

24 Sep'25

DAY 3



WE ARE UNSTOPPABLE MEAR GoDeeper with Bavencio



5 mins

Opening and objectives

Mohamed and Harshveer

20 mins

Strategy and Performance: Bavencio in UC

Amr, Harshveer, Mohamed and Niklas

10 mins

Bavencio growth workstreams

Tanguy

10 mins

Bavencio Ambition

Moderator: Mohamed

10 mins

• Russia ambition

Panel: Amr, Charlie & Tanguy

10 mins

• Turkey ambition

Russia and Turkey

Q/A

All

10 mins

Coffee break

10 mins

New Launch Markets workstream: Algeria

Moderator: Mohamed and Ihab

10 mins

Go Deeper' LMIC workstream: Egypt

Panel: Amr, Tanguy, Charlie

10 mins

Q/A

North Africa and Egypt

5 mins

When to kick-off Bavencio behavioral segmentation:

Charlie

5 mins

• Why it is important?

All

5 mins

• Optimal timing to start ? (Voting)

All

• Discussion

20 mins

Establishing UNSTOPPABLE LAUNCH with Bavencio:

Kaj Linna

10 mins

Lessons learned and insights

All

Q/A

Closing

A kitesurfer is riding a large, curling blue wave. The surfer is wearing a black wetsuit and is positioned in the lower center of the frame. A bright green kite is visible in the upper center, suspended in the air. The background is a deep blue sky with a subtle hexagonal pattern. The overall scene conveys a sense of adventure and fluidity.

**We don't fear the waves;
we flow through them.**

From Ambition to Reality: **TOGETHER**, We delivered against all odds with **BAVENCIO**®



Patients

~80,000 patients treated



Performance

-0.9% growth vs F2 2025
MEAR biggest growth driver @5.9%



LifeCycle Management

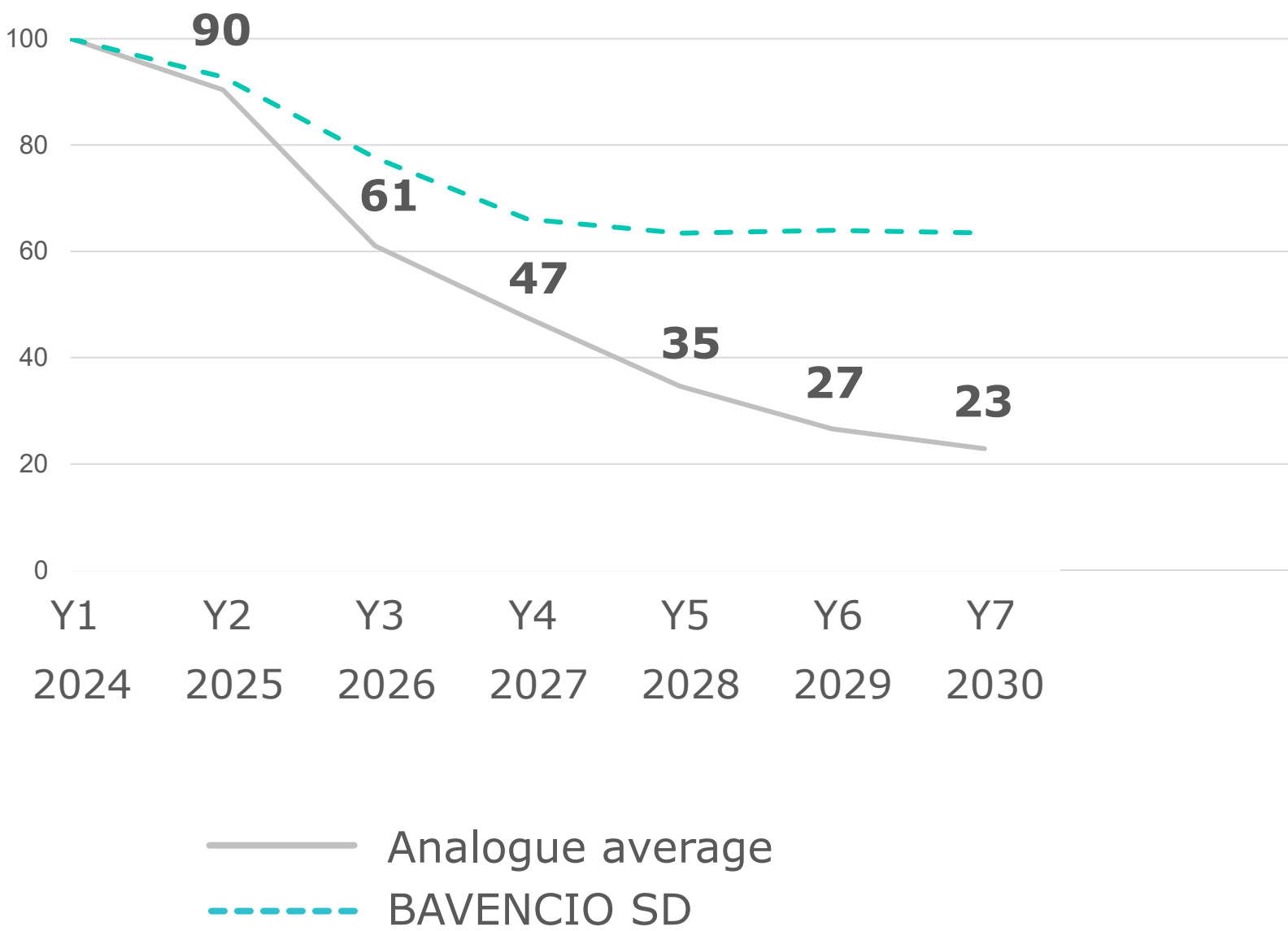
MEDLEY: Positive Study
JP RWE: New OS Benchmark
DISCUS: ESMO 2025 Readout



Competition

WE outperform analogue

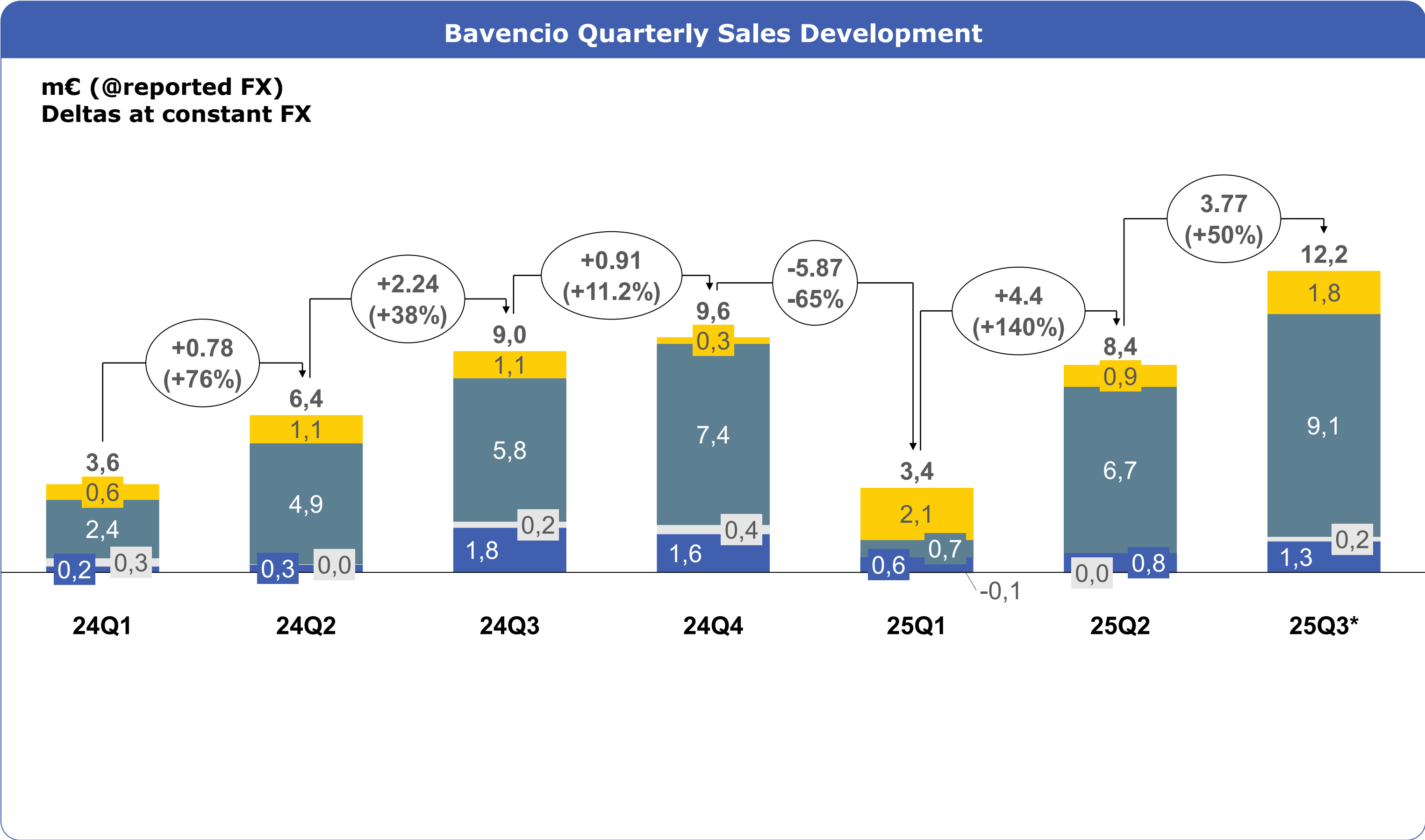
BAVENCIO sales projections do better than market analogues



Source: Evaluate Pharma, PriceRx, Datamonitor; Broker reports; L.E.K. research and analysis

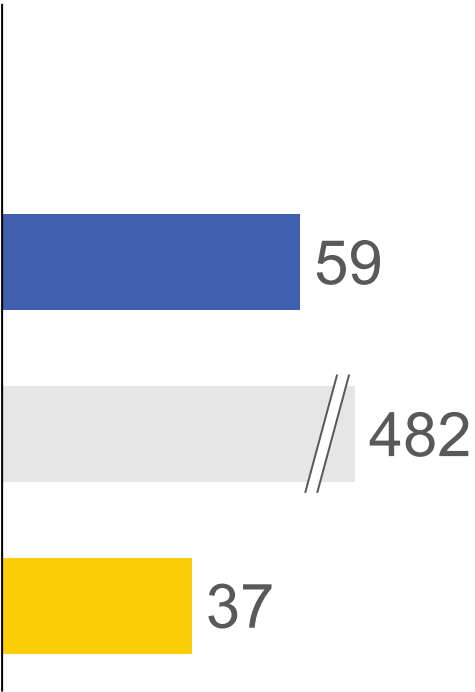
MEAR Bavencio Net Sales (quarterly evolution)

Russia Drives the Sales Rebound from Q2`25



- others
- Russia
- Saudi
- Turkey

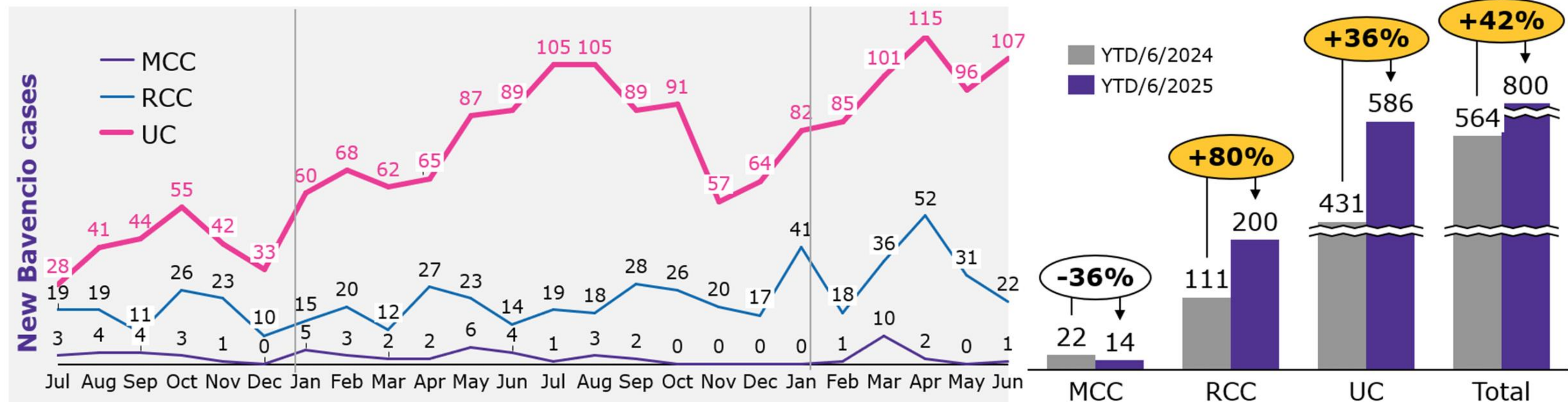
Evol. Q3'25 vs Q2'25 (%)



25Q3*: Q3 is consist of Jul. and Aug Act plus Sep in F2 due to Actual is not ready

Strong growth in new Bavencio cases in both UC & RCC

We aim to support 1,500 NEW cases in 2025



Must win battles

1. Maximize Bavencio maintenance in UC (offense/defense strategy)
2. RUS expanded access program
3. TR PDL standardization & maximize maintenance

YTG

1. Accelerated recruitment RU/TR
2. Launch DZ/LY/KZ

The waves will
always come –
what matters is
how we ride them



Defend our market position while capitalizing on all short to long-term growth opportunities

DEFEND competitive Markets: Differentiate and customize tactics to establish JBR' as Treatment of Choice in the competitive 1L mUC market.



LONG-TERM: DELIVER on our Life Cycle

UC

- ✓ Leverage JAVELIN Bladder MEDLEY
- ✓ DISCUSS: 3 vs 6 Cycles of Chemotherapy
- ✓ Execute NECTIN-4 expression/Amp strategy

Others

- ✓ Prepare for CAVE-2 readout in CRC
- ✓ Continue to explore adjuvant MCC opportunities

**High ASP/
Potential**

Driving higher demand from high ASP countries

Go Deeper LMIC

Accelerate deeper access to 9 priority markets

New Launch markets

New launch Markets (small under resourced)

Access

Markets with restricted access and funding expansion potential

Treatment rate

Focused opportunities to increase Tx rates



SHORT TO MID-TERM: Untap Growth opportunities

GROW Uncontested Market: Capitalize on growth opportunities and establish maintenance's role in 1L mUC while building brand loyalty and expanding HCP adoption. Execute launch excellence in new market.



Dual Mission²

1

2

DZ = Algeria, TW = Taiwan, TR = Turkey; EG = Egypt

A very Dynamic environment – Learnings & Opportunities

DEFEND Competitive markets

01

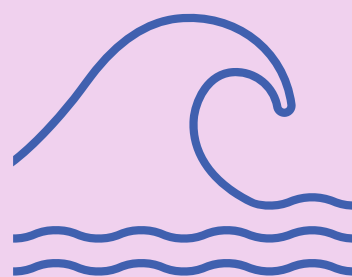
Competition wave is now a reality

HCPs see EV+P as highly efficacious despite cumulative toxicities for patients

HCP willingness to try EV+P is faster and steeper than expected

SoV challenged by EV+P hype and access to HCPs

BAVENCIO® maintenance limited by 1L platinum bottleneck



02

Riding with impact

Strong JBR dataset with consistent RWE; While EV+P RWE underwhelming vs RCT

EV+P Market Share ceiling in the US, Platinum rebound in Switzerland

We are making impact: key messages, HCP segmentation and patient profiles

Potential for fewer chemo cycles (e.g. DISCUS) may improve pt experience



GROW Uncontested markets

03

Catching the next swell

Address patient unmet needs via prioritized Tx funnel levers

Wave of new launches in emerging markets

Expand access where there are restrictions (private, PD-L1+)

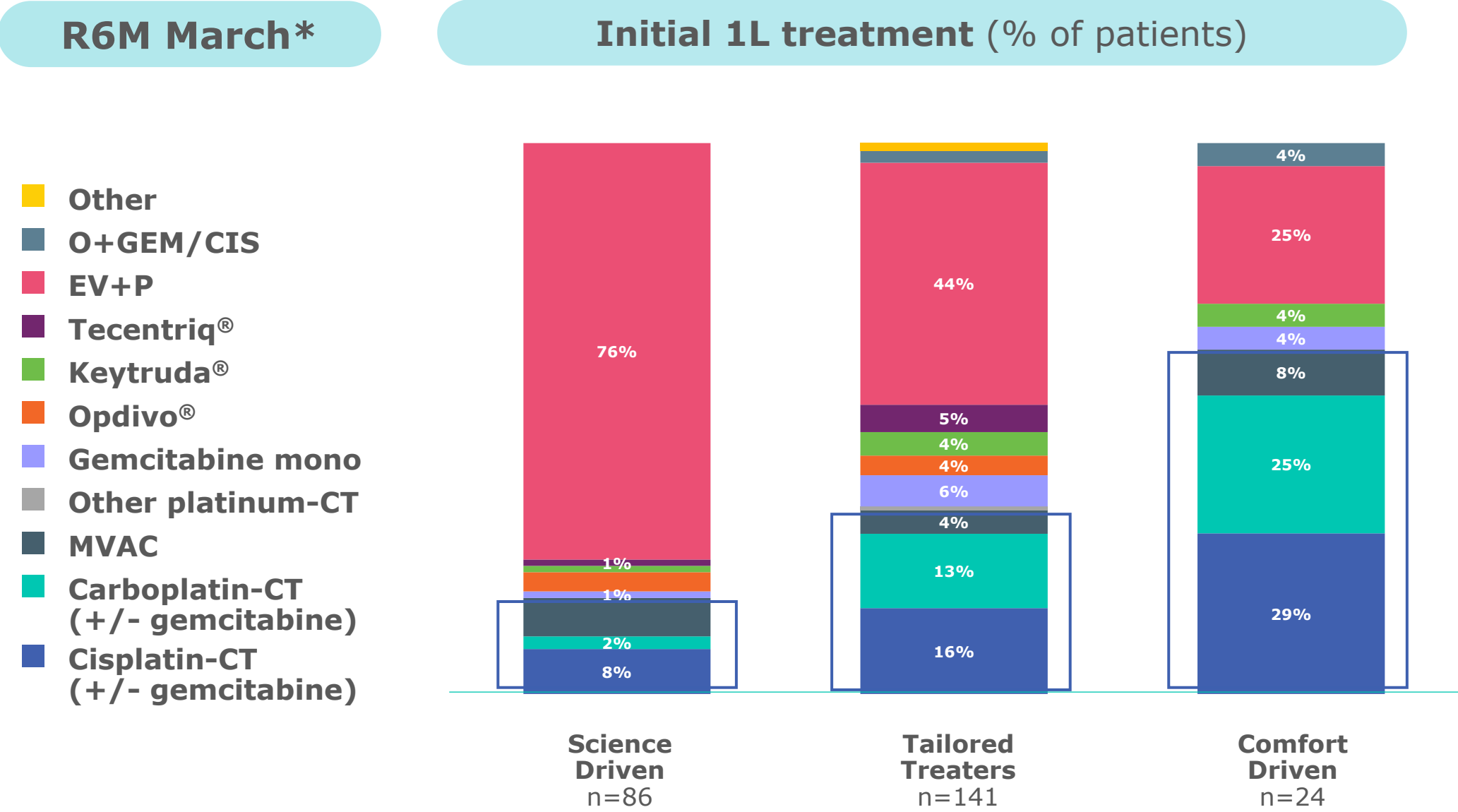
LCM: Positive MEDLEY study. EV+P adjuvant IA readout at ESMO



Key learnings:

HCP Segmentation works: Refocusing our efforts on winnable segments will drive topline efficiency & engagement impact

Our messaging on pt needs, extended QoS and Sequence strongly resonates with HCPs



BAVENCIO® messages		Extent motivating to use BAVENCIO®
Suitable for diverse patient groups (Incl. low tumor burden, high BMI, elderly)	★★★★	Very motivating
Extend quality of life	★★★ / ★★★★★	Somewhat / Very
Sequence benefit across 1L and 2L (OS benefit of 40+ months with Padcev 2L)	★★★ / ★★★★★	Somewhat / Very
Suitable for most 1L patients	★★	Somewhat
Extended overall survival benefit (29 / 30 months from the start of chemo)	★★	Somewhat
Real world experience	★★	Somewhat





■ Differentiation opportunities

Base: All PRF B patients (1L initiations)
Source: B10a What 1L unresectable locally advanced / metastatic treatment have you chosen and decided to initiate for this patient?
Source: SoV: Research Partnership UC Message Recall W2, fielding November 2024 – January 2025; Rep& MSL FT Source: Research partnership Message Recall (EU5/JP) W2 Nov'24/Jan'25;
MEAR Summit – September 2025



2026 Must-win Battles will pave our way to return to growth

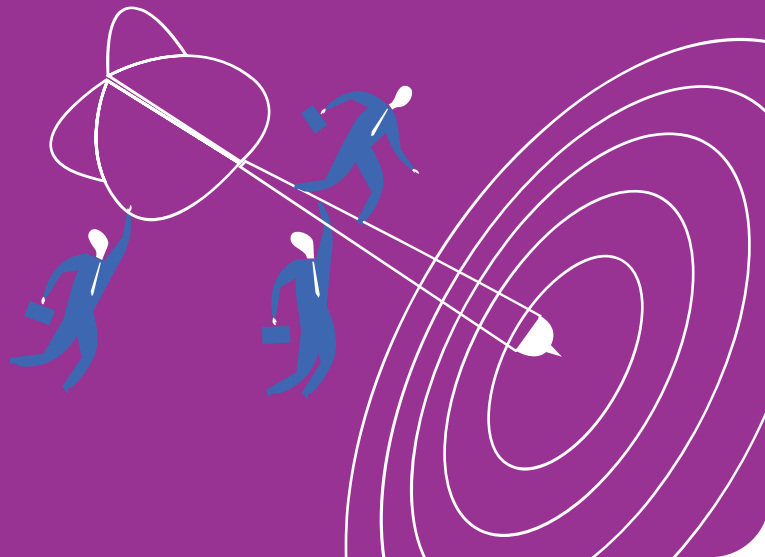
Answering for 4 Strategic Questions

ISSUE/ OPPORTUNITY	How can we ensure JBR’s value is differentiated vs competition?	How do we ensure JBR 100 is being preferred up front?	How can we continue to drive BAVENCIO®’s growth in mUC?	How can we maintain BAVENCIO® as mUC leader despite competition?
OBJECTIVE	Achieve favourable HCP perception on all our target patients’ profiles	Achieve >25% BAVENCIO® overall NET share >45% in uncontested markets	Achieve target for each lever throughout treatment funnel Defend pricing & remove access restrictions	Establish confidence through data generation & increase advocates
MUST-WIN BATTLE	Win our Target Patients’ Profiles	Reinforce JBR followed by EV as an optimal sequence	Capitalize on all growth levers	Establish BAVENCIO® as Tx of Choice in mUC
				
IMPERATIVE	SI1: Amplify Quality Survival	SI2: Anchor Optimal Sequence	SI3: Augment market position	SI4: Advance Advocacy & LCM

Big 4 Tactical buckets by market archetype

DEFEND

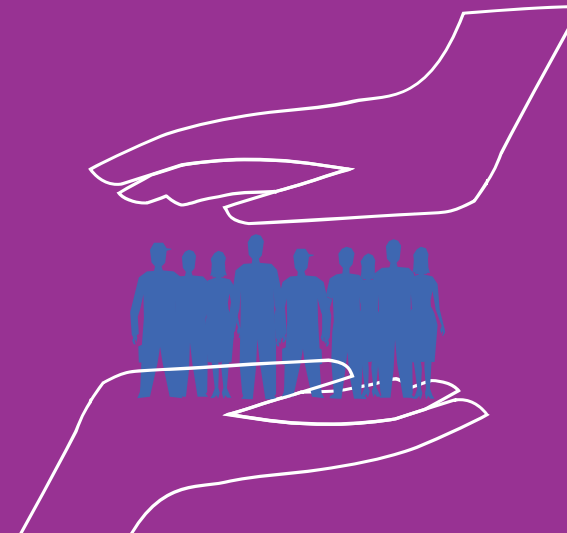
SoV maximization (HCP Access, Call Impact, Omnichannel)



P2P Engagement (AVENUES) & KOL Advocacy



Go-To-Market: Winnable HCP segmentation and patients profiles



AI enhanced Capability Building: Alnstein, MyEngage training



GROW

Go-to-Market: Prioritize Actionable Levers Based on Treatment Funnel



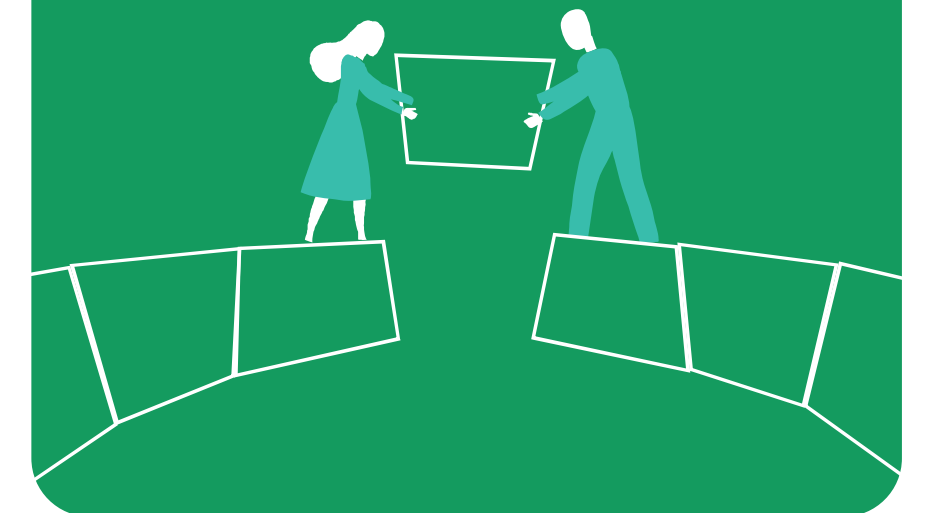
HCP Engagement: Convert Trialist & Rising Stars into Advocates



SoV Maximization (HCP Access, Call Effectiveness, Omnichannel engagement)



Access & Payer: Secure Access for All Eligible Patients



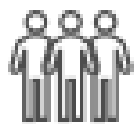
It's all about pulling the
right levers and steering
the bar to harness the
power of the wind



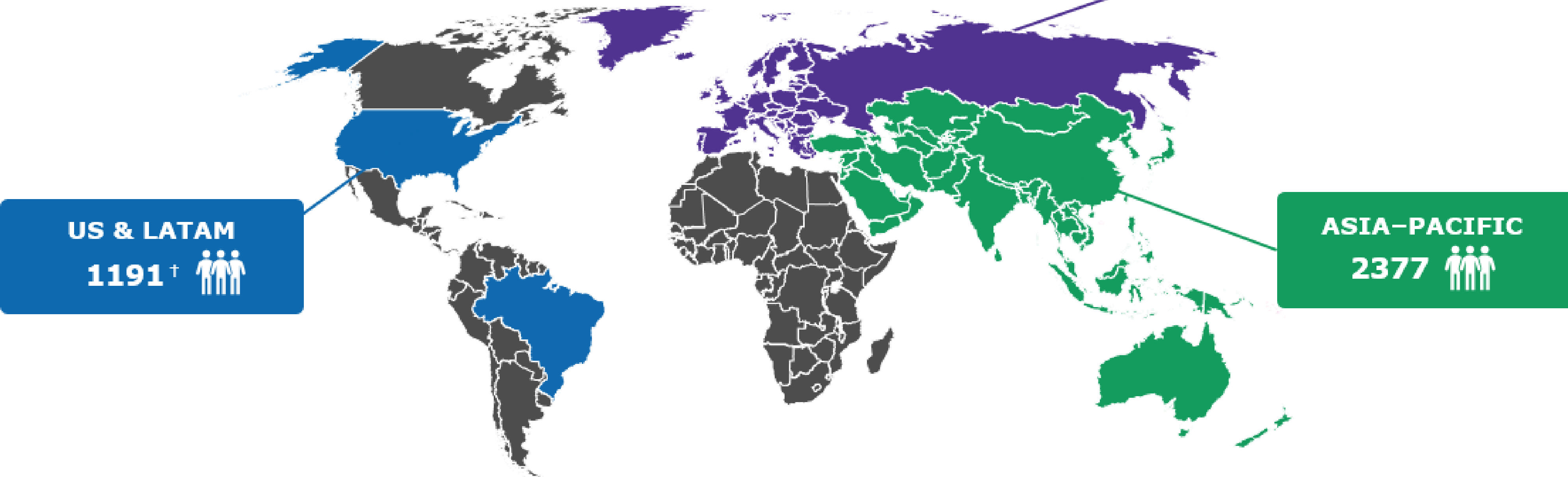
Robust evidence generation plan to differentiate Bavencio® and anchor JAVELIN Bladder regimen as a 1L ToC

#	2025	2026	2027	2028	2029
Evidence Generation	DU/MU; phII-III	RW NIS Subgroup analyses (AVENANCE, READY, AVENUE, SPADE, AVELLA, AVENUE, JAVEMACS, JAVEMACS-D, JAPAN PMS, FLATIRON, TEMPUS)			
	MU/GVAP/Local; phIV				
Evidence Generation	DU/MU; phII-III				
	Key ISS/ EP/ Independent Studies; phII-IV				

Global RWE for avelumab 1L maintenance* includes >5000 treated patients with la/mUC¹⁻³⁷



Patients in completed or ongoing clinical and RW studies



Study details of global RWE for avelumab 1L maintenance 

List may not be exhaustive of all completed or ongoing studies for avelumab 1L maintenance. Refer to the slide notes for the references.
*In patients who did not progress with 1L PBC.
[†]Europe and US numbers do not include the N=108 patients from the Bakaloudi study, because patients were reported as a single pooled population, with limited geographical baseline characteristics reported.
1L, first-line; la/mUC, locally advanced/metastatic urothelial carcinoma; PBC, platinum-based chemotherapy; RW(E), real-world (evidence).

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Tanguy

10 mins

Bavencio Ambition

- Russia ambition
- Turkey ambition

Moderator: Mohamed

Panel: Amr, Charlie & Tanguy

10 mins

Q/A

Russia and Turkey

10 mins

All

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Coffee break

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Q/A

North Africa and Egypt

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- Why it is important?
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20 mins

Establishing UNSTOPPABLE LAUNCH with Bavencio:

Kaj Linna

10 mins

Lessons learned and insights

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Closing

Recognizing 2 market dynamics to maximize revenue

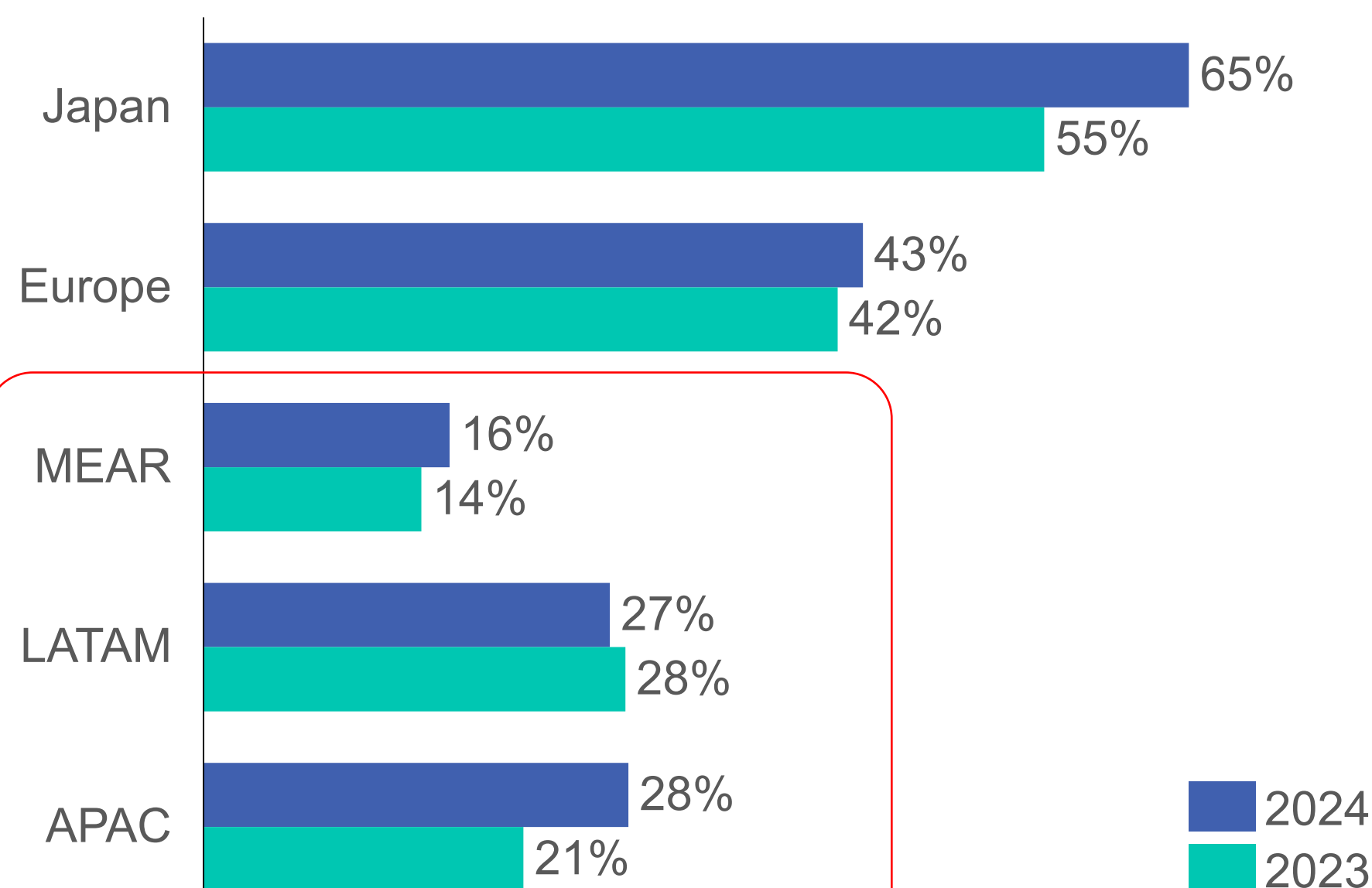


Unlocking Bavencio Growth Potential

There is room to catch up with Erbitux in emerging market

- In Europe, Bavencio accounts for **>40%** of combined Bavencio + Erbitux sales
- In key emerging markets, Bavencio's share remains significantly lower
- This gap signals untapped growth potential for Bavencio in emerging regions
- Strategic focus on market education, access, and positioning could elevate Bavencio's share toward higher levels

Bavencio Share of Combined Bavencio + Erbitux Sales



BAVENCIO® Growth Workstreams

Five workstreams identified with potential to drive topline growth with minimal incremental OPEX investment

Total of 24 countries in scope



Workstream 1: Access Expansion Potential

- Eliminate barriers to broader reimbursement at an acceptable price



Workstream 2: High Potential Markets

- Drive higher demand from high ASP countries with no immediate EV+P competition



Workstream 3: “Go Deeper” LMIC

- Facilitate availability and access for LMIC countries receiving regulatory approval in <12 months



Workstream 4: New Launch Markets

- Enhance support for newly launching markets with regulatory approval in '24/25



Workstream 5: Increase Treatment Rate

- Identify opportunities to increase treatment rates (e.g., MDT, targeting Uro's, 3rd party digital, etc.)

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5 mins
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Bladder Cancer

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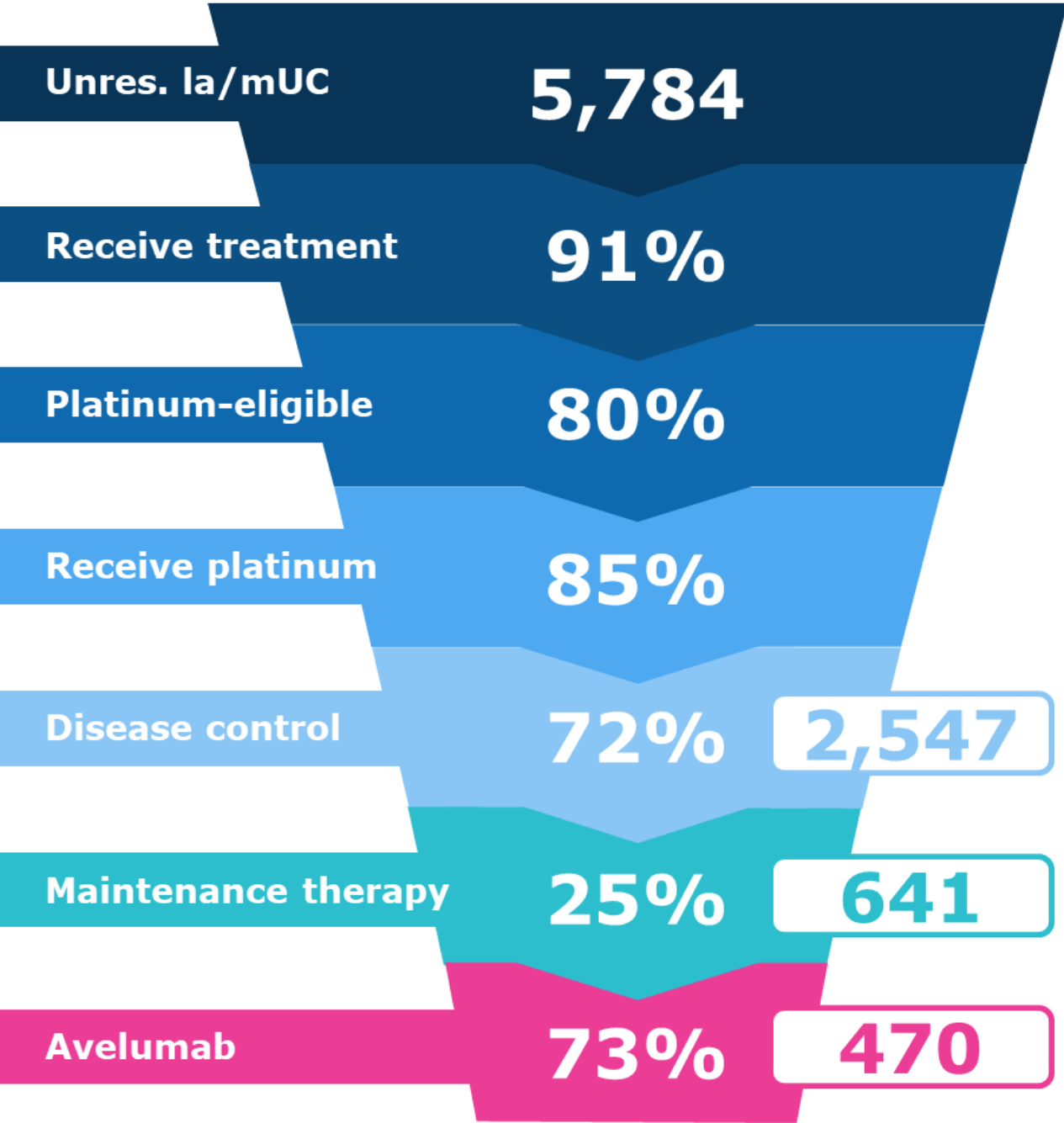
Charlie
All
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UC: size of opportunity is still high

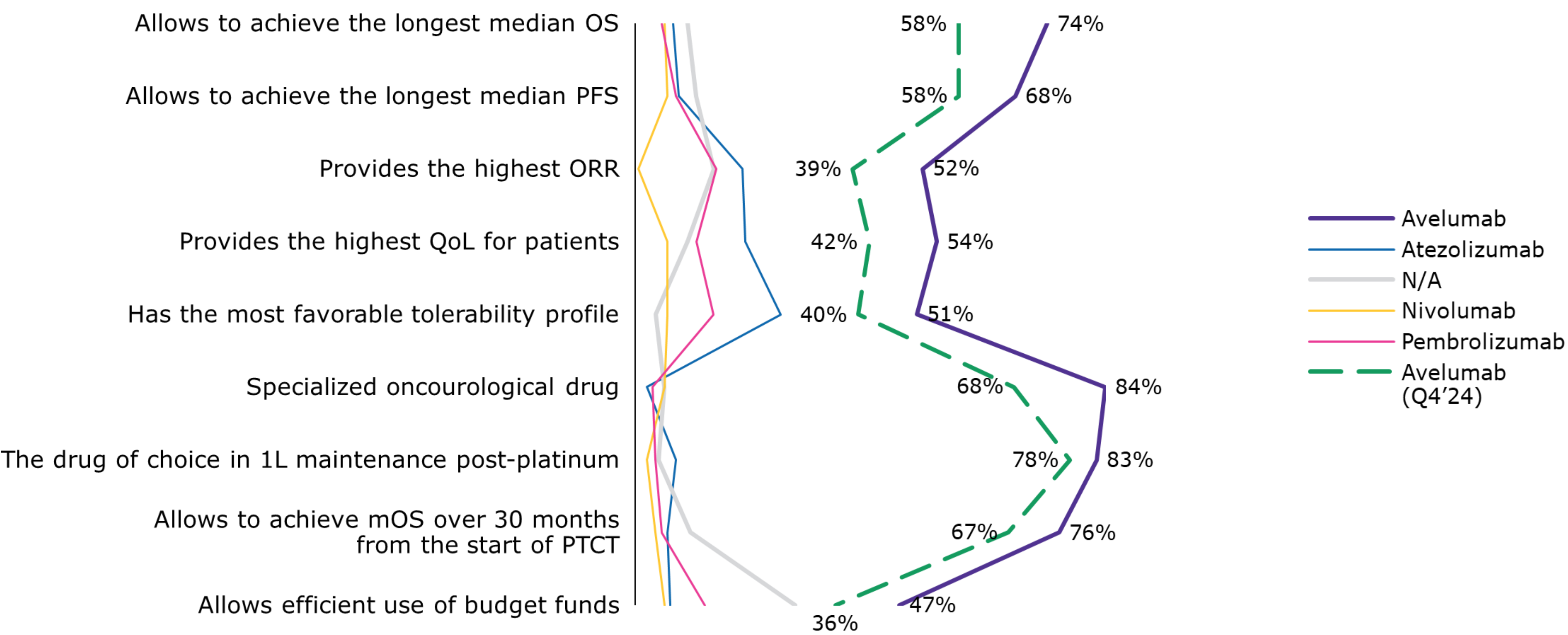


2023	Targets	Dynamics
70%	75%	n/a
85%	85%	n/a
70%	85%	+15 p.
70%	80%	+2 p.
50%	85%	n/a
340	90%	+38%

- Medical effort on platinum results in improved perception
- Still low percentage of qualified patients receive maintenance
- Still significant off-label usage of other IO in maintenance

CR RepCheck w2'24; MDLP; HTA association report; Kaprin et al. 2023

UC: Leadership in all key brand attributes

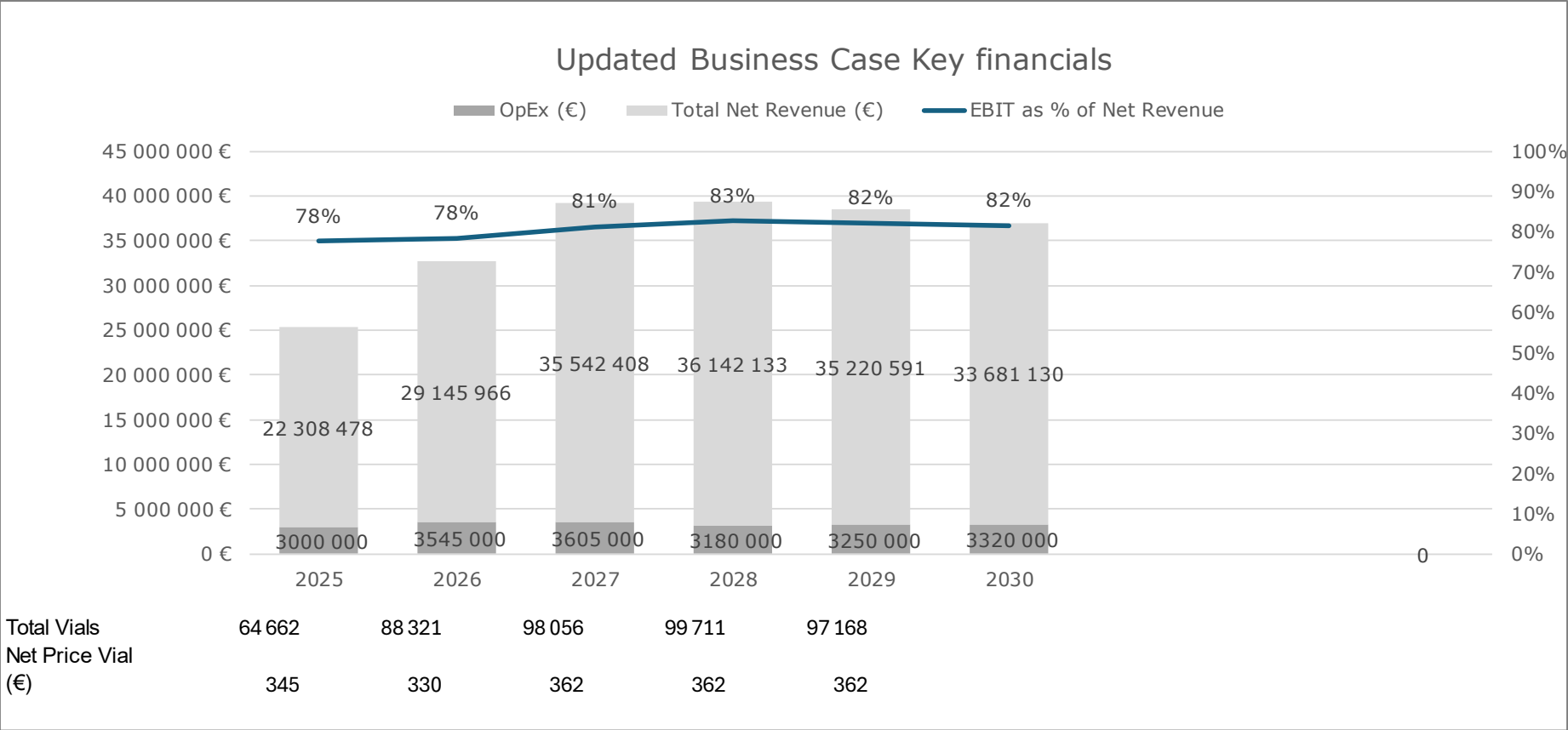


Current State and Growth Opportunities

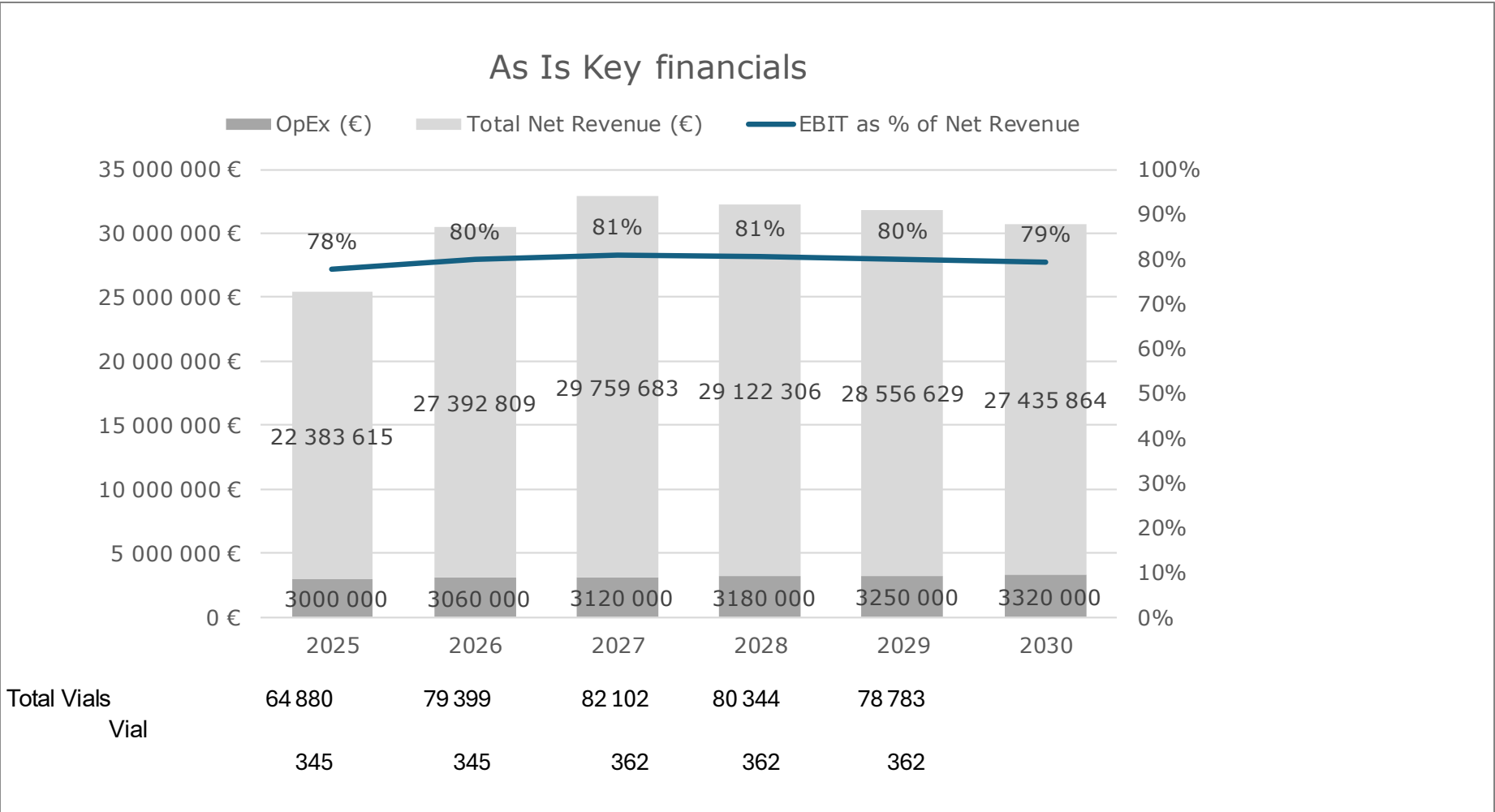
- In 2025, Bavenio's fourth year of full access in Russia, it will achieve 22.4m EUR and it is supplied to ~150 accounts
- Bavencio is widely accepted by HCPs as a SoC in UC and leads across all efficacy and safety attributes. It also grows its presence in RCC with 12% market share
- With National Oncology Program budget expected to be flat in the following 3 years, growth of the brand will slow down significantly with the current promotional model
- Russian oncology team sees the opportunity to boost Bavencio sales in 2022-30 with the following levers:
 - wide preceptorship programs in major national and international centers to 100 HCPs from regional hospitals to **boost confidence in JB 100 regimen**
 - implement regional follow-up programs to **stop patient leakage** in geographically spread regions
 - expand and design higher-flexibility Co-Financing Program to **increase availability in hospitals**
 - implement a series of market access programs to achieve **full access in Moscow City and drive adoption** in other large regions with low usage of Bavencio
- 2026 is the year of opportunity as EV will obtain full national access in 2027, and Astellas has registered its price at 50,000 RUB/vial (resulting in +26% to Bavencio's annual cost of treatment) leading to higher competition in UC
- With additional annual investment of 485k EUR in '26 and '27 we see an opportunity to increase Bavencio access and deliver additional ~28m EUR from '26 to '30

Financial Impact: +27.5m EUR in Sales over five years

Ambition



As Is



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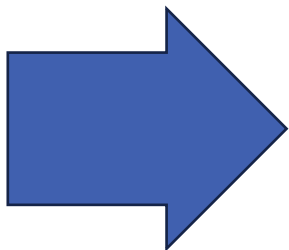
Closing

Türkiye Bavencio Ambition

Growth & Opportunity

As-is Scenario

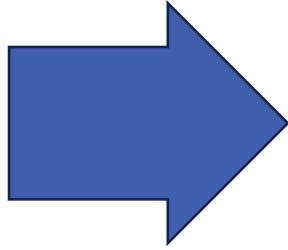
- Indicated and reimbursed for PD-L1(+) patients
- Main bottleneck confirmed by market research and field insights:
 - 1) PD-L1(+) ratio: 50%
 - 2) 10% improvement space in maintenance adoption rate



Proposed Scenario

- To register and get reimbursement for allcomers (Reimbursement approval in 2028*)
- Meanwhile, testing support at a center of excellence** in 2026 & 2027

**Anticipated timeline needs to be confirmed with global team*
***Needs global approval and evaluation by local compliance*



	2025	2026	2027	2028	2029	2030
PDL(+) ratio	59%	65%	70%	100%	100%	100%
Maintenance adoption rate	80%	85%	90%	90%	90%	90%
Incremental sales (M€)		1,0	1,9	3,9	6,2	7,0

Additional 20 M€
sales in 5 years on
top of as is trend

**Incremental
OPEX:Incremental
Sales is 1:6**

Türkiye Bavencio Ambition

Patient Flow w/ Testing Optimization & Label Update

Testing support in 2026-2027 & Reimbursement for expanded Bavencio label in 2028 & No EVP Reimbursement

Assumption	2025	2026	2027	2028	2029	2030
1L UC Population (Incident & Newly Recurrent)	2.867	2.953	3.042	3.133	3.227	3.324
% Ineligible (IO in Adj/clinical trials)	5%	5%	5%	5%	5%	5%
Treatment Rate (%)	95%	95%	95%	95%	95%	95%
PDL testing rate	85%	85%	85%	100%	100%	100%
PDL positivity rate	59%	65%	70%	100%	100%	100%
% Treated With IO Free Platinum Induction	95%	75%	70%	70%	70%	70%
% of Patients with CR, PR or SD (disease control on CT)	83%	83%	83%	83%	83%	83%
% of CR, PR or SD Who Receive IO Maintenance (without access limitation)	80%	85%	90%	90%	90%	90%
Bavencio Share of IO Maintenance Treated Patients (without access limitation)	82%	84%	86%	88%	88%	88%
Access %	100%	100%	100%	100%	100%	100%
Bavencio Net Share (Share of 1L Treated Patients)	26%	25%	27%	46%	46%	46%
New Bavencio Treated Patients	671	654	734	1301	1340	1380
Total Bavencio Treated Patients	769	908	1055	1651	1928	2098

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Algeria GoDeeper initiative

- **Improve Bavencio Access**

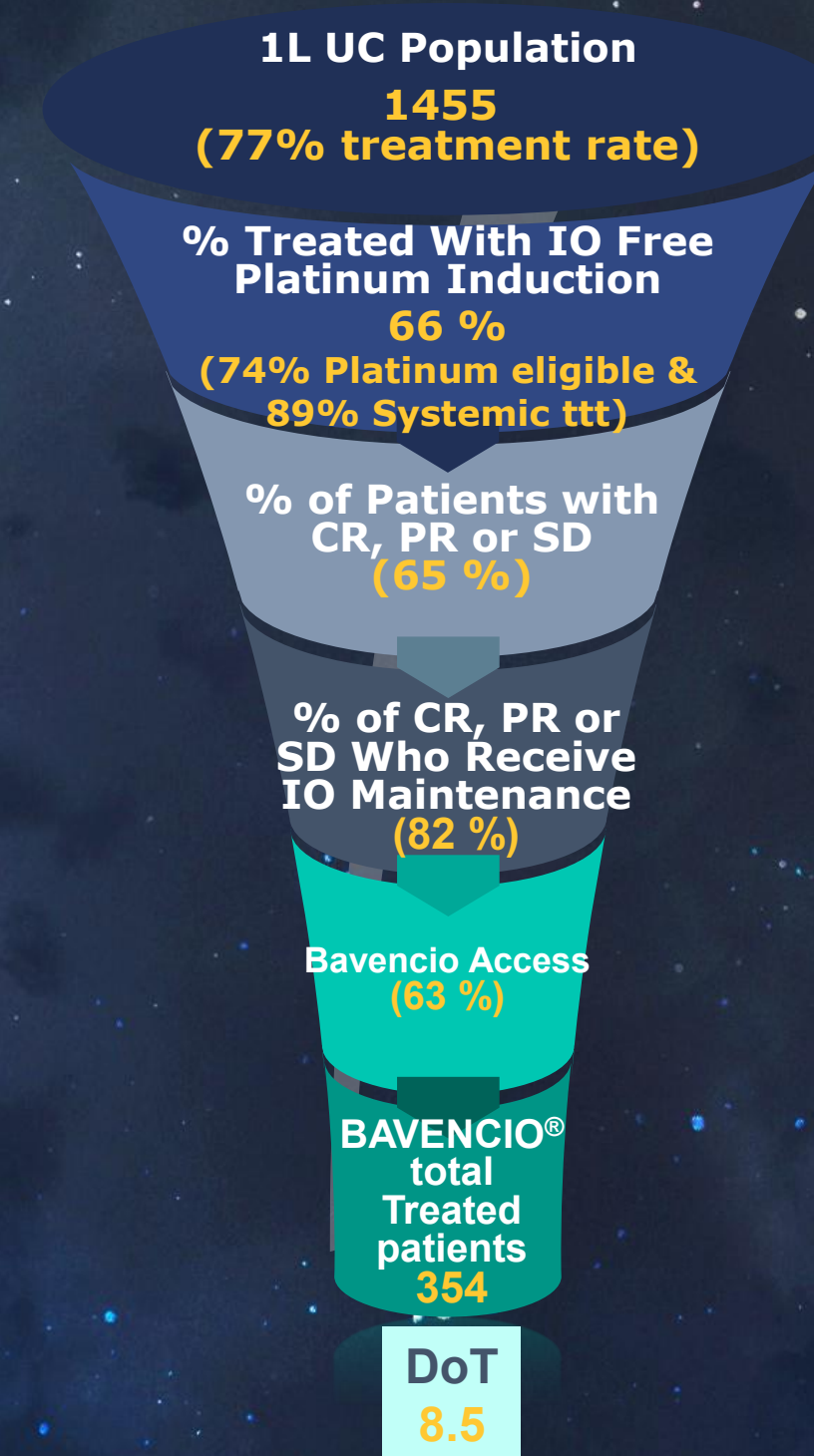
- Conduct Local Cost effectiveness Study
- Workshop with hospital pharmacists and PCH heads highlighting the costs effectiveness of Bavencio
- unlock PCH budget limit barriers

- **Maximize centers adoption of maintenance regimen and setting BAVENCIO as the SOC for UC**

- Top centers experts meeting to maximize maintenance regimen adoption and Bavencio forecast to optimize PCH Allocation
- Strengthen Merck SAFRO partnership to be the partner of choice to improve UC, RCC & MCC cancer management in Algeria

- **Cement BAVENCIO value proposition through Local data generation & accelerate BAVENCIO Launches for RCC & MCC indications**

- Set up a Local Study to drive local evidence generation to support use of BAVENCIO in 1L Ia/mUC
- RCC & MCC Ad Boards & Expert meetings to Gather Local Insights for RCC & MCC (Current treatments & unmet needs)
- Include Bavencio in RCC & MCC Local Guidelines



+30% sales growth

+200 BAVENCIO newly treated patients

versus base case scenario



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Go Deeper LMIC Workstream



Overview

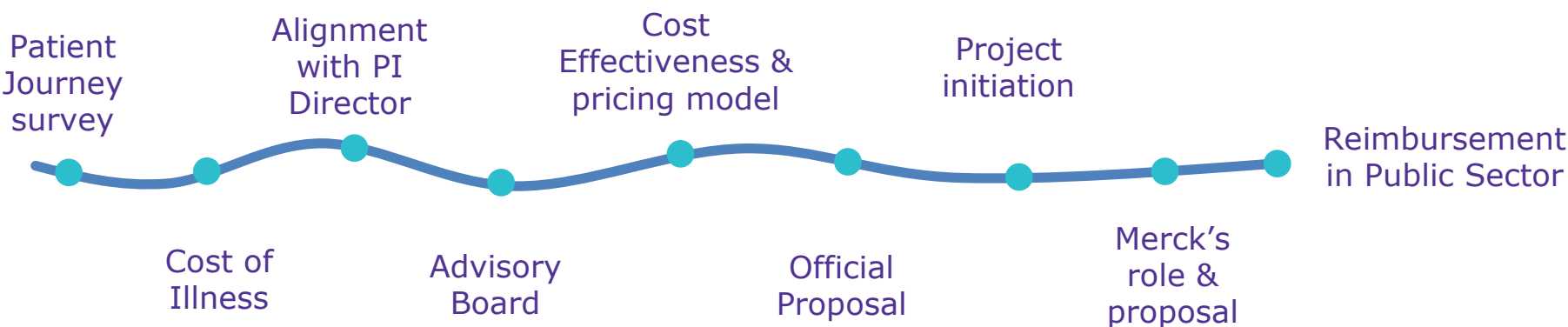
- BC stands as the 3rd most prevalent in Egypt.
- Being low-middle income country, access to medication is the main challenge for the patients representing by maximum about 15% in high-cost medications.
- More than 80% of the patients are treated in the MOH/NHO sector (public sector).
- The Governmental (Presidential) Initiatives started to build treatment protocols for some cancer types in focus.
- UC was not used to be one of their focus cancer type.



Establishing New UC Policy

To implement comprehensive, nationwide programs for bladder cancer **diagnosis** and **treatment**, integrate advanced medical technologies and treatment protocols, and enhance healthcare infrastructure and workforce capacity.

Process



Pillars



Establish a National BC Registry



Strengthening Early Detection and Diagnostic Capacity



Enhance MDT Collaboration



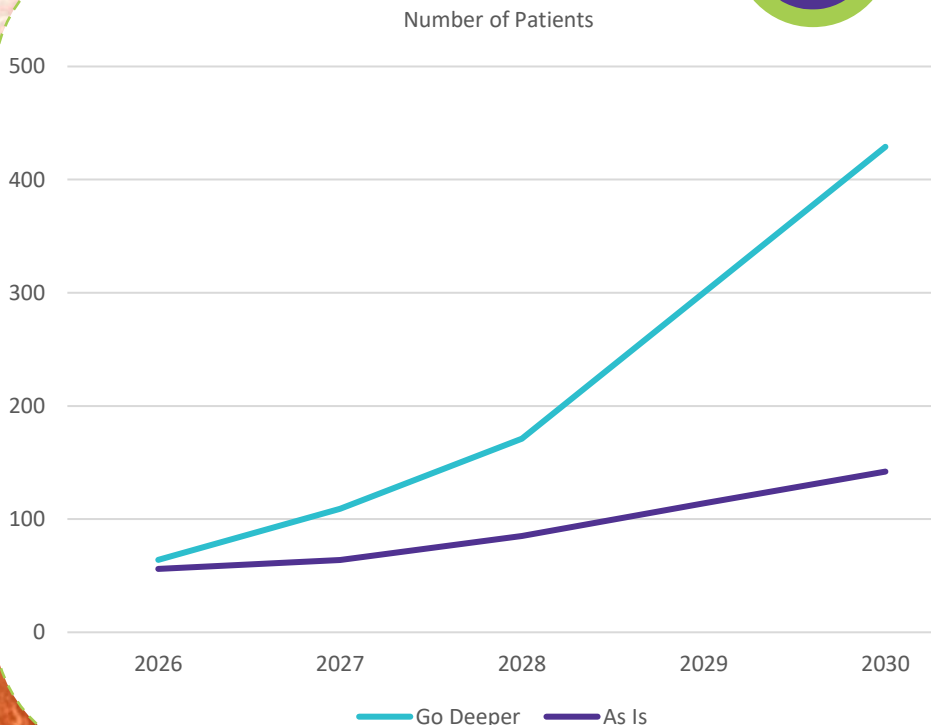
Ensuring Fair Pricing of Innovative Treatments



Optimize Patient Journey Beyond Medication



Ambition



- Helping BC patients in Egypt to have better opportunities of treatment.
- Bavencio access full coverage in governmental sector by 2030.
- 1000+ patients will receive Bavencio within 5 years.

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- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 5 mins
- 5 mins
- 5 mins
- 20 mins
- 10 mins

Opening and objectives

Mohamed and Harshveer
Amr, Harshveer, Mohamed and Niklas Tanguy
Moderator: Mohamed
Panel: Amr, Charlie & Tanguy
Russia and Turkey
All

Bladder Cancer

Strategy and Performance: Bavencio in UC
Bavencio growth workstreams

Bavencio Ambition
• Russia ambition
• Turkey ambition
Q/A

Coffee break

Bladder Cancer

New Launch Markets workstream: Algeria
Go Deeper' LMIC workstream: Egypt
Q/A

Moderator: Mohamed and Ihab
Panel: Amr, Tanguy, Charlie
North Africa and Egypt

When to kick-off Bavencio behavioral segmentation?
• Why it is important?
• Optimal timing to start ? (Voting)
• Discussion

Charlie
All
All

Establishing UNSTOPPABLE LAUNCH with Bavencio:
Lessons learned and insights
Q/A

Kaj Linna
All

Closing

What is the best time to launch Bavencio behavioral segmentation & establish Bavencio in key patient profiles?

1. Today
2. 9-12 months before EV-302 launch & reimbursement.
3. 3-6 months EV-302 launch & reimbursement



Segment 1:
Science Driven



Segment 2:
Tailored Treaters



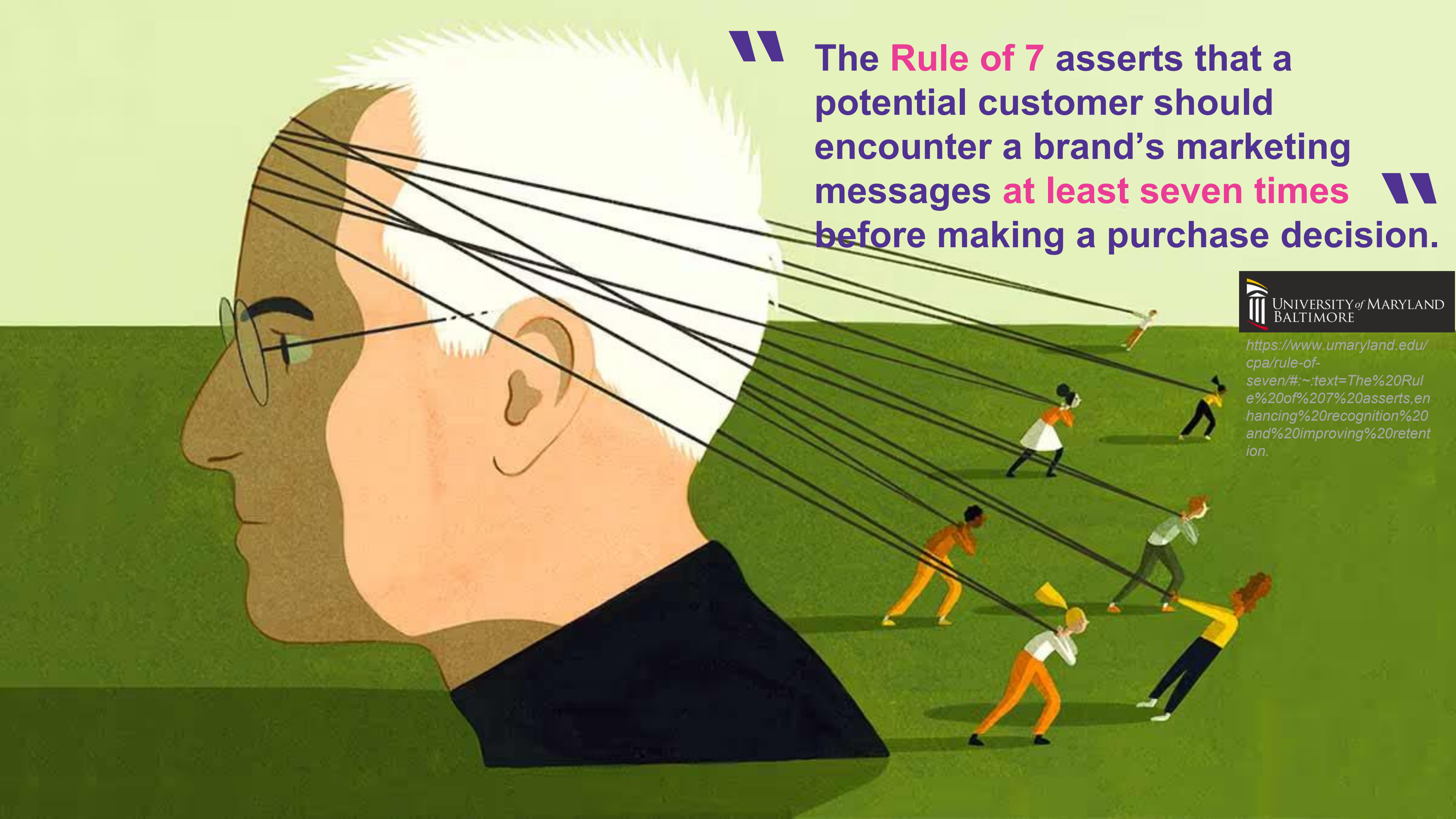
Segment 3:
Comfort Driven



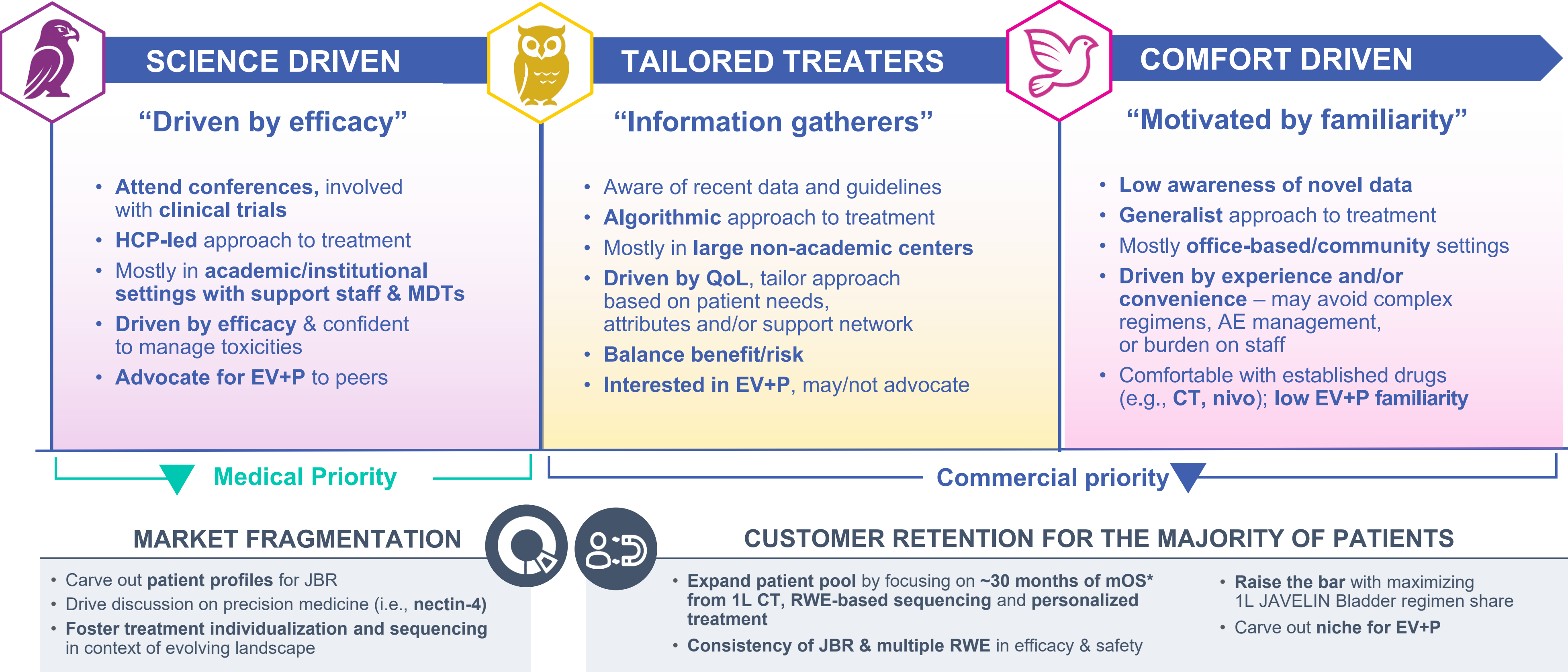
The **Rule of 7** asserts that a potential customer should encounter a brand's marketing messages **at least seven times** before making a purchase decision.



<https://www.umaryland.edu/cpa/rule-of-seven/#:~:text=The%20Rule%20of%207%20asserts,enhancing%20recognition%20and%20improving%20retention.>



Tailor conversations based on HCP's intrinsic attitude & motivation to achieve impactful engagements & call to action



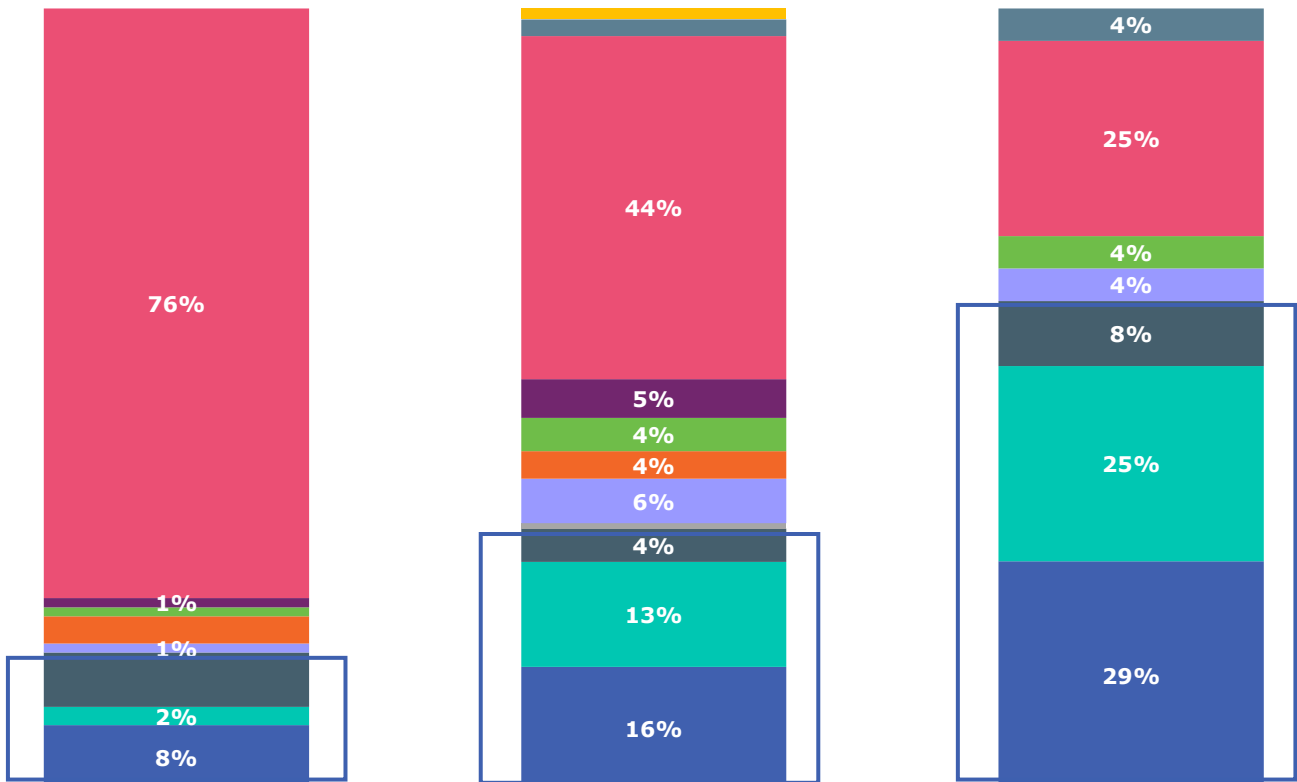
1L=first-line; AE=adverse event; CT=chemotherapy; EV+P=enfortumab vedotin + pembrolizumab; HCP=healthcare professional; JBR=JAVELIN Bladder regimen; MDT=multi-disciplinary team; mOS=median overall survival; nivo=nivolumab; QoL=quality of life; RWE=real-world evidence. See footers in speaker notes.

HCP Behaviour Segments work!

R6M March*

Initial 1L treatment (% of patients)

- Other
- O+GEM/CIS
- EV+P
- Tecentriq®
- Keytruda®
- Opdivo®
- Gemcitabine mono
- Other platinum-CT
- MVAC
- Carboplatin-CT (+/- gemcitabine)
- Cisplatin-CT (+/- gemcitabine)



SCIENCE
DRIVEN



TAILORED
TREATERS

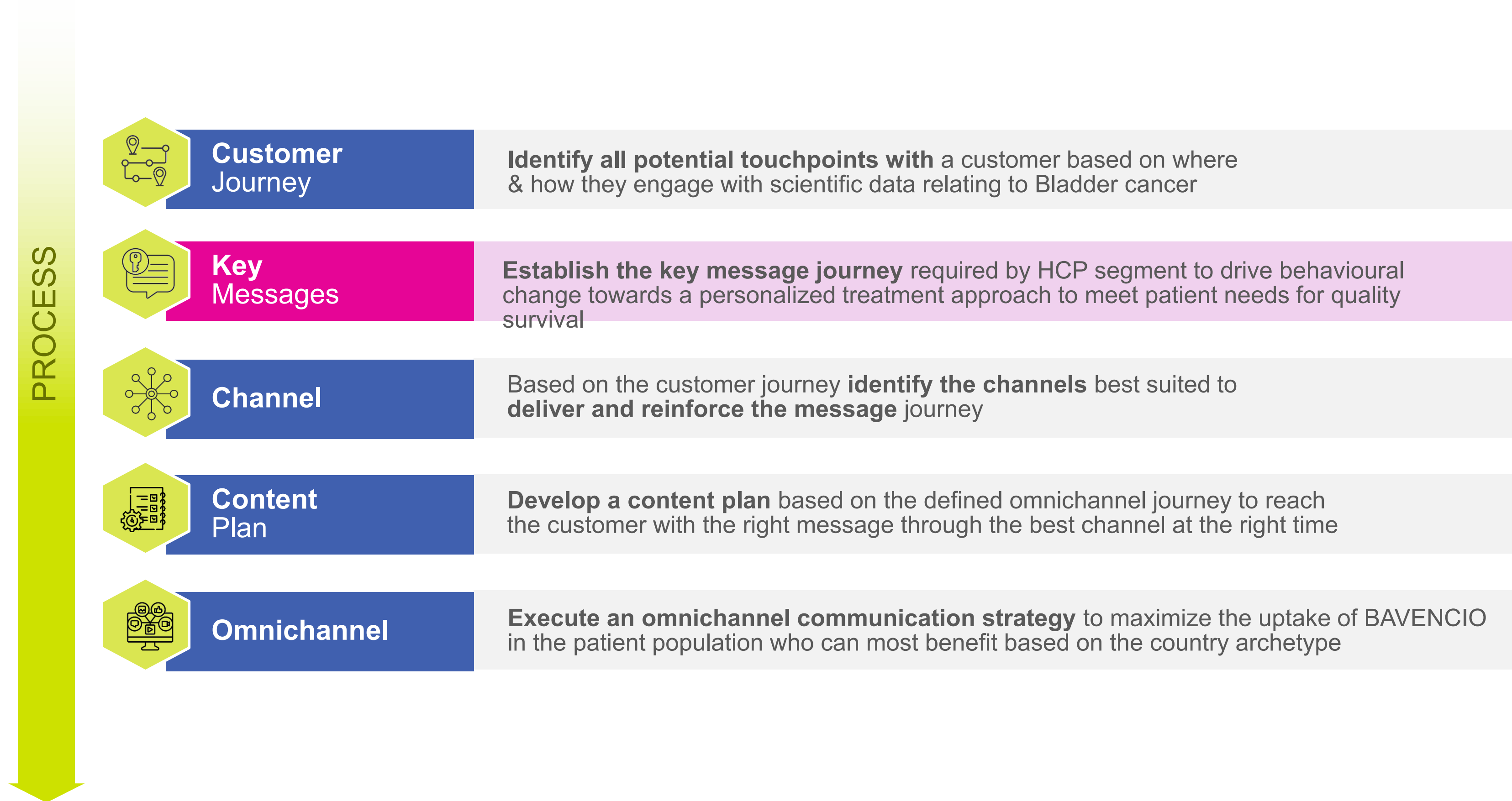


COMFORT
DRIVEN



Focusing our efforts on winnable segments will drive topline efficiency & behavior change

Customer journey to maximize impact and engagement



HCP=healthcare professional.

Objective: Personalize treatment choice to meet Patient Needs

SCIENCE DRIVEN



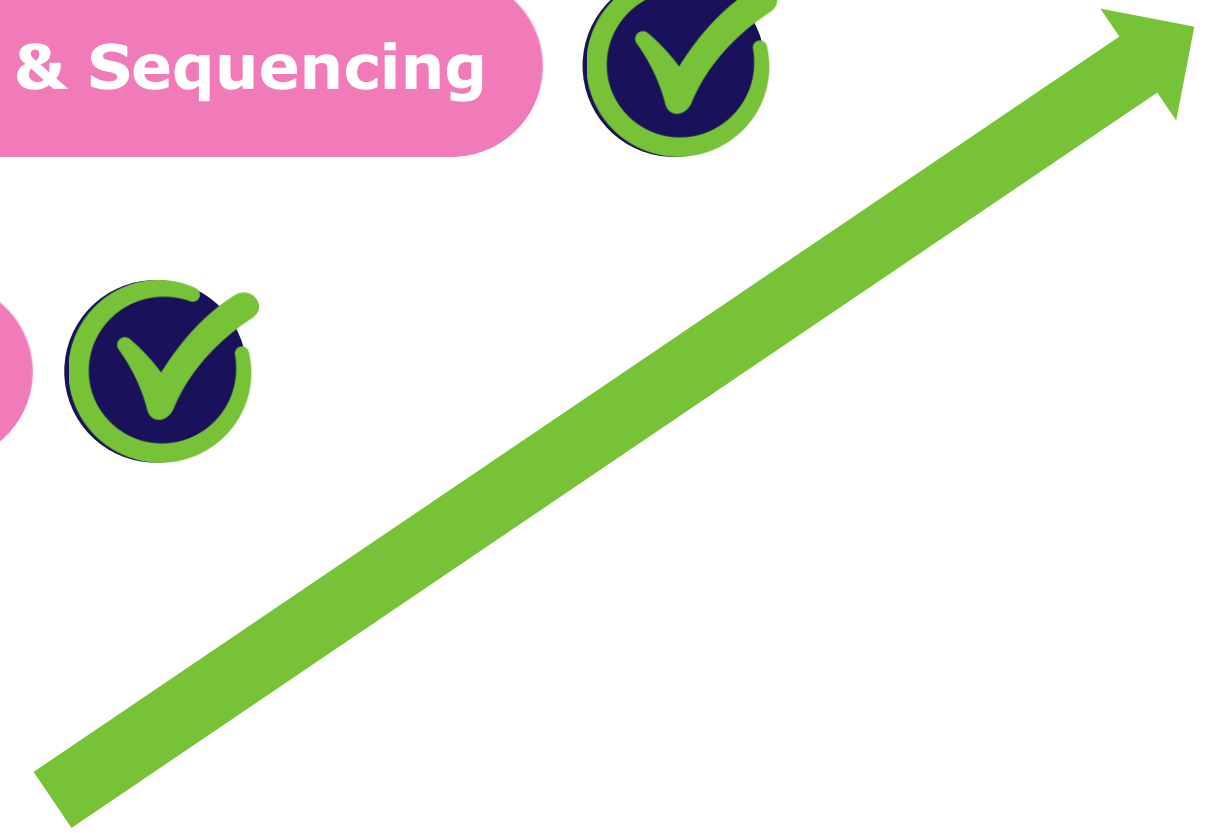
Selects treatment based on efficacy

Personalize Tx to meet Patient needs

Patient Selection for JBR

RWE & Sequencing

Improve outcomes with 3 cycles

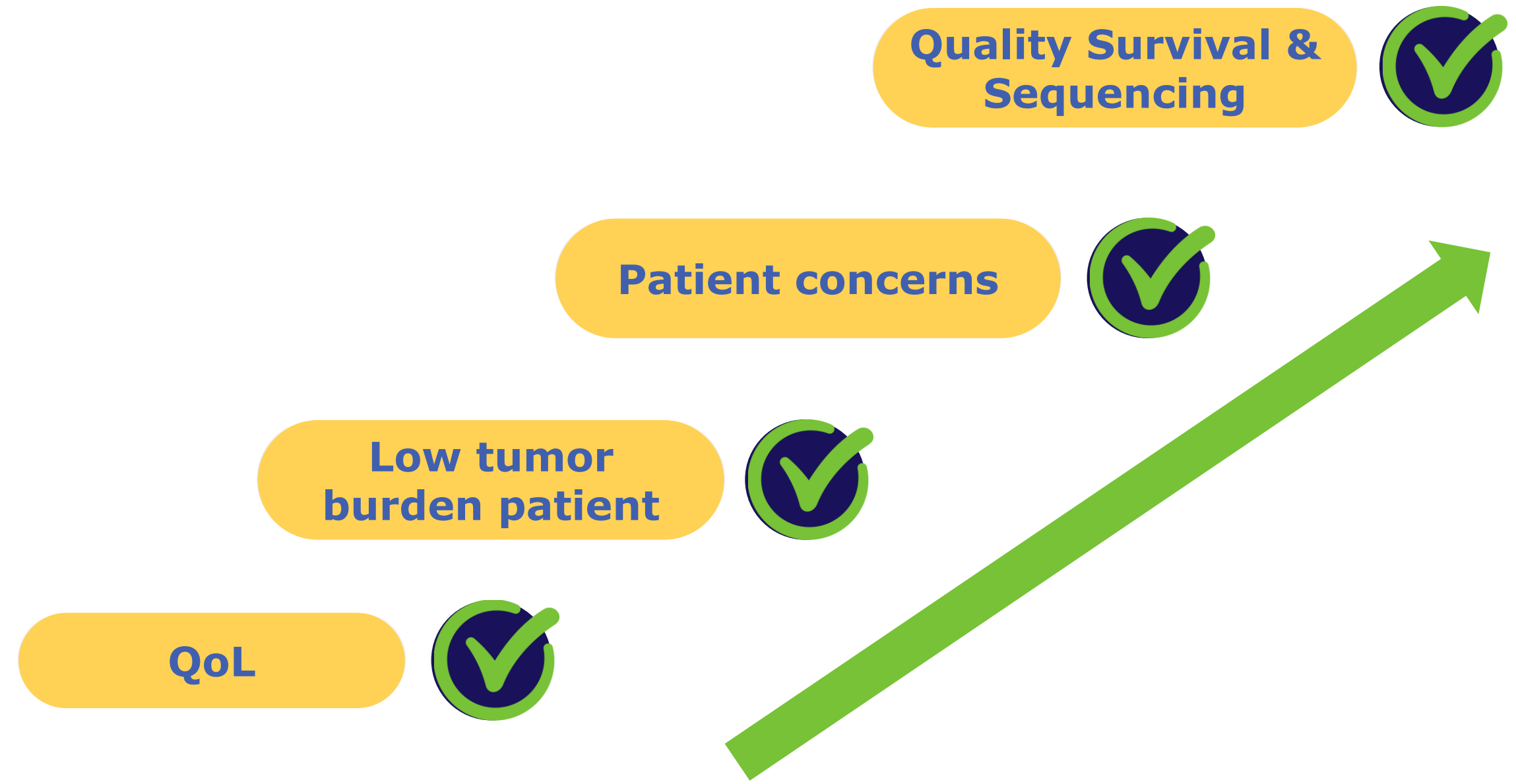


Objective: Embed Quality Survival as primary treatment objective

TAILORED TREATERS



Considers Patient Needs in Treatment choice



Objective: Improve patient management with deintensified JBR

COMFORT DRIVEN



Selects treatment based on experience

Improve QoL



Increase % of patients receiving maintenance



Improve Tx management



Quality Survival



24 Sep'25

DAY 3



WE ARE UNSTOPPABLE MEAR GoDeeper with Bavencio



- 5 mins
- 20 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 10 mins
- 5 mins
- 5 mins
- 5 mins
- 20 mins
- 10 mins

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When to kick-off Bavencio behavioral segmentation:

- Why it is important?
- Optimal timing to start ? (Voting)
- Discussion

Charlie

All

All

Establishing UNSTOPPABLE LAUNCH with Bavencio:

Lessons learned and insights

Kaj Linna

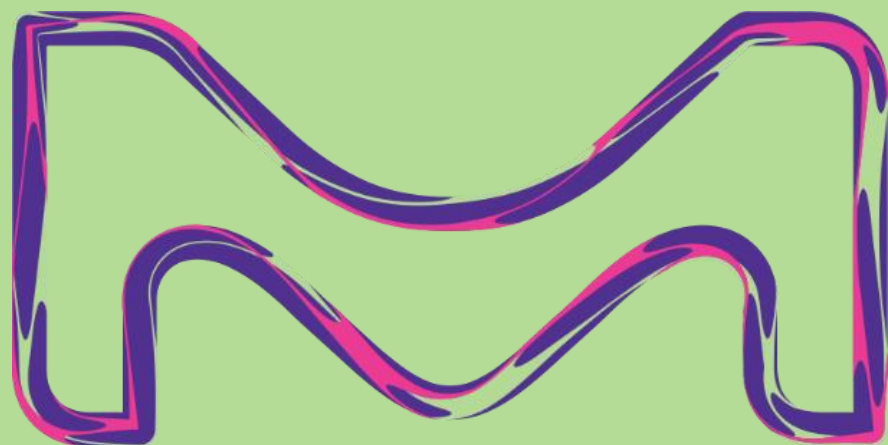
Q/A

All

Closing

Establishing UNSTOPPABLE LAUNCH with Bavencio

Sep 24, 2025



MERCK

What is your ambition with BAVENCIO UC launch?

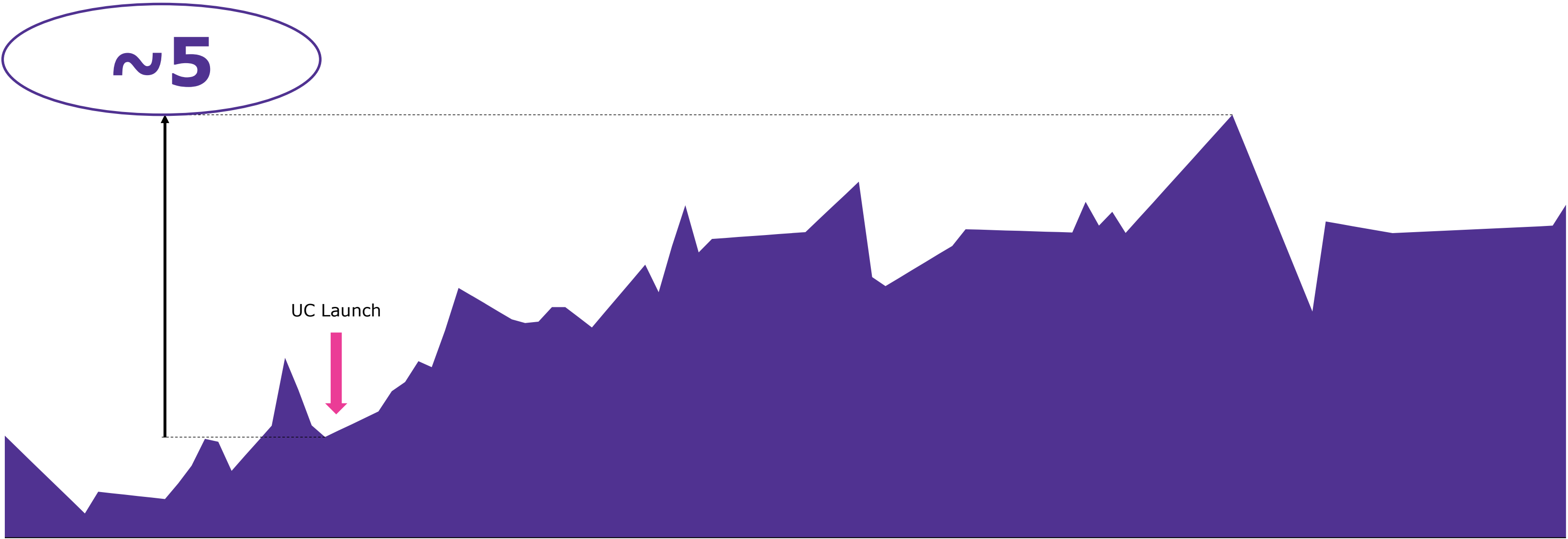
5 x

10 x

>20 x

Successful BAVENCIO UC launch?

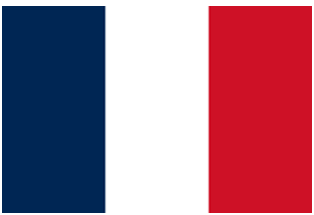
Vials per month by market (ex factory)



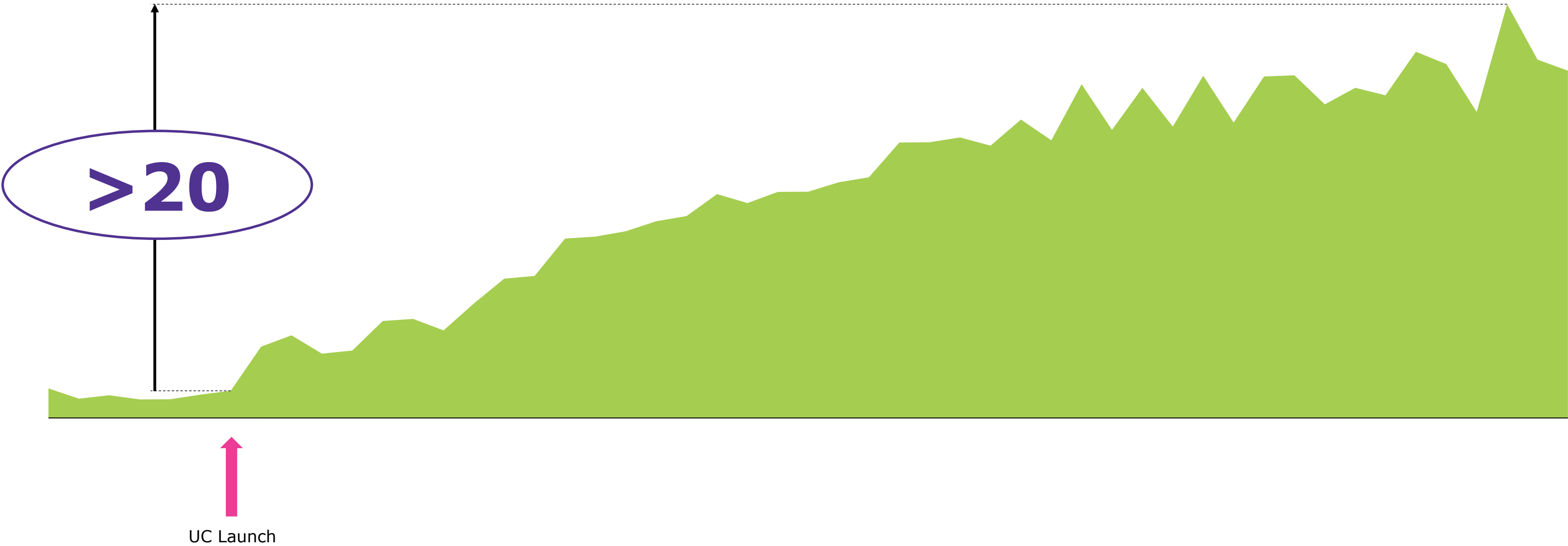
Successful BAVENCIO UC launch?



Most successful BAVENCIO launch to date

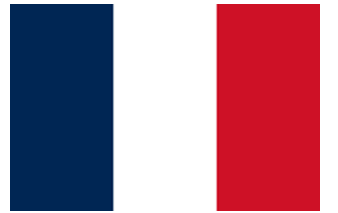


Vials per month by market (ex factory)

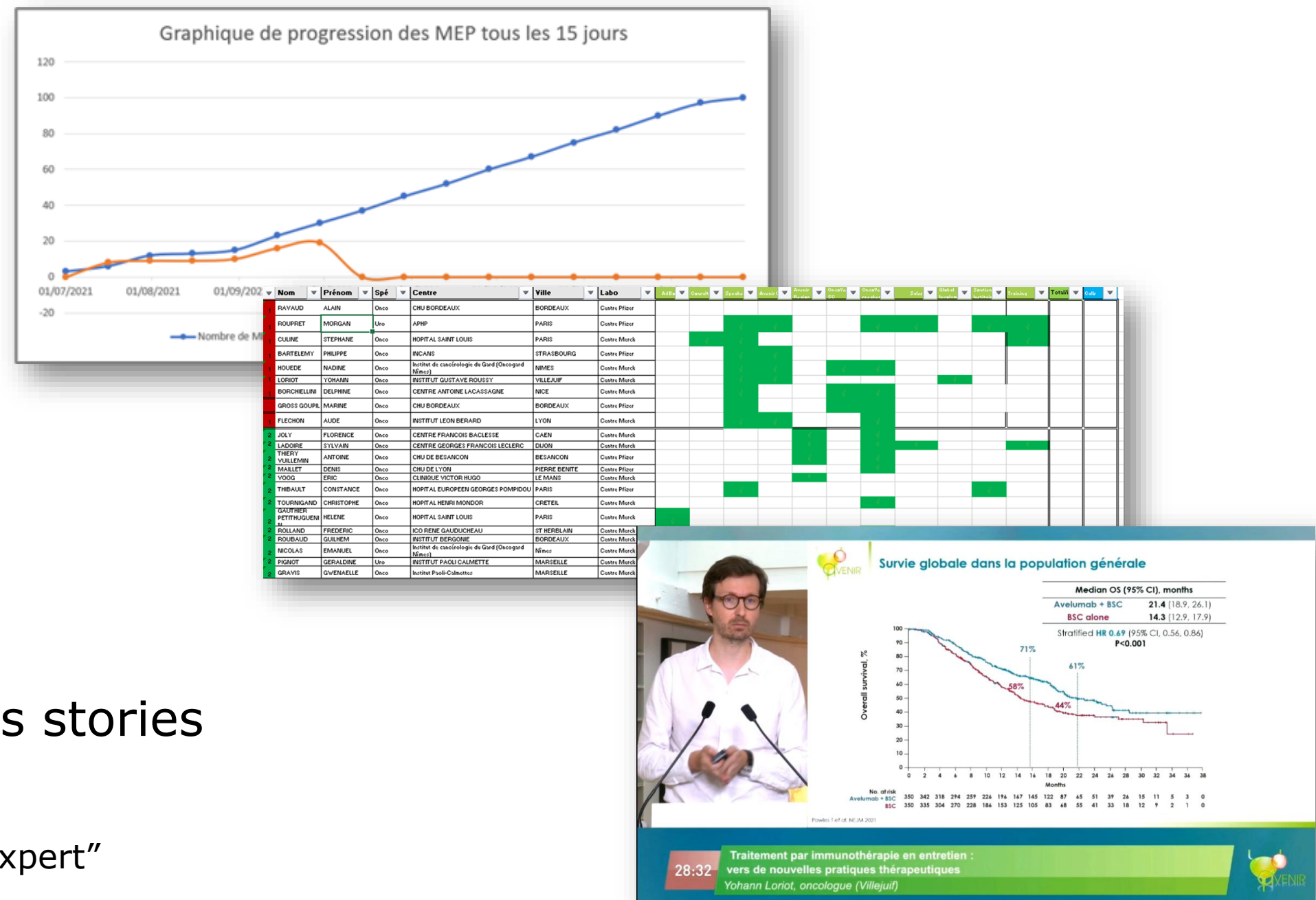


Learnings

Why was BAVENCIO UC launch was a success in FRANCE?

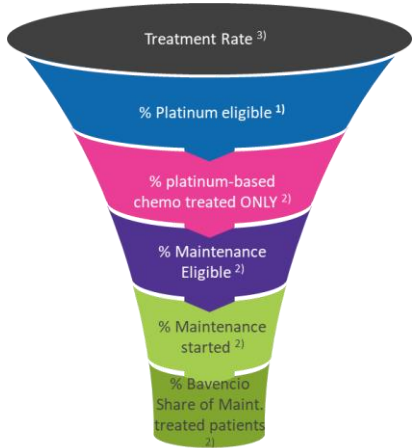
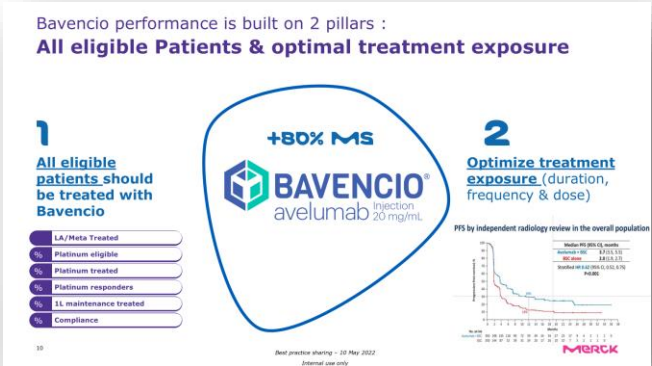
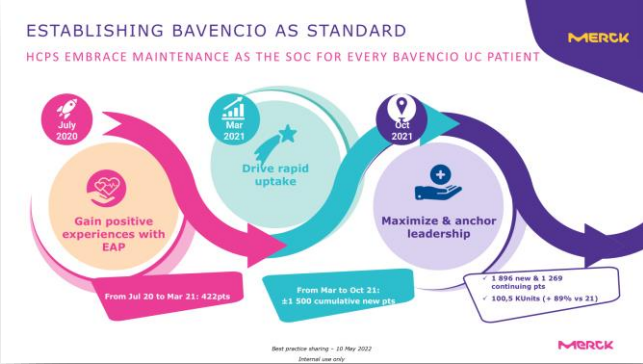
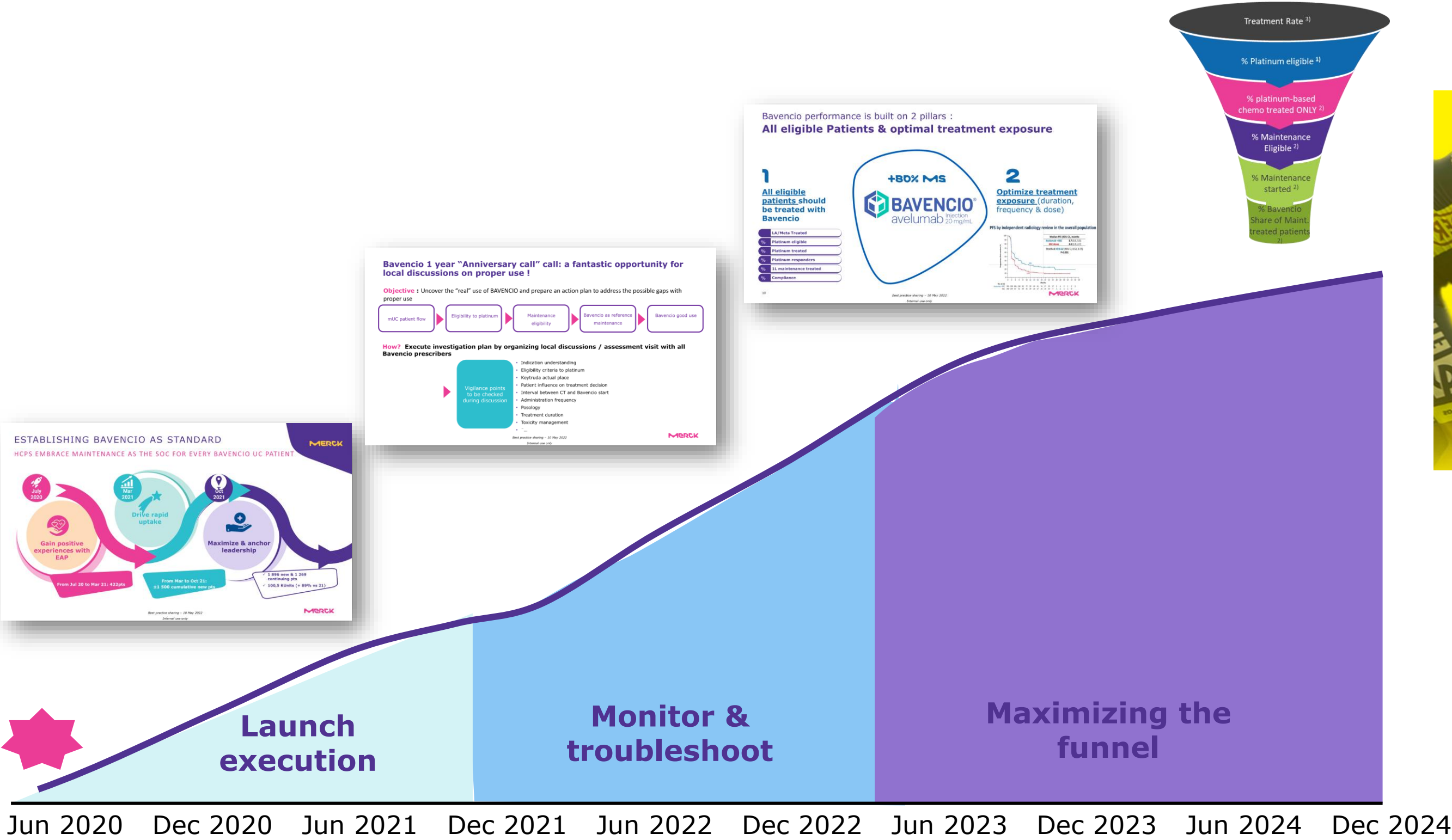
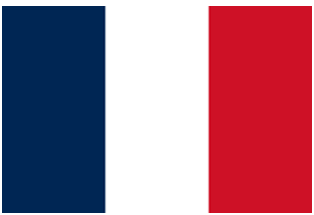


- **Early Access**
- **KTL engagement**
 - Data generation (AVENANCE)
 - Guidelines
 - KOL plan
- **P2P cascade**
 - National SAM "Avenir"
 - More than 30 local events "Onco Vessie"
 - Therapy Management & Sharing success stories "Grand Reporter Vessie"
 - Regional round table meetings "Meet-the-expert"
- **FFE**
 - Resourcing & Targeting adherence



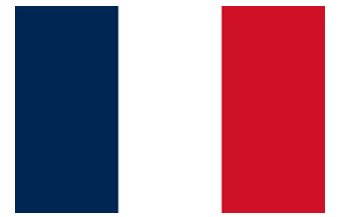
Learnings

What made French performance exceptional?

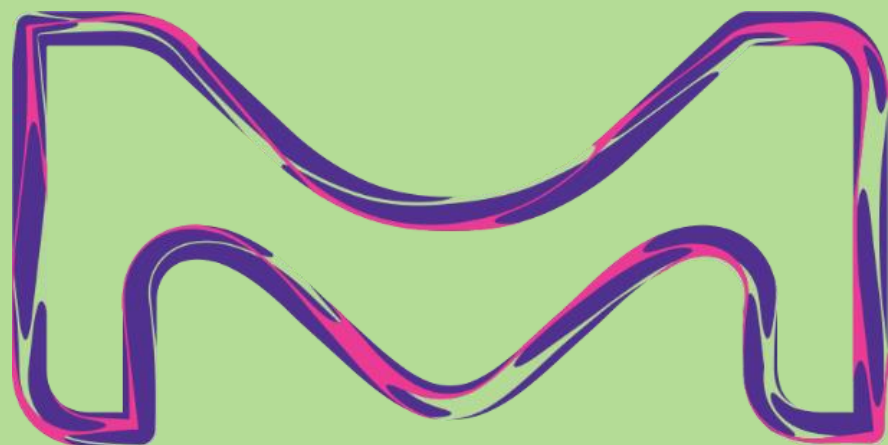


Learnings

What made French performance exceptional?



WEareunstoppable



Best practice sharing – 10 May 2022

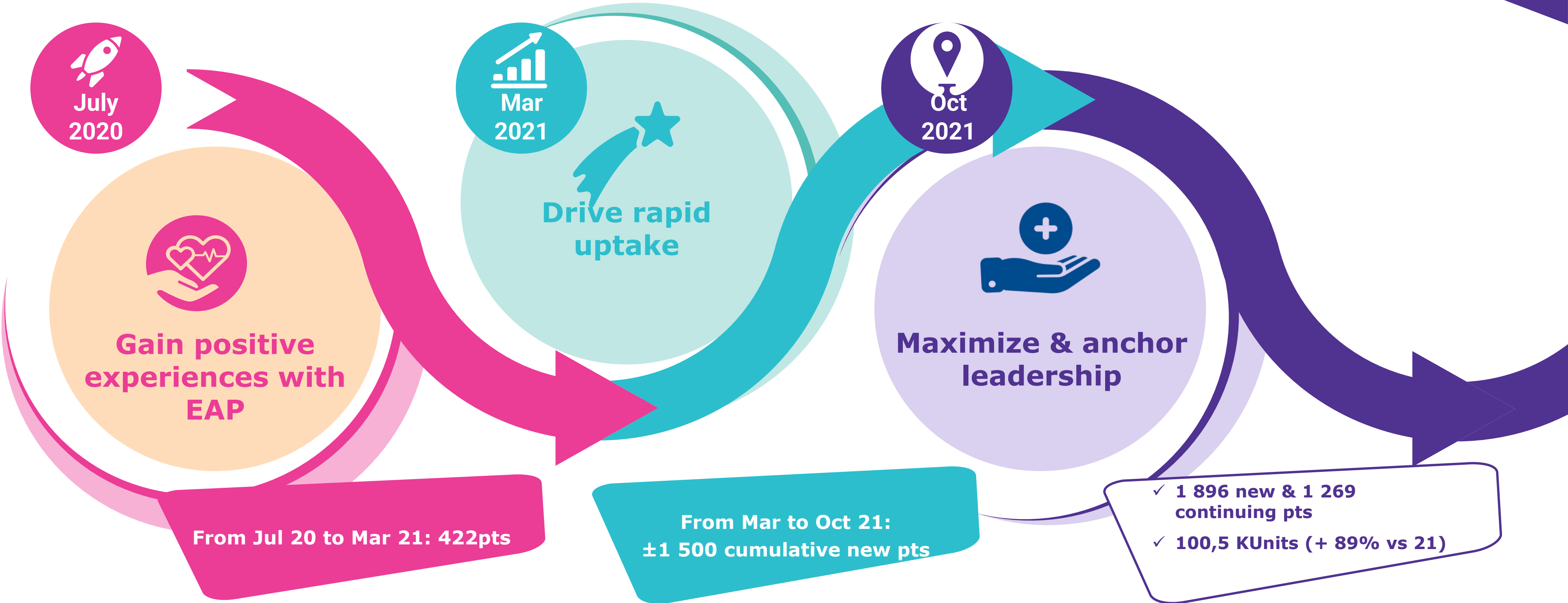
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MERCK

ESTABLISHING BAVENCIO AS STANDARD

HCPS EMBRACE MAINTENANCE AS THE SOC FOR EVERY BAVENCIO UC PATIENT

MERCK



MERCK

Bavencio performance is built on 2 pillars :

All eligible Patients & optimal treatment exposure

1

All eligible patients should be treated with Bavencio

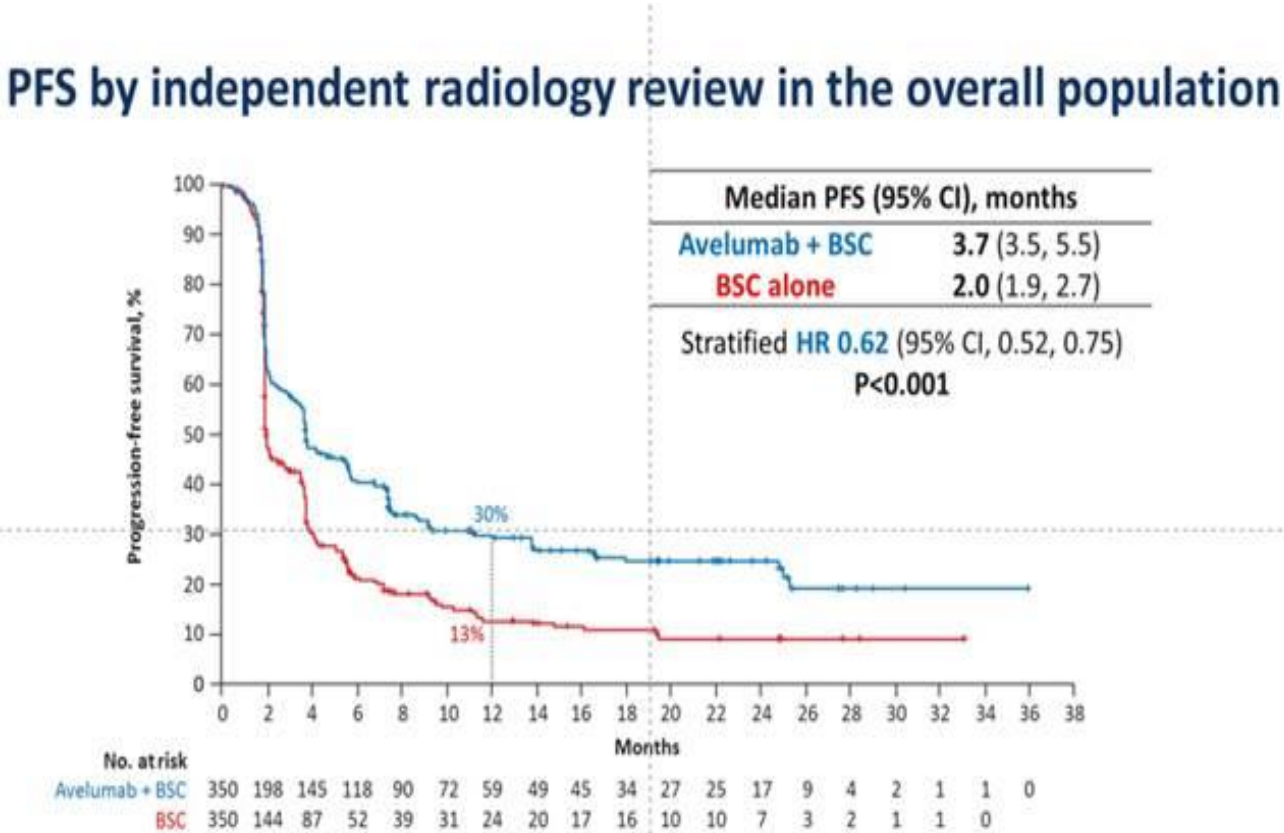
- LA/Meta Treated
- % Platinum eligible
- % Platinum treated
- % Platinum responders
- % 1L maintenance treated
- % Compliance

+80% MS

 **BAVENCIO**[®]
avelumab Injection
20 mg/mL

2

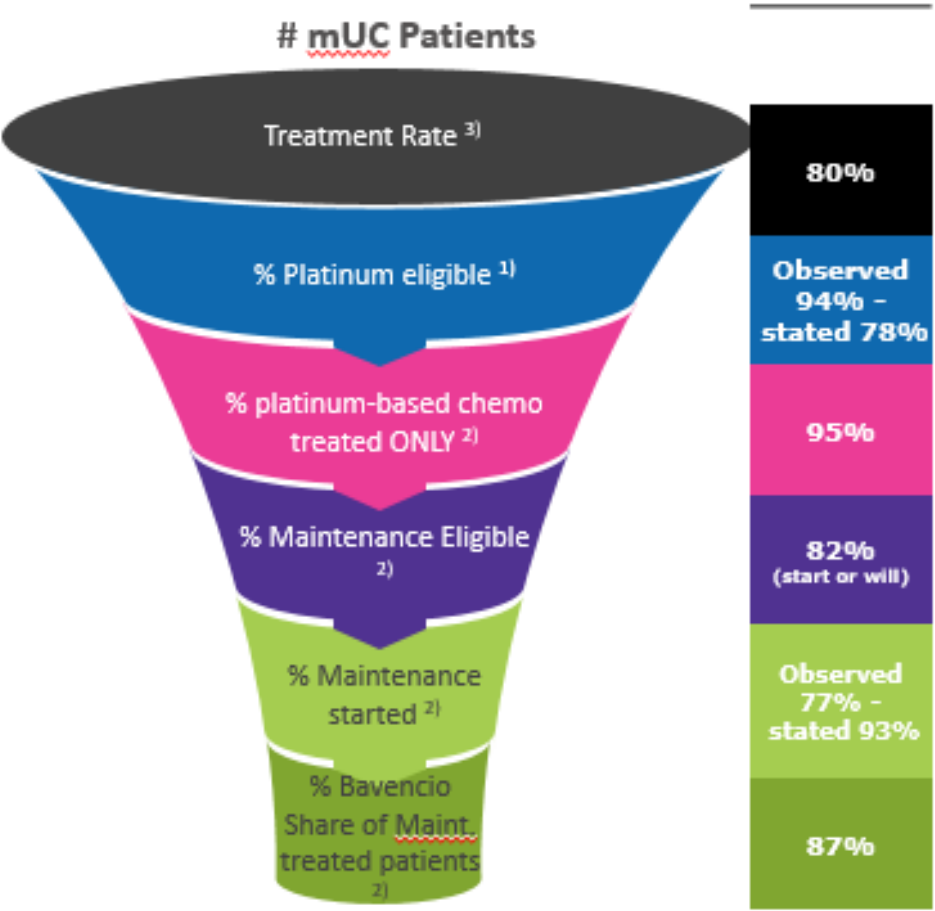
Optimize treatment exposure (duration, frequency & dose)



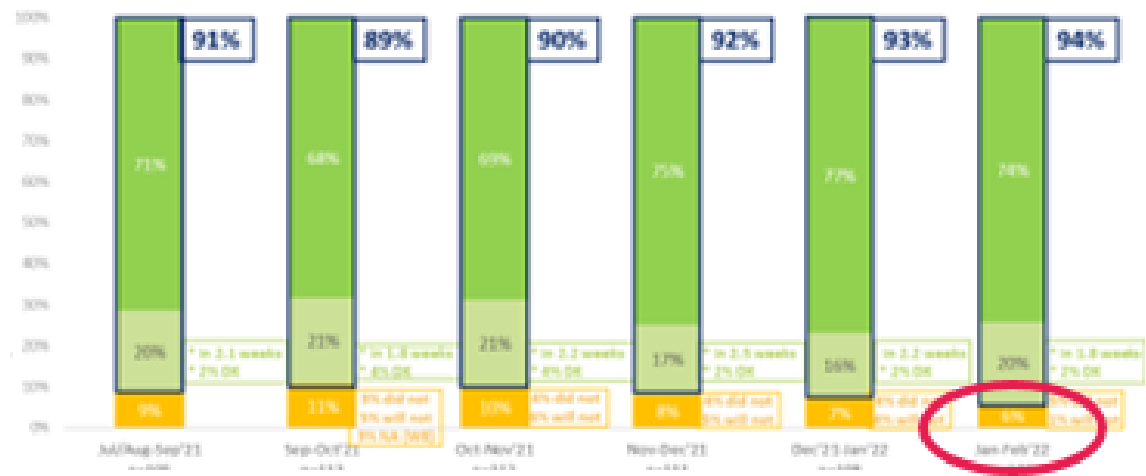
Tracker and sales dynamic

TRACKER A+A

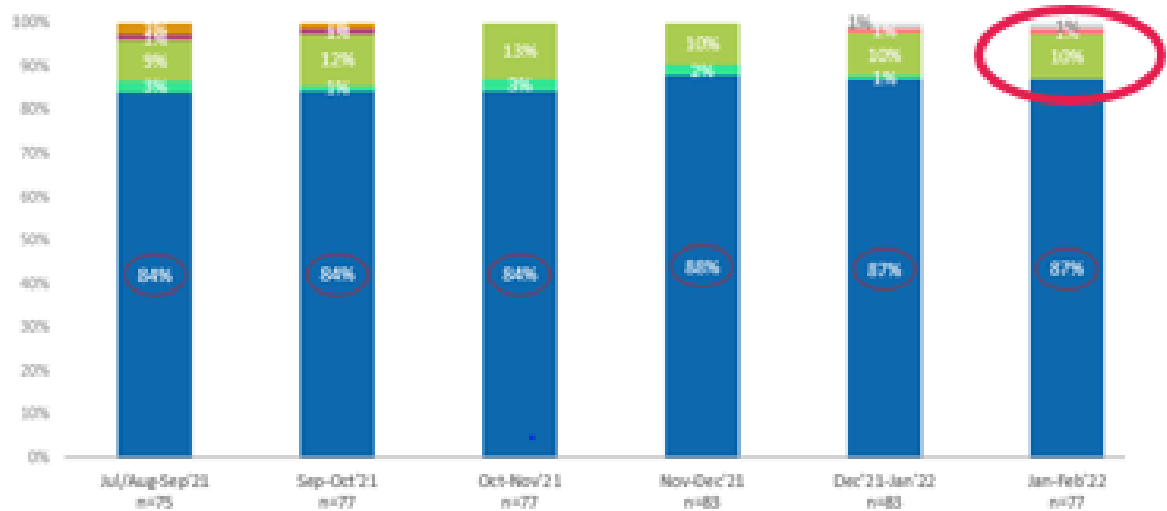
mUC Patients



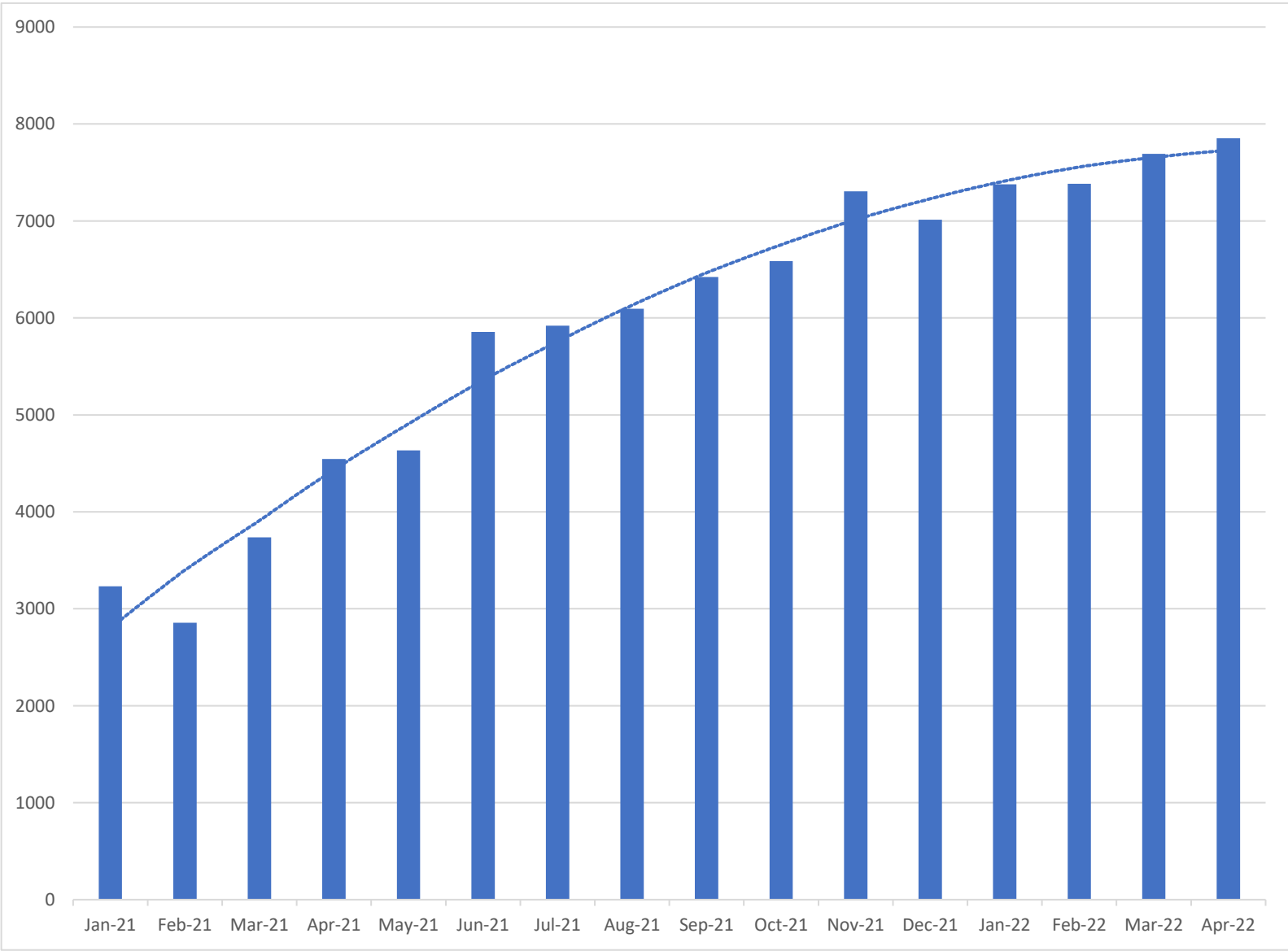
Maintenance treatment

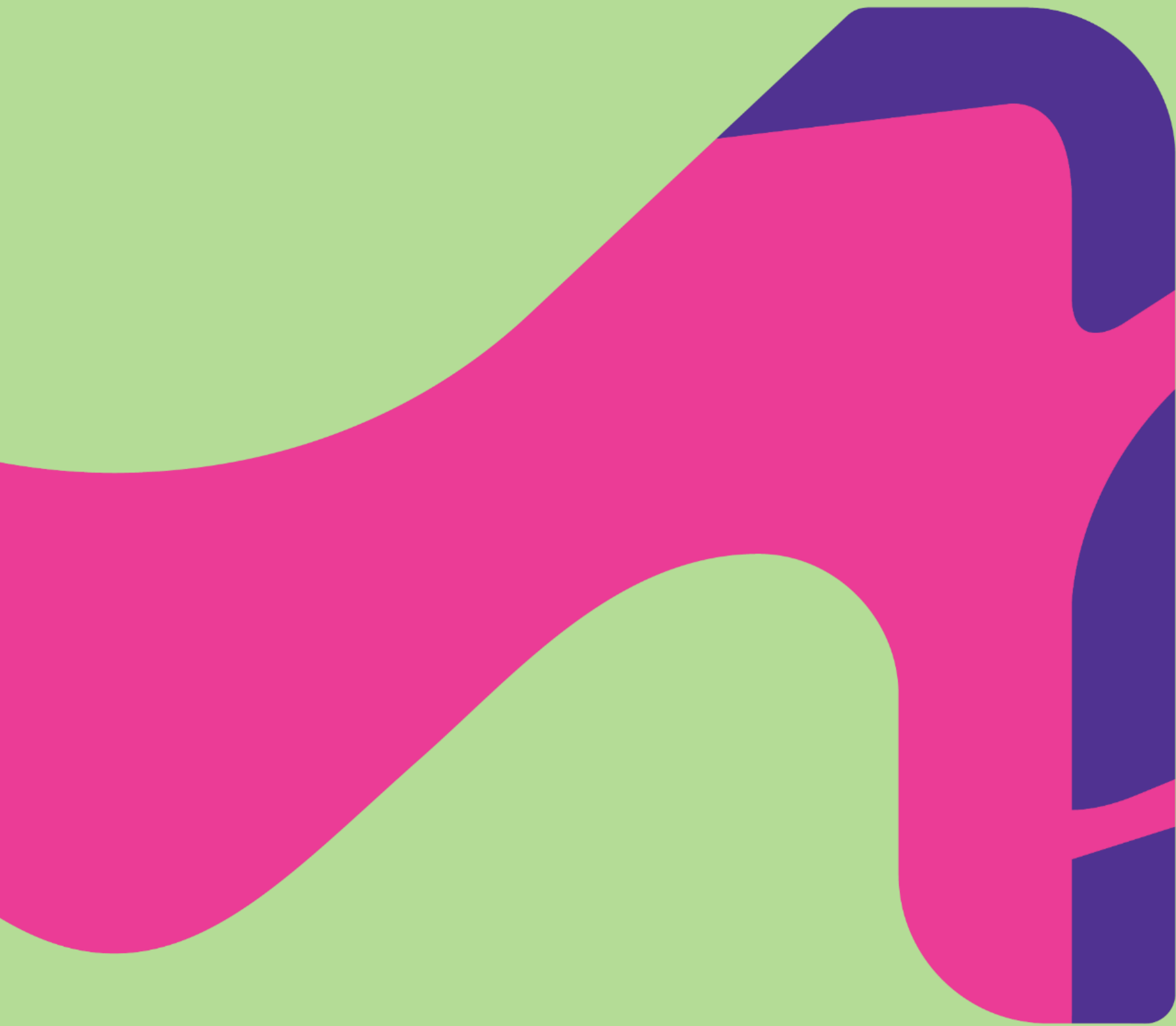


Bavencio MS



SALES units





1 year
anniversary call

+ training
document

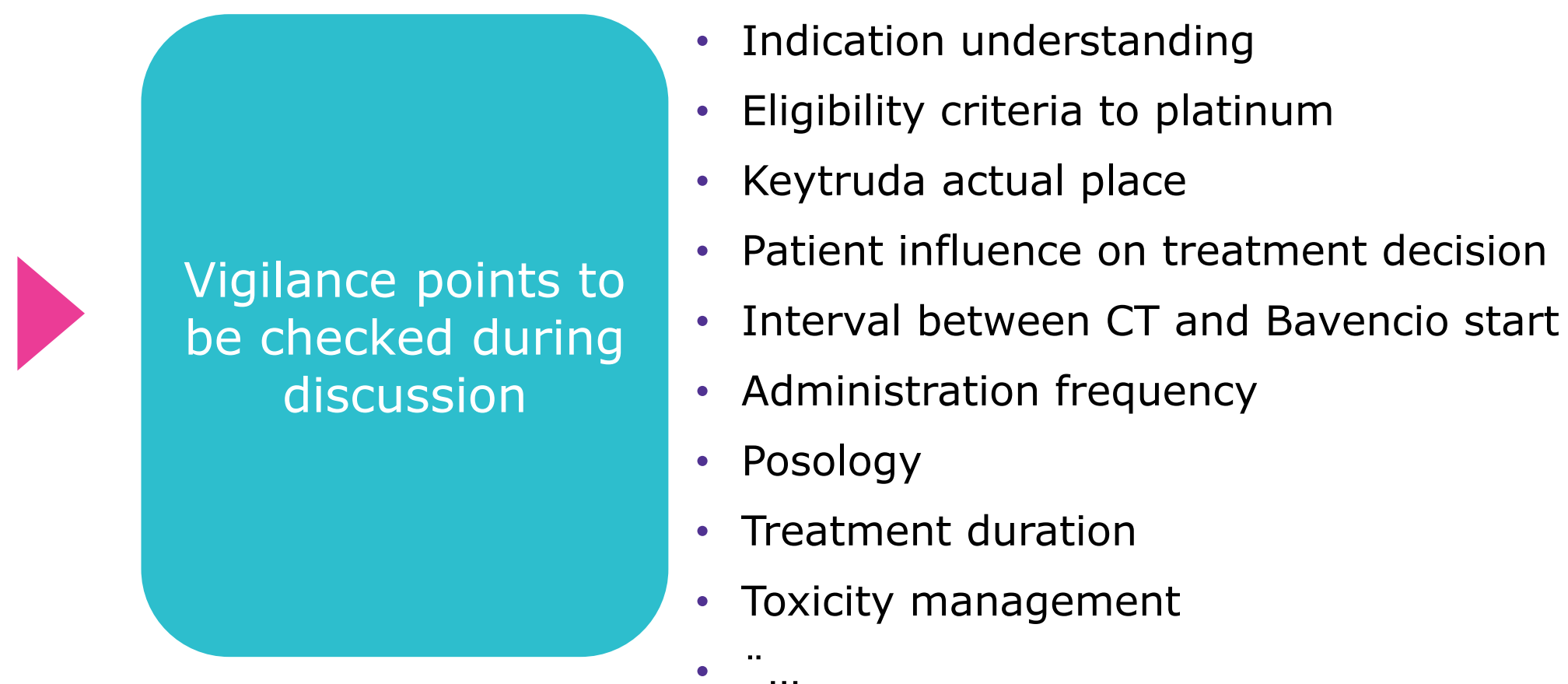
MERCK

Bavencio 1 year “Anniversary call” call: a fantastic opportunity for local discussions on proper use !

Objective : Uncover the “real” use of BAVENCIO and prepare an action plan to address the possible gaps with proper use

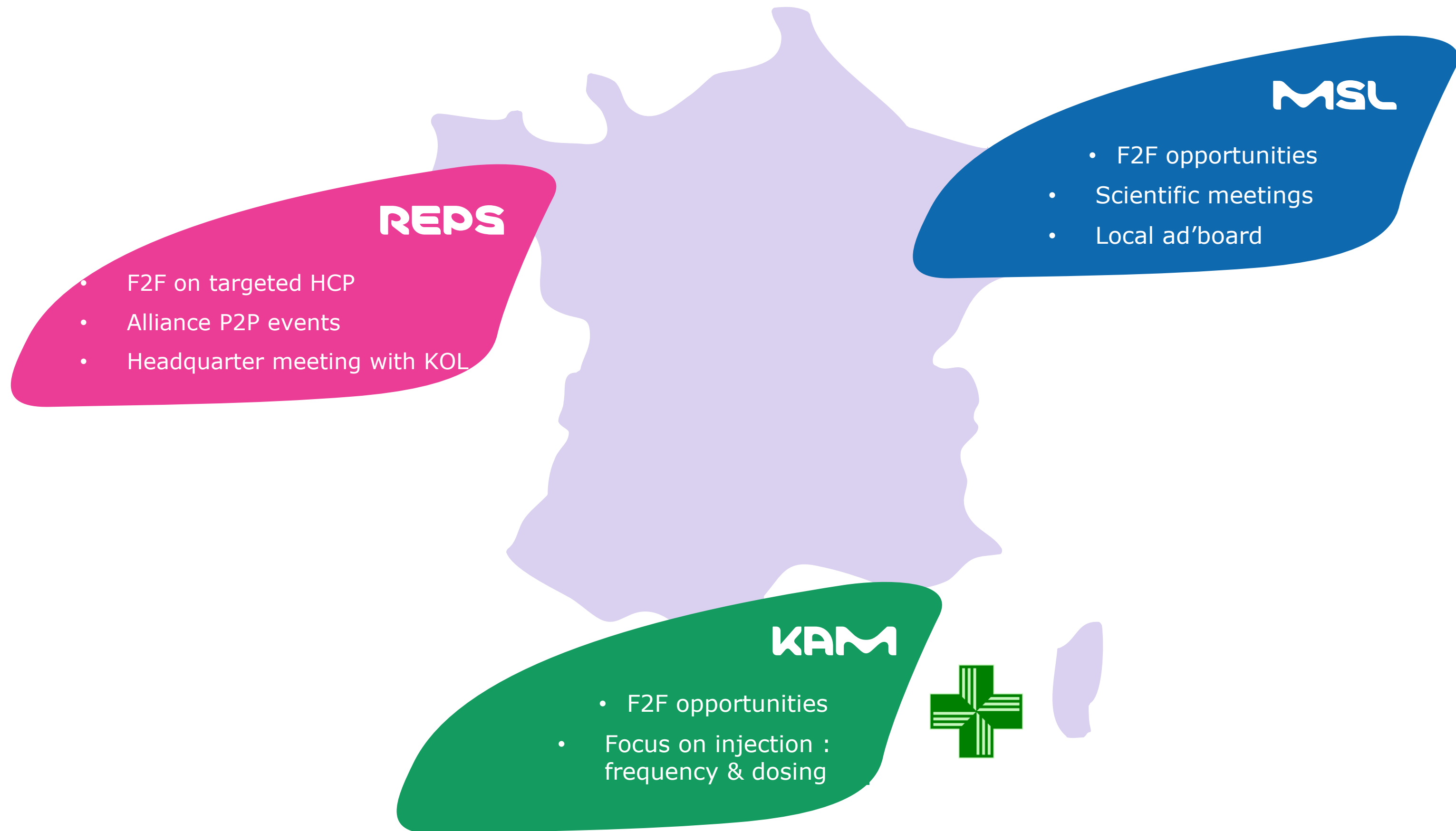


How? Execute investigation plan by organizing local discussions / assessment visit with all Bavencio prescribers



“Anniversary call” :

A cross functional initiative : 360° everywhere



Training document (available in english)

Extensive list of particular attentions and questions to HCPs

For all themes training document includes:

1. UC PATIENT FLOW

Particular attention	Questions	Remember
<ul style="list-style-type: none">Understand well patient flow	<ul style="list-style-type: none">How clinical trials impact current patient flow ?	
<ul style="list-style-type: none">Good understanding of indication : urothelial carcinoma is not only bladder cancer	<ul style="list-style-type: none">Within your Bavencio patients, what is the split between bladder cancer and upper urinary tract tumors?	<ul style="list-style-type: none">Bavencio indication = urothelial carcinoma = urothelium of lower or upper part of urinary tract . Even if 90% of urothelial carcinoma are bladder cancer .(1)
<ul style="list-style-type: none">Identify all influencers (urologists) and their role in the multidisciplinary meetings	<ul style="list-style-type: none">Who are involved in the treatment decision ? How is treatment decision taken ?	

2. PLATINUM ELIGIBILITY

Particular attention	Questions	Remember
<ul style="list-style-type: none">Eligible patients must have received platinum (= gem/carboplatin or gem/cisplatin or MVAC)	<ul style="list-style-type: none">What is the proportion of your patients eligible to platinum ?Is there any situation of patient not receiving platinum base CT in L1? Why?What are your criteria to determine eligibility to cisplatin ? & carboplatin?What is your CT standard ? (gem/cisplatin or gem/carbo or MVAC)?	<ul style="list-style-type: none">Ineligibility criteria to platinum are : Renal function very altered (Creatinin poor performance status (ECOG PS ≥3) or âge/comorbidities not allowing optimal protocol. Out of these criteria, patients must receive either cisplatin or carboplatin. (1)
<ul style="list-style-type: none"># of cycles of platinum based CT	<ul style="list-style-type: none">How many CT cycles do you prescribe (for patients who support platinum)What is your initial target ? (6 cycles?)	<ul style="list-style-type: none">4 to 6 cycles of CT were necessary to prescribe Bavencio Maintenance in JB100 (3)Javelin bladder 100 demonstrated Bavencio benefit whatever number of CT cycle but median OS numerically higher for patients receiving 6 cycles (3)

3. BAVENCIO MAINTENANCE ELIGIBILITY

Particular attention	Questions	Remember
<ul style="list-style-type: none">All non progressive patients are eligible to Bavencio maintenanceCheck progression definition and if Bavencio used in all non progressive patients	<ul style="list-style-type: none">Who are the patients, non progressive after CT induction, who would not receive maintenance treatment ? Why? In which proportion?Even for PDL1 - ? With Histological variant ?Which immunotherapy do you use in L1 maintenance setting? (Keytruda check). How do you handle histological variant ?	<ul style="list-style-type: none">Every patient non progressive after CT induction (approx. 80% (1)) are eligible to Bavencio maintenance whatever platinum CT received, response level and PDL1 status → and as soon as there is a urothelial carcinoma +/-histological variant (2).
<ul style="list-style-type: none">Watch & Wait strategy sometimes preferred by oncologists to reserve immunotherapy for 2L	<ul style="list-style-type: none">Is there any patients you would rather favor watch & wait strategy? If yes, why?	<ul style="list-style-type: none">In JB 100, Bavencio maintenance strategy in L1 demonstrated significant overall survival benefit over Watch & wait strategy (and 70% of patients in the control arm did receive immunotherapy in L2, mostly pembrolizumab) (3)
<ul style="list-style-type: none">A few patients may prefer not receive maintenance treatment after CT induction	<ul style="list-style-type: none">Are there any patients not in favor or receiving maintenance treatment?Does the HCP present treatment strategy from the start : induction CT + immunotherapy maintenance?	
<ul style="list-style-type: none">Delay between CT induction stop and Bavencio start	<ul style="list-style-type: none">How much time is there between induction end and maintenance start?	<ul style="list-style-type: none">It is possible to start Bavencio maintenance as soon as platinum-based CT ends, for non progressive patient. Urothelial carcinoma is very aggressive. It is important not to wait too long before starting maintenance. (2)

4. BAVENCIO AS REFERENCE MAINTENANCE TREATMENT + EXPOSURE

Particular attention	Questions	Remember
<ul style="list-style-type: none">Oncologists may sometimes not be convinced by long term treatment (melanoma or other tumors experience, ...). Risks of discontinuations after 12, 14, 18 ... months of treatment, especially in CR patients.Check definition of "progressive Bavencio patient"	<ul style="list-style-type: none">Does the physician plan a fixed duration of treatment from the start?What does the treatment until progression mean for him ?Does he actually treat until progression in real life setting ? Any spacing ?	<p>Bavencio prolongs significantly the life of some patients, the long-term responders. And if the disease is still controlled after 12, 18 months and more, the patient got the chance to respond to Bavencio. Why would the HCP take the risk of early discontinuation?</p> <ul style="list-style-type: none">In JB100 trial, about ¼ of Bavencio treated patients were still controlled after 24 months. (3)All patients had been treated until progression or unacceptable toxicity in JB100. (3)Urothelial carcinoma is an aggressive disease, (much more than melanoma) that can progress quickly. Stopping treatment early is taking the risk of an early progression.It is recommended to follow Javelin Bladder 100 protocol and then treat until progression to get a chance to observe OS significant survival benefit shown in JB100.There is currently no data nor recommendation supporting early discontinuation of treatment.
<ul style="list-style-type: none">Patients may sometimes get tired of every 2 weeks injections rhythm	<ul style="list-style-type: none">Do some of their patients express the intention to stop treatment ?	

4. BAVENCIO AS REFERENCE MAINTENANCE TREATMENT + EXPOSURE

Particular attention	Questions	Remember
<ul style="list-style-type: none">All maintenance eligible patients must receive Bavencio (standard of care in national and international guidelines)	<ul style="list-style-type: none">What is the treatment used by the HCP in maintenance eligible patients? When are you using Keytruda ?	<ul style="list-style-type: none">Bavencio is the standard of care in international guidelines. Bavencio is the only approved and reimbursed treatment in L1 maintenance setting because only Bavencio demonstrated significant OS benefit in L1. Keytruda is indicated in L2 or later. (1)
<ul style="list-style-type: none">Frequency. Check there is no confusion vs other IO (every 3 weeks) at the start or after a few cycles	<ul style="list-style-type: none">Do all patients receive Bavencio every 2 weeks ? Even after 1 year or more ?	<ul style="list-style-type: none">Bavencio efficacy demonstration in JB100 was obtained with a every two weeks treatment schedule. ½ life of Bavencio is estimated at 6,1 days and does not enable to modify the frequency. Every two weeks treatment is the schedule enabling to observe the benefit demonstrated in JB100(3).
<ul style="list-style-type: none">Dose conform to SmPC	<ul style="list-style-type: none">Is 800 mg dosing used for all Bavencio patients ?	<ul style="list-style-type: none">800mg flat dosing enables to simplify treatment administration and to maintain efficacy. (2).

5. BAVENCIO PROPER USE

Particular attention	Questions	Remember
<ul style="list-style-type: none">Good mastery of toxicity profile of Bavencio and good use	<ul style="list-style-type: none">Does the physician prescribe the premedication ?Does he possess all the information necessary to use Bavencio in a safe way before, during and after treatment ?Does he know well the expected adverse events with Bavencio??	<ul style="list-style-type: none">Get back if needed to the good use described in SmPC:General toleranceAdministrationGood use

Focus

Questions

Knowledge

To have in mind before asking question to HCP

The questions to ask to the HCPs

What the rep have to know to address if necessary

Best practice sharing – 10 May 2022

Internal use only



Training material

Examples of particular attentions and questions to ask to HCPs

Particular attention	Questions	Remember
<ul style="list-style-type: none">• Good understanding of indication : urothelial carcinoma is not only bladder cancer	<ul style="list-style-type: none">• Within your Bavencio patients, what is the split between bladder cancer and upper urinary tract tumors?	<ul style="list-style-type: none">• Bavencio indication = urothelial carcinoma = urothelium of lower or upper part of urinary tract . Even if 90% of urothelial carcinoma are bladder cancer .(1)
<ul style="list-style-type: none">• Eligible patients must have received platinum (= gem/carboplatin or gem/cisplatin or MVAC)	<ul style="list-style-type: none">• Is there any situation of patient not receiving platinum base CT in L1? Why?• What are your criteria to determine eligibility to cisplatin ? & carboplatin?	<ul style="list-style-type: none">• Ineligibility criteria to platinum are : Renal function very altered (Creatinin poor performance status (ECOG PS ≥3) or âge/comorbidities not allowing optimal protocol. Out of these criteria, patients must receive either cisplatin or carboplatin. (1)
<ul style="list-style-type: none">• All non progressive patients are eligible to Bavencio maintenance• Check progression definition and if Bavencio used in all non progressive patients	<ul style="list-style-type: none">• Who are the patients, non progressive after CT induction, who would not receive maintenance treatment ? Why? In which proportion?• Even for PDL1 - ? With Histological variant ?• Even for patient with CR after CT	<ul style="list-style-type: none">• Every patient non progressive after CT induction (approx. 80% (1)) are eligible to Bavencio maintenance whatever platinum CT received, response level and PDL1 status → and as soon as there is a urothelial carcinoma +/-histological variant (2).
<ul style="list-style-type: none">• Frequency. Check there is no confusion vs other IO (every 3 weeks) at the start or after a few cycles	<ul style="list-style-type: none">• Do all patients receive Bavencio every 2 weeks ? Even after 1 year or more ?	<ul style="list-style-type: none">• Bavencio efficacy demonstration in JB100 was obtained with a every two weeks treament schedule. ½ life of Bavencio is estimated at 6,1 days....
<ul style="list-style-type: none">• Oncologists may sometimes not be convinced by long term treatment Risks of discontinuations after 12, 14, 18 ... months of treatment, especially in CR patients.	<ul style="list-style-type: none">• Does the physician plan a fixed duration of treatment from the start?• Does he actually treat until progression in real life setting ? Any spacing ?	<p>Bavencio prolongs significantly the life of some patients, the long-term responders. And if the disease is still controlled after 12, 18 months and more, the patient got the chance to respond to Bavencio. Why would the HCP take the risk of early discontinuation?</p>