UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): October 26, 2026

Imunon, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-15911**	**52-1256615**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

997 Lenox Drive, Suite 100 **Lawrenceville, NJ**	**08648-2311**
(Address of principal executive offices)	(Zip code)

(609) 896-9100
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**IMNN**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On October 26, 2026, Imunon, Inc. (the "Company") made available an investor presentation (the "Investor Presentation"), which the Company expects to use in connection with investor calls and/or conferences. A copy of the Investor Presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Imunon, Inc. Investor Presentation October 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMUNON, INC.

Date: October 26, 2026

By: */s/ Josh Blacher*
Name: Josh Blacher
Title: Chief Financial Officer

IMUNON

Developing medicines harnessing the capability of DNA to power body's immune system

Investor Presentation

Nasdaq: IMNN

OCTOBER 2026

Safe Harbor Statement

DISCLOSURES

For the purposes of this notice, the "presentation" that follows shall mean and include the slides that follow, the oral presentation of the slides by members of management of Imunon, Inc. ("IMUNON" or the "Company") or any person on their behalf, any question-and-answer session that follows such oral presentation, hard copies of this document and any materials distributed at, or in connection with, such oral presentation. The information contained in this presentation is for informational purposes only.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the therapeutic use for which such product candidates are being studied.

FORWARD-LOOKING STATEMENTS

IMUNON wishes to inform readers that forward-looking statements in this presentation are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including, but not limited to, statements regarding the timing of enrollment of the Company's clinical trials, statements regarding the potential of any therapies developed by the Company to fulfill unmet medical needs, the market potential for the Company's products, if approved, the potential efficacy and safety profile of our product candidates, and the Company's plans and expectations with respect to its development programs more generally, are forward-looking statements. We generally identify forward-looking statements by using words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances). Readers are cautioned that such forward-looking statements involve risks and uncertainties. These risks and uncertainties, based upon Imunon's current expectations and beliefs including those related to the future financial position and business strategy of the Company, are detailed in IMUNON's filings with the Securities and Exchange Commission. IMUNON assumes no obligation, except to the extent required by law, to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

Offering Summary

ISSUER:	Imunon, Inc. ("IMNN" or the "Company")
EXCHANGE/SYMBOL:	Nasdaq Capital Market: IMNN
OFFERING TYPE:	Best Efforts S-1 Follow-On
UPFRONT GROSS PROCEEDS:	Up to $25.0 Million
POTENTIAL MILESTONE WARRANT GROSS PROCEEDS:	Up to $121.3 Million subject to the exercise of such warrants
SECURITIES TO BE OFFERED:	One share of Common Stock (or one pre-funded warrant in lieu thereof), with one Tranche A Warrant to purchase one-half of one share of Common Stock, one Tranche B Warrant to purchase one share of Common Stock, one Tranche C Warrant to purchase one share of Common Stock, and one Tranche D Warrant to purchase one share of Common Stock
ANTICIPATED USE OF PROCEEDS:	General corporate purposes, primarily for the clinical development of lead product candidate (IMNN-001), capital expenditures, and working capital, and potentially repayment of some or all of the amounts owed to Streeterville Capital
SOLE PLACEMENT AGENT:	Maxim Group LLC
ANTICIPATED PRICING:	To be determined

Proposed Milestone Warrant Summary

Tranche A Common Warrants:	Expire on the earlier of (i) the five-year anniversary of the effective date of stockholder approval of the issuance of the shares upon exercise of the Tranche A, B, C, and D Common Warrants (the "Warrant Stockholder Approval") or the date of issuance of such warrants (the "Initial Exercise Date"), as applicable, and (ii) 30 trading days after the public announcement of the secondary endpoint readout (defined as ORR, time to second line therapy, R0 Surgical Response, or Chemotherapy Response of 3) based on 75 OVATION 3 trial patients or more; provided that the daily VWAP of the common stock equals or exceeds 300% of the exercise price for 30 consecutive trading days
Tranche B Common Warrants:	Expire on the earlier of (i) the five-year anniversary of the Initial Exercise Date or the Warrant Stockholder Approval, as applicable, and (ii) 30 trading days after the public announcement of the secondary endpoint readout based on 220 patients or more of the planned enrollment in OVATION 3 trial, provided that the daily VWAP of the common stock equals or exceeds 300% of the exercise price for 30 consecutive trading days
Tranche C Common Warrants:	Expire on the earliest of (i) the five-year anniversary of the Initial Exercise Date or the Warrant Stockholder Approval, as applicable, (ii) 30 trading days after the public announcement of full enrollment of the trial, no evidence of futility and an independent data monitoring committee recommendation to continue the trial, provided that the daily VWAP of the common stock equals or exceeds 300% of the exercise price for 30 consecutive trading days; or (iii) 30 trading days after public announcement of interim analysis at 60% of ITT events meeting the FDA aligned, pre-specified threshold for success on the overall survival primary endpoint in the OVATION 3 trial
Tranche D Common Warrants:	Expire on the earlier of (i) the seven-year anniversary of the Initial Exercise Date or the Warrant Stockholder Approval, as applicable, and (ii) 30 trading days after public announcement of positive final overall survival primary endpoint with a p-value below the FDA-agreed threshold for approval

Investment Thesis

Funding IMNN-001 IL-12 Registrational Study for 1st line Ovarian Cancer

First-in-Class Immunotherapy with favorable safety profile and clinically meaningful OS efficacy results in a randomized, well controlled Phase 2 trial in newly diagnosed ovarian cancer population

Unlocking First-In-Class IL-12 Immunotherapy

- IL-12: Biology was never the problem. Systemic Protein delivery was.
- IMNN-001 is different: Locally delivered DNA plasmid producing IL-12 where the disease lives.
- Level of Clinical Evidence observed in Phase 2. Phase 2 was not powered for OS; Phase 3 is powered and includes 2 interim analyses for early stopping for efficacy and support for a future BLA submission, full approval

Ovarian cancer represents a multi billion-dollar unmet medical need

- IMNN-001 has been granted Fast Track by the FDA
- Orphan status has been established in the U.S. and EU

Data driven registrational study design based on strong evidence

- +14.7-month median OS benefit with IMNN-001 vs. SoC Alone (45.1 vs. 30.4 months)
- +24.2-month median OS benefit with PARP inhibitors (65.6 vs. 41.4 months)
- Consistency of Evidence:
  - OVATION 2: All Primary and Secondary Endpoints, and Safety Profile, Favor IMNN-001
  - MRD trial: independent phase 2 trial preliminary data favors IMNN-001 with Lower residual disease rate (44.4% vs. 66.7%), higher circulating tumor (ctDNA) clearance (87.5% vs. 62.5%), and no evidence of disease after frontline therapy (100% vs 56%)
  - Biologic effects as measured by biomarkers demonstrate evidence of remodeling of Tumor Microenvironment

Registrational study ongoing

- Newly diagnosed, advanced ovarian cancer, eligible for to NACT treatment, 500 patient trial
- Definitive primary endpoint is overall survival
- Design includes 2 planned interim analyses enabling early stopping for success, BLA filing for full approval

Great Unmet Need: Recurrence Rates are High and Survival Rates are Low

Patient Outcomes and Frontline Standard of Care Unchanged for more than 25 years

Epithelial ovarian cancer (EOC) is insidious and usually diagnosed at an advanced stage. Though EOC initially responds to treatment, the recurrence rate is high. Recent treatments delay progression, but overall survival has not improved. Hence there is a need for effective therapy for patients with EOC.



20,000
new cases diagnosed each year in US, 13,000 deaths

300,000
new cases diagnosed worldwide

80%
diagnosed in late stage (III/IV)

70%
recurrence rate within 2-5 years after initial treatment

>60%
will die within 5 years of diagnosis

IMNN-001, Imunon's novel IL-12 immunotherapy, has the potential to be first-in-class IL-12 Immunotherapy and provide a break-through in today's frontline standard of care

Sources: Cancer Statistics, American Cancer Society; Globocan; SEER database. CDC

IL-12 Has Compelling Biology but Historical Delivery & Safety Limitations

IL-12 activates both innate and adaptive immune systems in immunogenic tumors, but its development has been limited by delivery and safety challenges

EOC is an immunogenic cancer where immune-cell infiltration in tumors is associated with improved outcomes, supporting therapeutic approaches that restore anti-tumor immune activity

IL-12'S MULTIFACETED IMMUNE ACTIVATION SUPPORTS ITS POTENTIAL IN EOC



Activation of Innate Immune Response: Enhances NK-cell proliferation and cytotoxic activity



Activation of Adaptive Immune Response: Activates proliferation and anti-tumor cytotoxicity of CD8+ T cells



Drives Maturation of CD4+ cells: Drives naïve CD4+ T cells toward a Th1 phenotype

Increases IFN-γ levels: Promotes the production of IFN-γ, enhancing antigen presentation and inhibiting angiogenesis

HISTORICAL CHALLENGES WITH SYSTEMIC RECOMBINANT IL-12 THERAPY



Systemic toxicity: Due to IL-12's potent immune-stimulatory activity, prior systemic IL-12 therapies have been limited by widespread inflammation and severe immune-related toxicities



Limited durability of IL-12 levels: Recombinant IL-12 has a short circulating half-life, which has limited the ability for previous systemic IL-12 therapies to maintain durable levels of IL-12 without frequent or higher dosing



Inability to locally achieve sustained therapeutic levels: Due to dose limiting toxicities and IL-12's short half-life, prior IL-12 therapies have struggled to achieve therapeutically relevant levels in the tumor microenvironment (TME)

Previous barriers to IL-12 development have been with delivery and safety, rather than a lack of biological rationale

IMNN-001's Differentiated Approach to IL-12 Delivery

Local, durable, and safe IL-12 delivery at the tumor site with repeat dosing representing a key differentiating feature of IMNN-001's DNA-mediated approach

IMNN-001 uses the Theraplas® platform for non-viral delivery of an IL-12–encoding plasmid, enabling repeat intraperitoneal administration and local cytokine expression



IL-12 plasmid vector

Carries the IL-12 gene and regulatory elements for expression



Synthetic DNA delivery system

Protects plasmid from degradation and facilitates uptake across cell membrane



IMNN-001

Plasmid encased in the nanoparticle delivery system

IMNN-001 is administered intraperitoneally (IP) and taken up by local cells, which are then transfected to produce IL-12 protein in the vicinity of the tumor

IMNN-001's differentiated approach allows it to overcome historical barriers to IL-12 therapy

Local IL-12 delivery mitigates systemic toxicity: IP administration of IMNN-001 ensures local expression of IL-12 while limiting systemic activation and reducing immune related adverse events (irAEs)

DNA plasmid delivery enables sustained IL-12 levels: By delivering IL-12 via a DNA plasmid, IL-12 is generated locally by cells in the tumor microenvironment, with each treatment producing durable levels of IL-12 for over 7 days

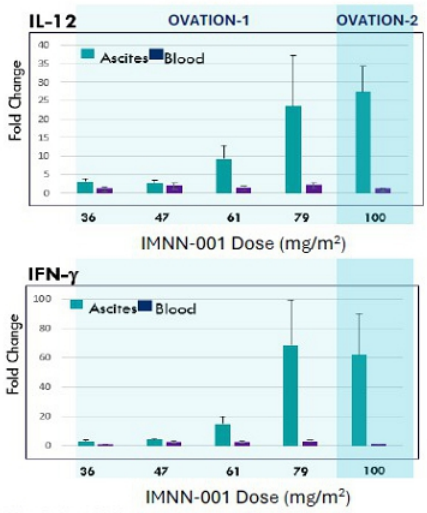
Non-viral delivery allows repeat dosing: IMNN-001's nanoparticle delivery system avoids anti-vector immunity associated with viral approaches, enabling repeated dosing

Combination Opportunity: IMNN-001's local immune priming may support combinations with existing and emerging therapies by countering EOC's immunosuppressive tumor microenvironment

Biomarker Data Support Local Target Engagement and TME Remodeling

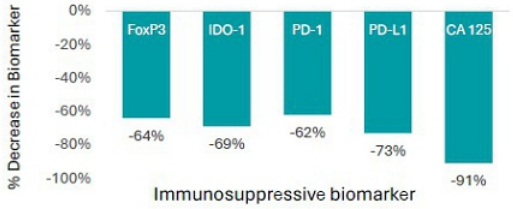
IMNN-001 increases IL-12 levels within the ascites without increasing systemic levels, helping shift the tumor microenvironment from immunologically "cold" to "hot"

IMNN-001 achieves local increase in IL-12 in dose dependent manner, without elevating levels in the blood

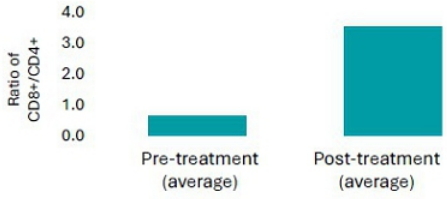


Adapted from Thaker P, Clin Cancer Res, 27:553, 2021

LOCAL IL-12 EXPRESSION LEADS TO TUMOR SPECIFIC IMMUNE ACTIVATION



IMNN-001 treatment resulted in **reduced immunosuppressive biomarkers in the tumor**, suggesting remodeling of the TME to a more immunologically active state



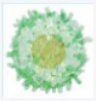
IMNN-001 leads to greater cytotoxic T-cell presence in the TME, indicating that **IMNN-001 is turning the TME from "cold" to "hot"**

IMNN-001 Safely Targets the Micro-Environment of Ovarian Cancer

Local production of safe and durable levels of a powerful anti-cancer immune agent, IL-12

Safe administration weekly, demonstrated in up to 17 doses over a 6-month period

INTERLEUKIN 12 INDUCES STRONG ANTI-CANCER IMMUNITY THROUGH MULTIPLE MECHANISMS



Stimulates the proliferation of CD-8 positive T-cells and natural killer (NK) cells and their cytotoxic activity against the tumor



Shifts the differentiation of naive CD-4 positive T-cells toward a TH-1 phenotype, further enhancing the immune response



Promotes cellular production of the potent immune mediator IFN-γ and TNF-α. IFN-γ promotes the expression of anti-angiogenic molecules, halting the growth of new blood vessels that supply oxygen to the tumor



IL-12 may inhibit regulatory T-cells that suppress immune responses by "hiding" the tumor from the body's immune system

IMNN-001 transforms the Tumor Microenvironment **by activating both arms** of the Immune system: Innate and Adaptive Immunity

IMNN-001 turns "cold" tumors into immunologically active "hot" tumors

IMNN-001 Consistent Safety Profile: OVATION-2, OVATION-3 and MRD Trial Safety

IMNN-001 Continues to Allow Safe and Tolerable Repeated Delivery of Tumor-Localized IL-12

OVATION 2, PHASE 2 - KEY SAFETY OBSERVATIONS:

- None of the systemic dose-limiting toxicities associated with IV recombinant IL-12 were observed with IP IMNN-001
- Cytokine release syndrome (CRS) did not occur with IMNN-001 treatment
- No elevation of immune related A/E
- Most common treatment-emergent adverse events:
  - *Abdominal pain, nausea, vomiting*
  - *Significant improvement in control of abdominal pain when an analgesic regimen was instituted*

MRD TRIAL SAFETY OBSERVATIONS:

- Favorable benefit/risk profile further strengthened by MRD trial
- Patients successfully treated with IMNN-001 maintenance therapy, and patients were safely treated with IMNN-001 in combination with Bevacizumab

INDEPENDENT DATA MONITORING COMMITTEE REVIEWS:

- OVATION-3 IDMC (May 2026): no safety concerns; continue without modification
- MRD study IDMC (Aug 2026): no safety concerns; continue without modification

IMNN-001: A Potential Breakthrough in Newly Diagnosed Ovarian Cancer

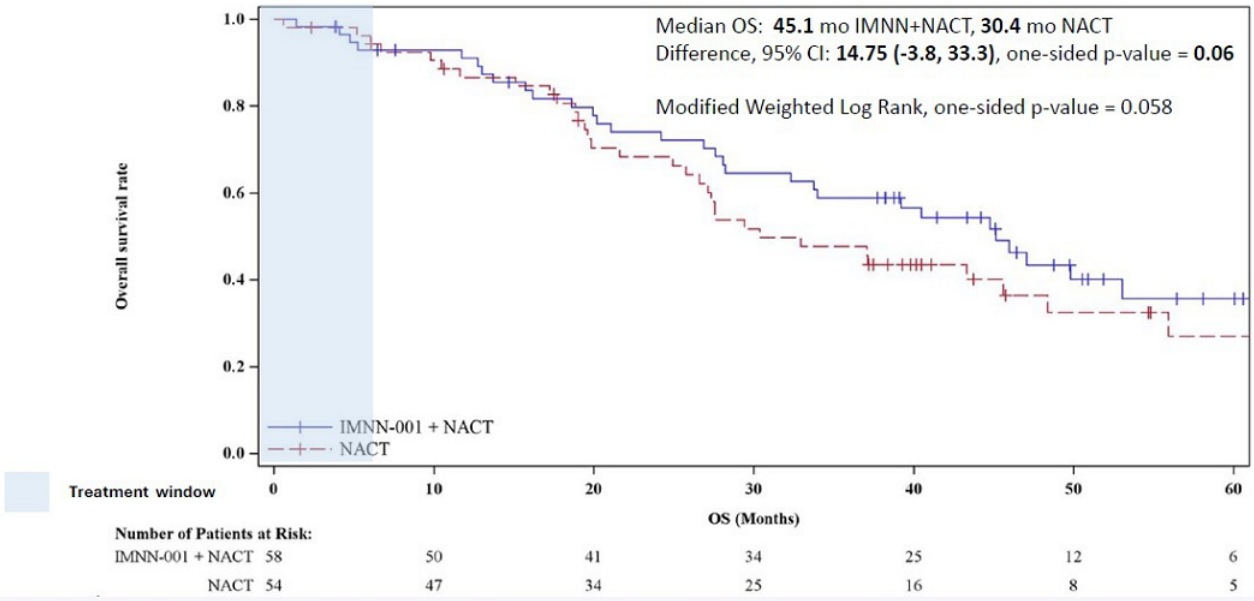
01 No other frontline ovarian cancer trial has shown an OS improvement; IMNN-001 has a favorable benefit/risk profile

02 Large randomized Phase 2 OVATION-2: 14.7-month OS improvement by IMNN-001 over standard of care, 95%CI (-3.8, 33.3), 24-month OS improvement in patients treated with PARPi

03 IMNN-001 may be the 1st immuno-therapy for ovarian cancer, with the potential to transform the standard of care

04 Phase 3 OVATION-3 Study: FDA-aligned registrational trial enrolling, treatment with IMUNON-manufactured API

OVATION 2 Data Show Continued IMNN-001 Overall Survival Improvement

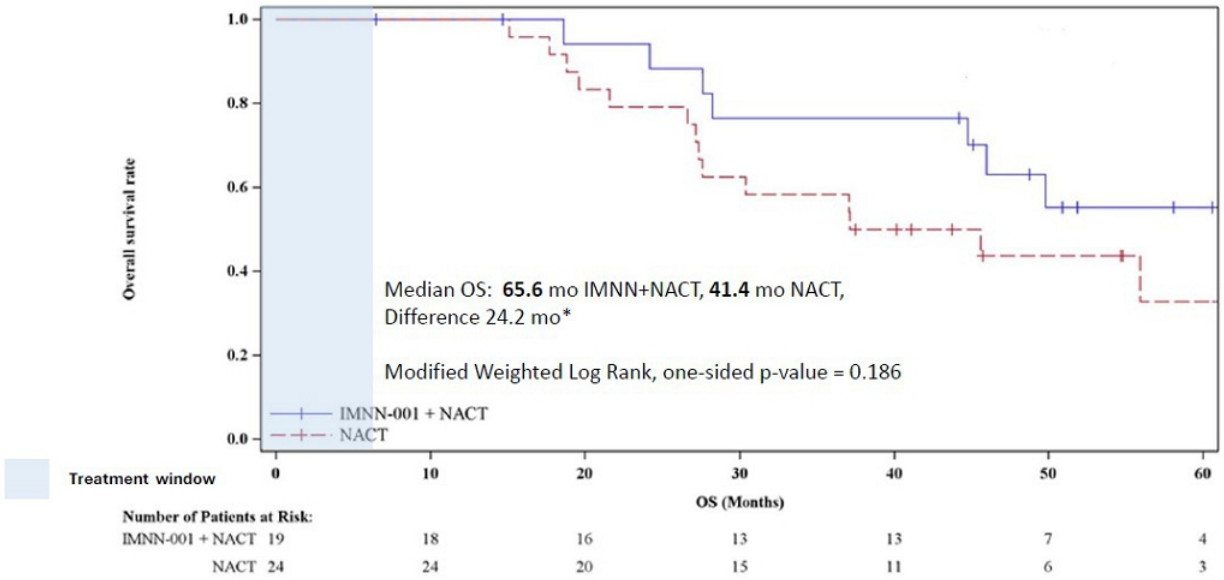


Number of Patients at Risk:

IMNN-001 + NACT	58	50	41	34	25	12	6
NACT	54	47	34	25	16	8	5

ITT, all-comers: July 2024 Δ medians 11.1 mo → Final Analysis (Dec 2025): **Δ medians 14.7 mo**

OVATION 2 PARPi-Treated Show 24-month IMNN-001 Overall Survival Improvement



Number of Patients at Risk:							
IMNN-001 + NACT	19	18	16	13	13	7	4
NACT	24	24	20	15	11	6	3

PARPi maintenance treated: July 2024 Δ medians NE → *Final Analysis (Dec 2025): **Δ medians 24.2 mo**

*Due to the small event rate, CI for the difference in medians can't be estimate

Our Phase 3 Clinical Research is of Great Importance to the Medical Community

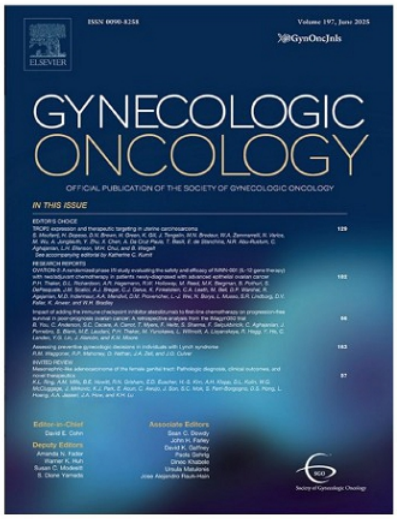
Our Landmark Phase 2 Study was Showcased at ASCO with a Platform Presentation

2025 ASCO ANNUAL MEETING

A Phase I/II study of the Safety and Efficacy of IP IMNN-001 in combination with N/ACT in patients newly-diagnosed with advanced EOC: Updated Survival Analysis from OVATION-2 Trial

P. Thaker, D. Richardson, A. Hagemann, R. Holloway, M. Reed, M. Bergman, B. Pothuri, S. DePasquale, J. Scalici, A. Begar, C. Darus, K. Finkelstein, C. Leath III, M. Bell, D. Warshal, R. Agajanian, M. Indermaur, A. Mendivil, D. Provencher, LJ Wei, L. Musso, S. Lindborg, D. Faller, K. Anwer, W. Bradley.

Premal H. Thaker, MD
David & Lynn Mutch Distinguished Professor of Obstetrics & Gynecology
Chief of Gynecologic Oncology, Interim. Director of Gynecologic Oncology Clinical Research. Professor in Gynecologic Oncology.
Washington University School of Medicine



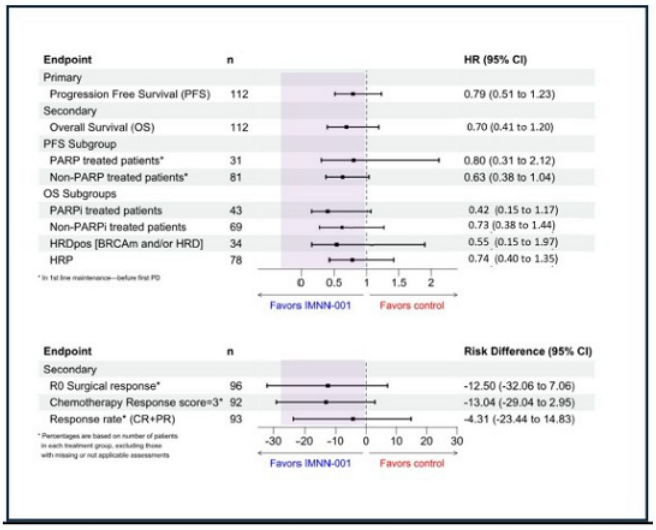
– Published in Gynecologic Oncology, Peer Reviewed, Premier Medical Journal

Consistent treatment effects favoring IMNN-001 across all Phase 2 efficacy endpoints, favorable safety, and biomarker validation suggests potential for reproducibility in phase 3

Phase 2 Clinical Endpoints associated with Overall Survival

Randomized Trial Design	Randomized 1:1 comparison against the current chemotherapy SoC reduces confounding and strengthens confidence that the observed signal reflects IMNN-001 treatment effect
Treatment effect consistently favored	IMNN-001 + N/ACT effect was consistently favored across all primary and secondary efficacy endpoints in comparison to N/ACT alone
IMNN-001 overcomes safety challenges	IMNN-001 has demonstrated a consistent safety profile across multiple studies with no cytokine release syndrome, no dose limiting toxicities, and no serious systemic immune related adverse events
Biomarker Validation	Local IL-12 and IFN-γ production, together with tumor-specific immune activation, provides evidence of biological activity and validates IMNN-001's proposed mechanism
Preliminary MRD Trial results	Preliminary MRD findings from independent randomized study are directionally consistent with OVATION-2, with lower MRD positive rates and increased ctDNA clearance

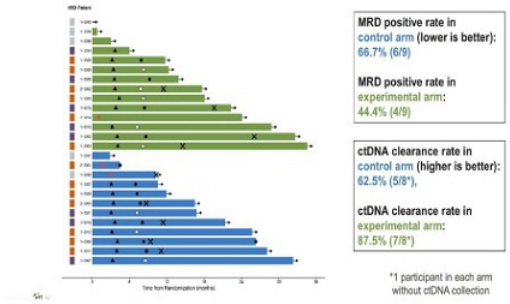
TREATMENT EFFECT CONSISTENTLY FAVORS IMNN-001 ACROSS ENDPOINTS



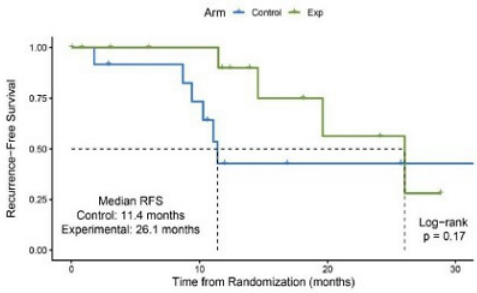
MRD Translational Study: Deep Responses and Immune Remodeling in the IMNN-001 Arm

IMNN-001 Shows Lower MRD-Positive Rate, Higher ctDNA Clearance, and Longer Recurrence-Free Survival

TREATMENT COURSE & OUTCOME BY PATIENT (ITT COHORT)



RECURRENCE-FREE SURVIVAL: MEDIAN TWICE AS LONG WITH IMNN-001



44.4%
MRD-positive rate, experimental arm (vs. 66.7% control)

87.5%
ctDNA clearance rate, experimental arm (vs. 62.5% control)

26.1 months
Median recurrence-free survival, experimental (vs. 11.4 mo control)

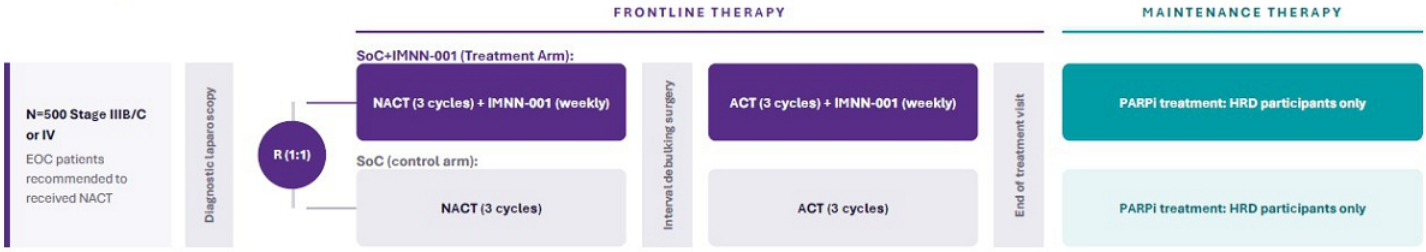
100%
Reached NED after frontline therapy, experimental (vs. 56%)

N=26 ITT (12 control, 14 experimental); RFS log-rank p=0.17. Source: IMUNON 2026 R&D Day, September 23, 2026 (slides 23–26).

PHASE 3 DESIGN

OVATION-3 Is Designed to Prospectively Confirm the OS Effect

OVATION-3 is an ongoing randomized, controlled Phase 3 trial evaluating IMNN-001 in women with newly diagnosed advanced ovarian cancer eligible for neoadjuvant chemotherapy



- **Registrational design:** 500 patients randomized 1:1 to IMNN-001 + N/ACT versus N/ACT alone
- **Primary endpoint:** OS, with protocol-specified maintenance and stratification incorporated to support balanced treatment arms and robust interpretation
- **Regulatory alignment:** Phase 3 protocol, statistical analysis, and cGMP for Phase 3 and commercial product have been aligned with FDA
- **Execution:** Enrollment on track with original planning rate, with full enrollment targeted for early 2029
- **Planned interim analyses:** The event-driven design includes interim analyses with potential early stopping for efficacy and support for a future BLA submission, full approva
- **Secondary and exploratory endpoints:** that further evidence efficacy, safety and patient perspectives/QoL

TARGETED TIMELINE:

H2 2025	2026-28	Q1 2029	Event-driven Interim 1 / Interim 2	Final OS analysis
First patient	Enrollment / follow-up	Target full enrollment	Potential early efficacy stopping / BLA pathway	

ACT: adjuvant chemotherapy, R: randomization

Projected milestones are based on the current enrollment assumptions and study planning; subject to change based on study progress and operational factors

UPCOMING CATALYSTS

Key Anticipated Near-Term Milestones for OVATION-3 & IMNN-001

Enrollment progress, scientific presentations, and data readouts supporting the registrational pathway

~ Dec 2026 — **OVATION-3 iDMC Review**
Independent Data Monitoring Committee assessment of safety and trial progress

Q1 2027 — **MRD study reaches 100% patients enrolled**
Trial reaches 30 patients randomized and treated

~July 2027 — **Secondary Endpoint analysis based on 75 or more OVATION-3 Patients, S-1 Tranche A milestone**
OVATION-3 75 or more patients enrolled (end of Q1 2027).

~ Q2 2027 — **OVATION-3 iDMC, next formal review**
Next review, in ongoing assessment of safety review and trial progress. Trigger when ~100 patients enrolled

End of 2027 — **100% OVATION-3 Site Activation**
Full site network activated to support continued enrollment momentum

Q1 2028 — **Secondary Endpoint analysis based on 220 or more OVATION-3 Patients, S-1 Tranche B milestone**
OVATION-3 220 or more patients enrolled

Projected milestones are based on the current enrollment assumptions and study planning; subject to change based on study progress and operational factors

IMNN-001 Current and Potential Future Indications

Theraplas Platform Capable of a Pipeline of DNA-Based Transformative Medicines

PLATFORM	DELIVERY	PROGRAM	INDICATION(S)	DISCOVERY	IND ENABLING	PHASE 1	PHASE 2	PHASE 3
TheraPlas	IP	**IL-12 (OVATION 3)**	Newly Diagnosed Adv. Ovarian Cancer	IMNN-001				enrolling
		IL-12 in combination with Avastin*	Newly Diagnosed Adv. Ovarian Cancer	IMNN-001			enrolling	
		IL-12 (OVATION 2)	Newly Diagnosed Adv. Ovarian Cancer	IMNN-001			complete	
		IL-12 in combination with Immune checkpoint Inhibitors	Newly Diagnosed Adv. Ovarian Cancer	IMNN-001	Ready			
		IL-12	Colorectal Cancer	IMNN-001	Ready			
		IL-12	Pancreatic Cancer	IMNN-001	Ready			
	Intra-tumoral	**IL-12**	Glioblastoma	IMNN-001				

IL-12 in combination with Avastin*: in partnership with Break Through Cancer.

COMBINATION STRATEGY

IMNN-001's Potential for Combinatorial Strategies

IMNN-001 is evaluated in combination with established ovarian cancer therapies, and its ability to create an immunostimulatory TME provides rationale for combinations with emerging modalities

COMBINATIONS IN CLINICAL EVALUATION



PARPi Maintenance

OVATION-2 PARP-treated patients showed a larger numerical OS improvement with IMNN-001 of 24 months compared to 14 months in the ITT, suggesting a potential synergy between PARPi treatment and IMNN-001



VEGF Inhibition

IMNN-001 is currently being evaluated with bevacizumab in randomized MRD study, with potential synergy from bevacizumab reducing VEGF levels, while IMNN-001 may further inhibit VEGF production

FUTURE COMBINATION OPPORTUNITIES



Immune Checkpoint Inhibitors

IMNN-001 may address the immunosuppressive TME that has previously limited ICI efficacy in ovarian cancer, as clinical data has shown that IMNN-001 increases CD8+ T-cell infiltration and reduces immunosuppressive cell populations



ADCs

Combination with ADCs may extend the benefit observed in OVATION-2 with IMNN-001 plus standard chemotherapy by combining targeted tumor-cell killing with IMNN-001–mediated immune activation

NCI/CTEP CRADA (September 2026)

Under a Cooperative Research and Development Agreement with the National Cancer Institute's Cancer Therapy Evaluation Program, NCI investigators will evaluate IMNN-001 in new solid tumor indications and combination regimens under the NCI Experimental Therapeutics (NExT) Program.

IMUNON in Phase 3, Well Positioned with Potential for Early Stopping

Executing against the plan

Robust Data from 112 patient OVATION-2 (Phase 2) demonstrating IMNN-001 improvement over SoC

- Confidence in Phase 3 trial based on consistency of clinical data across all endpoints and subgroups
- Final Data validated continued OS benefit

Innovative statistical design with planned interim analysis for potential early stopping for success and BLA filing to support FDA approval:

- Enhancements added to Phase 3: OS is the primary endpoint, stratification and population balance for interpretability, QoL scales added for pricing and reimbursement
- Broad indication of women newly diagnosed with ovarian cancer who are eligible for neoadjuvant chemotherapy (N/ACT)

Successful meetings with FDA and alignment

- Protocol, statistical analysis plan, cGMP plan for Phase 3 and commercial product

Imunon team is well-positioned to execute on Phase 3 clinical trial

- Great collective depth and breath of experience; strong track record of delivery while managing expenses and ability to fund the program to drive the business forward

OVATION-3 (Phase 3) clinical trial ongoing, FPV July 2025

- Site activation in progress, patient enrollment remains on track to deliver the timeline.
- Enrollment pace of 0.5 patients/site/month vs. 0.3 planning assumption and 0.2 observed in OVATION-2 and generally representing the industry benchmark.
- Protocol submission to site activation in approximately 6 months; protocol approval to first patient randomized in approximately 2 months, roughly ⅓ of the external industry benchmark
- Full enrollment targeted for Q1 2029
- FDA aligned, pre-specified interim analyses enables potential earlier approval
- Final Study readout, anticipated Q2 2031

OV-3 Trial statement and timelines are subject to ongoing progress and operational factors

Corporate Information



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Appendix

Slides for use in discussion as back-up

IL-12 and its Effector IFN-γ: Critical Drivers of Antitumor Immunity

Harnessing Both Innate and Acquired Immunity

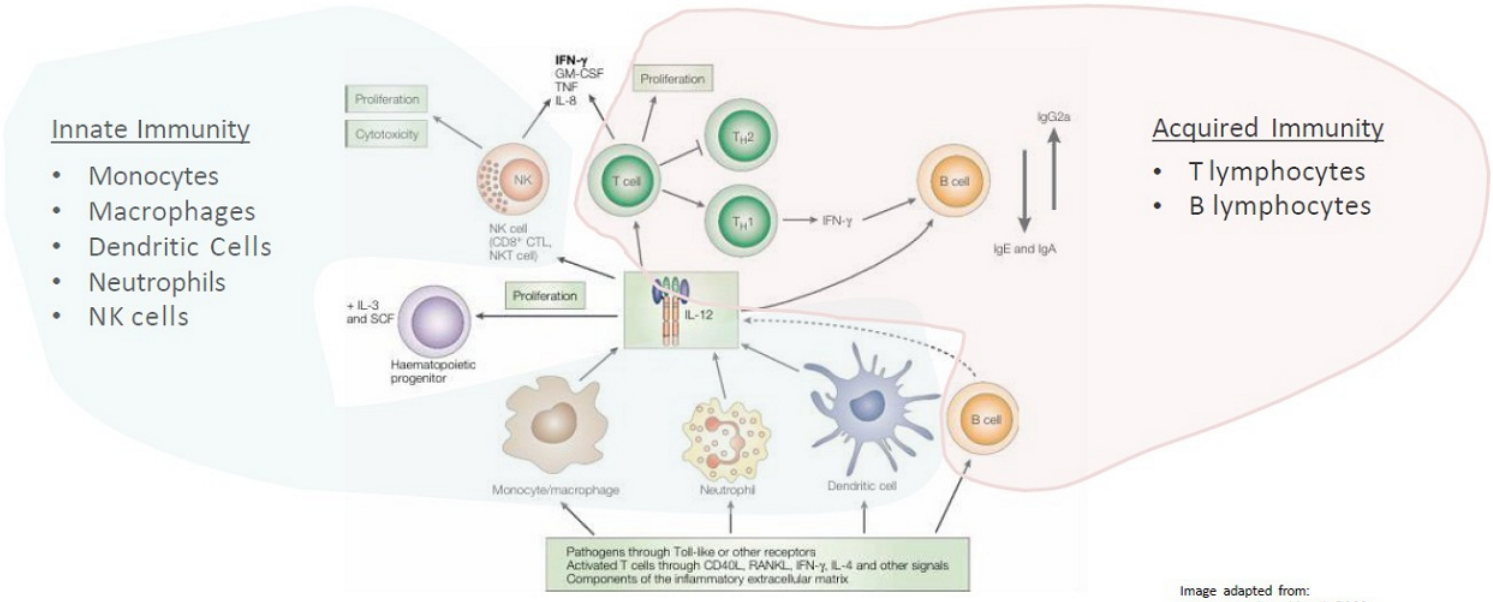


Image adapted from:
Giorgio Trinchieri March 2003
Nature Reviews Immunology 3(2):133-46

IFN-γ Effects in Cancer are Multifactorial and Powerful

Not Just Immune-Related but Also Affecting Pathways Regulating Cancer Progression, Angiogenesis and Apoptosis

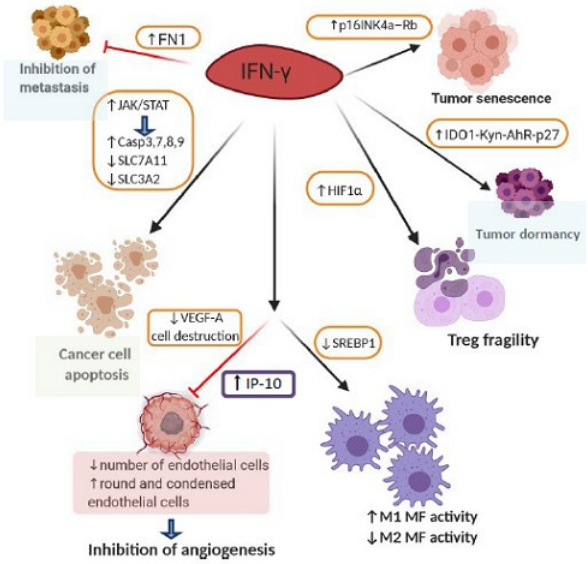


Image adapted from:
Jorgovanovic D *et al.*, . Biomark Res. 2020

OVATION-3 Phase 3 Planned Timeline



Expected Patient Enrollment

50% enrolled – Q1 2028

100% enrolled – Q1 2029



Formal Interim Analysis, Primary Endpoint

IA#1, 60% of events (n = 147), estimated Q1 2030

IA#2, 80% of events (n = 196), estimated Q3 2030



Final Study Readout

total events (n=245), estimated Q2 2031

Other Events

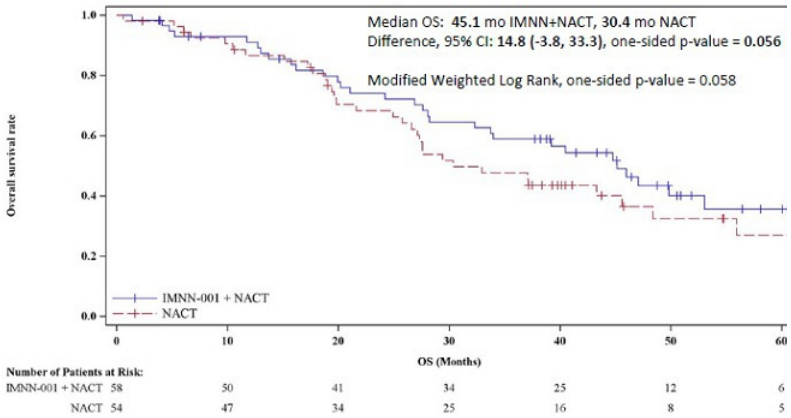
- Protocol Amendment Submission – June 2026 (under FDA review)
- Health Canada Submission – targeting Q4 2026
- All Sites Activated – targeting EOY 2027

OVATION 2 Data Show Continued IMNN-001 Overall Survival Improvement

Protocol Amendment submitted to FDA to strengthen Design and Analysis plan

Protocol Amendment motivated by:

- FDA OS in Oncology Clinical Trials Guidance
  - Discussion of 2-stage analysis strategies
- Magnitude of the final OV-2 Overall Survival
  - FDA's guidance enabling sensitivity focused where the largest treatment effect is observed
- Patient and Investor interest in shorter trial duration



Number of Patients at Risk:

IMNN-001 + NACT	58	50	41	34	25	12	6
NACT	54	47	34	25	16	8	5

OVATION-3 Amendment: Strategic Protocol Refinements with goal to Maximize Development Value

Design and analysis plan modifications submitted & under review with FDA

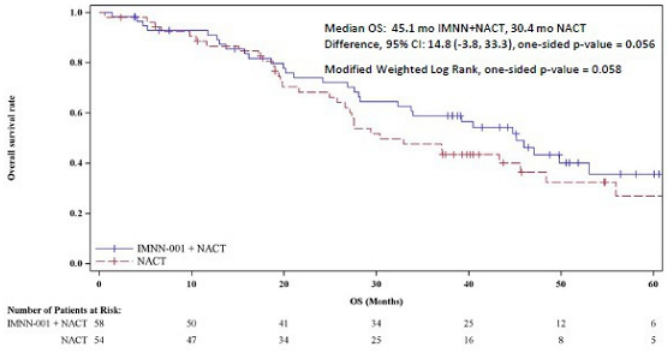
What Changed and Why:

Statistical Approach: Now with a primary statistical strategy and optional model.

- ✦ Alignment with FDA Guidance for Overall Survival in Oncology Clinical Trials
- ✦ With magnitude of final OV-2 OS data, enables sensitivity focused where the largest treatment effect is observed

Target Population for IA : Now full ITT population vs HRD+, followed by ITT

- ✦ Strategic changes expands the patient population for the label, without altering the timing of trial catalysts, Interim Analysis 1 and 2
- ✦ Goal of reducing the time to full trial read out for ITT population



We believe these changes will drive enhanced value to the program

FINAL TRIAL ENDPOINT ESTIMATED 2 YEARS EARLIER
LARGER COMMERCIAL OPPORTUNITY (full ITT)
IMPROVED PROBABLITY OF REGULATORY SUCCESS

Amendment Plans for IA and Full Trial Readout Earlier than Current Protocol

Trial focus on entire Neoadjuvant-eligible Newly Diagnosed OC Population. No need to sequence HRD+ before ITT population

Current Protocol

Designed with a sub-set population as initial readout focus (HRD, and full ITT is secondary)

- With HRD+ subgroup success – label includes ~40% of neoadjuvant OC population
- With ITT population success – label includes entire neoadjuvant OC population
- ITT and HRD+ cohorts both powered

Time to meaningful catalyst was focused on HRD+ cohort Interim Analysis

- Estimated timing of Interim 1 and Interim 2, Q2 2030, Q2, 2031, respectively
- End of Full Trial readout: if IA does not hit, end of trial is 7 years from the beginning of the trial, 4 years after LPI, Q2 2033

Amended Protocol

Designed with primary focus on **full ITT population** with interims for early readout

- With ITT population success – label includes entire neoadjuvant OC population
- ITT population powered

Time to meaningful catalyst: Full ITT event-driven Interims

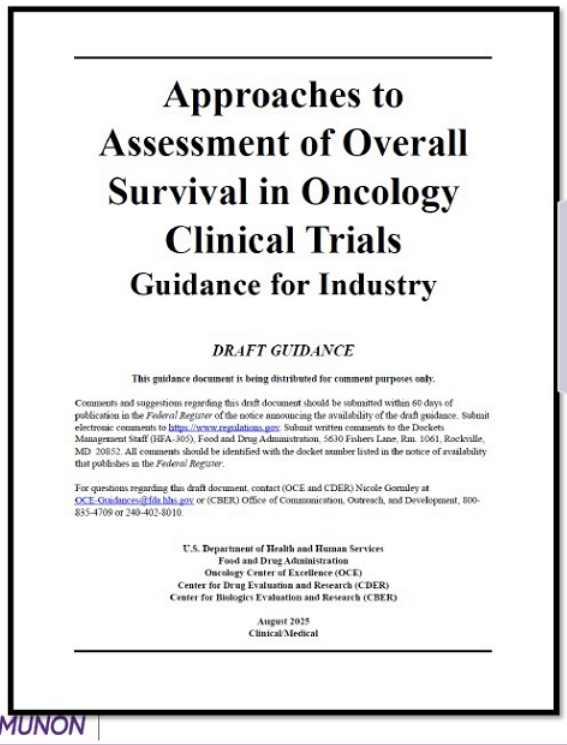
- Interim #1, n = 147 (60% of events), Q1 2030
- Interim #2, n = 196, (80% of events), Q3 2030
- End of Trial readout: **5 years** from beginning of trial; **2 years** after LPI, Q2 2031
- **Enabling final ITT trial in full readout of ITT population in the same timeframe as the IA for the HRD population in the Current Protocol.**

HRR status collection remains; timing is no longer rate limiting to randomization and start of treatment

OVATION 3 Amendment Goals: Aim to Maximize the Probability of Trial Success

- Primary Endpoint focused on 500 All-Comer's population, 245 targeted OS events for full trial
- Amendment leverages and aims to align with FDA's recent draft guidance on the assessment of overall survival in oncology clinical trials
  - Study power using traditional Log-Rank methodology
  - Added: pre-specified methodology for use If proportional hazards assumption does not hold
- Design remains consistent with original protocol
  - Dosing Schema identical
  - Lightened patient burden (e.g., removed unnecessary testing, delayed required timing of HRD testing)
  - Potential early stopping for success remains: IA timing was reconfigured for optimal timing for 500 patient trial
- Removing operational requirement of HR status prior to enrollment allows focus on larger population group, more efficient enrollment and speed to results AND
- 2-year reduction in the time of the full trial, without delaying time to the Interim Analyses for the ITT population

Timely FDA OS Guidance Motivates OV-3 Amendment to Maximize Study Power



Approaches to Assessment of Overall Survival in Oncology Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE and CDER) Nicole Gormley at OCE-Guidances@fda.hhs.gov or (CBER) Office of Communication, Outreach, and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

August 2025
Clinical/Medical

- Sponsors should provide supplementary and/or sensitivity analyses based on different methods and/or assumptions to inform the evaluation of overall survival and the robustness of results, particularly if the intercurrent event rate is high, uncertainty is high, or results are marginal. Appropriate sensitivity analyses should evaluate the robustness of results, and tipping point analyses could help evaluate how sensitive the observed results are to various assumptions. Supplementary analyses should target different estimands and can provide supportive information regarding overall survival.
  - If non-proportional hazards are anticipated, sponsors should specify in the SAP additional sensitivity analyses to evaluate the robustness of the overall survival results. Supplementary analyses, such as landmark survival rates, restricted mean survival time, or other metrics, should be specified in the SAP and may provide supplementary information to further characterize overall survival.

Applying FDA Guidance

Weighted Log-Rank for Overall Survival

Emphasizing Clinically Meaningful Portion of the Survival Distribution

Why Weighted Log-Rank?

Standard Log-Rank

Gives equal weight to every death across the entire follow-up period.

Non-Proportional Hazards

Common in modern oncology (delayed effects, crossing curves). Standard LR loses power.

Clinical Misalignment

May under- or over-emphasize early or late tails that are less relevant to typical patients.

The Potential Clinical Advantage

Focus on the Middle of the Distribution

For fatal diseases, the clinically meaningful differences occur in the central portion of the survival curve — around the median — where most patients experience their outcome.

- Weighted functions (e.g., Weighted Log Rank) can emphasize the middle of the time distribution
- Aligns statistical power with clinical relevance and patient experience
- Improves sensitivity to treatment effects that matter for decision-making

KEY POINT: Weighted log-rank puts statistical emphasis where it is clinically meaningful — the middle of the survival distribution.