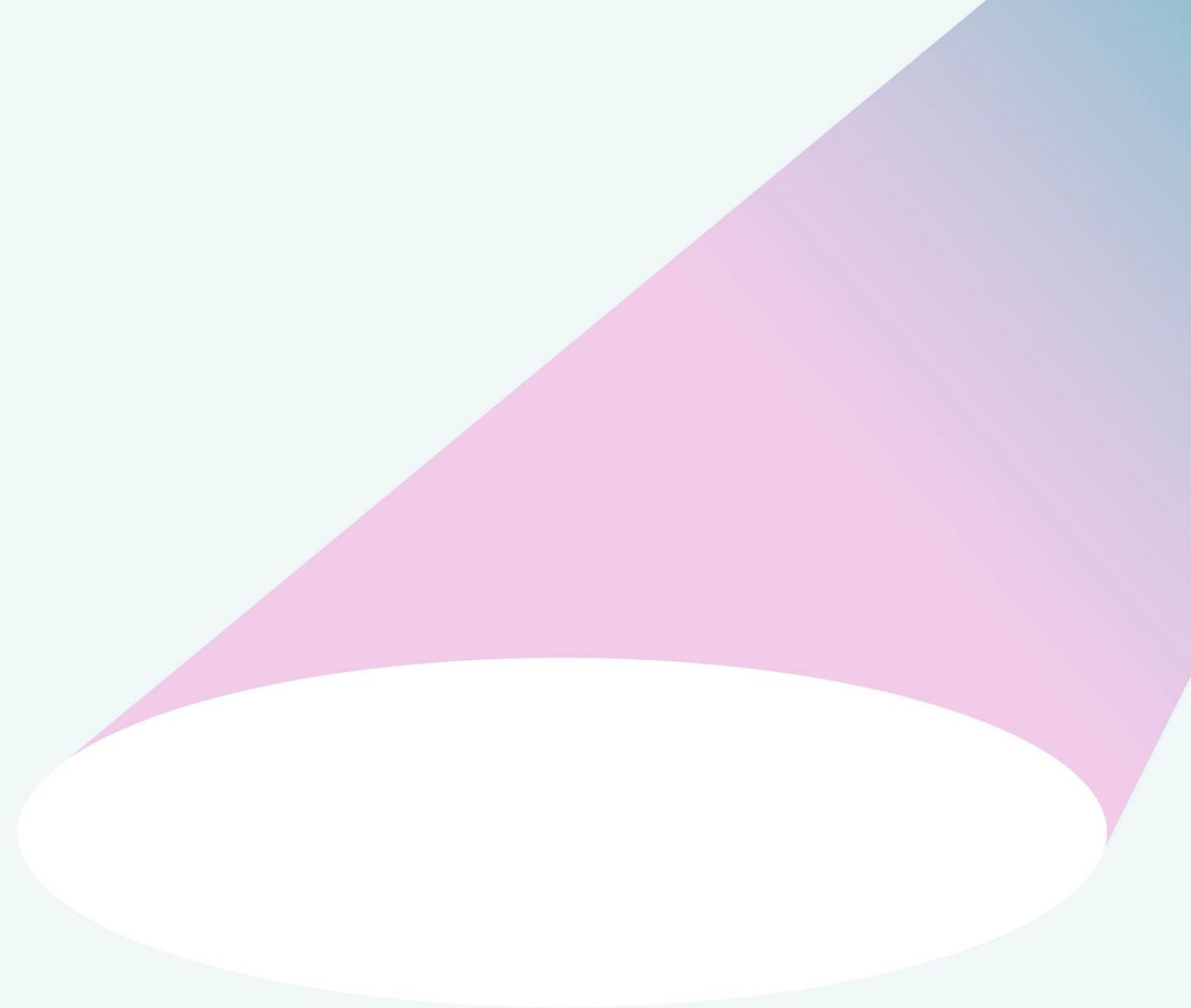


29 MAYO-2 JUNIO | CHICAGO

2026 **ASCO**[®]
ANNUAL MEETING

SPOT LIGHTS 2026

FARMACIA HOSPITALARIA AL DÍA EN ONCOLOGÍA



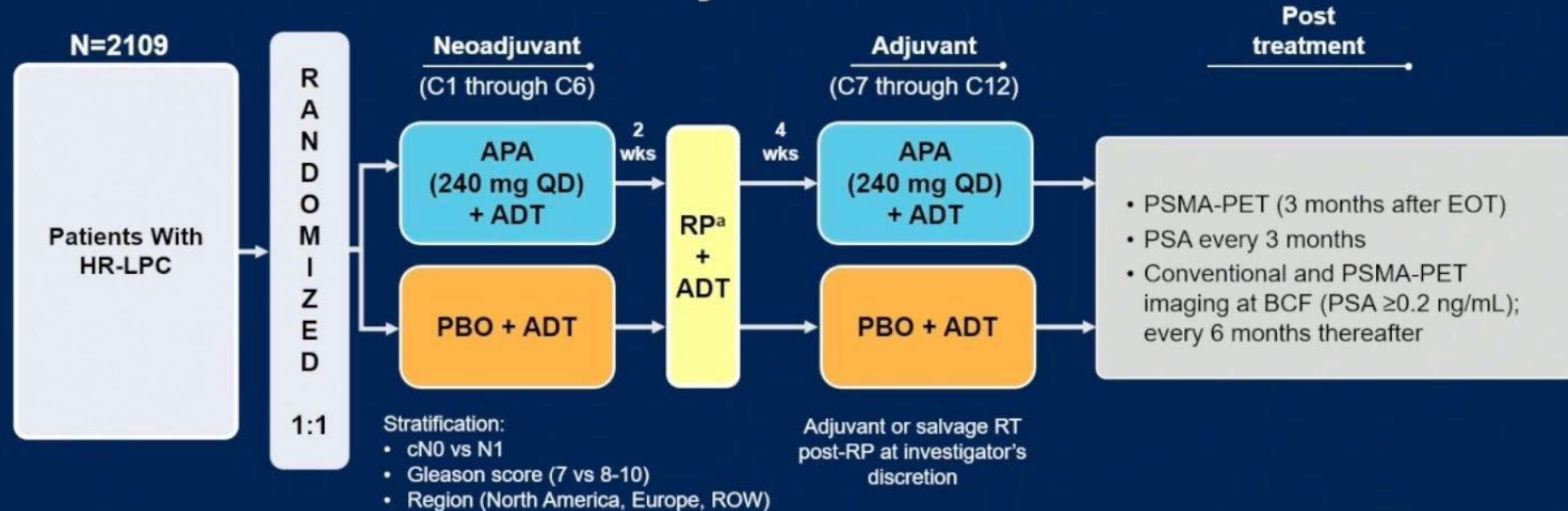
Una iniciativa científica de:



Con el patrocinio de:

REGENERON[®]

PROTEUS: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in HR-LPC



- To complement these data, a substudy is ongoing to further inform on the role of APA + ADT + RP versus RP alone

Patients randomized from July 15, 2019, to June 30, 2022.

Protocol Amendment 7 for including PSMA-PET into MFS assessment (April 14, 2022).

APA, apalutamide; BCF, biochemical failure; C, cycle; EOT, end of treatment; PBO, placebo; PSA, prostate-specific antigen; PSMA-PET, prostate-specific membrane antigen positron emission tomography; QD, daily; ROW, rest of the world; RT, radiation therapy.

^aAPA/PBO is stopped 2 weeks prior to planned RP and then resumed 4 weeks after RP. Cardiovascular risk prophylaxis and venous thromboembolism prophylaxis given based on risk.

Objetivo Primario Dual (Evaluados por BICR)

- **pCR/MRD:** Respuesta patológica completa o enfermedad residual mínima (definida como ypT0 o \leq ypT2; tumor \leq 5 mm).
- **MFS:** Supervivencia libre de metástasis (detectada por imágenes convencionales, PSMA-PET, histopatología o muerte).

Puntos Finales Secundarios (En orden jerárquico)

- **EFS:** Supervivencia libre de eventos.
- **Tiempo hasta la primera terapia posterior.**
- **TTDM:** Tiempo hasta la metástasis a distancia (por imágenes convencionales o PSMA-PET).
- **NED a los 4 años:** Sin evidencia de enfermedad a los cuatro años.
- **MFS:** Supervivencia libre de metástasis (específicamente por imágenes convencionales).
- **Tiempo hasta supervivencia libre de PSA con recuperación de testosterona.**

Dual Primary End Point Met: pCR/MRD



9-fold improvement in pCR/MRD at RP after 6-cycle neoadjuvant APA + ADT vs PBO + ADT

Exploratory end point of RCB (\leq ypT2, N0, \leq 0.25 cm³) corroborates pCR/MRD:

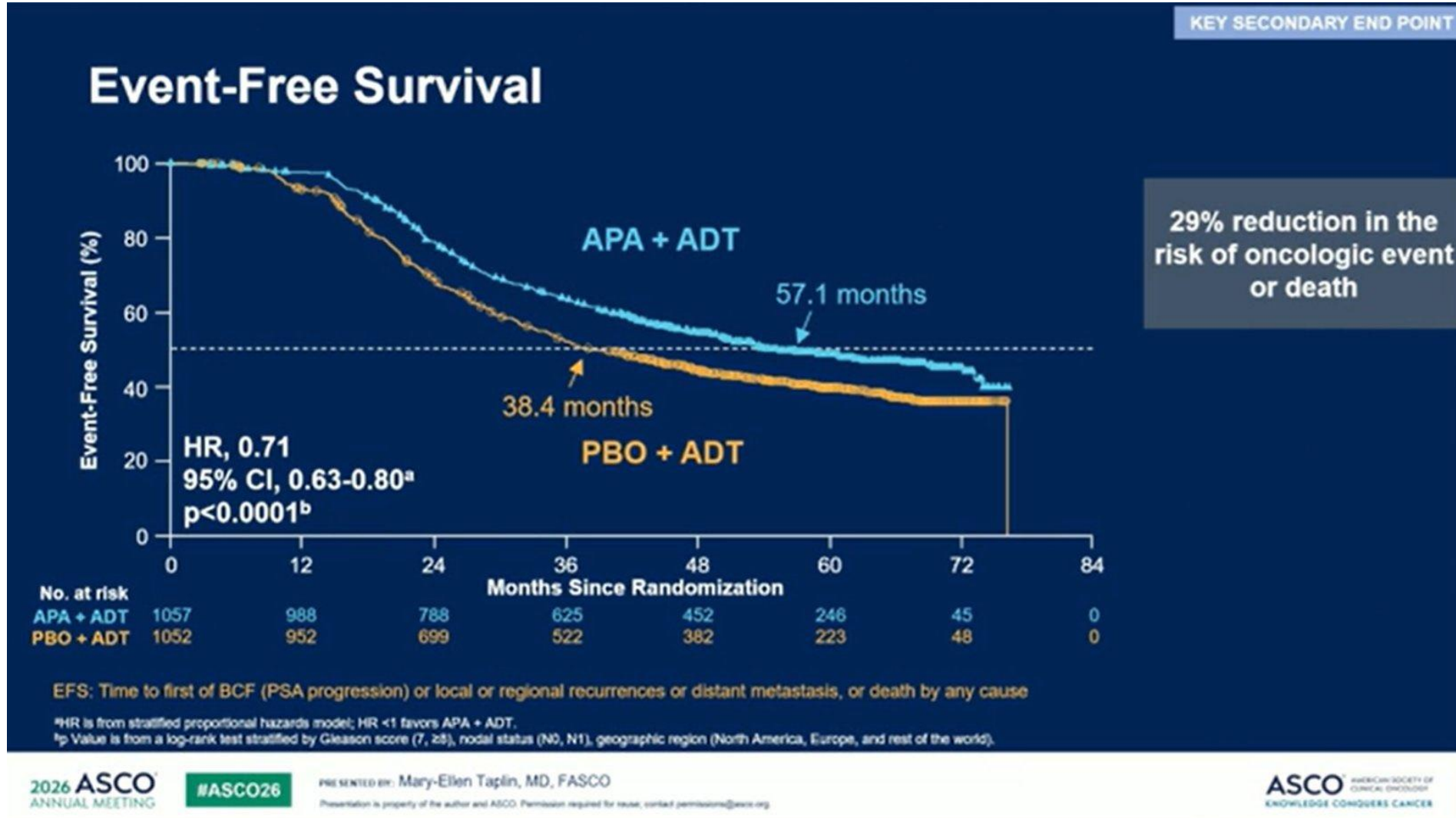
- APA + ADT vs PBO + ADT, 30.6% vs 11.7%
- OR, 3.36; 95% CI, 2.67-4.23; p < 0.0001

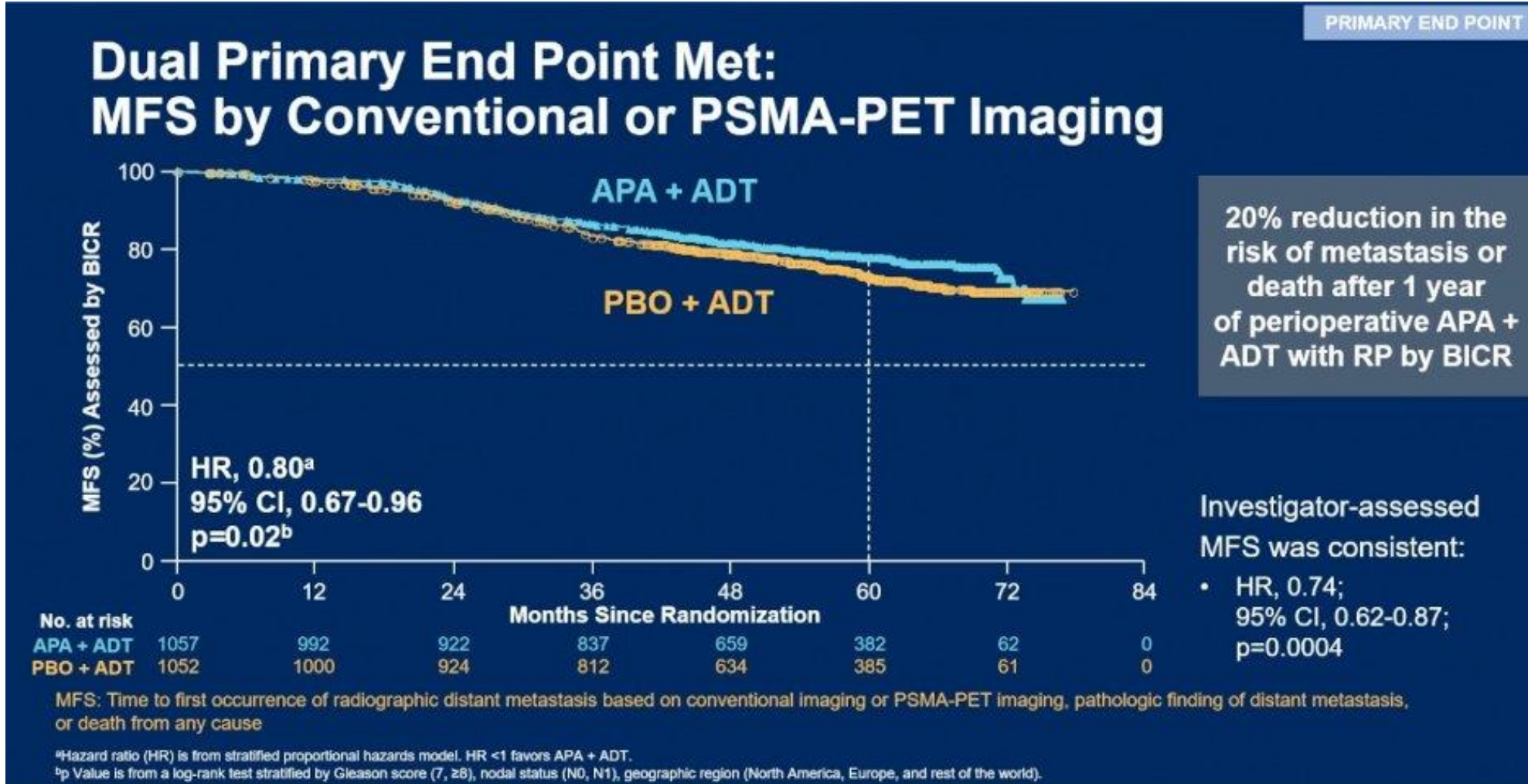
pCR/MRD: Minimal residual tumor \leq 5 mm (greatest dimension of largest tumor lesion) in prostate-confined disease (\leq ypT2, N0) or no tumor identified (ypT0)
RCB: Residual cancer burden \leq 0.25 cm³ in prostate-confined disease (\leq ypT2, N0)

Error bars indicate 95% confidence intervals (CIs). Odds ratio (OR) is from a logistic regression adjusted for stratification factor; OR >1 favors APA + ADT.

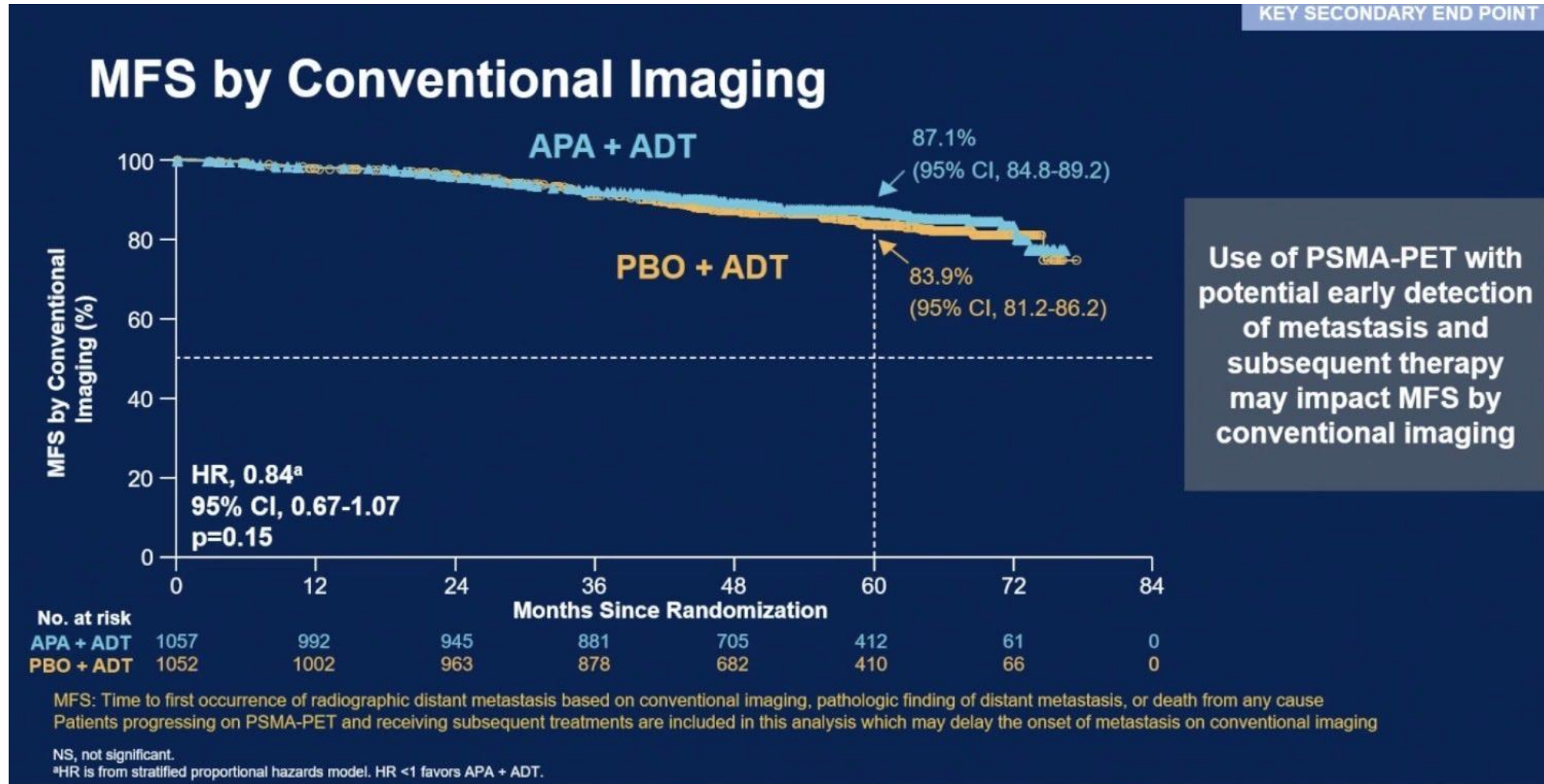
^ap Value is based on Cochran-Mantel-Haenszel test stratified by Gleason score (7, \geq 8), nodal status (N0, N1), geographic region (North America, Europe, and rest of the world).

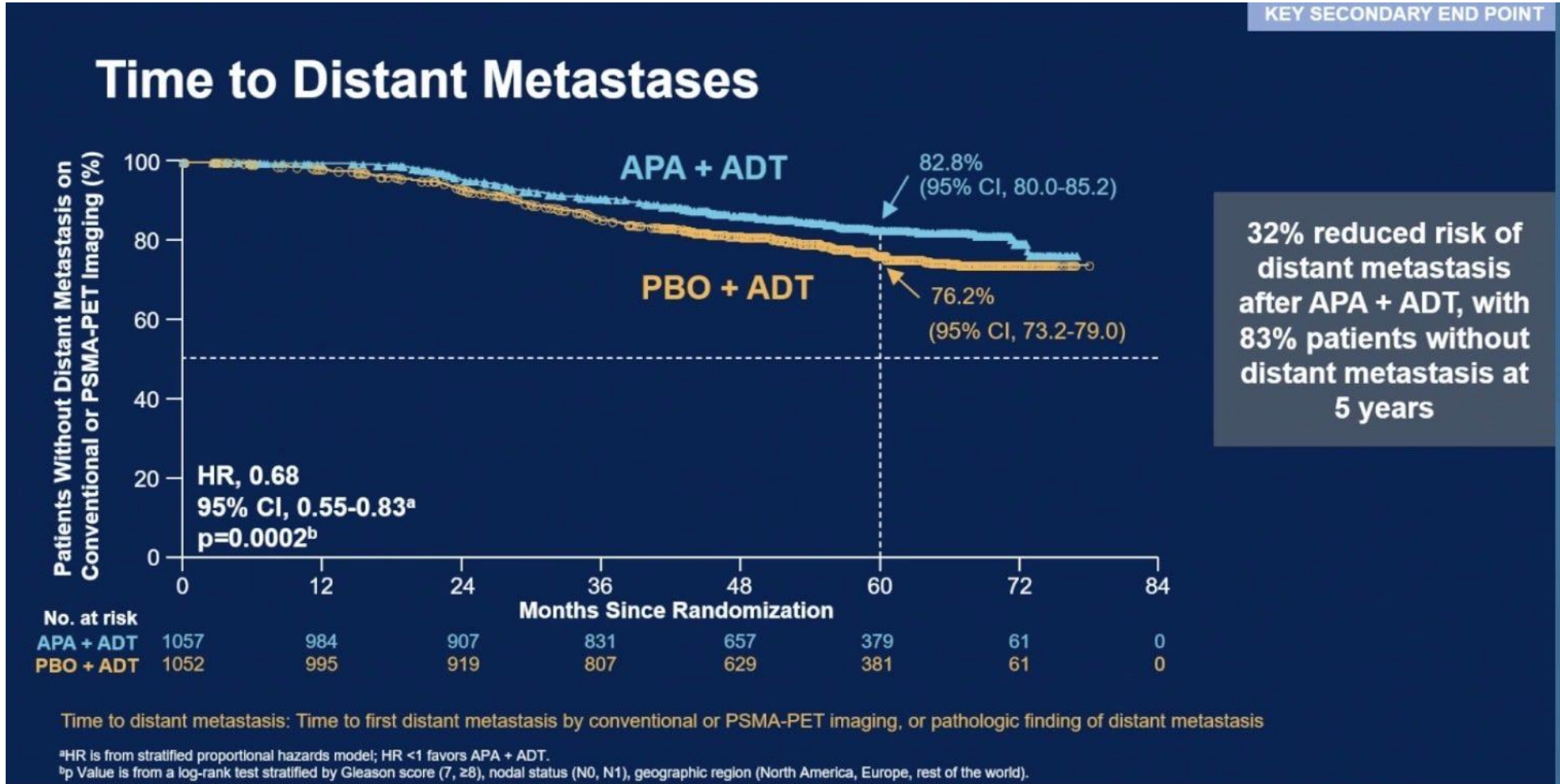
Perioperative (neoadjuvant and adjuvant) apalutamide (APA) + androgen deprivation therapy (ADT) vs placebo (PBO) + ADT with radical prostatectomy (RP) in high-risk localized or locally advanced prostate cancer (HR LPC/LAPC): Final analysis of the PROTEUS phase 3 study.

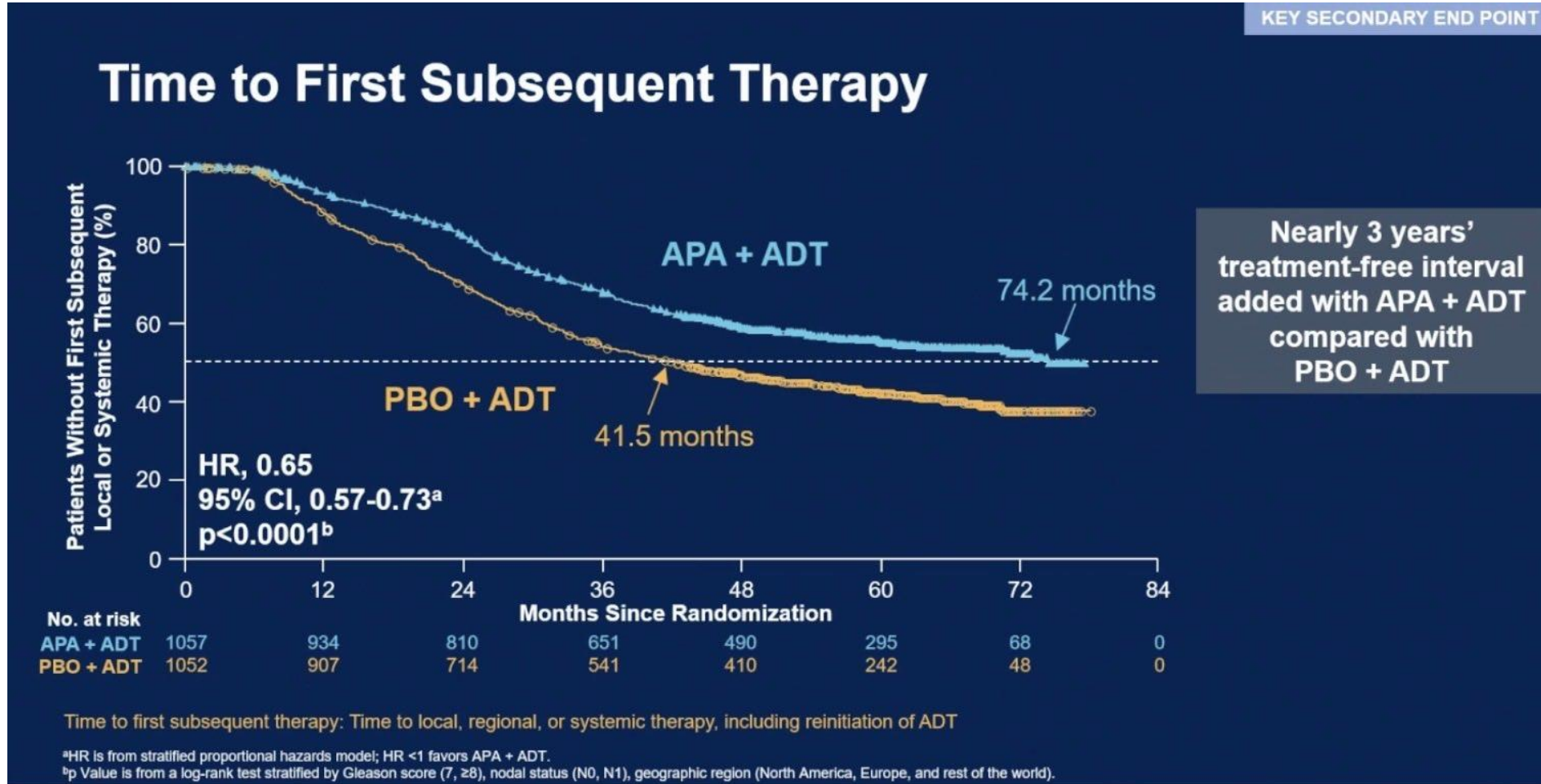




Perioperative (neoadjuvant and adjuvant) apalutamide (APA) + androgen deprivation therapy (ADT) vs placebo (PBO) + ADT with radical prostatectomy (RP) in high-risk localized or locally advanced prostate cancer (HR LPC/LAPC): Final analysis of the PROTEUS phase 3 study.







SECONDARY END POINT

Frequency of Treatment-Related Adverse Events

	Safety Population, n (%)	APA + ADT (n=1050)	PBO + ADT (n=1050)
All grades	Treatment-related AE	1000 (95.2)	985 (93.8)
Grade 3/4	Treatment-related AEs	289 (27.5)	198 (18.9)
	Treatment-related AEs leading to dose reduction ^a	118 (11.2)	24 (2.3)
	Treatment-related AEs leading to dose interruption ^a	126 (12.0)	46 (4.4)
All grades	Treatment-related AEs leading to death ^b	7 (0.7)	1 (0.1)

AE, adverse event.

Treatment-related AEs are those that occurred on or after the first dose of study drug through the last dose of study treatment + 30 days or prior to the start of subsequent therapy, whichever is earlier, or any AE that is considered treatment related regardless of the start date of the event. An AE is categorized as related if assessed by the investigator as possibly, probably, or very likely related to study drug (apalutamide or placebo), ADT, or RP.

^aAEs leading to treatment interruption or dose reduction are based on AE action taken. ^bIncludes grade 5 events; AEs leading to death are based on AE outcome of fatal.

Limitaciones

- El brazo control (ADT) NO es el estándar de tratamiento actual.
- NO está validado que la MFS mediante PET-PSMA sea un subrogado de la SG

Conclusions

PROTEUS sets a new standard of care in HR-LPC

Unprecedented Study Design	Enhanced Disease Control of RP	Known Safety Profile	More to Come
<ul style="list-style-type: none">• Largest size to date• Novel end points• PSMA-PET inclusion	<p>Significant benefit:</p> <ul style="list-style-type: none">• 9× greater pCR/MRD• 20% less risk of MFS• 29% less risk of recurrence or death• 3 years longer time to next treatment	<p>Tolerability of APA+ADT consistent with prior studies</p>	<ul style="list-style-type: none">• Substudy comparing with direct RP• Biomarker assessment• Surgical outcomes• Pathology correlates