INSIGHTS INTO RANGE OF MOTION (ROM) AND PHYSICAL FUNCTION (PF) CHANGES EXPERIENCED BY PATIENTS WITH TENOSYNOVIAL GIANT CELL TUMOR (TGCT) IN THE MANEUVER PHASE 3 TRIAL: RESULTS FROM EXIT INTERVIEWS

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CONCLUSION

- **Similar to the findings of the clinical trial data, ROM and physical function were highlighted as important aspects of the patient experience**
- **This study highlights the baseline impact of TGCT on ROM and physical function, with most patients reporting difficulties in these domains**
- **Most patients treated with pimicotinib reported improvements in ROM and physical function at the end of Part 1 of MANEUVER**
- **Most patients confirmed their understanding of Patient-Reported Outcomes Measurement Information System-Physical Function (PROMIS-PF) measures and ROM and confirmed their relevance to their affected joint**
- **Results support the content validity of PROMIS-PF measures used in MANEUVER. In this exit interview analysis, a 1- or 2-category change was clinically meaningful for improvement in PROMIS-PF items (bending/kneeling, going outside the home, lifting or carrying, and household work). Anchor-based analysis of the MANEUVER trial data established a 3–5-fold improvement in the PROMIS-PF total score as a clinically meaningful improvement**

PLAIN LANGUAGE SUMMARY

- **TGCT is a rare disease where an abnormal growth of cells (tumor) forms in and around a joint. Without proper treatment, TGCT can cause lasting joint damage and reduced quality of life**
- **The MANEUVER trial compared pimicotinib with a placebo (‘dummy’ treatment) for the treatment of TGCT**
- **Health authorities are interested in understanding patients’ experiences with treatments. To capture this, some patients in the MANEUVER trial took part in interviews after 24 weeks in the trial. These interviews explored how patients’ ability to carry out daily activities and move their joints changed after taking pimicotinib, and what level of improvement they considered meaningful**
- **Before the trial, most patients had difficulties in moving the affected joint and doing everyday activities. During the interviews, most patients who received pimicotinib reported better joint movement and improved ability to do daily activities**
- **Patients also said the tools used in this study to measure these improvements were relevant to them and easy to understand**

INTRODUCTION

- TGCT is a rare and locally aggressive soft-tissue tumor driven by the overexpression of colony-stimulating factor-1 (CSF-1). This growth factor promotes the recruitment, proliferation, and accumulation of CSF-1 receptor (CSF-1R)–expressing inflammatory cells at the tumor site[1–3]
- While not life threatening, TGCT can cause joint destruction, pain, and stiffness. These pathological changes directly impair physical function and ROM, impacting a patients’ ability to perform daily activities and leading to reduced quality of life[1–4]
- The current standard of care for TGCT is surgery, which is limited by high recurrence rates and cumulative morbidity. Other treatment options include systemic treatments and active surveillance. Long-term use of systemic treatments requires consideration of both clinical benefit and tolerability over time[2,4]
- Pimicotinib is an oral, once-daily, potent, and highly selective small molecule CSF-1R inhibitor[5]
- In the Phase 3 MANEUVER trial (NCT05804045), pimicotinib demonstrated early, robust, and durable tumor responses that significantly reduced tumor burden and improved TGCT-associated clinical outcome assessments (including ROM, Worst Pain numeric rating scale [NRS], Worst Stiffness NRS, and PROMIS-PF), with a tolerable and manageable safety profile[6]
- Exit interviews explored the impact of TGCT on physical function and ROM during the MANEUVER trial and assessed the content validity of PROMIS-PF and relative ROM measures

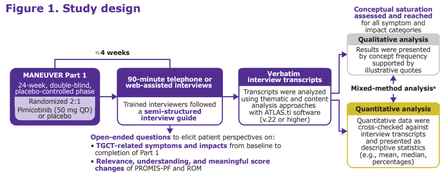
OBJECTIVE

- To characterize patient-perceived changes in ROM and physical function among a subgroup of patients enrolled in the global Phase 3 MANEUVER trial

METHODS

- Exit interviews were conducted as part of the MANEUVER trial among patients with TGCT who completed the 24-week, double-blind, placebo-controlled phase (Part 1) (**Figure 1**)
- Telephone or web-assisted interviews were conducted across 6 countries (Canada, China, Italy, Spain, The Netherlands, and the USA) within 4 weeks of completion of Part 1 of MANEUVER
- Saturation of concepts was assessed on symptoms and impacts experienced at baseline and was reached for all symptom and impact categories
- The PROMIS-PF is a self-administered 121-item bank that assesses various aspects of physical functioning[7]
  - In MANEUVER, physical functioning was assessed in patients with TGCT using the PROMIS-PF short form for upper and lower extremities (**Figure 2**)[6]
- ROM was assessed, using a goniometer (a handheld device used to measure joint mobility), against a ROM standard reference value to obtain relative ROM values[6]

Figure 1. Study design



[a]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 outcome (PRO)
QD, once daily

Figure 2. PROMIS-PF items for Upper and Lower Extremities[7]

PROMIS-PF: Upper Extremities

1. Ability to carry a laundry basket up a flight of stairs
2. Ability to exercise for 1 hour
3. Ability to dress yourself (e.g., buttoning up clothes, tying shoelaces)
4. Ability to go outside of the home (e.g., to the shop)
5. Ability to push open a heavy door
6. Ability to carry a heavy object (>10 pounds/5 kg)
7. Ability to do heavy work around the house (e.g., scrubbing floors, moving furniture)
8. Ability to do moderate work around the house (e.g., vacuuming, sweeping)
9. Ability to lift or carry groceries
10. Ability to change a light bulb overhead
11. Ability to lift 10 pounds (5 kg) above your shoulder

PROMIS-PF: Lower Extremities

1. Ability to go for a walk for at least 15 minutes
2. Ability to dress yourself (e.g., buttoning up clothes, tying shoelaces)
3. Ability to push open a heavy door
4. Ability to carry a heavy object (>10 pounds/5 kg)
5. Ability to go up and down stairs at a normal pace
6. Ability to carry a laundry basket up a flight of stairs
7. Ability to stand for 1 hour
8. Ability to exercise for 1 hour
9. Ability to go outside of the home (e.g., to the shop)
10. Ability to do heavy work around the house (e.g., scrubbing floors, moving furniture)
11. Ability to do moderate work around the house (e.g., vacuuming, sweeping)
12. Ability to lift or carry groceries
13. Ability to bend, kneel, or stoop

RESULTS

DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

- Overall, 20 patients were interviewed (pimicotinib, n=12; placebo, n=8)
  - Most patients were female (65.0%) and half resided in the USA (25.0%) or The Netherlands (25.0%)
  - The mean (standard deviation [SD]) age was 43.0 (13.5) years
- Most patients had a lower extremity (95.0%; n=19/20) affected by TGCT and one patient had an upper extremity (5.0%; n=1/20) affected (**Table 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 (%)	
USA	5 (25.0)
The Netherlands	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

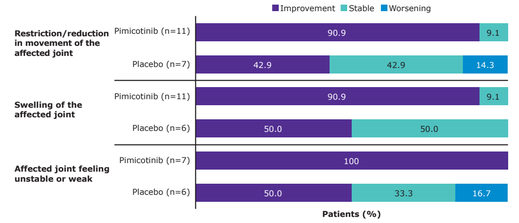
PATIENT-REPORTED IMPACT ON ROM AT BASELINE AND AT THE END OF PART 1 OF MANEUVER

- At baseline, most patients reported “restriction/reduction in ROM” (90.0%; n=18/20), “swelling” (85.0%; n=17/20), and “feeling unstable or weak” (65.0%; n=13/20) in the affected joint
- Of patients who answered questions on TGCT symptoms related to ROM, nearly all patients treated with pimicotinib reported improvement in symptoms compared with baseline; most patients in the placebo group reported improvement or stabilization of symptoms (**Figure 3**)
  - Only patients in the placebo group reported worsening of symptoms at the end of Part 1 compared with baseline (**Figure 3**)

RELEVANCE OF ROM

- Among patients responding to questions on the relevance of ROM (N=11), all reported that the movements used to assess ROM were relevant to their affected joint
  - Of those patients, 72.7% (n=8/11) perceived relevance to their knee, 18.2% (n=2/11) perceived relevance to their foot, and 9.1% (n=1/11) to their hip

Figure 3. Patient-reported change in symptoms related to ROM at the end of Part 1 of MANEUVER reported retrospectively in exit interviews

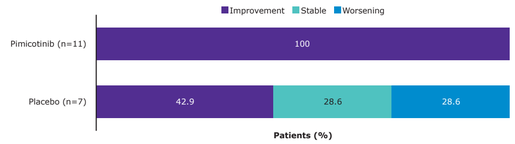


Some patients were not specifically asked or probed about some items due to the natural flow of the interview and/or time constraints. Data are reported for the patients who answered questions on these items during exit interview. Interview guide question: “Now, I would like to ask you to think about how your symptoms have changed since you entered the clinical trial and completed Part 1 of the MANEUVER study, approximately 6 months after entering the clinical trial”; PRO scores were derived from patients’ responses provided during interviews. As these responses relied on patient recall, there is a potential for recall bias

PATIENT-REPORTED IMPACT ON PHYSICAL FUNCTION AT BASELINE AND AT THE END OF PART 1 OF MANEUVER

- At baseline, 95.0% (n=19/20) of patients reported at least one impact in a PROMIS-PF domain, including restrictions in walking, lifting, climbing stairs, and bending
- During interviews, improvements in PROMIS-PF items compared with baseline were reported by 11/11 patients (100%) treated with pimicotinib and 3/7 patients (42.9%) treated with placebo (**Figure 4**)

Figure 4. Patient-reported change in physical function at the end of Part 1 of MANEUVER reported retrospectively in exit interviews



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. Interview guide question: “Which items are relevant to you?” and “Are the items easy to understand and interpret?” PRO scores were derived from patients’ responses provided during interviews. As these responses relied on patient recall, there is a potential for recall bias

RELEVANCE AND UNDERSTANDING OF PROMIS-PF

- Of patients questioned about PROMIS-PF (lower extremity) measures, all confirmed their understanding (100%; n=11/11) and its relevance to them (100%; n=17/17)
- The patient with an upper extremity affected by TGCT confirmed their understanding of PROMIS-PF (upper extremity) measures and its relevance to them
- Of patients reporting on meaningful improvement thresholds for four of the PROMIS-PF items, most found a 1- or 2-category change meaningful (**Table 2**)

Table 2. Patient-reported level of meaningful improvement in the PROMIS-PF (Lower Extremity) measure

Level of improvement that would be meaningful	Total n (%)	Illustrative patient quotes
PROMIS-PF short form: Lower Extremity		
“Does your health now limit you in doing heavy work around the house like scrubbing floors, or lifting or moving heavy furniture?”	3/20 (15.0)	*“I can answer you in a nutshell. Anything that is heavy work, which involves exerting great physical strength, posed the greatest challenges for me.”* – Patient with TGCT in the knee
1-category change	1/3 (33.3)	*“But to me, meaningful is even a change in 1 point. Going from “unable to do” to “with a lot of difficulty” is a meaningful difference to me, because that’s better than being unable to do something. Any change is important, any change for the better.”* – Patient with TGCT in the knee
2-category change	1/3 (33.3)	*“If it went from quite a lot to very little.”* – Patient with TGCT in the knee
3-category change	0	N/A
4-category change	1/3 (33.3)	Patient: *“Wanting to do everything without any difficulty. That’s my target.”* Interviewer: *“So going from a 1 to 5 is what you’re saying would be meaningful--okay.”* Patient: *“Anything in between is not living anymore for me.”* – Patient with TGCT in the hip
“Does your health now limit you in lifting or carrying groceries?”	1/20 (5.0)	Interviewer: *“Which question do you think is most relevant to you?”* *“Carry things.”* – Patient with TGCT in the knee
1-category change	1/1 (100)	Interviewer: *“… how about from 5 to 4…?”* *“I would be satisfied.”* – Patient with TGCT in the knee
2-category change	0	N/A
3-category change	0	N/A
4-category change	0	N/A
Does your health now limit you in going OUTSIDE the home, for example to a shop or to visit a doctor’s office?”	2/20 (10.0)	*“So the thing is that I understand this question as going out, not as a physical part, but maybe more tired or more limping or more in pain. So the rest of the people around are going to begin to ask and not feel sorry but be, I don’t know, change the plans, or yeah. So it’s a lot of thinking before going out, like how are they going to be able to behave or if they are going to ask something or if, I don’t know, that’s why.”* – Patient with TGCT in the knee
1-category change	0	N/A
2-category change	2/2 (100)	Interviewer: *“[…] you said a 3, somewhat, was your worst level. And how much should that improve for you to say that that is a meaningful treatment? Would that be to very little or to not at all?”* *“To not at all.”* – Patient with TGCT in the knee
3-category change	0	N/A
4-category change	0	N/A
“Does your health now limit you in bending, kneeling, or stooping?”	7/20 (35.0)	*“The last one [stooping].”* – Patient with TGCT in the hip
1-category change	6/7 (85.7)	*“To somewhat would be already a meaningful change, so a 1… Because I think to jump from with quite a lot of struggle to somewhat of a struggle is very big. But just the jump down from being unable to do something to being able to do something with quite a lot of struggle is not as big. I think that gap is way smaller.”* – Patient with TGCT in the hip
2-category change	1/7 (14.3)	*“Again, I would say—it would have to be at least 2 points of a jump for it to be meaningful.”* – Patient with TGCT in the knee
3-category change	0	N/A
4-category change	0	N/A

STUDY LIMITATIONS

- Due to time constraints, some patients were not specifically asked or probed about every item, resulting in missing responses within the total sample
- Only one patient had an upper extremity affected by TGCT, thus limiting the generalizability of interpretations 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 generalizability to the broader TGCT population
- Due to broad topic scope, patients were asked to choose one question from the first section of the Upper or Lower Extremity PROMIS-PF questionnaire (“without any difficulty” to “unable to do”) and one question from the second section (“not at all” to “cannot do”) most relevant to their problems with the affected joint when reporting on meaningful change, to allow for suitable discussion and minimize patient burden within the 90-minute interview timeframe
- Patient-reported TGCT symptoms and impacts at baseline relied on retrospective recall during interviews and so were subject to recall and memory biases

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AUTHOR DISCLOSURES

Vinod Ravi has received consulting fees and honoraria from EMD Serono. Paul Kamudoni, Andrea Phillips Beyer, and Niki Karachaliou are employees of the Healthcare business of Merck KGaA, Darmstadt, Germany and its affiliates. Qingping Zou is an employee of Abbisko Therapeutics. Amy Clark, Agkreta Leventi, 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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