ONO PHARMACEUTICAL CO., LTD.

R&D Day - ROMVIMZA -

May 20, 2025

[Number of Speakers]	5	
	Toichi Takino	Representative Director, President and Chief Operating Officer
	Ryuta Imura	Senior Director, Corporate Communications
	Matthew L. Sherman	Executive Vice President, Chief Medical Officer, Deciphera Pharmaceuticals
	Margarida Duarte	Executive Vice President, Global Chief Commercial Officer, Deciphera Pharmaceuticals
	Michelle DiNapoli	Senior Vice President, US Commercial, Deciphera Pharmaceuticals

Presentation

Imura: Thank you very much for attending ONO PHARMACEUTICAL CO., LTD.'s R&D Day. I am Imura from Corporate Communications to serve as your master of ceremonies for today.

Now, it's 9:00 AM Japan time and let us start the event, which is being held in hybrid style with those attending from this venue and online. And today, we have simultaneous interpretation, so please select your language from the button on Zoom.

So, without further ado, let me introduce to you today's attendees from ONO.

First, from the Tokyo office, we have Toichi Takino, Representative Director, President and Chief Operating Officer.

Takino: Good morning. Thank you very much for attending. The weather forecast is that it will be a very hot day. Thank you very much for coming to this office.

Imura: In February we received approval for ROMVIMZA in the US, and that is the main topic for today's presentation. Also, we have three speakers from Deciphera from Boston. Now let me introduce you to these executives from Deciphera.

First is Executive Vice President, Chief Medical Officer, Matthew Sherman, together with Executive Vice President, Global Chief Commercial Officer, Margarida Duarte and Senior Vice President, US Commercial, Michelle DiNapoli. These are the three speakers from Deciphera today.

Now let me introduce today's agenda. First, we have the opening address by President Takino with some slides. After that, from the three speakers from Deciphera, we will hear about ROMVIMZA.

As for the materials for this event, we have already shared it with you via e-mail this morning, so please find it.

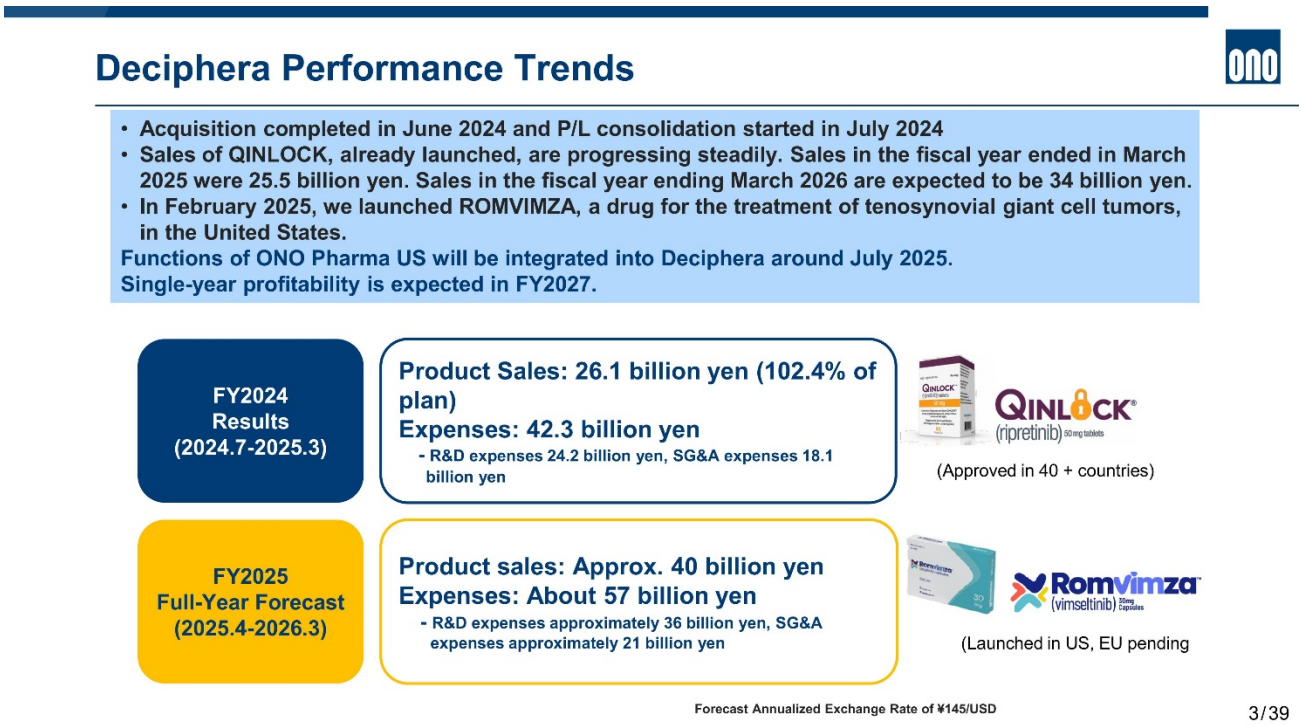
Now, I would like to invite President Takino for the opening remarks. So, Mr. Takino, the microphone is yours.

Takino: So, good morning to you all. During today's R&D Day, we would like to focus on ROMVIMZA, which was launched in the US in February this year. And we will also hear about Deciphera's products. This event is to share with you our excitement and expectations.

So, as was mentioned a moment ago, we have three speakers from Deciphera, the company we acquired as a subsidiary. You will hear the details about ROMVIMZA and other new products, about which I think you can ask questions later.

Thank you very much for your kind attendance.

First, I'd like to give you an introduction with some slides.

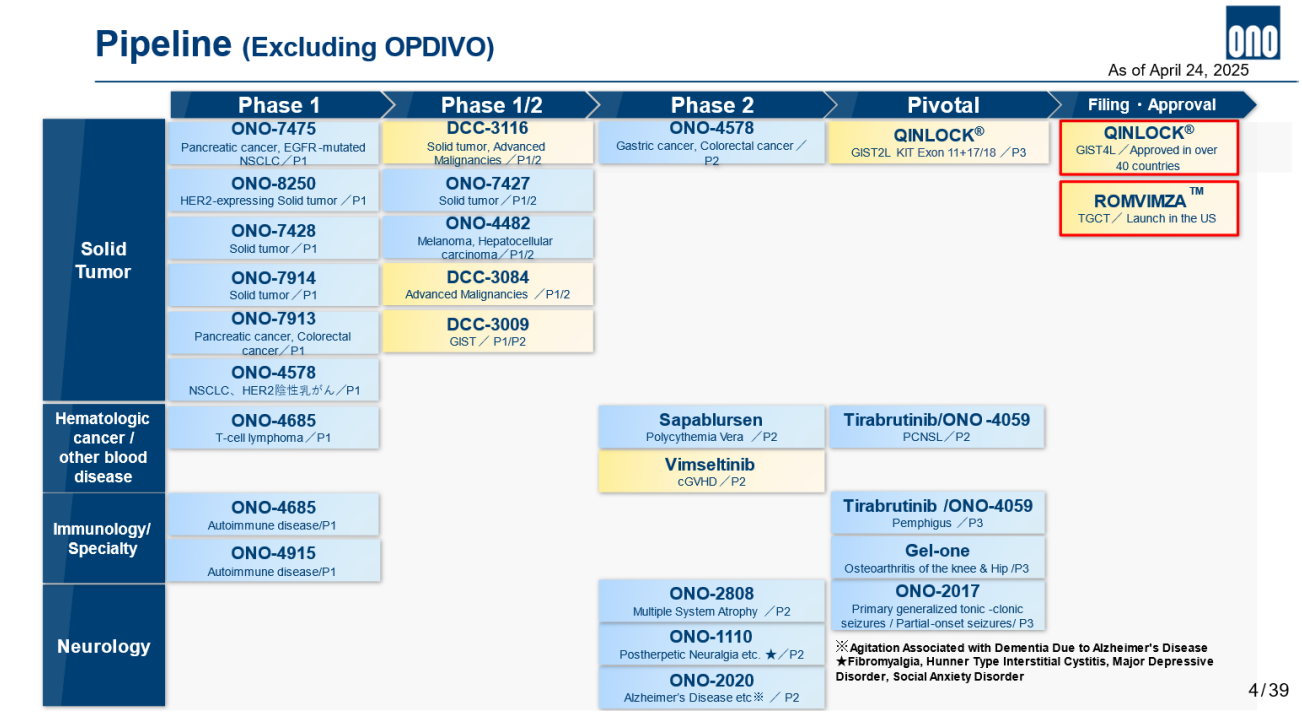


This slide was explained during the earnings call the other day. It's about the performance trend of Deciphera alone.

Going forward, ONO will strive to become a global specialty pharma company. And we have ONO Pharma USA, known as OPUS, as our subsidiary in the US. The functions and personnel of ONO Pharma USA will be integrated into Deciphera in July this year. This is the plan that we have.

After launching its first product, QINLOCK, Deciphera's second product, ROMVIMZA, was approved in the US. Also, it is to be approved in Europe and launched in the near future. So far, we have seen a very stable and sound performance of these two products to date. This fiscal year, about JPY 40 billion in sales is expected from these two products.

In addition, by integrating ONO Pharma USA into Deciphera, we can establish or enhance our infrastructure process and governance this fiscal year. So, this is a very important year for us.



Next page, please.

On this page, I think you are familiar with this table. So, this is the development pipeline, excluding OPDIVO. The areas highlighted in yellow are the original pipeline of Deciphera. In addition to the one which is already launched, there are some in the Phase I and II stages for which we have high expectations. And I think Mattsan will introduce these to you later.

Deciphera will be at the center of the global development and commercialization of Tirabrutinib/ONO-4059, which is scheduled to be submitted to the FDA for approval within this fiscal year. Deciphera will also lead the global development and commercialization of Sapablursen, for which we recently obtained global rights from Ionis.

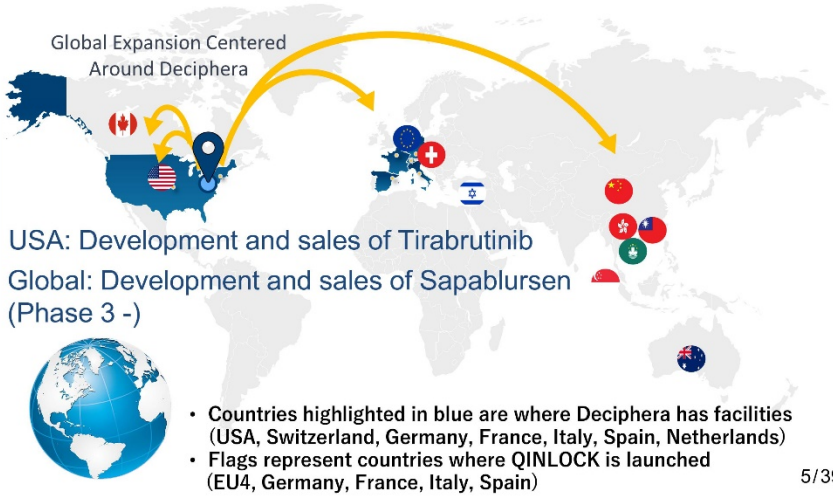
We also plan to proceed with global clinical trials for other early-stage development projects.

Synergy with Deciphera

In July 2025, integrate US and European development and sales operations into Deciphera to centralize and accelerate global market expansion.

deciphera® a member of ONO PHARMA

Integration of US and European development and sales operations with Deciphera in July 2025



- Countries highlighted in blue are where Deciphera has facilities (USA, Switzerland, Germany, France, Italy, Spain, Netherlands)
- Flags represent countries where QINLOCK is launched (EU4, Germany, France, Italy, Spain)

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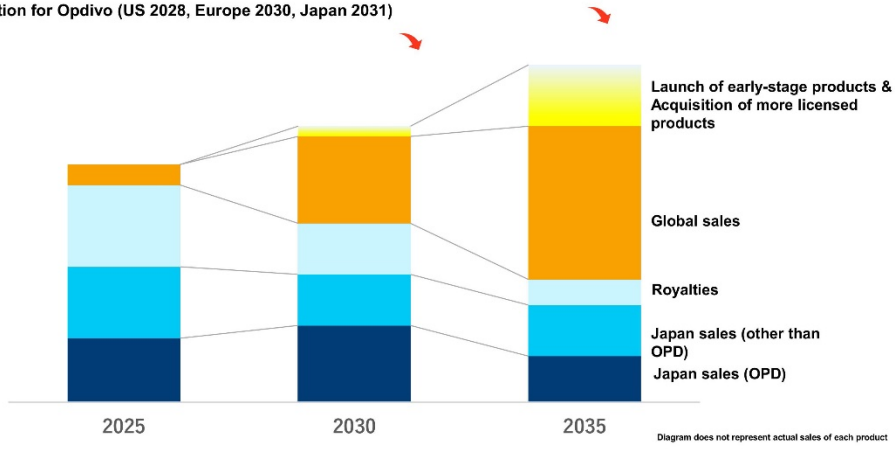
Next page, please. Let me briefly touch upon this slide.

This is the image of what I am talking about. So, we are now proceeding with the integration of the business units and it's going very smoothly. Going forward, let me repeat, we are going to accelerate our global expansion with Deciphera at the center.

Sales Projection for the Next 10 Years

+ Increase sales of global products (QINLOCK, ROMVIMZA, VELEXBRU, Sapablursen)
+ Royalties for Opdivo's subcutaneous formulations and compounds will continue after the patent for the intravenous formulation expires
+ Launch of ONO-2017 and Gel-One in Japan
+ Launch of in-house products
- During 2025 to 2026, patents for diabetes-related products (Forxiga, Glactiv) will expire.
- Patent expiration for Opdivo (US 2028, Europe 2030, Japan 2031)



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This is my last slide. On occasion of the earnings call, I already explained this slide, which shows you the projection of our sales growth in the coming 10 years.

From now on, we face the patent expiration of diabetes-related products and OPDIVO. So, we can expect a decline in revenue. But QINLOCK and ROMVIMZA, these two Deciphera products, as well as VELEXBRU and sapablursen, and other global products, will contribute to sales growth, and we are going to accelerate the pace of growth. Additionally, OPDIVO's subcutaneous formulation was launched in the US and Europe. So, the royalty income from this can be expected for 10 years after launch.

On the other hand, in the Japan market, from now we have cenobamate, ONO-2017. And we announced a partnership for Gel-One. Treatment for arthritis will contribute to the growth in sales. And of course, as our own proprietary products, we have many compounds, such as ONO-2020, -1110 and -4578. We have many compounds which we are excited about.

So, with the success with these products, in general, we can go on to the next phase of growth. In addition, we are going to have licensed-in products. We'll be active with licensed-in products so that we can further enhance the pipeline.

Next, this orange part of the graph, will be led by Deciphera for growth. I'd like to invite the people in charge of this from the Deciphera side to talk about ROMVIMZA. So, now, the microphone is yours.

Thank you very much. That's all for me.

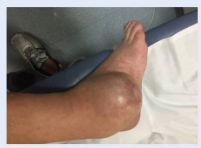
Imura: So, thank you very much, Mr. Takino. Now, the members from Deciphera, when you are ready, please start your presentation. First, I'd like to invite Matt-san from development.

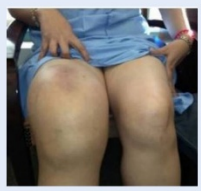
Sherman: Thank you for joining today's R&D meeting. I am Matt Sherman, Chief Medical Officer at Deciphera. I am joined by Margarida Duarte, Global Chief Commercial Officer, and Michelle DiNapoli, Senior Vice President of US Commercial.

Tenosynovial Giant Cell Tumor: A Locally Aggressive Tumor Associated with Substantial Morbidity

DIAGNOSIS AND PATIENT BURDEN

- Long path to diagnosis
- High disease burden
- Severe pain
- Limited function
- Swelling
- Stiffness





UNMET NEED

- Existing Product: Black box warning and Risk Evaluation and Mitigation Strategy (REMS) program due to hepatotoxicity risks; rejected by EMA
- Unmet need remains for effective CSF1R inhibitor with favorable safety profile

Ankle image courtesy of Tap WD, et al. ASCO 2018, abstract 11502; Knee image courtesy of Tap WD, et al. N Engl J Med. 2015;373:428-437.
Notes: CSF1R=colony-stimulating factor 1 receptor; EMA=European Medicines Agency; TGCT=tenosynovial giant cell tumor

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I'd like to begin by discussing tenosynovial giant cell tumor, or TGCT, and our recently approved drug, ROMVIMZA.

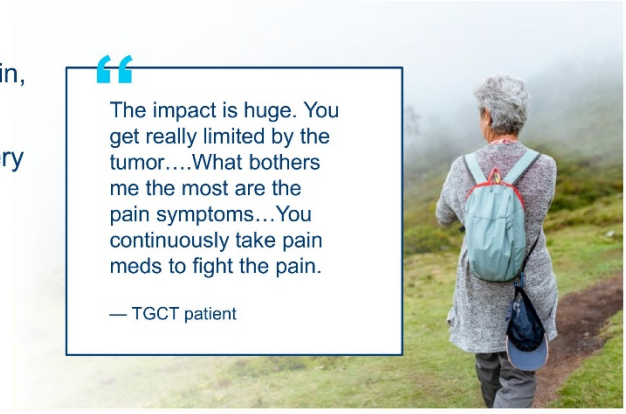
TGCT can be a difficult chronic condition associated with severe pain, swelling, stiffness, and loss of mobility, all of which can severely limit patients' daily activities and quality of life, including their ability to continue to work or function independently.

Patients with TGCT are typically diagnosed in their 30s, 40s, or 50s and are expected to have a normal lifespan. But without effective treatments, this disease can have a profound impact on their ability to lead a normal, active, healthy life.

ROMVIMZA™ | TENOSYNOVIAL GIANT CELL TUMOR

Significant Unmet Medical Need

- TGCT is a locally aggressive tumor with substantial morbidity including severe pain, limited function, swelling, and stiffness
- Many patients are not amenable to surgery or have disease recurrence after one or more surgeries
- ROMVIMZA (vimseltinib) is the first FDA approved therapy without a black box or a REMS program
- No approved therapies yet in Europe



Notes: FDA=U.S. Food and Drug Administration; REMS=Risk Evaluation and Mitigation Strategies; TGCT=tenosynovial giant cell tumor

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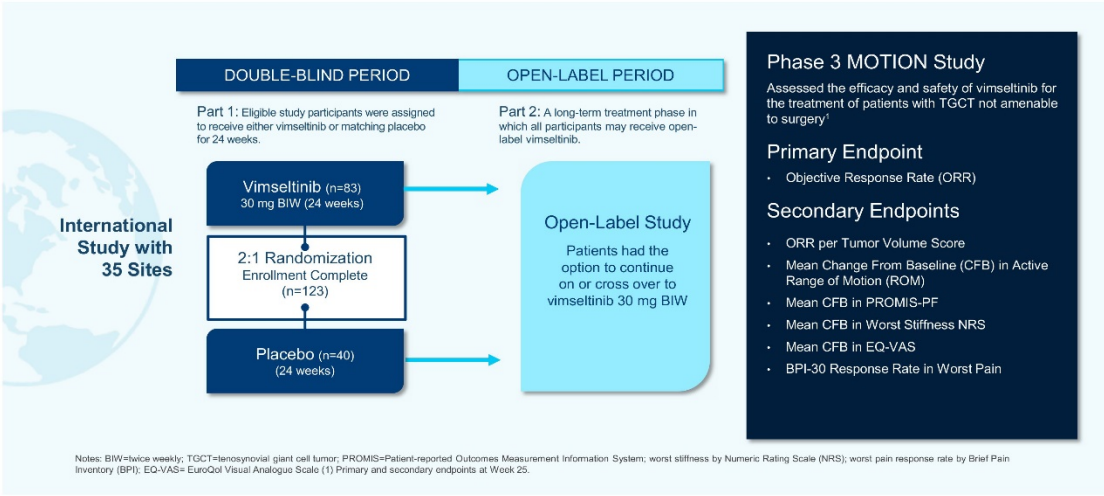
Although TGCT severely impacts the lives of patients, a significant unmet medical need remains. Surgery is often not an option for many patients, and those who undergo surgery may experience recurrence of their disease. These surgical procedures also bring the risk of long and painful recovery times, which can be debilitating for patients.

ROMVIMZA is the first FDA-approved treatment for TGCT that does not have a black box warning or require a REMS program. Also, there are currently no approved therapies for TGCT in Europe, highlighting the ongoing treatment gap.

ROMVIMZA™ | PHASE 3 MOTION STUDY OF PATIENTS WITH TGCT

A Multicenter, Randomized, Placebo-Controlled, Double-Blind Study

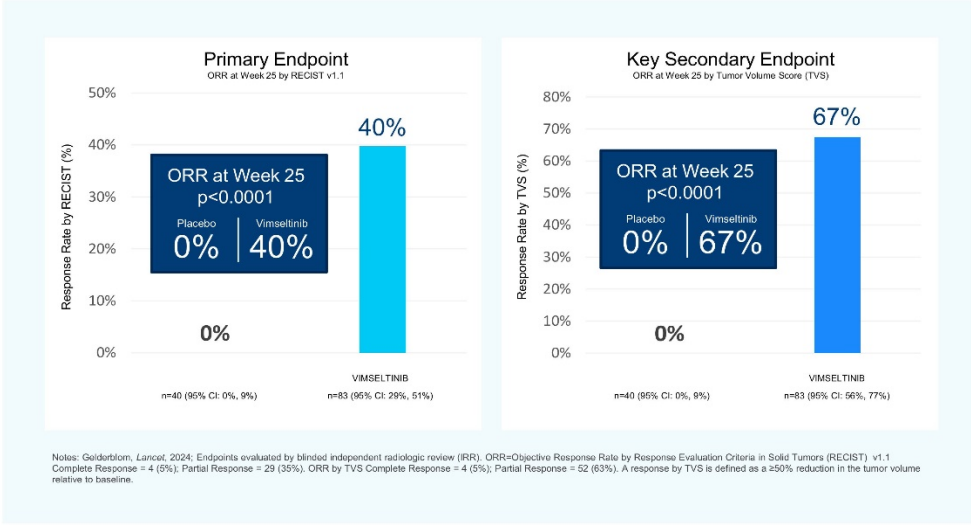


Stepping back to discuss the data supporting our FDA-approved label, the Phase III MOTION study was designed to assess the efficacy and safety of ROMVIMZA in patients with TGCT not amenable to surgery. 123 patients were randomized 2:1 to receive either ROMVIMZA or placebo. The primary endpoint of the study was objective response rate at week 25 compared to placebo.

In addition to ORR, MOTION evaluated a number of key secondary endpoints that are an essential part of the overall efficacy picture. These measures of how patients feel and function play an incredibly important role in treatment decisions and inform patient interest in starting and staying on TKI therapy.

ROMVIMZA™ | PHASE 3 MOTION STUDY OF PATIENTS WITH TGCT

Study Met Primary and All Six Secondary Endpoints



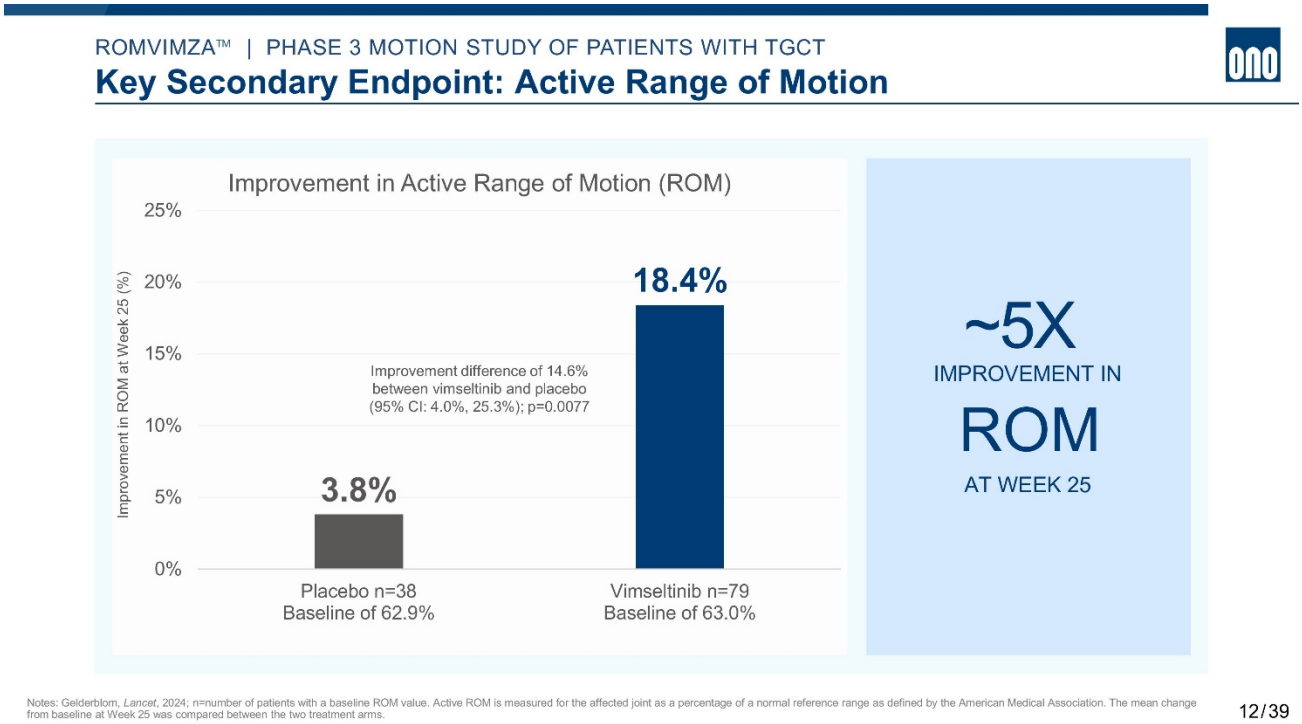
In October of 2023, we reported that MOTION met its primary endpoint, demonstrating statistically significant and clinically meaningful improvement in response rate at week 25 compared to placebo.

As you can see on the left, the ORR was 40% for ROMVIMZA compared to 0% for placebo, with a very highly significant p-value of less than 0.0001.

ROMVIMZA also provided significant improvement in all six key secondary endpoints, including tumor volume score, active range of motion, physical function, stiffness, quality of life, and worst pain response. These results were both clinically meaningful and highly statistically significant compared to placebo.

Success on the first key secondary endpoint, response by tumor volume score, is also shown here on the right, with ROMVIMZA demonstrating a 67% response rate compared to 0% for placebo.

Considering these impressive data, we are thrilled that ROMVIMZA is now approved by the FDA and available for patients in need.



TGCT can have a significant impact on patients' range of motion, and we're also very pleased that patients treated with ROMVIMZA demonstrated a fivefold improvement in active range of motion at week 25 compared to placebo.

Treatment with ROMVIMZA showed an improvement of 18.4%, while placebo patients showed an improvement of 3.8%.

ROMVIMZA Provided Statistically Significant and Clinically Meaningful Improvements Versus Placebo

At week 25	Vimseltinib n = 83	Placebo n = 40	*P*-value	Statistically significant	Clinically meaningful
Active Range of Motion					
% Mean change from baseline (SE)	18.4 (6.5)	3.8 (7.2)		✓	✓
% Difference (95% CI), *P*-value	14.6 (4.0 to 25.3)		***P* = 0.0077**		
PROMIS-Physical Function					
Mean change from baseline (SE)	4.6 (1.0)	1.3 (0.9)		✓	✓
Difference (95% CI), *P*-value	3.3 (1.4 to 5.2)		***P* = 0.0007**		
Worst stiffness Numeric Rating Scale					
Mean change from baseline (SE)	−2.1 (0.2)	−0.3 (0.3)		✓	✓
Difference (95% CI), *P*-value	−1.8 (−2.5 to −1.1)		***P* <0.0001**		
EQ-Visual Analogue Scale					
Mean change from baseline (SE)	13.5 (2.4)	6.1 (2.9)		✓	✓
Difference (95% CI), *P*-value	7.4 (1.4 to 13.4)		***P* = 0.0155**		
BPI worst pain					
n (% Response rate[a])	40 (48)	9 (23)		✓	✓
% Difference (95% CI), *P*-value[b]	26 (4 to 42)		***P* = 0.0056**		

Notes: Gelderblom, *Lancet*, 2024; [a]Responder: Experienced at least a 30% decrease in mean BPI worst pain and did not experience a 30% or greater increase in narcotic analgesic use. [b]An unstratified exact CI was utilized. BPI= Brief Pain Inventory; CI= confidence interval; EQ-VAS= EuroQol Visual Analogue Scale; PROMIS-PF= Patient-Reported Outcomes Information System Physical Function; ROM= range of motion; SE= standard error

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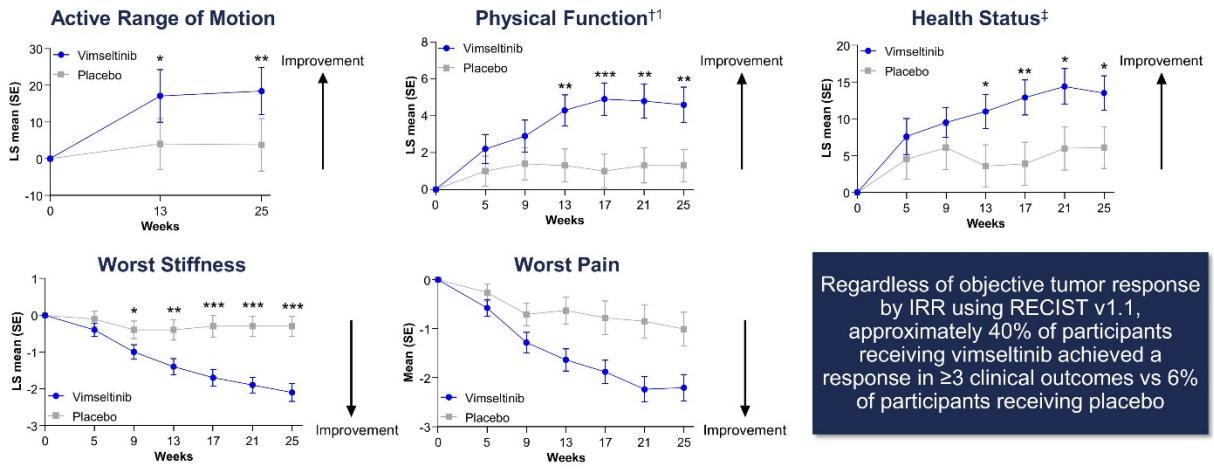
Here, we can see that ROMVIMZA outperforms placebo across all secondary endpoints at week 25. It is important to note that these improvements were both statistically significant and clinically meaningful.

ROMVIMZA Provided Statistically Significant and Clinically Meaningful Improvements Versus Placebo



Notes: Gelderblom, *Lancet*, 2024; Data cutoff: August 22, 2023. *P <0.05; **P <0.01; ***P <0.0001. †) Physical function as assessed by PROMIS-PF (TGCT specific) . ‡) Health status as assessed by EQ-VAS. 1) Gelhorn HL, et al. J Patient Rep Outcomes. 2019;3:6. BPI= brief pain inventory; EQ-VAS= EuroQol Visual Analogue Scale; IRR= independent radiological review; LS= least squares; PROMIS-PF= Patient-Reported Outcomes Measurement Information System Physical Function; RECIST v1.1= Response Evaluation Criteria in Solid Tumors version 1.1; ROM= range of motion; SD= standard deviation; SE= standard error; TGCT= tenosynovial giant cell tumor.

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These improvements in the secondary endpoints are further demonstrated here and, regardless of objective tumor response, approximately 40% of patients receiving ROMVIMZA achieved a response in three or more clinical outcome assessments compared to just 6% of patients receiving placebo.

ROMVIMZA Was Generally Well Tolerated with Few Discontinuations Due to Treatment Emergent Adverse Events

TEAEs in ≥15% of participants in either treatment arm	Vimseltinib n = 83		Placebo n = 39[a]	
Preferred term, n (%)	All grades	Grade 3/4	All grades	Grade 3/4
Periorbital edema	37 (45)	3 (4)	5 (13)	0
Fatigue	27 (33)	0	6 (15)	0
Face edema	26 (31)	1 (1)	3 (8)	0
Pruritus	24 (29)	2 (2)	3 (8)	0
Headache	23 (28)	1 (1)	10 (26)	0
Asthenia	22 (27)	1 (1)	9 (23)	1 (3)
Nausea	21 (25)	0	8 (21)	1 (3)
Blood CPK increased	20 (24)	8 (10)	0	0
AST increased	19 (23)	0	1 (3)	0
Arthralgia	16 (19)	0	6 (15)	1 (3)
Rash	16 (19)	0	2 (5)	0
Rash maculopapular	16 (19)	1 (1)	0	0
Edema peripheral	15 (18)	0	3 (8)	0
Hypertension	14 (17)	4 (5)	4 (10)	1 (3)
Diarrhea	10 (12)	0	8 (21)	1 (3)

- Most TEAEs were Grade 1/2
- Serum enzyme elevations were consistent with the known mechanism of action of CSF1R inhibitors[1,2]
- TEAEs led to treatment discontinuation in 6% of participants receiving vimseltinib[b]
- There was no evidence of cholestatic hepatotoxicity, drug-induced liver injury, or hair/skin hypopigmentation

Notes: Gelderblom, *Lancet*, 2024; [a]One participant randomized to placebo never received treatment. [b]Reflects treatment discontinuations at data cutoff; AEs are attributed to part 1 or part 2 based on AE start date and may have occurred in part 2 for some participants. 1) Pognan F, et al. *Curr Res Toxicol*. 2022;3:100091. 2) Radi ZA, et al. *Am J Pathol*. 2011;179(1):240-7. AE= adverse event; AST= aspartate aminotransferase; CSF1R= colony-stimulating factor 1 receptor; CPK= creatine phosphokinase; TEAE= treatment-emergent AE.

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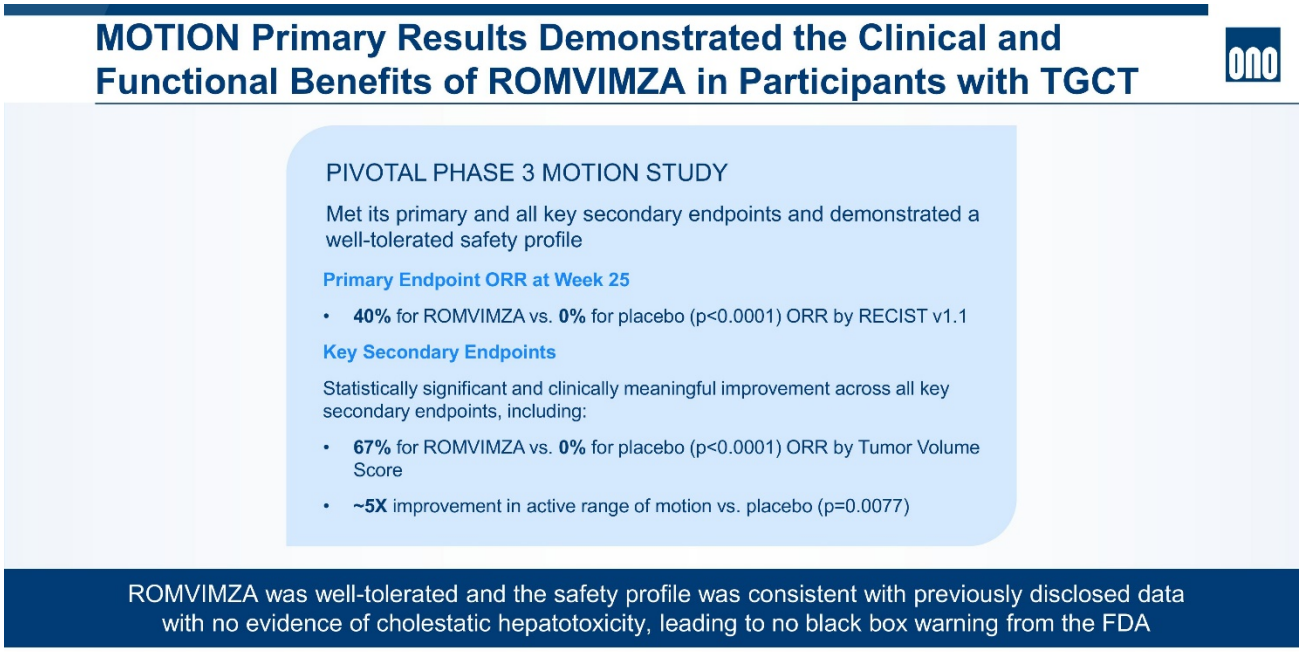
The most common treatment emergent adverse events were usually Grade 1 or 2. The only Grade 3 or 4 events in more than 5% of patients were increased levels of CPK.

It is important to remember that the increase in serum enzymes is consistent with the known effects of CSF1 receptor inhibitors. CSF1 receptor inhibition impacts the ability of macrophage-derived cooker cells in the liver to clear these enzymes, resulting in increased serum levels. This observation is distinct from the cholestatic hepatotoxicity reported with a comparable existing product, which we have not seen in either the MOTION or the Phase I and II studies.

Only 6% of patients in the ROMVIMZA arm discontinued treatment due to a treatment emergent adverse event in the MOTION study. Additionally, there was no evidence of drug-induced liver injury or hair or skin hypopigmentation.



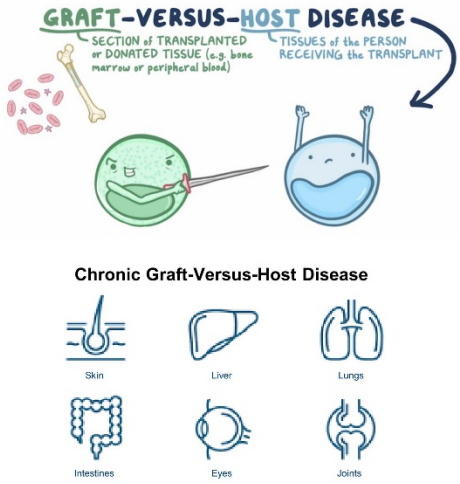
To summarize, ROMVIMZA delivered exceptional results across the MOTION study, primary, and key secondary endpoints, demonstrating its clinical and functional benefit for patients with TGCT.

ROMVIMZA was also well tolerated, and the safety profile was consistent with previously discussed disclosed data. As I mentioned, ROMVIMZA showed no evidence of cholestatic hepatotoxicity that was seen with the comparable existing product . And unlike this existing product, ROMVIMZA does not come with a black box warning.

Based on these results, we believe ROMVIMZA has the potential to become the new standard of care for TGCT patients.

ROMVIMZA™ | CGVHD

New Growth Opportunity in Chronic Graft vs. Host Disease



- As an oral agent, ROMVIMZA may offer best-in-class CSF1R option as single agent or in combination with other oral cGVHD therapies
- Chronic GVHD affects 30-50% of allogeneic hematopoietic cell transplant recipients (14,000 U.S. prevalence)
- Significant unmet medical need in steroid refractory patients (~50%); movement toward combination therapy
- ROMVIMZA single-agent Phase 2 study in cGVHD initiated in 4Q 2024 and ongoing

Notes: cGVHD=chronic graft versus host disease; (1) Deciphera market research; (2) Phase 2 study conditional and subject to FDA approval. Figures: Osmosis.org 2022; National Cancer Institute, 2021.

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Moving on now to what we believe is an exciting additional opportunity for ROMVIMZA, chronic graft versus host disease, or chronic GVHD.

Chronic GVHD affects 30% to 50% of all allogeneic hematopoietic stem cell transplant recipients, or approximately 14,000 patients in the US. There is a significant unmet medical need for approximately half of these patients who do not respond to treatment with steroids.

As an oral agent, we believe ROMVIMZA may become a best-in-class CSF1 receptor treatment option, either as monotherapy or in combination with other oral therapies.

We initiated a Phase II study of ROMVIMZA as a single agent in chronic GVHD patients in Q4 of last year, and the study is now actively enrolling patients.

As you can see, there is a lot to be excited about for ROMVIMZA across TGCT and chronic GVHD.

I would now like to turn the presentation over to Margarida to discuss the TGCT market overview and commercial opportunity. Margarida?

Duarte: Thank you, Matt. I will now cover the TGCT market overview and opportunity, and we'll then hand it over to Michelle, who will share some color on the recent ROMVIMZA launch in the US.

Deciphera Is at a Major Inflection Point

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At Deciphera, we are at a major inflection point for our organization and continue to make remarkable progress.

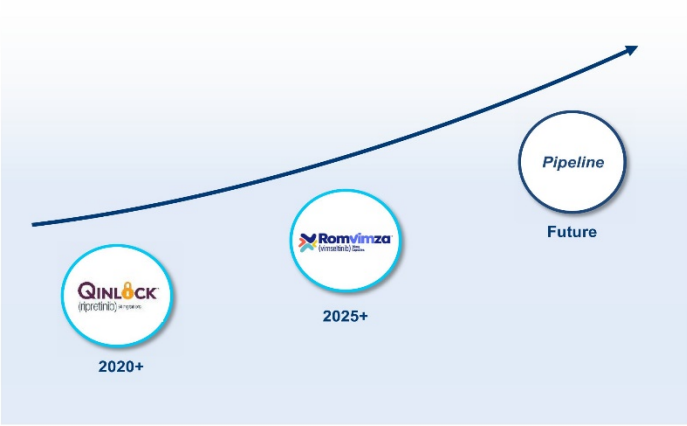
Recently, we became a multiproduct company. QINLOCK has already been approved in over 40 countries around the globe for the treatment of GIST, and ROMVIMZA was recently approved in the US for the treatment of TGCT. ROMVIMZA is currently under review by the European Medicines Agency, and we look forward to sharing updates as they become available.

As Matt mentioned, there is significant unmet medical need in TGCT that was not addressed by available treatment options. ROMVIMZA's FDA approval unlocks significant opportunities to address this treatment gap and make a real impact for patients suffering from this chronic and debilitating condition.

When we look at ROMVIMZA's clinical profile, it becomes even more obvious why we are so excited about its potential. Its profile is very compelling. We have a differentiated product that is positioned for market share and market growth, thanks to its demonstrated patient benefit, and we believe it will make a significant impact for patients suffering from TGCT.

Of course, none of this would be possible without the dedicated team we have in place. This team is incredibly motivated to bring ROMVIMZA to patients and continue executing on QINLOCK success. This is truly an exciting time for Deciphera.

Building on Our Success with QINLOCK

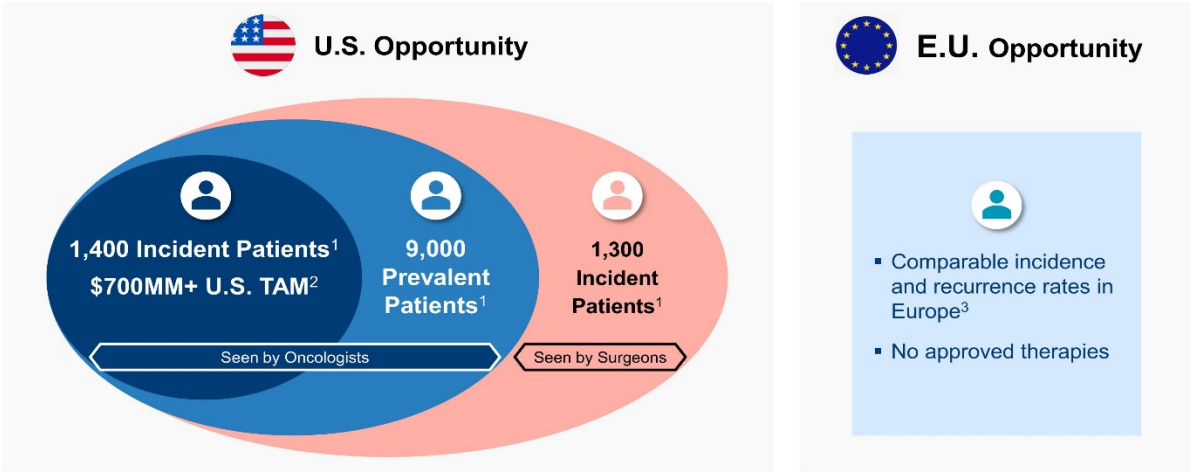


Complementary Commercial Opportunities

- Established relationships with physicians who treat GIST and TGCT
- 70%-80% overlap in US prescribing physicians for GIST and TGCT
- MOTION study deployed in major sarcoma sites across the globe

Building upon our established success with QINLOCK, Deciphera is well positioned for continued progress with multiple drivers of growth as part of ONO. For the launch of ROMVIMZA, we are engaging with the many of the same oncologists we have called on over the last five years since we launched QINLOCK since there is considerable overlap between the prescribing physicians for GIST and TGCT. This overlap with familiar oncologists creates a unique opportunity to streamline our approach, offering multiple advantages, including a highly capital-efficient commercial footprint and the ability to leverage established relationships with key prescribers at launch.

Significant Opportunity to Benefit Patients with TGCT



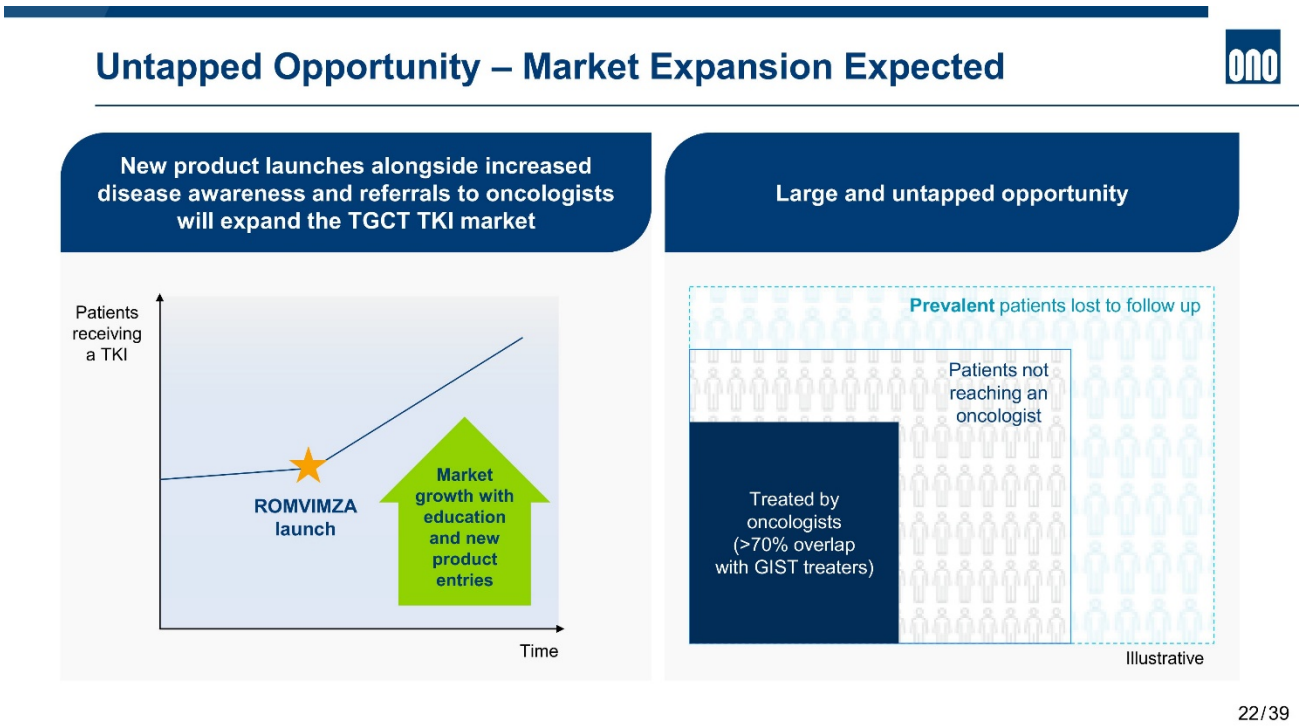
Notes: TAM=total addressable market; (1) Deciphera internal analysis of U.S. claims data; eligible patients defined as diagnosed, Rx-treated, and recently engaged with a medical oncologist (or a surgeon); claims data span 2012-2022; estimates shown are for 2022; prevalent estimate includes incident patients; estimates are inherently uncertain; (2) Total addressable market calculated as estimated Rx-treated patient incidence x 24 months duration x current pexidartinib WAC price and assumes opportunity at steady state. (3) Mastboom et al. Acta Orthopaedica. 2017;88(6):688-694

There is a significant opportunity to benefit patients with TGCT, and I believe we are very well positioned to maximize it and change the standard of care. Our current priority is to execute an exceptional launch of ROMVIMZA in the US, and we are thrilled with what we are seeing in these few months following FDA approval.

To seize this opportunity, it's critical that we leverage our deep understanding of the TGCT patient journey and the market landscape. Our focus at launch is on the approximately 1,400 incident and 9,000 prevalent patients who are diagnosed and treated with systemic therapy and, importantly, are seen by an oncologist.

This core group of patients presents a substantial market, but the potential extends even further. We estimate the USD 700 million totally addressable market opportunity in the US based on approximately 1,400 incident patients alone.

Beyond this core opportunity, we see significant additional potential for future growth, which includes patients who have not yet engaged with an oncologist as well as the opportunity in Europe, where we expect comparable epidemiology and where currently there are no approved therapies for TGCT.



All in all, there is an untapped opportunity in TGCT that we believe we can unlock due to ROMVIMZA's exceptional clinical profile, differentiated label, and our dedicated and talented team.

To realize this potential, we must address the key challenges in the patient population. Currently, we estimate that only a subset of patients are seen by oncologists, with many lost to follow-up or in a cycle of non-successful surgeries or pain medications.

Furthering awareness and education, the launch of ROMVIMZA and the eventual launch of other products will increase the number of patients we engage with an oncologist for the treatment of TGCT and, ultimately, are treated with the TKI.

This shift represents a large opportunity to transform the treatment landscape for TGCT in the coming years with significant benefit for patients who have been waiting for a solution for years.

I will now turn it over to Michelle to discuss the US commercial launch of ROMVIMZA. Michelle?

DiNapoli: Thank you, Margarida.

Just Launched in the US

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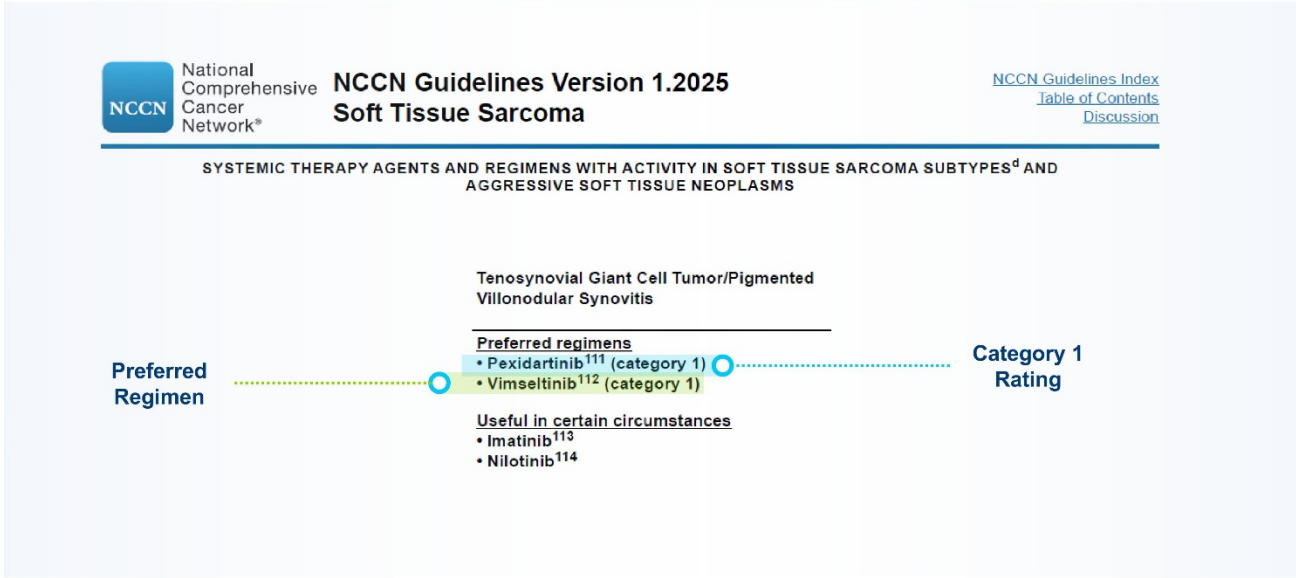
ROMVIMZA's recent FDA approval is a significant milestone, reflecting the critical need for new treatment options for TGCT patients. ROMVIMZA was approved under the FDA's priority review program, underscoring the unmet medical need for these patients and the strong clinical data from the MOTION trial.

The strength of the clinical data speaks volumes, particularly in terms of the patient population ROMVIMZA is intended to help. ROMVIMZA is indicated for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

We believe this indication presents an important alternative for TGCT patients when surgery is no longer the best option and represents a meaningful eligible patient population. There has been very positive early receptivity of ROMVIMZA's approval from various channels, including popular oncology news outlets, key opinion leaders, and, importantly, patient advocacy groups. This initial enthusiasm is a strong indicator of the broader impact ROMVIMZA is likely to have.

Given the desire for TGCT education in the marketplace, patient advocacy groups, namely TGCT Support, have become an important and trusted source of guidance for TGCT patients across the globe. Their partnership in generating awareness of ROMVIMZA's approval and educating the patients around the clinical data has been a crucial resource in informing patients about this newly available option.

ROMVIMZA Added to the NCCN Guidelines as Preferred Regimen



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Furthermore, the National Comprehensive Cancer Network, or NCCN, guidelines were updated within weeks of ROMVIMZA's approval to add the therapy as a preferred regimen with a category 1 rating, representing the robustness of the data. This rapid inclusion in the guidelines highlights the immediate recognition of ROMVIMZA's value in the treatment landscape. The NCCN guidelines are the recognized standard for clinical direction and policy in cancer care, and having ROMVIMZA's inclusion so quickly after launch will pave the way for generating a new standard of care for systemic TGCT and clearing the path for patient access.

Two FDA-Approved Treatments for TGCT in the US: ROMVIMZA and Existing Product

	ROMVIMZA	Existing Product
Indication	Indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.	Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.
MOA	Kinase inhibitor that targets CSF1R.	Small molecule tyrosine kinase inhibitor that targets CSF1R, KIT, and FLT3 harboring an ITD mutation.
Black Box Warning	**No Black Box Warning.**	**Black Box Warning** for hepatoxicity i.e. fatal liver injury, including vanishing bile duct syndrome. Monitoring and prompt cessation of Existing Product may not eliminate the risk of serious and potentially fatal liver injury.
REMS Program	No	Yes - Existing Product is available only through a restricted program under a REMS, because of the risk of hepatotoxicity.
Dosing	Twice-weekly	Twice-daily
Dietary Restrictions	**None; be taken with or without food.**	**Must be taken with a low-fat meal. Avoid grapefruit juice.**
Contraceptive Restrictions	**None.** Patients must be on effective birth control while on and for 1 month after the final dose.	**Avoid hormonal birth control, since pexidartinib can render hormonal birth control ineffective** Patients must be on effective non-hormonal birth control while on and for 1 month after the final dose.
Hair and Skin Color Changes	**No**	**Hair color changes, skin pigment changes** (hypopigmentation, depigmentation, discoloration, hyperpigmentation), photosensitivity reactions.

Reminder: There are no head -to-head clinical trials comparing the efficacy or safety of ROMVIMZA to Existing Product. No compari sons between the efficacy and safety of ROMVIMZA and Existing Product can be made

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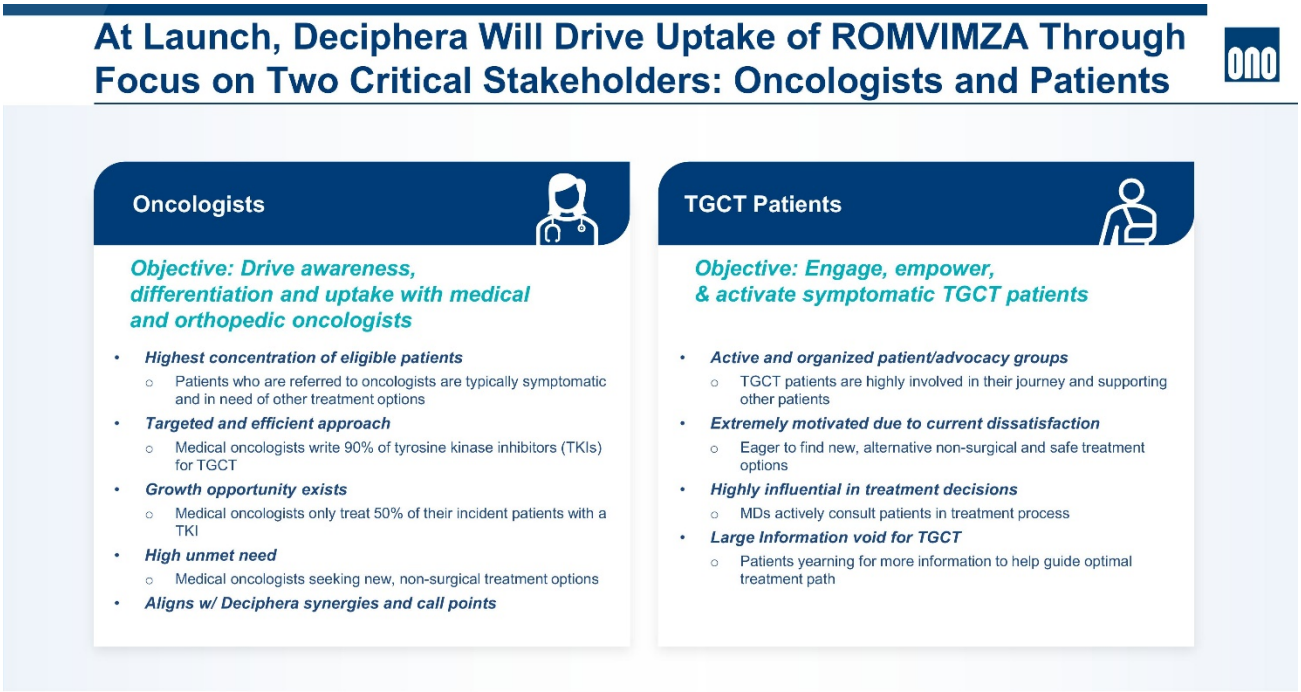
ROMVIMZA is the second TKI in the US indicated for TGCT, with the first being the existing comparable product. However, there are several key differences between the two therapies, particularly when it comes to their FDA-approved labels.

Most notable is the safety profile, where the existing comparable product has a black box warning for hepatotoxicity and fatal liver failure, a risk that may not subside with the cessation of treatment. Due to these serious safety concerns, this product can only be prescribed under a Risk Evaluation and Mitigation Strategy, or REMS, program that is implemented by the FDA to ensure safety through frequent patient monitoring for the duration of treatment.

In contrast, serious and fatal liver injuries have not been observed with ROMVIMZA, and therefore, ROMVIMZA is not subject to a REMS program. This is an important distinction that is deemed extremely favorable for both physicians and patients.

In addition to safety, there are lifestyle and convenience differences between the two treatments and unique features of ROMVIMZA that convey patient convenience and flexibility that have been proven to be very important to patients, namely ROMVIMZA is dosed less frequently at twice weekly compared to twice daily for the existing comparable product, does not have any dietary or contraceptive restrictions, and no evidence of the hair and skin color changes that are seen with the existing comparable product.

These differentiating factors have resonated positively with HCPs as well. In market research, healthcare physicians who treat TGCT patients found ROMVIMZA's clinical profile compelling, and these differences over the existing comparable product were very meaningful when choosing a preferred treatment option.



Deciphera's approach to driving adoption of ROMVIMZA for TGCT is focused on two critical stakeholders: oncologists, both medical and orthopedic, as well as patients. To effectively engage these stakeholders, it's important to first understand the dynamics surrounding each one.

As it relates to oncologists, it is important to note that patients who are referred to oncologists for their TGCT are often seeking other treatment options beyond surgery due to their symptomatic disease. These patients may or may not have had prior surgeries, and those who have had surgery likely have recurrent disease. In the US, oncologists write the vast majority of TKI prescriptions. However, they are only treating 50% of the TGCT patients currently under their care with a TKI, often due to lack of confidence in the available treatments.

As a result, a substantial number of symptomatic patients are currently under the care of an oncologist but are not treated with a TKI. These patients are most likely to continue to advance in their need for systemic therapy. This gap in treatment provides a significant opportunity for ROMVIMZA.

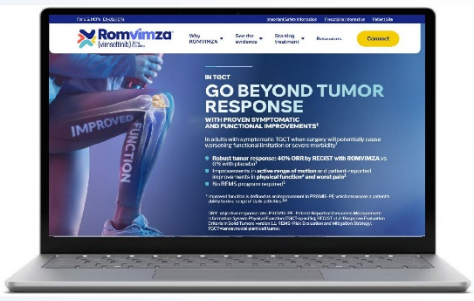
TGCT is treated both in academic centers and in the community by sarcoma treaters. And therefore, there is a very high overlap between healthcare practitioners who see these patients and those the Deciphera commercial team is engaging with for QINLOCK. These are familiar physicians, and the call point is a synergistic one for both QINLOCK and ROMVIMZA.

Differentiating ROMVIMZA with these HCPs, highlighting the unmet need in TGCT, and amplifying the patient voice as it relates to needing better alternatives are key launch objectives for Deciphera. However, reaching oncologists alone is not enough. Patients with TGCT play a pivotal role in driving demand for new treatment options, even more so than in other oncologic diseases.

TGCT patients are highly organized and engaged with patient advocacy groups due to the lack of resources and education about the disease. This is a group that is seeking information and alternative options due to their dissatisfaction with surgery, particularly after the first recurrence and experiences of setbacks from debilitating surgeries and often long recoveries.

Due to the quality-of-life focus in TGCT, patients have strong influence over treatment decisions and physicians' willingness to prescribe. These patients often will refuse additional surgery and self-advocate for other options, including self-referring to oncologists and sarcoma specialists.

Deciphera Is Swiftly Driving Awareness Of ROMVIMZA Approval With Oncologists



www.romvimzahcp.com

- ✓ Reach to Sarcoma Centers of Excellence
- ✓ Third Party Educational Webinars
- ✓ **Increased** website traffic

HCP Media Highlights

- ***Strong HCP interest***
  - **>9K visits to ROMVIMZAHCP.com**
- ***Eligible Patients Identified***
  - **Steady increase in Prescribing Information and Product Fact Sheet downloads**
- **Intent To initiate Patients on ROMVIMZA**
  - **Increased traffic to Deciphera Access**

POSITIVE FEEDBACK FROM HCPS[1]

> A better drug than pexidartinib, especially in terms of toxicity.
> – Medical Oncologist

> Side effect profile and duration of response is great, ROMVIMZA is a great option over the others.
> – Medical Oncologist

> When orthopedic surgeons see this, they will recognize that patients should be referred earlier to receive this medicine.
> – Medical Oncologist

[1]HCP feedback

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Building awareness of ROMVIMZA approval with this group and educating them around the importance of consulting with an oncologist to consider non-surgical treatment options and this newly indicated TKI is an important driver of demand for ROMVIMZA. Building upon the positive reception we've seen, we're observing tangible results from our efforts to engage oncologists and raise awareness.

As stated in our objectives, with only a few months into launch, Deciphera has been successful in swiftly driving this awareness of approval with oncologists. This early success has been reflected in the feedback we've received from our customers. To date, it has been extremely positive, especially as it relates to the safety profile and the improvement over other currently available options.

Likewise, Deciphera is Driving Awareness of ROMVIMZA and TGCT Education with Patients

www.romvimza.com

www.TGCTtruth.com

Patient Media Highlights

- **Strong Patient Interest**
  - **>11K visits to ROMVIMZA.com**
- **Intent to Request ROMVIMZA from HCP**
  - **Doctor Discussion Guide downloads**
- **Intent to Start Treatment**
  - **Deciphera Access Point visits**

Earned Media Highlights

- 3rd party webinars regarding TGCT aligned with ROMVIMZA approval

EXCITEMENT FROM PATIENT COMMUNITY

> Patients are making appointments to ask about ROMVIMZA!
> – Patient Advocate

> I know a patient who showed their HCP the ROMVIMZA PI to talk about treatment!
> – Patient Advocate

> We have a webinar series dedicated to the evolving treatment landscape of TGCT.
> – Patient Advocate

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Likewise, awareness activities directed at patients have been positively received and advocacy groups have shared that patients are learning about this new treatment option to discuss with an oncologist. We have heard several cases where patients are sharing the prescribing information with their doctor and requesting a trial with ROMVIMZA.

ROMVIMZA Has Demonstrated Positive Market Receptivity

Positive Product Impressions

- Strong positive reaction to no REMS and no black box warning
- Minimal liver toxicity with no hair depigmentation
- Viewed as effective with rapid improvement in symptoms and tumor response
- Twice weekly dosing with no food restriction

Broad Prescriber Base

- ROMVIMZA Rx coming from Sarcoma Centers of Excellence, academic, community and government accounts

Fast Patient Access

- Positive Feedback on product profile from Payers
- Early and Broad Payor Coverage
  - -- Commercial
  - -- Medicare
  - -- Medicaid
  - -- Veterans Affairs
- Limited evidence of New to Market Blocks

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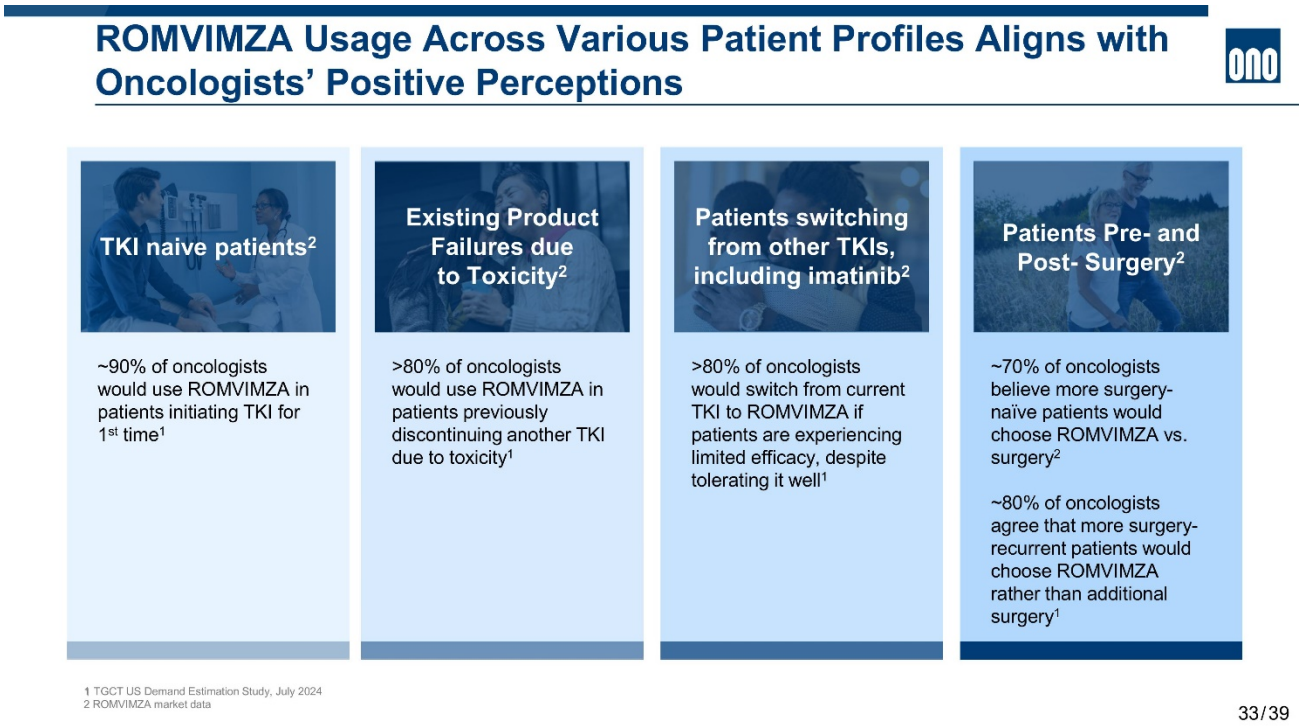
Overall, we are pleased with the positive feedback we have received regarding ROMVIMZA's clinical profile, including its efficacy, safety, tolerability, and convenience. This positive reception is further reinforced by the diverse group of prescribers we've seen so far. To date, early ROMVIMZA prescribers have come from a broad base, including sarcoma centers of excellence, academic facilities, community facilities, and government

accounts, such as Veterans Affairs Hospitals. Adoption has been seen in various geographies across the US. We believe having early awareness and early adoption from these various segments is a strong indicator of a sustained adoption in these centers.

In addition to prescriber adoption, access for patients has also been a key priority, and we've seen strong progress. As expected, patient access has been quick with broad payor coverage, limited new-to-market blocks, and overall positive payer feedback regarding ROMVIMZA's clinical profile and price.



Lastly, along with a strong prescriber and payer feedback, the patient profiles of these first patients-prescribed ROMVIMZA align with our expectations based on prelaunch market research and are strong indicators for sustained adoption. This alignment is an important sign that ROMVIMZA is meeting the needs of a diverse patient population. To date, we have seen evidence of ROMVIMZA patients who are TKI-naive, existing product failures due to toxicity, patients switching from other TKIs, including imatinib, which we know is the most widely prescribed TKI for TGCT, and patients both surgery-naive and recurrent after previous surgery.

We believe these various patient profiles who have been prescribed ROMVIMZA are an early indication of the vast potential patient pool and market growth for TKI treatment in TGCT.

Considering the positive early uptake and diverse patient profiles, we believe ROMVIMZA has the opportunity to quickly become the best-in-class treatment for TGCT and grow the currently defined market potential well beyond what the existing comparable product has demonstrated, as well as build a strong foothold in advance of competition.

This potential for growth is not limited to the US. Additional opportunity exists with the potential launch in Germany and other further market expansion globally. Additionally, we are excited about the potential label expansion into chronic GVHD and exploring plans to commercialize in that disease state.

With that, I'll turn it over to Matt to discuss Deciphera's earlier pipeline. Matt?

Sherman: Thank you, Michelle.

I will now briefly walk through our unique approach to kinase inhibition, our proprietary discovery platform, and the exciting early-stage programs it has generated.

Solving Limitations of Classical Kinase Inhibitors

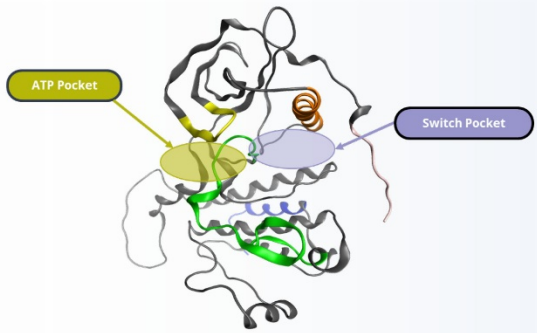
We take advantage of variation in the switch-control amino acid environment to design superior, drug-like molecules

Higher kinase specificity

- Enhanced kinome selectivity
- Stabilize inactive form of the kinase
- Fewer off-target effects

Increased potency

- Insensitive to cellular [ATP]
- Extended pharmacology



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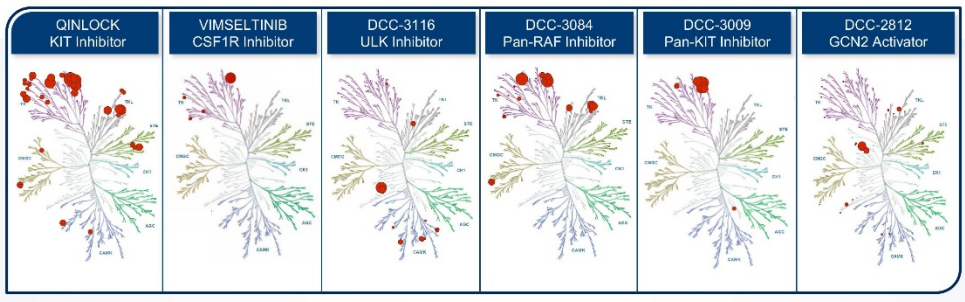
At Deciphera, we take advantage of variation in the switch-control amino acid environment to design highly specific molecules that target the switch-control activation loop pocket instead of the ATP binding pocket. This leads to higher kinase specificity, with enhanced kinase selectivity and fewer off-target effects. It also leads to increased potency because the drug does not compete with cellular ATP.

Switch Control Platform has Delivered Multiple Approved Agents and Clinical Stage Compounds

QINLOCK (ripretinib) 50 mg tablets
Romvimza (vimseltinib) 30mg Capsules



Notes: CSF1R=colony-stimulating factor 1 receptor; GCN2=general control nonderepressible 2; KIT=KIT proto-oncogene receptor tyrosine kinase; RAF=rapidly accelerated fibrosarcoma; ULK=unc-51-like autophagy-activating kinase.

Deciphera has developed two FDA approved drugs

Additional compounds are in pre-proof-of-concept clinical studies or entering development in 2025

Sustainable platform for development of future kinase inhibitors and activators

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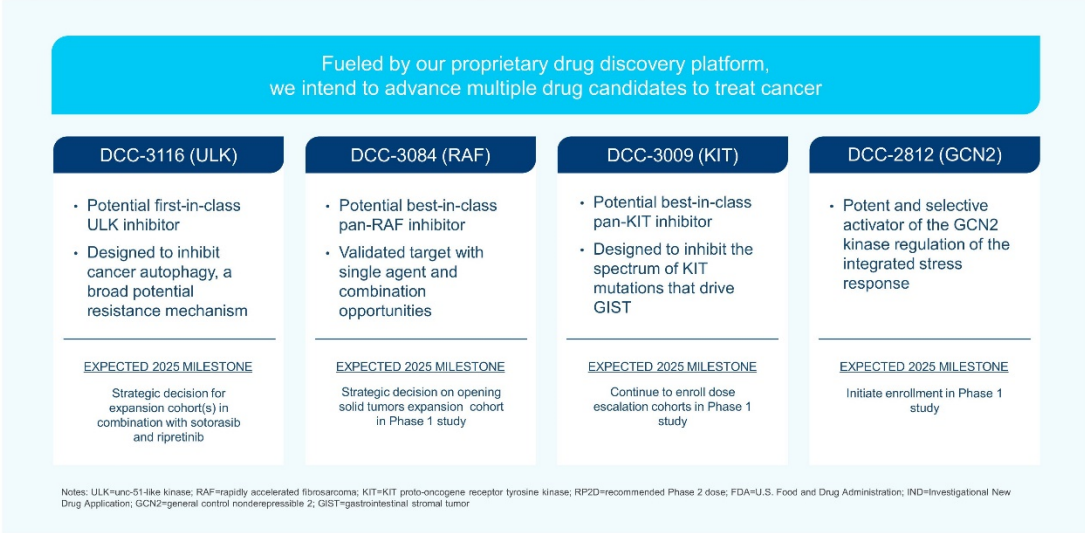
As you can see in the figures shown here, Deciphera's switch control platform has delivered multiple approved agents and clinical stage compounds.

Deciphera has developed two FDA-approved drugs, QINLOCK and ROMVIMZA, and we have additional compounds in pre-proof-of-concept studies for entering clinical development this year. We believe we have a sustainable platform for the development of future kinase inhibitors and activators.

Driving Innovation Through Our Proven Discovery Engine



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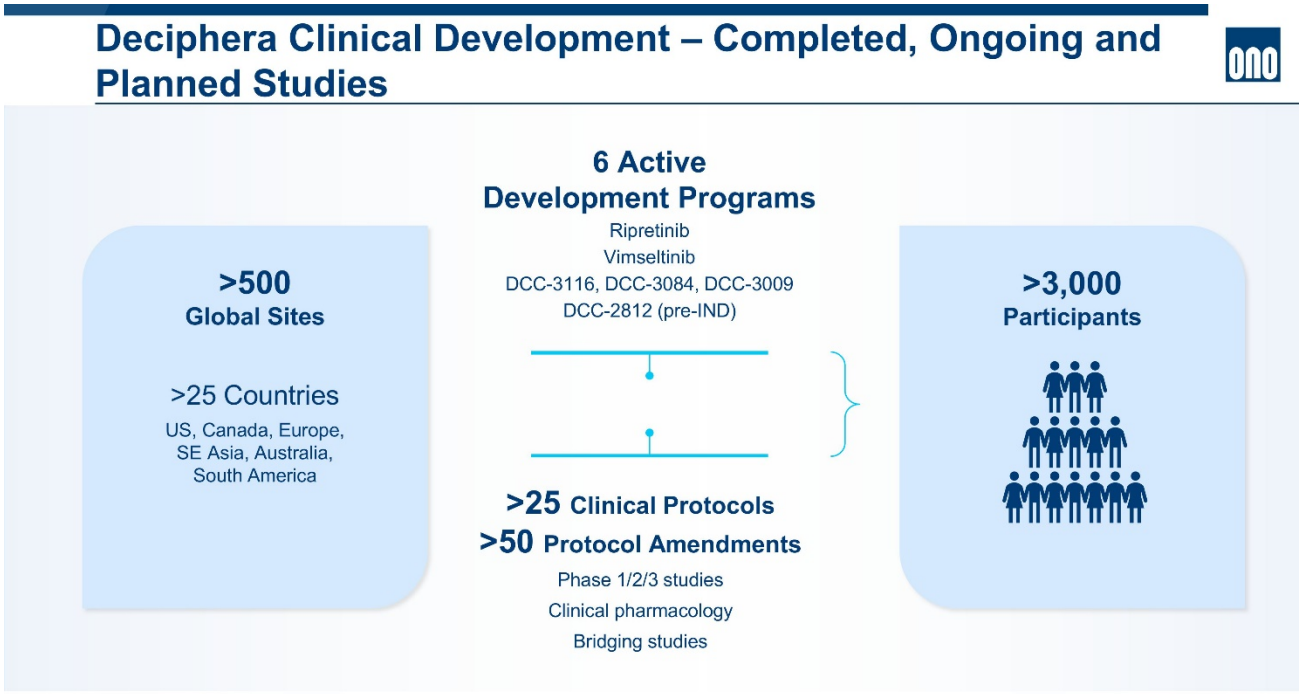
Beyond QINLOCK and ROMVIMZA, I'm also very excited about the potential of our clinical and research pipeline to fuel Deciphera's growth.

DCC-3116 is our potential first-in-class ULK kinase inhibitor designed to prevent cancer resistance by inhibiting autophagy. DCC-3084 is our potential best-in-class pan-RAF inhibitor. DCC-3009 is our potential second-generation best-in-class pan-KIT inhibitor designed to inhibit the spectrum of KIT mutations that drive GIST. And DCC-2812 is a potent and selective activator of the GCN2 kinase involved in the integrated stress response.



We at Deciphera are proud of the work that we have done and continue to do in clinical development. We have a small but powerful team and six active development programs and, over the past several years, have opened more than 25 clinical protocols and over 500 investigational sites in 25 countries, treating more than 3,000 participants. We are passionate and tenacious in our efforts to improve the lives of people with cancer.

Thank you. That concludes my presentation. I will now turn the presentation back to Takino-san.

Takino: Thank you very much.

Questions & Answers

Imura : Now, we'd like to entertain the questions from the audience.

Yamaguchi : I am Yamaguchi from Citi. I have several questions based on page 22 of your presentation regarding market opportunity.

Can you tell us how many patients are now treated with the existing comparable product on the dark blue side? And how many people out of 1,400 are waiting to get your treatment? So, can you give me the number of patients you are targeting including the patients that are being treated with the existing comparable product?

Thank you.

Duarte : I think it's a relevant question because it shows, this slide really shows the opportunity and the substantial number of patients that are waiting or have been waiting for ROMVIMZA.

So, regarding your first question about the existing comparable product, it's difficult for us to specify how many patients are or were on this product. Just to name some facts, this product, according to public information last year, this product in 2024, so calendar 2024, not fiscal year, it sold more or less USD 40 million in terms of its revenue in the US. So, this is the number that we have in mind when it comes to the opportunity that the existing comparable product is exercising, which is also under the premise of the number of patients that they are treating.

Regarding your second question, can you remind me, it was about the 1,400 incident patients that are waiting for ROMVIMZA. Can you repeat the question?

Yamaguchi : I think there are still patients who are waiting for your treatment. So, how many people are waiting for your treatment? And after their surgeries, there is no other option. So, how many patients out of the 1,400 who are waiting are the first users of your drug?

Duarte : Yes. It's a good question.

So, what I can tell you, and Michelle can also speak to this to the type of patient profiles that we are seeing, but out of the 1,400 incident patients, all these patients that are incident to oncologists, they are seen by oncologists, all of them are on systemic therapy, either with a pain medication or a steroid or a TKI. And I can tell you that when we looked at this data, only 50% of the patients were on a TKI. So, out of the 1,400 incident patients, only half was on a TKI. So, I think this already shows you that many patients were waiting for ROMVIMZA. And this is why also in our patient profiles, we are seeing patients that are TKI-naive that were waiting for ROMVIMZA, as Michelle mentioned in her prepared remarks.

Yamaguchi : Lastly, regarding the blue part**,** the 9,000 prevalent patients who are not at the moment being treated by the doctors, that's my understanding, how long it will take those patients to be diagnosed and treated because if you have the drugs, more treatment will happen. So, is that the right way to understand this? Thank you.

Duarte : Yes. So, the 9,000 prevalent patients, they are already seen by oncologists. So, all the part in blue, both the 1,400 incidents and the 9,000 prevalent patients, they are already seen by oncologists. And that's why your question makes a lot of sense because this is our focus…because in the US, the vast, vast majority

of TKIs are prescribed by oncologists. So, the focus at our launch is not only on the 1,400 incidents, but also the 9,000 prevalent patients.

The difference between both circles is that while in the dark blue, the 1,400 incidents, half of the patients are on the TKI. In the 9,000 prevalent patients, they are treated mostly with pain medication or steroids. Very few patients are treated with a TKI. So, this is why we really believe that the market can grow if we increase the number of patients on the TKI. But our focus is both on the incident and prevalent on the blue circles because they are already with oncologists.

Yamaguchi : Okay, thank you.

Hashiguchi : I'm Hashiguchi from Daiwa. I have two questions.

My first question: in the past three months since the drug was approved, who has started treatment? Which is more common, patients who have been using another TKI and have switched to ROMVIMZA, or patients who have not been treated with TKI before, that is, naïve patients who have started ROMVIMZA?

DiNapoli : Yes. Thank you for the question.

We're very excited about the patient profiles that we're seeing so early in this launch. We have seen patients that have never seen a TKI before, patients who have been previously with the TKI, and those that may or may not have had surgery. So, early in launch, we've seen all of these types of patients thus far, which is very exciting because we think that sets up an opportunity for those that have seen a TKI in the past, whether it's an existing comparable product, or imatinib, which is a big population of the patients. And we know that some of those patients haven't seen the efficacy benefit that they would have liked and therefore discontinued. So, that's a big patient pool that we think could be good candidates for ROMVIMZA moving forward.

We also know that the profile of the existing comparable product was a big hindrance for physicians and patients adopting that product. So, as Margarida said, we know there are patients out there that need systemic therapy but maybe have not been referred to an oncologist for evaluation because the treatment options were not favorable. And now, we believe this referral pattern to the oncologist can increase because there are better options out there for oncologists to prescribe.

Also, as Margarida said, only half of these patients that are under the care of an oncologist are currently treatied with a TKI, a lot of times because the treatment options weren't favorable, and we think we can increase that treatment rate as well. So, we think we will continue to see all of these patients, patients who have seen TKIs in the past, both existing comparable product and imatinib, as well as those that are new to TKI treatment, and increase the patient pool that gets referred to an oncologist for evaluation.

Hashiguchi : The second question is for Matt-san. As Takino-san mentioned before, development of various products in the future will be done with Deciphera at the center. From your perspective, Matt-san, what kind of products are you interested in developing in the current Ono Pharmaceutical pipeline? If there is a pipeline that you think will be enhanced with the power of Deciphera, please let us know. Also I think Takino-san mentioned the willingness to introduce newly developed products from third parties in the future, but from your point of view, I would like to know what kind you would want to acquire that would be exciting for Deciphera.

Sherman : Thank you for the question. So, the question relates to the Deciphera pipeline and which drugs perhaps are more exciting to me or to Deciphera.

But I'd really like to just step back and just again highlight the work that we've done over the many years. So first, getting QINLOCK approved for the treatment of GIST patients in 2020. And our initial study was for the

treatment of fourth-line GIST patients, and that informed the FDA and the EMA in over 40 countries around the world for the approval in treating fourth-line GIST patients.

We now have the INSIGHT study ongoing in second-line GIST patients who harbor a mutation in Exon 11 and 17/18. And those mutations in Exon 17/18 represent the switch control pocket of the KIT kinase, where sunitinib, the approved agent for second-line patients is inactive. And in an exploratory study we did based on the INTRIGUE study in second-line patients, in that subset of patients harboring that specific mutation, we had a 44% response rate for QINLOCK versus 0% for sunitinib. And the median progression-free survival was 14.2 months for QINLOCK versus only 1.5 months for sunitinib.

So, the confirmatory Phase III trial INSIGHT in only 54 patients is ongoing, and we're very excited about the potential of QINLOCK in second-line GIST patients with that specific mutation. And also, as I highlighted, the extension of ROMVIMZA into chronic graft versus host disease can be a very nice opportunity for increasing the opportunity for ROMVIMZA.

Another agent was approved for the treatment of chronic graft versus host disease. That's the CSF1 receptor antibody, but that requires an IV administration every two weeks. And so, the need for an oral therapy for patients with chronic GVHD is highly sought after by the treating physicians.

And then, of course, our other pipeline, as we've discussed, remains very exciting. One new opportunity that was mentioned that was recently discussed was the in-licensing of sapablursen in antisense oligonucleotide that ONO Pharma in-licensed from Ionis for the treatment of polycythemia vera. And that will be a program that I look forward to updating in the future.

Hashiguchi : Thank you.

Imura : Thank you very much. Any other questions from the floor? Wada-san, please.

Wada : I am Wada from SMBC Nikko. I have a basic question about the science.

So, the existing comparable product has a warning, and it has a toxicity issue. Has the kinase responsible for the toxicity been identified? This is my first question.

Sherman : It was a question related to the toxicity of the existing comparable product and particularly the hepatotoxicity. Yes.

So, as we've noted, it is not an effect of the inhibition of CSF1 receptor. Other agents, including vimseltinib and other investigational drugs have not shown that same cholestatic hepatotoxicity. In some documents that have been discussed with the FDA for the existing comparable product, it may be related to a specific pharmacophore, a metabolite of that product that is generated in patients, leading to the cholestatic hepatotoxicity. So, it seems to be a unique effect for that agent, the existing comparable product, and not seen with other CSF1 receptor inhibitors.

Wada:

And related to that, on page 37, you mentioned you were looking into switch-pockets of kinase inhibitors. Among the kinase inhibitors, there are so-called allosteric-type inhibitors, meaning kinase selectivity is high. Can any of the six kinase inhibitors listed on page 38 be considered allosteric inhibitors?

Sherman : Yes. Thank you for the question.

So, what we have focused on our research efforts at Deciphera is looking for small molecule inhibitors of protein kinases that target the switch-control pocket that is demonstrated on one of those slides. And that's

a distinct area of the protein from the ATP-binding pocket. And most of the small molecule kinase inhibitors that have been developed and approved in the field of oncology target the ATP-binding pocket, compete with the ATP substrate that the kinase uses to phosphorylate downstream proteins.

But Deciphera, by targeting the switch-control pocket, has found agents that are different in their activity, more selective, and do not compete with the cellular ATP concentrations. And the pipeline that I show on the next slide do represent compounds that are all switch-pocket kinase inhibitors or activators. GCN2, for one example, is our newest molecule for which we filed an IND in the US to start human trials this year, and that is an activator of a kinase that is involved in integrated stress response leading to cell death.

Wada : Thank you very much for the answer.

Imura : Thank you. Ueda-san, please.

Ueda : [Ueda]. I'm from Goldman Sachs Securities. I have a question. These are basic questions. Now that you have shown the comparison with an existing comparable product, what are the risk factors for the start of vimseltinib?

You have mentioned the convenience and safety advantages of the existing comparable product, but we would like to know if this differentiation can be expected to lead to an increase to the size your company envisions?

While there were no other effective options so far, the existing comparable product has started very gradually. Please tell us what are the bottlenecks, whether the issues will be eliminated by the safety that you have introduced this time, and whether there are any risk factors. Thank you.

DiNapoli : So, thank you. So, like I had said, we do believe that the existing comparable product's uptake was hampered by its safety profile and also the REMS program, which limited the number of physicians who made decisions to prescribe and therefore, limited the experience that many oncologists were able to realize with prescribing the existing product.

So, we do feel like ROMVIMZA has positive differentiation, not only in efficacy, but also safety and convenience. And we think that this will be a powerful reason why physicians will prescribe, so not only will surgeons refer who were previously sort of gatekeeping patients from referring them to an oncologist because the perception was that the treatment for TGCT with the safety profile of the existing comparable product was worse than the disease itself, was more dangerous than the disease itself. And we feel like because of ROMVIMZA's profile, surgeons will be more likely to refer patients to an oncologist and not gatekeep them.

And also, patients themselves are more willing to go to an oncologist because they feel they have a better option with ROMVIMZA and a safer option with ROMVIMZA. Whereas with the existing comparable product, they didn't want to go through a REMS program. They didn't want to take on the safety risk of liver failure. Please remember that these are young patients and otherwise healthy patients. So, taking on that safety risk was definitely a limiting factor. So, we do feel our product differentiation will be the thing that unlocks a bigger market for patients to go and ask for ROMVIMZA and for physicians to be willing to prescribe ROMVIMZA.

Ueda : Thank you so much.

The second question is on your joining the ONO Group. I'd like to know what kind of changes have happened since you joined the ONO Group. How is integration going with regard to the current organization and R&D budgets after the integration. So, could you share your perspective? And in the future, I understand the

organization will be integrated. So, how about the fit of the organizational cultures? So, do you see any challenges, for example, in the integration of the corporate cultures?

Duarte : I can start, and then maybe I also hand over to my colleagues to complement. So, for us, I mean, I speak also for myself, I come from a background of big pharma. I spent 11 years at Amgen. I also come from companies like Alnylam, AstraZeneca early in my career. So, I am very much used to companies that are global, with headquarters in other countries with a very strong pipeline, which is the case of ONO, with expertise, very much R&D, commercial expertise.

So, speaking for myself, I mean, I am excited about the challenge. Under the umbrella of ONO, we feel that now we have a bigger pipeline, a bigger pipeline that we can work with, not only with the Deciphera pipeline, but also with the ONO pipeline. And we can also join forces with helping also ONO, bringing QINLOCK and ROMVIMZA to Japan and other countries like South Korea, but also together, go to more markets and have bigger impact for patients.

So, personally, I feel very comfortable being under the umbrella of a bigger organization. And again, it's not new for me because that's my background. But maybe asking my colleagues for any comments.

DiNapoli : I believe that there's also synergies in our missions. Both ONO and Deciphera have really focused on patient care. I think like Margarida said, like having a global footprint and resources to invest appropriately in bringing more medicines to the market is very powerful certainly for Deciphera. And I think we have the opportunity to think strategically about licensing opportunities, more so than we would have been able to if we weren't joined with ONO. So, we have an opportunity to really develop a robust pipeline that can commercialize globally and prioritize strategically.

Ueda: Thank you so much. That's all. Thank you.

Sherman : And also, I can just add a little bit of my experience. Similar to Margarida's, I've had the opportunity to be in smaller companies that have then been acquired by larger global pharmaceutical companies. My first biotechnology experience with a company called Genetics Institute, one of the early-stage biotechnology companies in the Boston, Cambridge area. And that was acquired by Wyeth-Ayerst Research.

And in that capacity, I was able to bring a small molecule to development, first antibody drug conjugate that was approved in the US and also approved in Japan. That company was then acquired by Pfizer. So again, that's the natural history of innovative small companies.

The next company I worked at was Acceleron Pharma for 12 years, and that was a successful biotech company in the Boston, Cambridge area, but then was acquired by Merck. So again, the transition from a small innovative company to a large multinational pharmaceutical company.

And I think the experience, the very deep research experience that ONO has will bring many exciting opportunities for global development. And you can see on this pipeline slide, there's a number of three proof-of-concept compounds that are being developed either in Japan, Korea, and Taiwan by ONO, or outside the region and more global in the US and globally.

And then, the very deep business development experience that ONO has will be another excellent catalyst for bringing in new molecules, as most recently evident by the in-licensing of sapablursen. So, I think it brings together both small company innovation, the deep research from a large pharmaceutical company, and bringing together two cultures that are working together very, very well.

Imura : Thank you very much. And now, Mr. Wakao, please.

Wakao : Thank you very much for the presentation. I am Wakao from JPMorgan.

Regarding opportunities for ROMVIMZA in the EU, do you anticipate any differences between US and EU penetration? In the EU, you explained that there are no approved therapies. So, I expect a faster uptake there than in the US. However, our perception is that pharmacologic treatment options may still be relatively low. What are your expectations regarding the EU opportunity?

Duarte : The question, I can take it.

It's just an opportunity for me to reiterate how excited we are with what we are seeing in the US. I think Michelle mentioned that in her prepared remarks. I also mentioned it, the launch so far in the US is exceptional. And we would love to replicate the same in Europe if approved. I need to make this caveat that the review is still ongoing with the European Medicines Agency. So, we look forward to sharing more updates as they become available.

And you said it rightly. So, in Europe right now, there are no approved therapies. So, you could say that probably the unmet medical need is even higher in Europe. However, the market is also underdeveloped. We know that many patients are still with surgeons because there are no available treatment options. So many patients in Europe have not yet been referred to oncologists. So, if approved, this is a work that we will need to be doing also to refer patients from surgeons to oncologists because similar to the US, also in Europe, it's the oncologists who prescribe the vast majority of the TKIs. So, we need to have patients referred from surgeonss to oncologists.

So lastly, what I would like to say is that we have an incredible data package, a very, very compelling product. And in Europe, with QINLOCK, we have excellent relationships with KOLs because those KOLs who will be treating TGCT, many of them are already treating GIST with QINLOCK. So, we will be leveraging our strong relationships with the many countries where we have already launched QINLOCK and also the countries that we are preparing to launch QINLOCK.

Also, in Europe, once approved or if approved, we will also have the opportunity to leverage all the learnings from the US market. So, it's great for the team in Europe who is very committed as well and very motivated to potentially launch in the future. We'll be able to learn from all the excellent work that the US team is doing. And again, I could not be more excited with what we are seeing right now in the US and hearing from the KOLs. So, more to come, and I really hope that soon we can have more news regarding Europe.

Wakao : Thank you.

Matsubara : I'm Matsubara speaking for Nomura Securities. I have a question.

Pimicotinib is a competitor drug from Merck. It is described in the presentation material that the market will expand due to the patient background and the launch of a competing products. Their drug has shown an effective ORR of 54%. Could you give us your comment on your company's view on peak sales, share, and threat level in this context?

Duarte : Pimicotinib, I understand. Thank you. Yes. So, we have to see the data set of pimicotinib. Let me start with this. So, we know that the top line results were shared end of last year. So, end of 2024, the company released the top-line data. So, we have not yet seen the results. We also know from KOLs that they would like to see the detailed results , namely the subgroup analysis. So, there is interest also from us and also from the KOL community to understand the entire data set.

What I can say is that we are incredibly happy with ROMVIMZA. The feedback that we have from KOLs is exceptional so far. Also, the feedback from patients, we have anecdotes of patients who started on ROMVIMZA and shortly after pain was gone. So, with only three months after launch, it's exceptional what we are seeing in the market, the differentiated label that we have, the very compelling data that we have.

And like I mentioned before, we have very strong relationships already with these prescribers because the overlap with GST is very high. It's between 70% and 80% in the US. But what you said is very important in your question. So, potentially more entrants, pimicotinib or others, will help drive increase of awareness, increase in education, so expand the market potentially in the future, benefiting more patients. But I'm very pleased with where we are right now for ROMVIMZA.

Matsubara : Thank you.

Imura : Thank you very much. Now, Mr. Sakai.

Sakai : Hello, I am Sakai from UBS. I just have a couple of clarifying questions.

You have the patient numbers here. The first presentation that you made, or ONO made at the time of the acquisition, the total addressable market, and also the patient numbers in the US and Europe, is 15,000 patients. With today's presentation, what I'm interested in is how many patients will be able to undergo surgery here? And if the post-patient condition is bad as you described, why are doctors or people still going through with this surgery? And with the indication with vimseltinib it could be the first option. Why is the first choice surgery and post-surgery use of drug treatment. So, it hasn't really changed the situation. Is my understanding correct?

Duarte : Thank you for the question. So, I hope I have captured all the questions. But if I haven't, please let me know, and then I'll also invite Michelle to comment.

So, one of your questions is why surgery. So, it depends on the type, and maybe Matt can also help here, the type of TGCT, if it's localized or diffused TGCT. So, depending on the type, some patients can be cured by surgery. So that's why surgery is still the first option. It's still the first option for the treatment of TGCT.

But I also have to say, and Matt maybe can comment as well, that recently in some medical conferences, both surgeons and oncologists, they also have a question mark on the role of TKIs. So, now with ROMVIMZA and potentially other TKIs, they are also debating will surgery remain the first option, or will this change? Or will the standard of care change and the treatment approach? So, now with the launch of ROMVIMZA, it's very interesting how we may also shape the market.

But it's important to note that some patients are cured by surgery, but many relapse. Many patients relapse, and some patients can do a second surgery and a third surgery, and it's detrimental for patients. So, for these patients, naturally, there may be also a role for TKIs, but also some patients are inoperable. They are not indicated for surgery. That's why we are right now at the beginning of the launch of ROMVIMZA, and even KOLs and the medical community are questioning what is going to be the role of the surgery in the future for some patients? This is an ongoing discussion.

And maybe, Matt, you can comment here on what you're hearing from the science and the medical perspective.

Sherman : Yes. Thank you for the question, and thank you, Margarida.

So, as Margarida mentioned, TGCT can occur both in the localized form or diffuse form. The localized tumors tend to be smaller, maybe 1 centimeter in diameter, and often are in a smaller joint such as in the hand. And when patients present with the localized form of TGCT, they have a likelihood of being cured with surgery, and perhaps only 15% of those patients recur after surgery. So, it's still a complication for some patients, but not all the patients with localized disease.

The other form of TGCT is diffused, and those tumors typically are larger, on average more than 5 centimeters in size. And more than half of those patients will recur after surgery. So, you can see that there's a large number of patients that will recur after surgery. And many of these patients do have multiple surgeries.

In the Phase III MOTION study, more than 70% of patients had at least one surgery, and approximately 10% of patients had four or more surgeries. So, those can be very, very debilitating for patients. And also as Margarida indicated, the practice will change when there's a better tolerated small molecule drug available for those patients to not have surgery as a desperate measure for treating their disease.

Sakai : Okay, right. It's very clear. Thank you.

DiNapoli : I would just add one point on that from a commercial perspective. Because this is a rare disease, and as I said in my prepared remarks, there's not a lot of education for patients and even for physicians. Many, particularly in the community, many oncologists don't have a lot of experience treating TGCT.

So, our teams are doing a really important job of educating around some of the points that Matt just made around how many of these patients will recur. Having multiple surgeries often is not in the best interest of patients. And once a patient recurs, they are more likely to have multiple recurrences and the morbidity of surgery. So, we believe that as the team can educate on these points and drive awareness around the disease and some of the limitations of the various treatment options, this will also help sort of grow the TKI treatment rate as well.

Sherman : Just to add one more comment to follow Michelle's is, as we highlighted in our presentation, it's not just how the tumor responds to treatment, but it's also how the patient responds. And it's the way the patient feels and functions that really makes the medicine attractive for patients to use it who have a clinical need.

And we're very pleased to have the success of showing that in all the key secondary endpoints in our study, including the clinical outcome assessments of range of motion, physical function, worst pain, all showed the statistical improvement for patients treated with ROMVIMZA. And those endpoints are now incorporated into the US label for the product. So, that's really a very differentiated product, and there's usually a high bar to include these clinical outcome assessments or quality of life measures of how patients feel and function. But that's more meaningful to the patient rather than just the radiological decrease in the tumor size. So, that will be an attractive attribute for the medicine for patients.

Imura : Thank you very much. Are there any more questions from the floor? If not, now I'd like to entertain questions from the attendees online. The time is limited, but let me appoint Dion-san.

Buchner : Thank you very much. This is Dion, Pathology Associates.

I wonder, Matt, can you just maybe speak a little bit about the mechanism of action of TKIs in chronic GVHD. It's quite an interesting opportunity, specifically for an oral agent. And then also, Margarida, can you maybe just talk us through your exclusivity in different markets of vimseltinib, as well as maybe the timeline of the regulatory process in Europe.

Thank you very much.

Sherman : Thank you for the question. I can start by talking about the mechanism of ROMVIMZA or vimseltinib in chronic GVHD. And it's a very good question because chronic GVHD is when in patients who receive a bone marrow transplant, the transplanted cells then start attacking the host tissue. And it's a complication, as I mentioned, in 30% to 50% of patients who receive an allogeneic bone marrow transplant. And the standard

treatment of care for these patients is steroids, but steroids as a chronic immune-suppressing agent can come with many complications.

So, over the years, several other drugs have been investigated and have led to approval of multiple other agents by targeting different pathways. So, in fact, the BTK inhibitor ibrutinib is approved for chronic GVHD in the US. The JAK2 kinase JAKAVI is approved in the US for chronic GVHD. And more recently, the ROCK-1/2 inhibitor REZUROCK is also approved.

But fibroblasts or macrophages, macrophage-derived fibroblasts, such may be involved in certain manifestations of chronic GVHD that are not well served by the existing therapies, and particularly patients who suffer from skin sclerosis or bronchiolitis obliterans, fibrotic disease of their lungs as a complication of GVHD are not well served by the existing therapies. And by inhibiting the pro-inflammatory macrophages in this disease, which express the CSF1 receptor, then we feel there's the opportunity for ROMVIMZA to be a useful agent in this disease.

And this was, as I mentioned, demonstrated by the recent approval of a drug called axatilimab. That's an antibody directed against the CSF1 receptor that was approved in the US for chronic GVHD, but it does require an intravenous infusion over 30 minutes every two weeks. So, it shows the demonstration of the importance of the pathway about the need for an oral agent for treating the disease.

Buchner : Thank you, Matt.

Duarte : I can now go to the second part of your question.

So, regarding Europe, so last summer, Deciphera issued a press release stating that our submission to the European Medicines Agency had been approved. So, since then, the product is under review, and we are in close contact with the EMA. there are really no timelines for an EMA approval. So, we are following very closely the discussion with the authorities. And again, we very much look forward to commenting and also disclosing once this information is available.

Regarding your second question on exclusivity, this is not information that we have already put out there. So, we have not yet disclosed that.

Buchner : Understood. Thank you very much.

Imura : Thank you very much. We are running out of time now. So, if you do not have any more questions, we would like to close this event now. Do we have any questions? None. Okay.

So, thank you very much for your participation in our R&D Day. This concludes our event but let me show you one last slide.

And today was this R&D Day. And we also have another one on June 4, Japan time. So, for the next upcoming ASCO, we are going to make a presentation about tirabrutinib. And on June 4 R&D Day, we will introduce you to this tirabrutinib. So please consider this opportunity, too. And thank you very much.

This concludes the R&D Day on ROMVIMZA. Thank you again for your participation from early in the morning. Thank you very much.