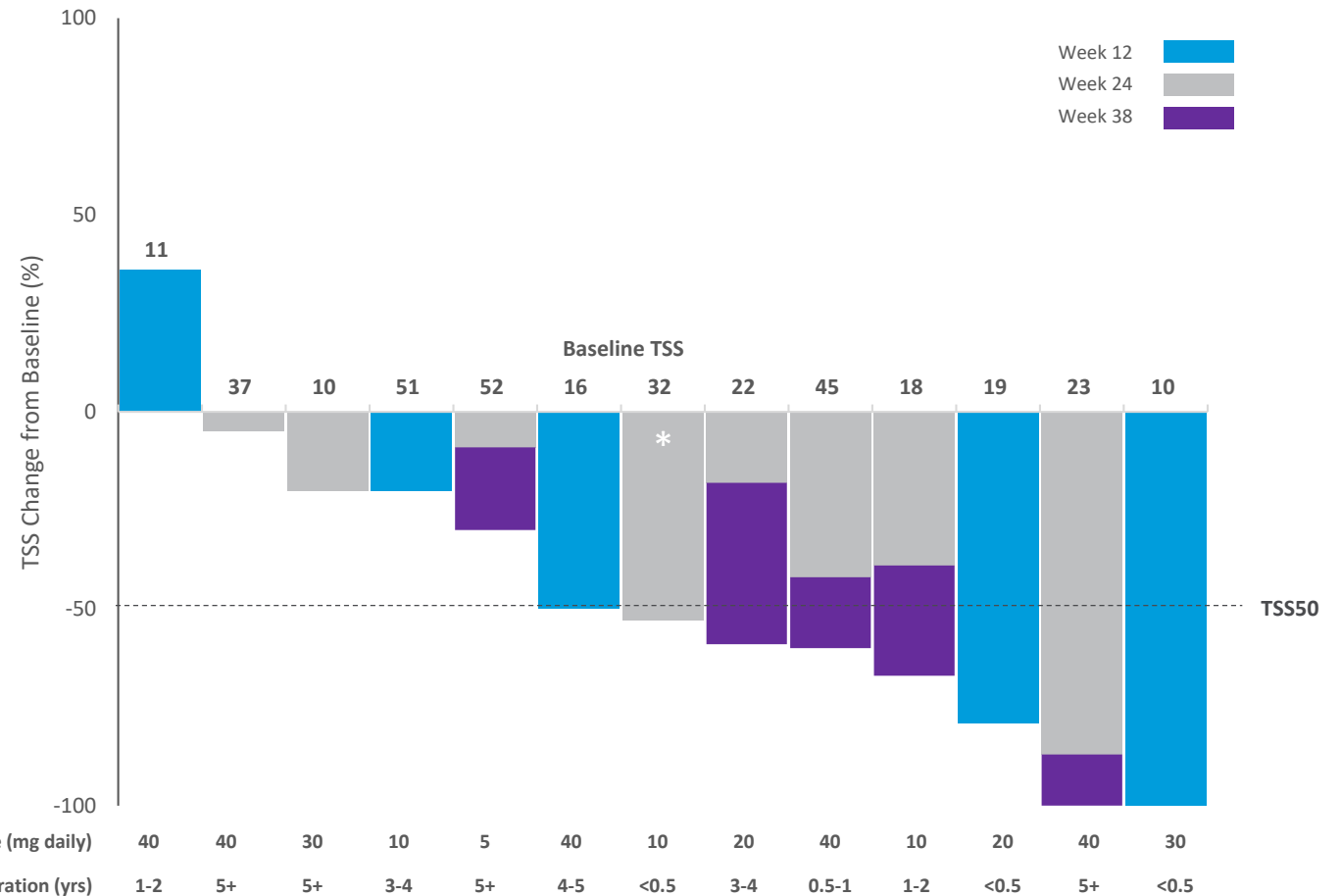
<sup>1</sup> Tan et al ASH 2024

# Total symptom score over time

## Substantial reduction in TSS observed in the majority of patients<sup>1</sup>

- 8/13 pts (62%) reached TSS50 up to Week 38
- Improvement in TSS continue over time
- TSS improvement despite a prior RUX duration of 2+ years and low doses ( $\leq 20$  mg per day)
- No changes in RUX dose

<sup>1</sup> Tan et al ASH 2024



Week 12 data shown where subsequent visits have not yet occurred

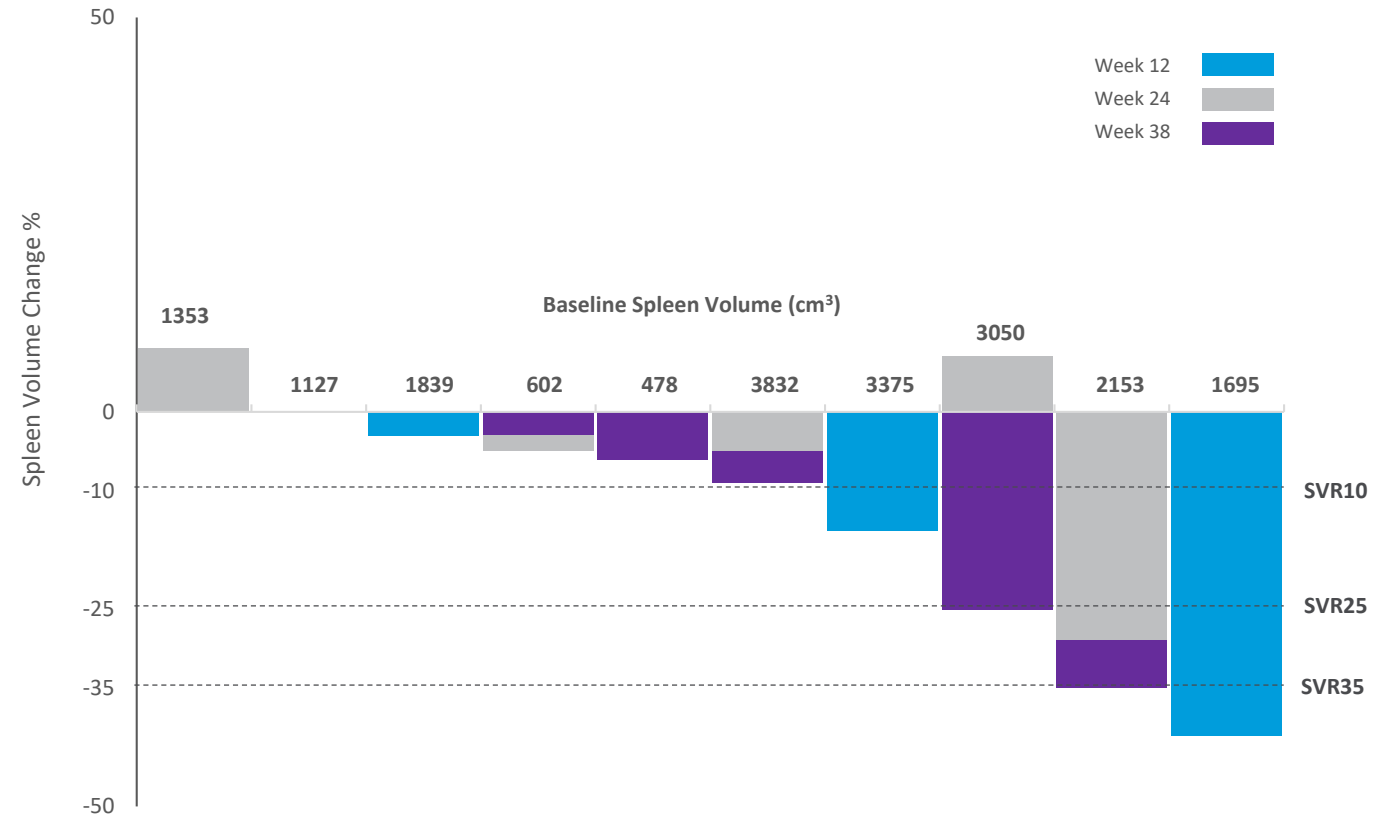
\*RUX dosing interrupted from Week 4 – 12 due to SAE / surgical procedure

**62% of patients achieving TSS50 up to week 38 after long treatment periods on RUX is a clinically important finding**

# Spleen volume over time

## Additional reductions seen with longer treatment<sup>1</sup>

- 11/13 pts had spleen volumes at baseline > 450 cm<sup>3</sup>
- 9/11 pts (82%) had either stable or reduced spleen volume
- Additional improvements at Weeks 24 and 38 without changes to RUX
- Spleen volume reduction observed despite prior RUX duration of 2+ years and low doses (≤20 mg per day)



<sup>1</sup> Tan et al ASH 2024

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BL RUX Dose (mg daily)	40	20	30	10	20	40	10	5	40	40
Prior RUX Duration (yrs)	5+	<0.5	<0.5	1-2	3-4	5+	3-4	5+	0.5-1	1-2

N.B: 2 pts with spleen volume < 450 cm<sup>3</sup> at baseline omitted from plot

1 pt who interrupted RUX dosing from Weeks 4–12 and from Week 15 onwards omitted from plot

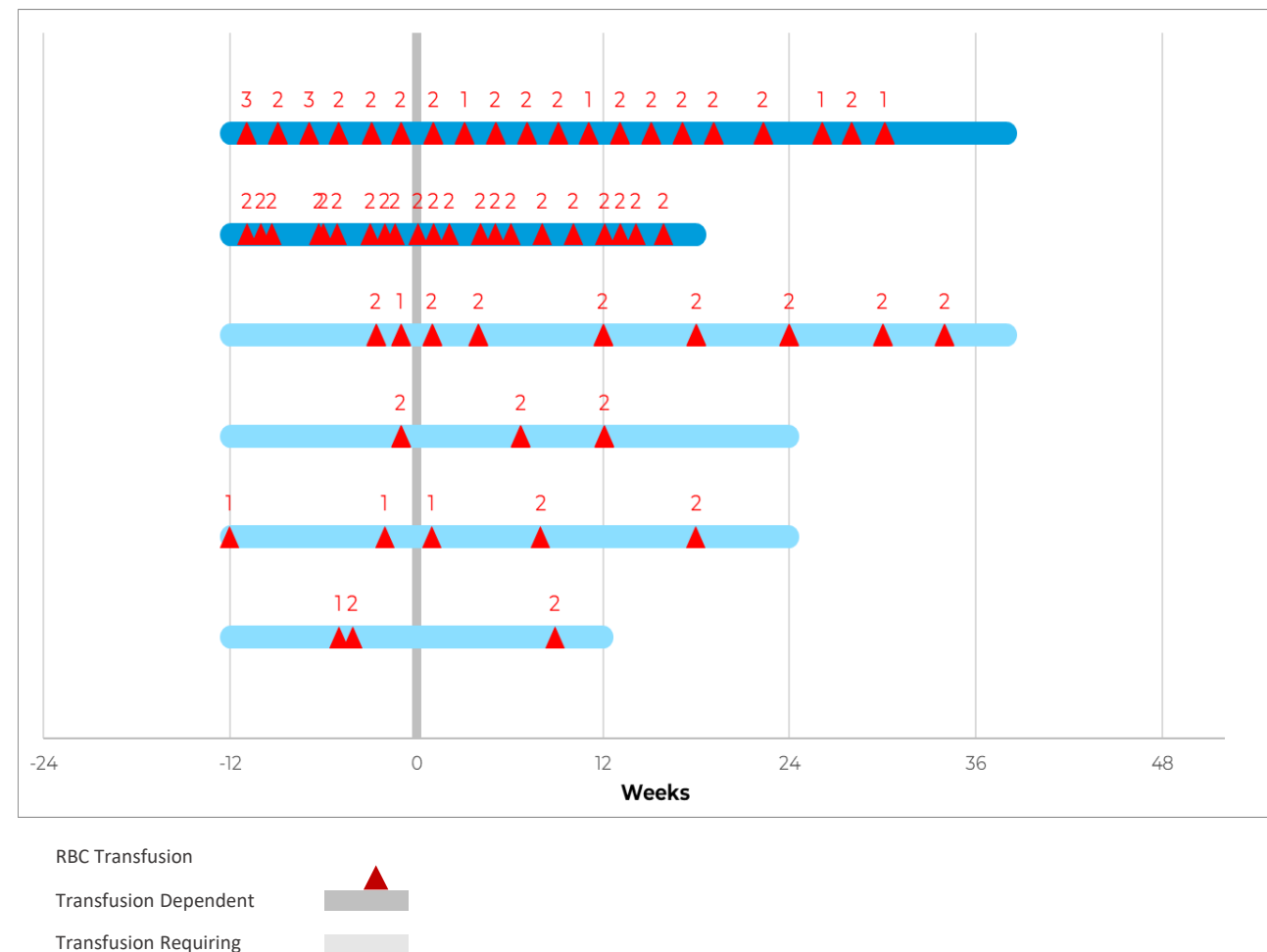
**SVR35 is a threshold commonly used in clinical trials and by regulators**  
**SVR25 is considered clinically meaningful in a sub optimal population**

# Hematology parameters

## Stable with some observed decreases in transfusion burden<sup>1</sup>

- Of the 13 pts with  $\geq 3$  months treatment, at baseline:
  - 2 transfusion dependent
  - 4 receiving transfusions
  - 7 not receiving transfusions
- 1/2 transfusion dependent pts had over 50% reduction in RBC transfusions
- 5/7 pts not receiving transfusions had stable hemoglobin levels
- 8/13 pts had stable or improving platelet counts

<sup>1</sup> Tan et al ASH 2024

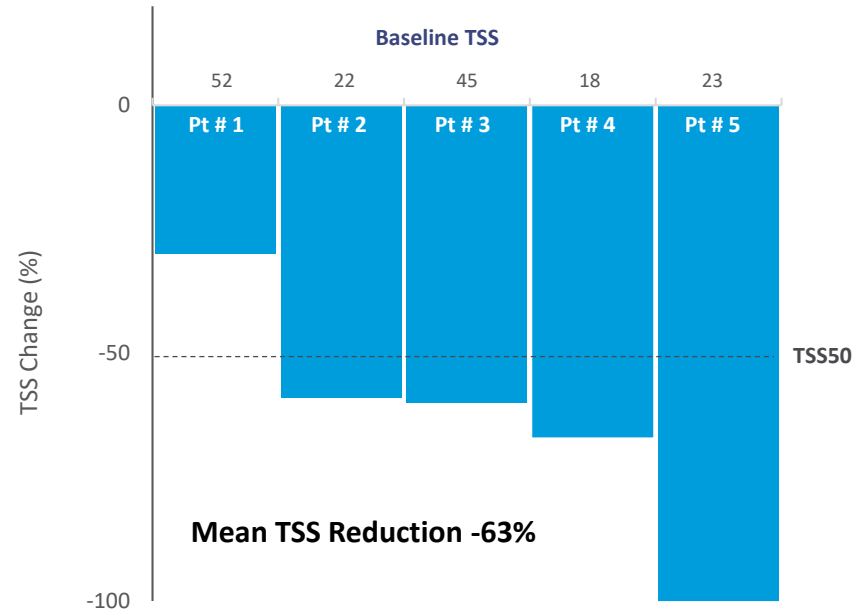


Monitoring ongoing haematological safety and efficacy outcomes is a key factor in fully characterising the profile of SNT-5505 after 12 months therapy



# Efficacy outcomes at Week 38

Longer duration of therapy leads to additional improvements<sup>1</sup>



BL RUX Dose  
(mg daily)

5

20

40

10

40

Prior RUX  
Duration (yrs)

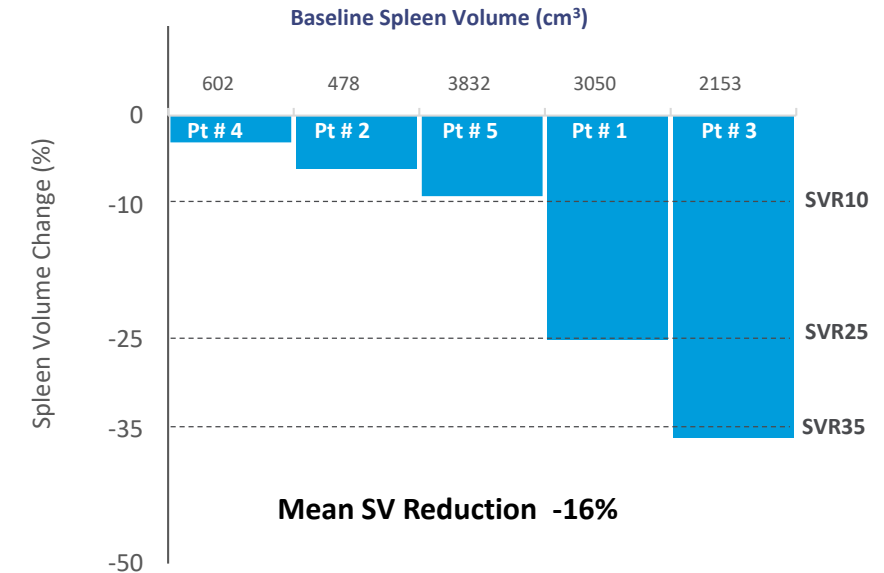
5+

3-4

0.5-1

1-2

5+



BL RUX Dose  
(mg daily)

10

20

40

5

40

Prior RUX  
Duration (yrs)

1-2

3-4

5+

5+

0.5-1

**TSS improvements that are sustained or even improving with longer treatment periods is a key differentiating point from existing treatments**

<sup>1</sup> Tan et al ASH 2024

# Competitive landscape

Data from comparative open label phase 2 studies for drugs currently under later stage development in MF

Drug	Latest Program Status	Phase 2 Open Label Trial results in suboptimal patient population				
		N	Baseline characteristics (median, range)	Safety Grade 3/4 events ≥ 10%	TSS50	SVR35
Pelabresib <sup>1</sup>	P3 naïve MF completed  Not pursuing suboptimal indication	86	Not reported	Thrombocytopenia 33% Anemia 19% Increased blast phase progression <sup>4</sup> All grade diarrhea (35%), constipation (25%), nausea (24%), abdominal pain (23%). Managed with standard prophylaxis	37% (30/81) at W24  not reported at W48	20% (19/81) at W24  20% (16/80) at W48
Navtemadlin <sup>2</sup>	P3 suboptimal recruiting	28	Rux duration: 21.6 mths (7-129)  SV: 2039 ml (650-3549)  TSS: 15 (2.2-49.1)	Thrombocytopenia 28% Anemia 18% All grade diarrhea (64%) and nausea (68%); require anti-diarrheal and anti-emetic prophylaxis in P3	32% (6/19) at W24	32% (6/19) at W24
Navitoclax <sup>3</sup>	P3 suboptimal completed accrual	34	Rux duration: 19 mths (4.4-71)  SV: 1695 ml (465-5047)  TSS: Not reported	Thrombocytopenia 56% Anemia 32% Pneumonia 12% Dose reduced 76% (Navitoclax), 68% (Rux) mainly due to AEs	26% (9/34) at W24	30% (6/20) at W24
SNT-5505	P2 suboptimal Trial ongoing <u>interim</u> results	16	Rux duration: 38 mths (5-89)  SV: 1553 ml (258-9781)  TSS: 23 (10-52)	Anemia 25% (not drug related) Urinary Tract Infection 12.5% Majority of AEs, mild (72% ≤ Grade 2) <u>No</u> treatment related SAEs <u>No</u> prophylaxis required for AEs	46% (6/13) at W12  80% (4/5) at W38	9% (1/11) by W12  20% (2/10) by W38

1 EHA and ASH 2022 abstracts; 2 EHA 2023 press release; 3 Harrison et al 2022 JCO publication; 4 OncoLive 2024

SV spleen volume, TSS total symptom score, GI gastrointestinal, Rux ruxolitinib; AE adverse event; SAE serious adverse event

**Interim data suggests that SNT-5505 has a well differentiated and competitive profile compared to existing drugs and those in later stage development**

# Strong interest in myelofibrosis assets from strategics

Target / Acquiror



Date of Announcement	Feb-2024	June-2023	July-2022
Drug Name	Pelabresib	Pacritinib	Momelotinib
Lead Indication / Phase (at transaction)	Myelofibrosis (Successful Phase 3 studies)	Myelofibrosis (Marketed)	Myelofibrosis (FDA Filed – June)
Deal Type	Acquisition	Acquisition	Acquisition
Upfront / Milestones (USD)	US\$2.9B	US\$1.7B	US\$1.9B
Earnout Payments / Royalty Rate (%)	Subject to regulatory approvals	None	None

Attractive commercial outcomes for drugs with phase 3 data expected to drive interest in SNT-5505 phase 2 data

# ASH interim data<sup>1</sup>: Conclusions and outlook

**Interim data suggests SNT-5505 combined with ruxolitinib may deliver deep and long lasting benefit to patients who are sub-optimally controlled on ruxolitinib alone**

Consistent with monotherapy data<sup>2</sup>, SNT-5505 is safe and well tolerated in combination with RUX in a broad population with high disease burden

Despite the relatively small sample size the absolute improvement in symptom score and the number of patients who achieve a TSS50 is very encouraging

Reductions in symptoms and spleen volume that continue to improve over time is a novel finding that indicates SNT-5505 has the potential to provide a significantly different and well tolerated treatment option for patients on a JAK inhibitor

Additional data from patients at 52 weeks will help inform clinical and regulatory discussions on the further development of SNT-5505 in MF in H1 2025

FDA guidance on pivotal study design targeted by mid 2025

*"This interim data confirms the excellent safety profile of SNT-5505 and also suggests that the mechanism of SNT-5505 may exert a long-term effect on the disease, with both symptoms and spleen volume continuing to improve as we now see patients on drug for 9 months. This hasn't been seen before with this class of drug and holds potential for real long-term benefits for MF patients. I look forward to seeing the data mature in the coming months to confirm these important early findings."*

Professor Claire Harrison, Professor of myeloproliferative neoplasms and clinical director at Guy's and St Thomas' NHS Foundation Trust

<sup>1</sup> Tan et al ASH 2024

<sup>2</sup> Vachhani P, et al. Blood 142 (2023) 625–627

# Multiple milestones targeted

**A\$15.0m Equity Raising via a two-tranche institutional placement provides funding required to deliver:**

## **MF combination clinical trial**

- Phase 2 study to deliver additional interim data from patients completing 12 months treatment H1 2025. Final data Q3 2025
- FDA discussions on pivotal study design to complete Q2 2025 contingent on additional phase 2 results
- Interest from strategics (Pharma and Biotech companies) to be explored in parallel during 2025

## **MDS combination clinical trials** (IIS grant funded studies)

- Phase 1c/2 Low/intermediate risk MDS trial to deliver 1c results by H2 2025
- Phase 1c/2 high risk MDS trial to deliver 1c results by H2 2025

## **iRBD/Parkinson's and scar trials**

- Phase 2 trials in areas of high unmet need to deliver clinical proof of concept data by H2 2025



# Equity Raising

# Shareholders & cash

## Financial Information (ASX: SNT)

Share price – 9 December 2024	\$0.067
Market cap	A\$92m
Proforma cash balance (30 Sep 2024) <sup>1</sup>	A\$10.4m
Enterprise value	A\$81.6m

Note:

1. Proforma cash of \$10.4m includes: cash (\$4.34m); 2024 R&D tax credit (\$4.56m); return of security deposit (\$0.9m) proceeds from the sale of the MBU (\$0.6m).

## Institutional Ownership

30 Sept 24

D&A Income Limited	19%
Platinum Investment Management Limited	15%
BVF Partners LP	7%
<b>Total Institutional Ownership</b>	<b>52%</b>

## Share Price & Volume - YTD



\*22 January volume 78.66m — crossing of stock between institutions after closure of fund

# Equity Raising Summary

## Offer Size and Structure

- Two tranche placement to raise \$15.0m (**Placement**) comprising the issue of approximately 250.0 million new fully paid ordinary shares (**New Shares**) in the following tranches:
  - **Tranche 1:** to raise approximately A\$12.4m utilising the Company's existing placement capacity under ASX Listing Rule 7.1; and
  - **Tranche 2:** to raise approximately A\$2.6m which will be subject to shareholder approval at a General Meeting ("EGM") expected to be held in late January or early February 2025. The majority of Tranche 2 will be taken up by large existing holders and will include an investment of approximately A\$0.59 million by KP Rx, a fund managed by a director of the Company ("**Tranche 2**").

## Offer Price

- New Shares to be issued under the Placement at a fixed offer price of A\$0.06 per New Share, which represents a:
  - 10.4% discount to the Company's last traded price on 9 December 2025<sup>1</sup>;
  - 10.6% discount to the 5-day volume weighted average price (VWAP);
  - 0.2% discount to the 10-day VWAP; and
  - 10.4% premium to the 30-day VWAP.

## Ranking

- New shares issued under the Offer will rank pari passu with existing shares on issue.

## Joint Lead Managers and Bookrunners

- Canaccord Genuity and Euroz Hartleys are acting as Joint Lead Managers and Joint Bookrunners to the Placement

<sup>1</sup> Last traded price of A\$0.067 per share

# Sources and Use of Funds

Not for release to US wire services or distribution in the United States



Funds including proceeds raising under the \$15m Placement provides a cash runway to June 2026<sup>1</sup> and will be used to fund the following targeted milestones:

## MF combination clinical trial

- Phase 2 study to deliver results H1 2025
- FDA discussions on pivotal study design targeting Q2 2025
- Additional preclinical studies and CMC development to support the MDS trials and an efficient start to a Phase 2c/3 clinical trial in H2 2025
- Interest from strategics sought in H2 2025

## MDS combination clinical trials

- Phase 1c/2 Low/intermediate risk MDS trial to deliver 1c results by H2 2025
- Phase 1c/2 high risk MDS trial to deliver 1c results by H2 2025

## iRBD/Parkinson's trial

- Phase 2 trial in severe sleep disorder/Parkinson's areas of high unmet need to deliver clinical proof of concept data by H2 2025

## Scarring trial

- Phase 1a/b trial in scar treatment of high unmet need to deliver clinical proof of concept data by H1 2026

## Drug development

- Protection of existing patent positions and next generation of inflammation / fibrosis drugs

## Employee research costs

- Funding of team with global track record in scientific research, drug development and commercialization

## General working capital and costs of the offer

Anticipated Sources of Funds <sup>1</sup>	A\$m
Existing cash as at 30 September 2024	\$4.3
Receipts in October 2024 <sup>2</sup>	\$6.1
Cash from grants (iRBD study)	\$2.1
R&D tax credits (FY25)	\$5.6
Placement proceeds	\$15.0
<b>Total Sources</b>	<b>\$33.1</b>

Targeted Uses of Funds	A\$m
MF combination clinical trial	\$11.8
iRBD/Parkinson's trial	\$2.9
Scarring trial	\$1.5
MDS trials	\$1.0
Drug development	\$1.1
Employee research costs	\$7.3
General working capital for FY25&FY26 and costs of Offer	\$7.5
<b>Total Uses</b>	<b>\$33.1</b>

<sup>1</sup> Any amounts received from the outstanding debt owed by the Acquirer (Arna Pharma) of the Mannitol Business Unit (as at 9 Dec 24 \$3.1m) will extend this runway. Although there remains significant uncertainty of the recoverability and timing of any such payments, if paid in full, will extend the cash runway to Sep 2026.

<sup>2</sup> 2024 R&D tax credit (\$4.56m); return of security deposit (\$0.9m) proceeds from the sale of the MBU (\$0.6m).

# Indicative Timetable

Event	Date
Announce completion of Placement, trading halt lifted and recommencement of trading	Thursday, 12th December 2024
Settlement of Tranche 1	Wednesday, 18th December 2024
Tranche 1 New Shares allotted	Thursday, 19th December 2024
Expected EGM approval to issue Tranche 2 New Shares	Late January / Early February 2025

Note: The above timetable is indicative only and subject to change. Subject to the requirements of the Corporations Act, the ASX Listing Rules and any other applicable laws, Syntara in consultation with the Joint Lead Managers, reserves the right to amend this timetable and withdraw the offer at any time





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# APPENDIX

# Risks

The Company's business is subject to a number of significant risks and uncertainties both specific to its business and of a general nature, some of which are summarised below.

As such, potential investors should be aware that investing in the Company's securities involves a high degree of risk and an investment in the Company should be regarded as a speculative investment.

Prior to deciding whether to apply for securities, potential investors should read and carefully consider this presentation and relevant announcements made by the Company to ASX in order to gain an understanding of the Company, its activities, operations, financial position and prospects and the risks and uncertainties associated with the Company. You should carefully consider these risks in light of your financial and investment objectives, financial situation and particular needs and seek advice from a qualified professional adviser.

If any of these risks were to occur, the future operating and financial performance and prospects of the Company as well as the value of its securities could be materially and adversely affected and you could lose part or all of your investment in the Company. Whilst some of the risk factors may be mitigated by appropriate commercial action, many are either wholly or in part outside of the control of the Company and its directors.

No guarantee as to maintenance of or appreciation in value, the payment of dividends or return of capital of the Company's securities is provided. Further, there can be no guarantee that the Company will achieve its stated objectives or that any forward-looking statement will eventuate.

The following sets out some of the risks associated with the Company.

For specific risks relating to the combination trial of SNT-5505, please refer to the Risk section under the heading "The clinical development of the Company's product candidates may not be successful". For specific risks related to the issues arising from the sale of the mannitol business unit, please refer to the Risk section under the heading "Mannitol business unit".

# Key business risks

## (a) Overview

The Company's business success is currently substantially dependent on its ability to successfully advance the clinical development of SNT-5505, SNT-6302 (and related back up compounds) and SNT-4728 in a timely manner. There is a risk that the clinical development of all or some of these product candidates or any of our other product candidates that it may develop in the future, may not be successful, may be delayed or may cost more than anticipated.

The Company's strategy involves advancing a pipeline of development assets through clinical development to the point where it is able to enter into collaborative partnerships deals and strategic alliances with other lifescience companies to advance the programs and enable us to maintain our financial and operational capacity. There is a risk that the Company may not be able to enter into these sorts of collaborative partnership deals, on acceptable terms, or at all.

There is a risk that the product candidates may not receive the regulatory approvals required to commercialise them, or that such regulatory approval may be delayed. Even if regulatory approval is obtained, there is a risk that the products are not a commercial success.

## (b) The clinical development of the Company's product candidates may not be successful

Before obtaining regulatory approval for the commercial sale of any of the product candidates the Company is developing, it is necessary to complete preclinical development and extensive clinical trials in humans to demonstrate the safety and efficacy of the relevant product. Clinical trials are subject to extensive regulation, are expensive, time consuming, subject to delay and their outcome uncertain. Failure can occur at any stage of the clinical testing or approval process. Phase I clinical trials are not primarily designed to test the efficacy of a product candidate but rather to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and schedules. Negative or inconclusive results or adverse medical events during a clinical trial could cause the clinical trial to be delayed, redone or terminated. Success in pre-clinical and early clinical trials is not a guarantee of future results nor does it ensure that later large scale trials will be successful.

The Company's clinical trial program is described in this presentation. *In particular, this presentation includes interim data from the Company's Phase 2 trial of SNT-5505 used in combination with ruxolitinib. Interim data may vary from the final outcome of the trial and is not a definitive indication of the final results.* The combination SNT-5505 trial and other existing trials being undertaken by the Company and future clinical trials may not show sufficient safety or efficacy to:

- warrant progressing to the next phase of development; combination trial, of SNT-5505, warrant further discussions with the FDA on the next pivotal trial for that drug
- generate sufficient partnership interest, enable the Company to secure a collaborative partnership deal with a life sciences company to enable the continued clinical development of any given product candidate to continue; or
- obtain regulatory approval to sell the product.

This may mean that the Company is unable to continue the development of one or more of its product candidates or generate revenue from those product candidates.

# Key business risks

## **(c) The time and cost to undertake clinical trials and obtain regulatory approval may be significantly more than expected**

The length of time and the cost necessary to complete clinical trials and to submit an application for marketing approval may vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors. Due to the Company's reliance on contract research organisations, hospitals and investigators to conduct clinical trials, the Company is unable to directly control the timing, conduct and expense of its clinical trials. There are numerous factors that could affect the timing of the commencement, performance and completion of clinical trials which may delay the clinical trials or prevent the Company from completing these trials successfully, which include:

- any inability to secure a collaborative partnership deal at the appropriate time to enable the clinical development of any given product candidate to continue;
- delays in securing clinical investigators or trial sites for the Company's clinical trials, delays in obtaining approvals for trials;
- slower than anticipated recruitment of patients who meet the trial eligibility criteria or the loss of patients during the course of the clinical trials;
- the requirement to repeat clinical trials or undertake additional large clinical trials;
- unforeseen safety issues or adverse side effects or fatalities;
- shortages of available product supply of the necessary standard; and
- problems with investigator or patient compliance with the trial protocols.

## **(d) The Company may be unable to enter into collaborative partnership deals**

An important element of the Company's strategy involves advancing a pipeline of product candidates through clinical development to the point where it is able to enter into collaborative partnerships deals and strategic alliances with other lifescience companies that can advance our programs and enable us to maintain our financial and operational capacity. These collaboration partners may be asked to assist with or take full responsibility for the clinical development, regulatory approval and commercialisation of a product or alternatively to assist with funding or performing clinical trials, manufacturing, regulatory approvals or product marketing. Generally, the Company will seek to enter into such partnership arrangements before entering into a phase III trial, but it may seek to do so earlier or later depending on the circumstances. The Company may not be able to negotiate these sorts of deals on acceptable terms, if at all, and cannot guarantee that any such partners will perform as required and meet commercialisation goals.

Even if the Company is successful in entering into such deals, these arrangements may result in the Company receiving less revenue than if it sold such products directly, may place the development and commercialisation of its products outside its control, may require it to relinquish important rights or may otherwise be on terms unfavourable to it.

The Company has demonstrated the value of the strategy when Boehringer Ingelheim acquired the development asset BI 1467335 from the Company in 2015. However, even after such success, ongoing risks remain. In that case, in 2019 Boehringer Ingelheim determined to cease development of BI 1467335 and returned the asset to the Company. As a result, the Company is no longer receiving payments in connection with that transaction and the development prospects of that asset in NASH have ceased.

# Key business risks

## **(e) The Company may not be successful in developing or securing new product candidates**

Although the Company already has an extensive product candidate pipeline, it continues to spend limited resources developing new product candidates. From time to time it also considers in-licensing potential new product candidates. There is a risk that its research and development programs may not yield, or that it may not be able to in-license, additional product candidates suitable for further investigation through clinical trials.

## **(f) Early stage company with limited revenue**

Even though the Company has been in existence for some time, it remains at an early stage of its development as a clinical stage drug development company. Historically, the Company's source of ongoing product sales income was from Aridol and Bronchitol but in October 2023 the Company restructured its operations and sold the mannitol business unit as the revenue generated by the business unit were not sufficient to cover its costs.

The Company's ability to generate sufficient revenue in the future depends on a number of factors, including:

- the successful clinical development of its product candidates, in particular, the success of the Company in advancing the development of SNT-5505;
- its ability to secure collaborative partnership deals in particular, the success of the Company in securing a collaborative partnership for SNT-5505;
- the ability of the Company or its partners to obtain all necessary regulatory marketing authorisations for the products in a timely manner as well as other approvals concerning pricing and reimbursement;
- the ability to manufacture sufficient quantities of products to the required standard and at acceptable cost levels;
- the commercial success of products developed by the Company and its partners; and
- ongoing success in researching and developing new product candidates.
- the Company's research activities being eligible for the Australian government R&D tax incentive and the Company meeting other eligibility criteria.

There is a risk that The Company will continue to incur losses from its operations and may not achieve or maintain profitability. The Company expects its expenses to increase in the short term in connection with continuing conduct of research and development projects and clinical trials. Over the longer term, The Company's costs will fluctuate, primarily dependent on the number, type and size of clinical trials, preclinical development and research projects being undertaken.

## **(g) Capital requirements**

The intended use of funds raised under this offer are set out elsewhere in this presentation. To achieve its goals, the Company will in the future require substantial additional funds which may be dilutive or that may not be available to the Company on favourable terms or at all. Its future funding requirements and the timing of that funding will depend on many factors, including in particular, the success of its clinical programs and whether it is able to enter into collaborative partnership agreements. If the Company is unable to obtain additional funds when required, the Company may be forced to delay, reduce the scope or eliminate one or more clinical trials or research and development programs or future commercialisation efforts.

The phase II trial of SNT-4728 in severe sleep disorders that leads to neurodegenerative diseases is being mainly funded by Parkinson's UK. The funding is provided at various milestones. If this funding agreement was terminated, including for the Company's unremedied breach of the agreement, the Company would be forced to delay, reduce the scope or eliminate the trial. Funding for the proposed German trial is pending and if it is not received, that trial will not progress.

# Key business risks

## h) Mannitol business unit

In October 2023, the Company sold its mannitol business unit. As at 9 December 2024, the Company's estimates that the acquiror owes the Company ~\$3.1m. While the Company is confident in its contractual position, and although the acquiror has made some payments over the prior 12 months, there remains uncertainty as to the timing and recoverability of amounts claimed by the Company and any offsetting amounts payable to the acquiror. Any continuation of the dispute with the acquiror could be costly and time-consuming and could divert management's attention from our business, and the outcome uncertain. There is a risk that the Company receives less than it has claimed. It is not practicable at this time for the Company to predict the amounts that will be paid by the acquiror and the cost to pursue the Company's remedies. Even if the issues in dispute are resolved, the acquiror (and its guarantor) may default on the amounts payable or may otherwise be unable to pay amounts owed. Additional amounts of deferred consideration are also payable by the acquiror in the future, including royalties. In the event the acquiror defaulted in any of its other future payment obligations, including if it ceased as a going concern, the amount of deferred consideration (including royalties) received by the Company may be impacted. The potential of royalties from the acquiror is inherently uncertain and subject to a range of factors including that the level of sales of Bronchitol and Aridol and certain of the acquiror's other products, over which the Company has no control. Notwithstanding the sale of the MBU, the Company maintains the risks for liabilities arising from the operation of the mannitol business prior to the sale. Other disputes or cross claims may arise with the acquiror, which could also be costly and time-consuming and could further divert management's attention from our business.

## (i) Regulatory approvals

The process to obtain regulatory authorisation is expensive, complex, lengthy and the outcomes uncertain. Failure can occur at any stage of the clinical testing or approval process. The Company and its partners (if any) may not be able to obtain marketing authorisations for some or all of its product candidates in key jurisdictions, or those authorisations may be delayed or subject to significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use.

## (j) Ongoing regulatory issues

Even after products receive regulatory authorisation, the Company and its collaborative partners may still face developmental and ongoing regulatory compliance difficulties. Regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Potentially costly follow-ups or post-marketing clinical studies may be required and previously unknown problems may result in restrictions on the marketing of the product and could include product withdrawal. If the Company fails to comply with regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend the Company or its partner's regulatory authorisation or restrict or change the approved indications for use or impose additional safety reporting requirements;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed;
- impose restrictions on the Company' or its partner's operations; or
- seize or detain products or require a product recall.

In addition, the law or regulatory policies governing pharmaceuticals may change. New regulatory requirements or additional regulations may be enacted that could prevent or delay regulatory approval of the Company' products or that may otherwise impact on the Company's ability to market, distribute and sell product. The Company cannot predict the likelihood, nature or extent of adverse government regulation that may arise.



# Key business risks

## **(k) Even if a product is approved, the product may not warrant launch or even if launched, may not be successful in the market**

There is a risk that the product candidates the Company is developing and future product candidates, even if they receive regulatory approval may not gain adequate market acceptance. The degree of market acceptance will depend on a variety of factors, including: the ability to demonstrate safety and efficacy and the prevalence and severity of any side effects; the level of support from clinicians; the relative convenience and ease of administration; cost-effectiveness compared to other treatments; the availability of reimbursement from national health authorities; the timing of market introduction and clinical profile of competitive products; and the success of marketing and sales efforts. Additionally, it is difficult to determine the portion of the patient population that might use the Company's products and there is a risk that the Company's estimates do not accurately reflect the number of patients in the target markets.

## **(l) Pricing and reimbursement**

The commercial success of any products obtain regulatory approval, is substantially dependent on achieving acceptable pricing and whether acceptable third-party coverage and reimbursement is available from government bodies, private health insurers and other third-parties. This process of obtaining pricing for products is time consuming and the outcomes in certain jurisdictions may not be sufficient to warrant the marketing of products in that jurisdiction.

An inability to obtain or delays in obtaining satisfactory pricing and reimbursement in certain jurisdictions may impair the Company and any partner's ability to effectively commercialize products in those jurisdictions. Even if products receive acceptable pricing and reimbursement, pricing and reimbursement levels are subject to change.

## **(m) Manufacturing**

The Company, its partners' or their contract manufacturers and suppliers, may fail to achieve and maintain manufacturing standards for a number of reasons, which could result in patient injury or death, product recalls or withdrawals, product shortages, delays or failures in product testing or delivery or other problems that could seriously harm the Company's (and its partners') business. Any interruption to the Company's or its collaboration partner's manufacturing capability could result in the cancellation of shipments and loss of product, resulting in delays and additional costs for the conduct of clinical trials.

## **(n) Competition**

The Company conducts business in a highly competitive industry in which there are a number of well established competitors that have significantly greater financial resources, sales and marketing organisations, market penetration and development capabilities, as well as broader product offerings and greater market and brand presence. There can be no assurances given in respect of the Company's ability to compete.

## **(o) Product liability claims and insurance**

The Company and its collaboration partners face product liability exposure with respect to its products and product candidates. Regardless of merit or eventual outcome, liability claims may result in decreased demand for the Company and its partners' products; injury to the Company's and its partners' reputation; withdrawal of clinical trial participants; costly litigation and potential contractual disputes; substantial monetary awards to patients and others; loss of revenues; and an inability to commercialise. The Company and its partners' may not be able to maintain insurance coverage at a reasonable cost nor obtain suitable or reasonable insurance coverage in respect of any liability that may arise and any claim for damages could be substantial.

# Key business risks

## **(p) Patents and trade secrets**

The Company uses patents or trade secrets to protect its technologies from unauthorised use by third parties. The term of patents may expire or may be challenged, invalidated or circumvented. There can be no assurances that the Company's patents will afford it significant commercial protection for its products.

## **(q) Enforcement and infringement of intellectual property**

Third parties may own or control patents or patent applications that the Company or its partners may be required to license to commercialise product candidates, that the Company or its partners may infringe, or that could result in litigation that would be costly and time consuming. As a result of intellectual property infringement claims, or to avoid potential claims, the Company or its collaboration partners might be prohibited from selling or licensing a product; required to expend considerable amounts of money in defending claims; required to pay substantial royalties or license fees; required to pay substantial monetary damages; or required to redesign the product so it does not infringe, which may not be possible or could require substantial funds and time.

## **(r) Dependence upon key personnel**

The key personnel, particularly in the Company's research and development and clinical areas, have a high degree of expertise and the Company is reliant on their continued service to maintain and develop its business. The loss of a key employee or the inability to recruit and retain high caliber staff to manage future anticipated growth could have a material adverse effect on the Company. The additions of new employees and departures of existing employees, particularly in key positions, can be disruptive and could also have a material adverse effect on the Company. Increases in recruitment, wages and contractor costs may adversely impact upon the financial performance of the Company.

## **(s) Litigation**

There has been substantial litigation and other proceedings in the pharmaceutical and biotechnology industries. Defending against litigation and other third party claims would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialisation efforts. If third parties are successful in their claims, the Company might have to pay substantial damages or take other actions that are adverse to the Company business.

## **(t) Change in laws**

The Company's business and the business of the third parties with which it operates are subject to the laws and regulations in a number of jurisdictions. Unforeseen changes in laws and government policy both in Australia, the EU, the US and elsewhere, including material and unforeseen changes to licensing and approval requirements or regulations relating to clinical trials, manufacturing, product approval and pricing could materially impact the Company's operations, assets, contracts and profitability.

# Foreign jurisdiction selling restrictions

This document does not constitute an offer of new ordinary shares (**New Shares**) of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

## Hong Kong

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the “SFO”). Accordingly, this document may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

## New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the “FMC Act”).

The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

# Foreign jurisdiction selling restrictions

## Singapore

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the “SFA”) or another exemption under the SFA.

This document has been given to you on the basis that you are an “institutional investor” or an “accredited investor” (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

## United Kingdom

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the New Shares.

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