PATIENT-REPORTED EXPERIENCES OF TENOSYNOVIAL GIANT CELL TUMOUR SYMPTOMS IN THE MANEUVER PHASE 3 TRIAL: INSIGHTS FROM EXIT INTERVIEWS

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CONCLUSIONS

- **Exit interviews from the MANEUVER trial confirmed the substantial symptom burden experienced by patients with tenosynovial giant cell tumour (TGCT), regardless of the joint affected.**
- **Pain and swelling were common symptoms, which impacted patient wellbeing and quality of life (QoL).**
- **Treatment with pimicotinib was associated with patient-experienced benefits in pain, stiffness, swelling, and range of motion (ROM), which was consistent with patient-reported outcome data in the overall MANEUVER population.**
- **These findings provide additional patient-centred evidence supporting the clinical benefit of pimicotinib in TGCT.**

PLAIN LANGUAGE SUMMARY

- **TGCT is a rare tumour that causes pain, swelling, stiffness, and difficulty moving the affected joint, meaning that patients may struggle with daily activities, work productivity, and mental and emotional wellbeing.[1–3]**
- **The MANEUVER trial compared pimicotinib with a placebo ('dummy' treatment) for the treatment of TGCT.[4]**
- **Understanding patient experiences with treatments is important. To capture this, some patients in MANEUVER took part in interviews after 24 weeks in the trial. During the interviews, patients were asked about their TGCT symptoms and how these symptoms changed after they started taking pimicotinib.**
- **Before the trial, most patients had pain, stiffness, swelling, and difficulty moving their affected joint. During the interviews, nearly all patients who received pimicotinib reported improvements in these symptoms. These improvements were also reported during the trial.[4]**

INTRODUCTION

- TGCT is a rare, locally aggressive, soft-tissue tumour that originates in the synovial lining of joints, bursae, and tendon sheaths, and causes them to thicken and overgrow.[1–3]
- Patients with TGCT frequently experience pain, stiffness, and limitations in physical function, which can significantly impact their daily activities, work productivity, and psychological wellbeing.[2,3,5]
- Sustained tumour control and clinically meaningful outcomes for patients such as pain, function, and QoL are important considerations for treatment selection.[2,5]
- Pimicotinib is an oral, once-daily, potent, and highly selective small molecule colony-stimulating factor-1 receptor inhibitor.[6]
- In the global phase 3 MANEUVER trial (NCT05804045), pimicotinib demonstrated early, robust, and durable tumour responses and improved TGCT-associated clinical outcome assessments, with a tolerable and manageable safety profile.[4]
  - Clinically meaningful improvements were observed in all patient-reported outcomes, including Worst Pain and Worst Stiffness Numerical Rating Scale (NRS), ROM, and Patient-Reported Outcomes Measurement Information System-Physical Function.[4]
- Understanding patient experiences beyond these clinical findings is important to establish the broader impact of TGCT and the benefits of pimicotinib treatment on symptoms, physical functioning, and overall wellbeing.

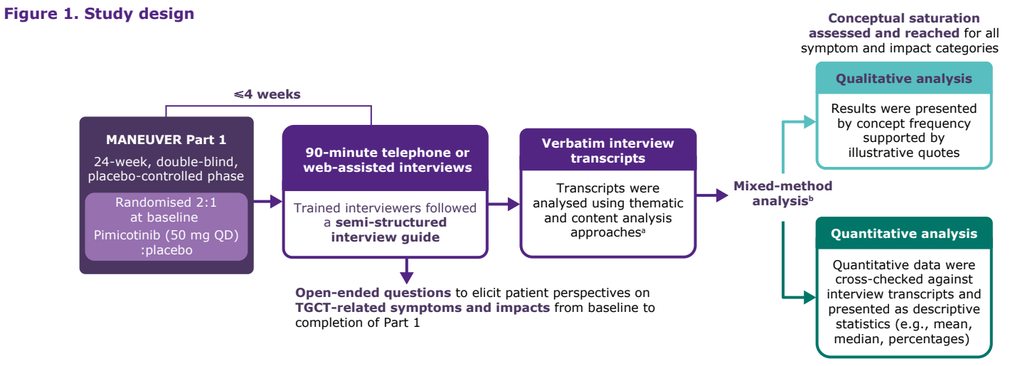
OBJECTIVE

- To characterise patient experiences of TGCT symptoms in the global phase 3 MANEUVER trial (NCT05804045) and explore changes after receiving placebo or pimicotinib.

METHODS

- All patients enrolled at participating sites who had completed the 24-week, double-blind, placebo-controlled phase (Part 1) of the MANEUVER trial of patients with TGCT and who met the eligibility criteria were invited to take part. Recruitment continued until the sample size (20 interviews) was deemed sufficient to reach concept saturation.
- Semi-structured ~90-minute telephone/web interviews were conducted as part of the MANEUVER trial among patients with TGCT across 6 countries (Canada, China, Italy, Spain, The Netherlands, and the USA) within 4 weeks of completion of Part 1 (**Figure 1**).
- Saturation of concepts was assessed on symptoms and impacts experienced at baseline and was reached for all symptom and impact categories.
- Quantitative data were presented as descriptive statistics (e.g., means, percentages, severity) and qualitative data were presented as concept frequencies (e.g., number and percentage of patients endorsing each concept).
  - Patients rated the severity of their symptoms at baseline, based on recall, and after Part 1 using an NRS of 0=not at all severe to 10=extremely severe.

Figure 1. Study design



[a]ATLAS.ti software (v.22 or higher); [b]Some qualitative data were triangulated with quantitative data to support interpretation of findings by gaining a better understanding of what constituted a meaningful change and meaningful treatment benefit based on the patient-reported outcomes.
QD, once daily.

RESULTS

DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

- Forty patients were screened for the exit interview study. However, not all were interviewed: 12 patients declined to participate, 4 withdrew initial consent, and 4 were not eligible as they had started Part 3 of the trial.
- Overall, 20 patients participated in exit interviews (pimicotinib, n=12; placebo, n=8; **Table 1**).
  - Most patients were female (65.0%) and half resided in The Netherlands (25.0%) or the USA (25.0%).
  - The mean (standard deviation [SD]) age was 43.0 (13.5) years.
- Joints affected by TGCT included the knee (n=13), foot (n=2), hip (n=2), ankle (n=2), and wrist (n=1).

Table 1. Demographics and clinical characteristics

	Total sample (N=20)		
Age, mean, years (SD)	43 (13.5)		
Sex, n (%)			
Female	13 (65.0)		
Male	7 (35.0)		
Country, n (%)			
The Netherlands	5 (25.0)		
USA	5 (25.0)		
Italy	4 (20.0)		
China	3 (15.0)		
Canada	2 (10.0)		
Spain	1 (5.0)		
	Total sample (N=20)	**Pimicotinib (n=12)**	**Placebo (n=8)**
Joint affected by TGCT, n (%)			
Lower extremity	19 (95.0)	11 (91.7)	8 (100)
Right knee	7 (35.0)	3 (27.3)	4 (50.0)
Left knee	4 (20.0)	3 (27.3)	1 (12.5)
Knee (not specified)	2 (10.0)	1 (9.1)	1 (12.5)
Ankle (not specified)	1 (5.0)	1 (9.1)	0
Left ankle	1 (5.0)	1 (9.1)	0
Left foot	1 (5.0)	0	1 (12.5)
Foot (not specified)	1 (5.0)	1 (9.1)	0
Left hip	1 (5.0)	0	1 (12.5)
Right hip	1 (5.0)	1 (9.1)	0
Upper extremity	1 (5.0)	1 (8.3)	0
Right wrist	1 (5.0)	1 (100)	0

PATIENT-REPORTED SYMPTOMS EXPERIENCED AT BASELINE

- At baseline, most patients reported pain (95.0%; n=19), stiffness/tightness (90.0%; n=18), restriction/reduction in movement (90.0%; n=18), swelling (85.0%; n=17), or weakness (65.0%; n=13) of their affected joint (**Table 2**).
  - At baseline, all symptoms experienced by patients had a mean severity score of ⩾6.
- Most symptoms were experienced across all TGCT-affected anatomical locations, excluding restriction/reduction of movement for foot, pain and weakness for wrist, and swelling for hip.

Table 2. TGCT symptoms experienced and their severity at baseline

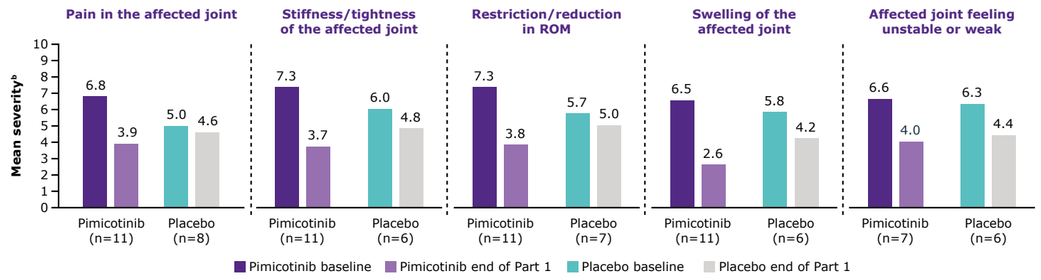
Symptom reported	Total patients experiencing symptom,[a] n (%)	Number of patients reporting on severity, n (%)	Severity rating,[b] mean	Illustrative patient quotes[c]
Pain in the affected joint	19/20 (95.0)	19/19 (100)	6.1	*"Painful […] the pain, it was, how do you call it, 'puncturing' within the knee." – Patient with TGCT in the knee*
Stiffness/ tightness of the affected joint	18/20 (90.0)	17/18 (94.4)	6.8	*"There was a lot of stiffness. Some days I would get up and your first step and almost fall to the ground." – Patient with TGCT in the knee* *"It varied. On an average day I would say 3, but if I walked a little or just went through it, it would be a 6 or a 7." – Patient with TGCT in the knee*
Restriction/ reduction in ROM	18/20 (90.0)	18/18 (100)	6.7	*"That's kind of hard. I don't know. I just noticed it slightly. It's slightly less flexible than my right foot. Like walking up and down stairs like it's not flexible enough to do that. But I'm still able to go up and down stairs. I don't know that one's kind of hard to quantify, I guess… Maybe like a 6..." – Patient with TGCT in the ankle*
Swelling of the affected joint	17/20 (85.0)	17/17 (100)	6.2	*"It was my left knee... My knee would be swollen all of the time because all of the fluid that was in my knee." – Patient with TGCT in the knee* *"I have swelling every time. Every time that bump is, I think, right now is also very big." – Patient with TGCT in the foot*
Affected joint feeling unstable or weak	13/20 (65.0)	13/13 (100)	6.5	*"I don't know if I can specifically quantify, like, that specific joint, but I don't know, maybe like a 5 or 6... Like, I don't know I'm still able to walk and stuff. It's just like sometimes I have to think about walking and stuff." – Patient with TGCT in the ankle*

[a]Interview guide question: "Can you think about your joint affected by TGCT during the month just before you started the clinical trial [month of year], and describe the symptoms you remember having during that time?"; [b]Symptoms used the following ratings: 0=no pain to 10=pain as bad as you can imagine; 0=no stiffness to 10=stiffness as bad as you can imagine; 0=not at all severe to 10=extremely severe; [c]Interview guide question: "When you rated the severity of these symptoms, what did you consider or think about when you selected your answer? (e.g., how bad it was; how often it occurred; how much it affected your emotional wellbeing, mental health, work, social interactions, or relationships or all of these?"

CHANGE IN PATIENT-REPORTED SYMPTOMS AT THE END OF PART 1

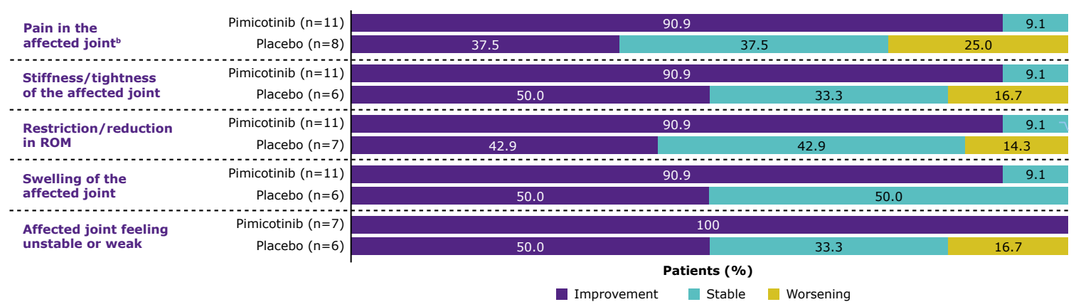
- Nearly all patients treated with pimicotinib reported improvement in their TGCT symptoms at the end of Part 1 (**Figures 2** and **3**).
  - Among patients who responded to questions on their change in symptoms from baseline to end of Part 1, almost all (90.9%; n=10/11) had improvement in swelling, and mean severity score reduced from 6.5 to 2.6 (placebo, 5.8 to 4.2).
    - *"It was quite severe, at 9 again… It was so swollen that I couldn't wear some trousers anymore, whereas now I could start wearing them again." – Patient with TGCT in the knee.*
  - Among patients who responded to questions on their change in symptoms from baseline to end of Part 1, almost all (90.9%; n=10/11) had improvement in pain, and mean severity score reduced from 6.8 to 3.9 (placebo, 5.0 to 4.6).
    - *"Before the trial, I would say it was always pretty much always a 9 or a 10 […] What did I think about? Just how I wasn't able to do normal activities, like standing for a long time, working, walking, going up and down a flight of stairs, just doing basic everyday activities that was very limited for me because of my knee." – Patient with TGCT in the knee.*
  - The majority of patients reported improvement in symptoms of stiffness (90.9%; n=10/11), ROM (90.9%; n=10/11), or weakness in the affected joint (100%; n=7/7) at the end of Part 1.
- No patients treated with pimicotinib reported worsening of symptoms at the end of Part 1; symptom worsening was only reported with placebo.

Figure 2. Patient-reported mean severity rating[a] at baseline and end of Part 1, among patients reporting each symptom at baseline



Some patients were not specifically asked or probed about some items due to the natural flow of the interview and/or time constraints. Data are reported for the patients who answered questions on these items during exit interview.
[a]Interview guide question: "Now, I would like to ask you to think about how your symptoms have changed since you entered the clinical trial [month of year] and completed Part 1 of the MANEUVER study, approximately 6 months after entering the clinical trial"; [b]Symptoms used the following ratings: 0=no pain to 10=pain as bad as you can imagine; 0=no stiffness to 10=stiffness as bad as you can imagine; 0=not at all severe to 10=extremely severe.

Figure 3. Patient-reported change in symptoms[a] at the end of Part 1 by treatment group



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[a]Interview guide question: "Now, I would like to ask you to think about how your symptoms have changed since you entered the clinical trial [month of year] and completed Part 1 of the MANEUVER study, approximately 6 months after entering the clinical trial"; [b]Symptoms used the following ratings: 0=no pain to 10=pain as bad as you can imagine; 0=no stiffness to 10=stiffness as bad as you can imagine; 0=not at all severe to 10=extremely severe.
Selected data previously presented at the ISPOR 2026 congress, 17–20 May 2026, Philadelphia, PA, USA; Ravi V et al. ISPOR 2026 [PCR58].

STUDY LIMITATIONS

- Due to time constraints, some patients were not specifically asked or probed about every item during the exit interview, resulting in missing responses within the total sample.
- Only one patient had a TGCT in the upper extremity, thus limiting the generalisability of findings for this specific patient population.
- Although concept saturation was achieved for both symptoms and impacts across the total sample, the small sample size may limit the generalisability to the broader TGCT population.
- Patient-reported TGCT symptoms and impacts at baseline relied on recall during interviews and may be subject to recall and memory bias.

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AUTHOR DISCLOSURES

Vinod Ravi has received consulting fees and honoraria from EMD Serono. Andrea Phillips Beyer and Marcis Bajars are employees of the Healthcare business of Merck KGaA, Darmstadt, Germany and its affiliates. Qingping Zou is an employee of Abbisko Therapeutics. Amy Clark, Savita Bakhshi Anand, and Carla Dias-Barbosa are employees of PPD Evidera Patient-Centered Research, Thermo Fisher Scientific, which was paid by the Healthcare business of Merck KGaA, Darmstadt, Germany, to conduct the study. Hans Gelderblom was a site Principal Investigator for Abbisko Therapeutics (fees paid to institution).

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