Leads Biolabs

Leads Biolabs: A Front-Runner in Next-Generation Immuno-Oncology Treatment

9887.HK

ESMO Data Update Review

October 2026

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    3L+ EP-NEC, 1L EP-NEC, 1L BTC, MSS CRC preclinical translational research

3. LBL-034 (GPRC5D/CD3)

4. Q&A



ESMO 2026: Differentiated Efficacy and Long-Tail Survival across IO2.0 + TCE

ESMO 2026: 7 studies across the **"IO2.0 + TCE" dual platforms - 3 proffered orals (1 LBA)** and **4 posters** - demonstrating the differentiated efficacy and long-tail survival of opamtistomig® (LBL-024), the BIC potential of LBL-034, and the comprehensive capabilities of the LeadsBody® TCE platform.

LBL-024 (PD-L1/4-1BB bispecific antibody)

1. **Reshaping the EP-NEC treatment landscape, with further evidence of long-tail survival:**
   3L+: mOS 8.7 mo, double the historical 3-4 mo; 12-mo OS rate 39.4%;
   1L: 18-mo OS rate 55.7% with chemo; mOS immature at 21.2 mo, vs historical 10.9-13.9 mo.
   ★ Potential in long-tail survival via immune activation, turning cancer into a chronic disease.
2. **Sustained efficacy in immune-cold tumors:**
   1L BTC ORR 70.0%, DCR 95.0%, mPFS 8.0 mo; FDA Fast Track Designation (FTD);
   ★ Durable benefit validated from EP-NEC to BTC.
3. **Benefit across all populations:**
   EP-NEC: benefit in later-line PD-L1 CPS<1 negatives; 1L 18-mo OS rate 50.1% in CPS<1;
   BTC: ORR 50% in 1L PD-L1-negative pts;
   ★ Supports an all-comer development strategy.
4. **Hepatotoxicity of first-generation 4-1BB drugs overcome:** >800 pts dosed, no DLT; low grade ⩾3 ALT/AST increased with 1L chemo; liver enzyme changes mostly grade 1-2 and transient; no new unexpected safety signals.

LBL-034 (GPRC5D/CD3 bispecific antibody)

5. **LBL-034 RRMM data validate the TCE platform, balancing efficacy and safety:**
   Efficacy: mPFS 21.8 mo (~2× approved same-target drugs), mDoR NR; EMD ORR 75%, BCMA-pretreated ORR 85.7%
   Safety: no DLT; CRS mostly low grade;
   ★ BIC potential, enabling TCE expansion into autoimmune diseases and solid tumors.

Note: Data cutoffs: 2026/08/16 (3L+ EP-NEC, N=96), 2026/06/30 (1L EP-NEC, N=69), 2026/09/01 (1L BTC, N=20), 2026/07/16 (RRMM 400-1200 μg/kg, N=41). See individual ESMO disclosures.

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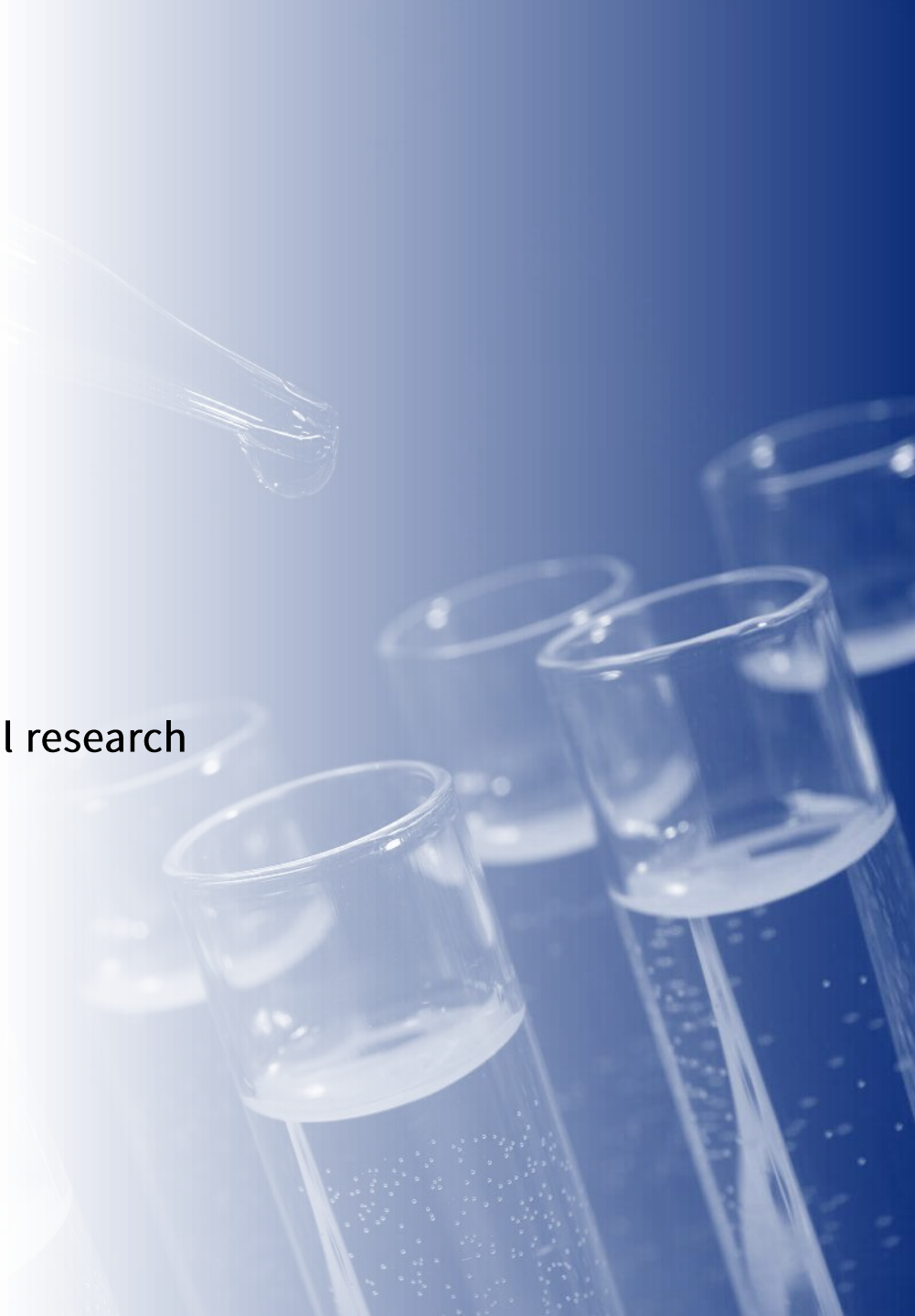
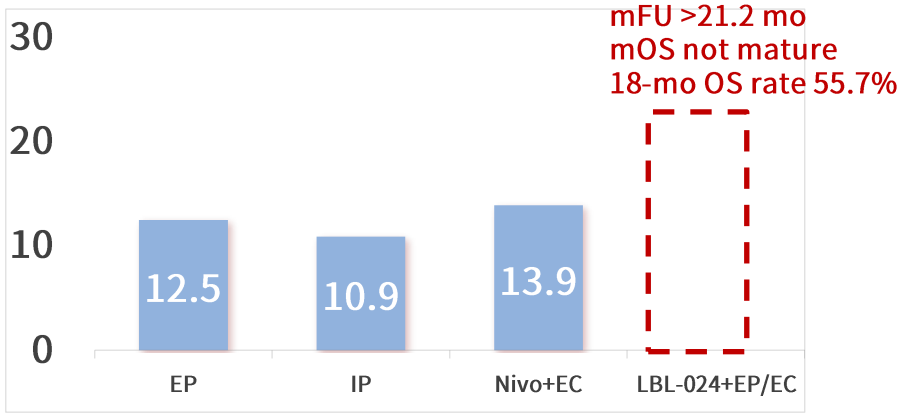
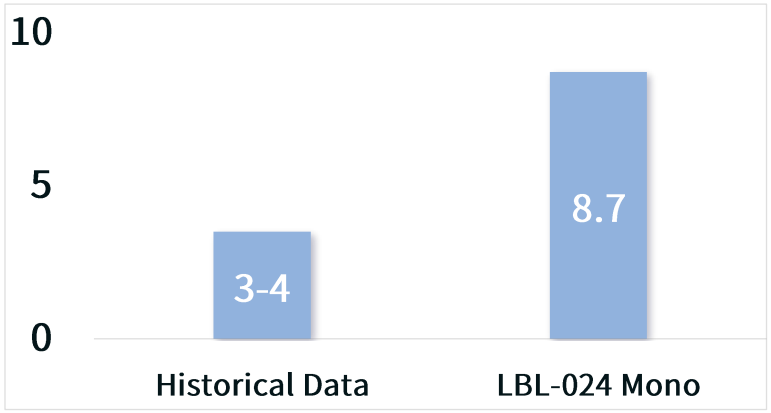


LBL-024 Adds Further Evidence in 1L and Later-Line EP-NEC, Achieving a True Survival Tail

1L EP-NEC median OS (mo) trend



3L+ EP-NEC median OS (mo) doubled



MADRID 2026 ESMO congress — 2026 ESMO Oral (Proffered Paper) 1L EP-NEC

2025 ASCO ANNUAL MEETING — 2025 ASCO Oral 1L EP-NEC

MADRID 2026 ESMO congress — LBA

Opamtistomig (LBL-024) monotherapy in advanced extrapulmonary neuroendocrine carcinoma (EP-NEC) after ≥2 prior lines of therapy: results from a pivotal, registrational phase IIb study of a novel PD-L1×4-1BB bispecific antibody

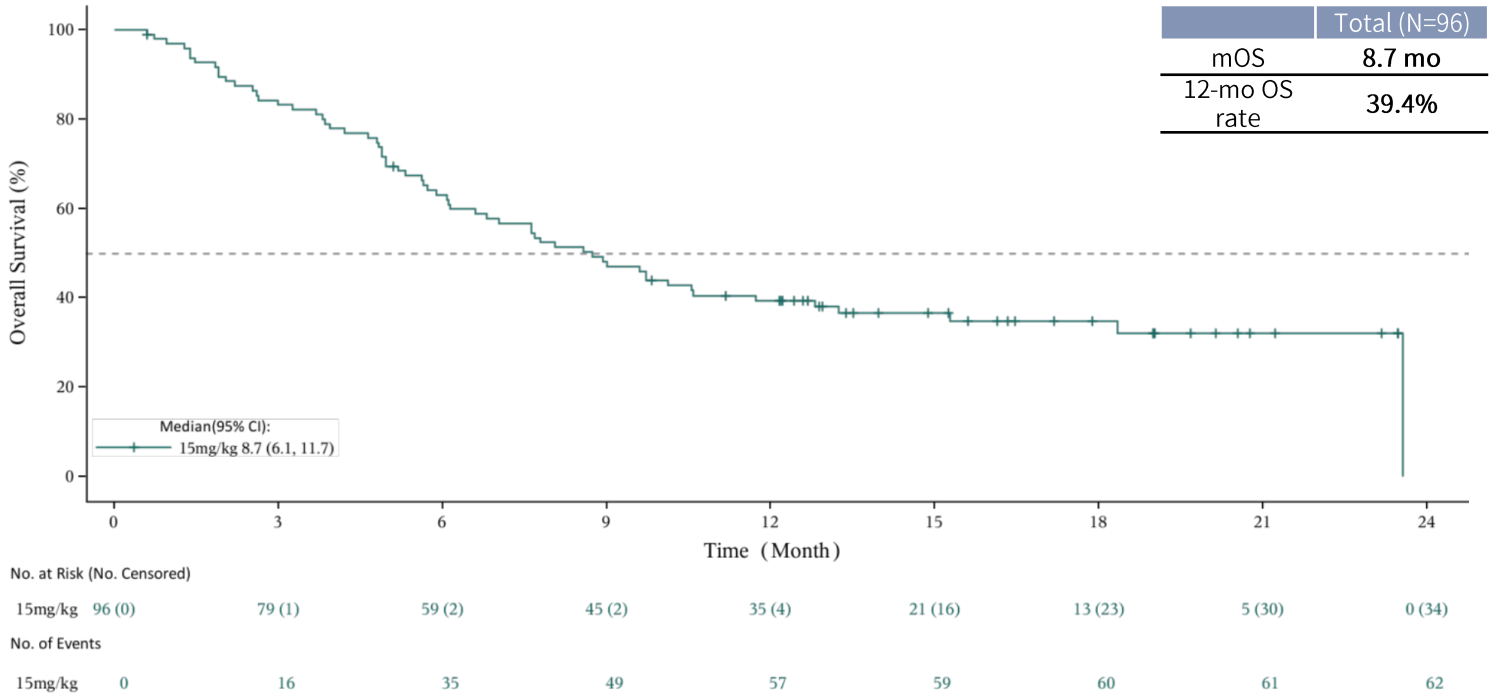
LBL-024 drives potent and durable anti-tumor immunity via PD-L1 blockade + 4-1BB co-stimulation, delivering long-tail survival benefit and turning cancer into a chronic disease

ESMO LBA Oral: LBL-024 Monotherapy in later-Line EP-NEC Achieves mOS of 8.7 Months, Demonstrating Robust Survival Benefit

LBL-024 Phase IIb Study: 3L+ PNEC, NCT05170958 | Data Cutoff: August 16, 2026

- As of Aug 16, 2026, 96 pts for 3L+ EP-NEC were enrolled; median follow-up 16.3 mo.
- **Robust survival benefit, mOS doubled vs historical:** 12-mo OS rate 39.4%, mOS 8.7 mo (historical mOS ~3-4 mo). Efficacy is independent of PD-L1 expression, supporting an all-comer strategy.

Overall survival KM curve



8.7 mo

Median OS

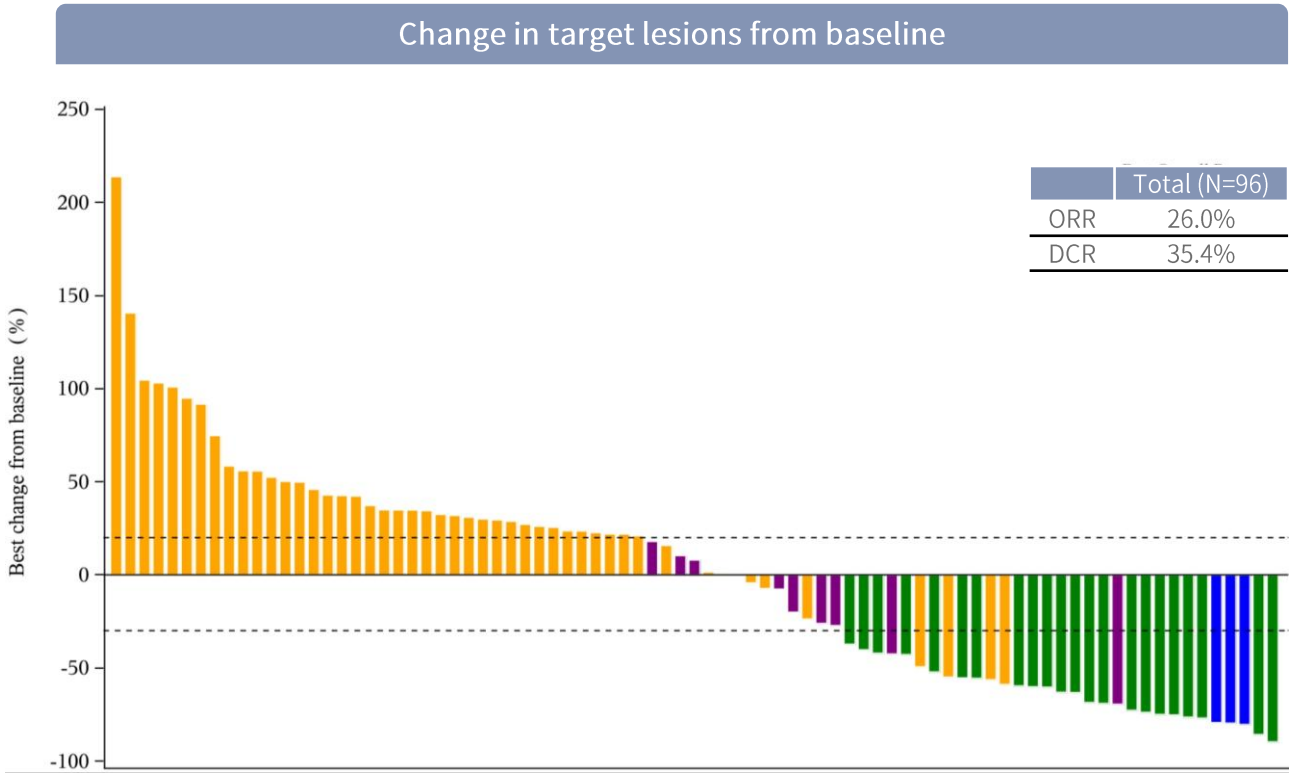
EP-NEC	SOC
1L	Platinum-based chemotherapy
2L	FOLFIRI/FOLFOX optional / ORR ~15%; mOS 5-7 mo
3L+	No recommended therapy; historical mOS 3-4 mo

mOS, median overall survival; mFU, median follow-up.

ESMO LBA Oral: LBL-024 in later-Line EP-NEC Achieves mDoR of 9.8 Months, Showing Durable Benefit

LBL-024 Phase IIb Study: 3L+ PNEC, NCT05170958 | Data Cutoff: August 16, 2026

- cORR 26.0%, mDoR 9.8 mo; 13 pts (13.5%) treated for >12 mo; 7 pts for >15 mo; 4 pts (including 3 CRs) for >20 mo. In the non-liver-metastasis subgroup, ORR 43.8% (14/32) and mOS 10.5 mo.
- **DoR reveals the long-tail value of immunotherapy:** mDoR markedly longer than PFS, with durable benefit in responders, the core driver of OS benefit and a unique advantage of immunotherapy.



9.8 mo

Median DoR

Cutoff date: August 16, 2026.

ESMO LBA Oral: Baseline Characteristics of LBL-024 in later-Line EP-NEC Consistent with Real-World Trends

LBL-024 Phase IIb Study: 3L+ PNEC, NCT05170958 | Data Cutoff: August 16, 2026

- Of 96 patients: 75.0% have received two prior lines of therapy, 25.0% received ⩾3L lines of therapy.
- 96.9% stage IV; 74.0% with ⩾2 organ metastases; 67.4% with liver metastases
- PD-L1-negative (CPS <1): 82.1% (of PD-L1-evaluable pts)

Parameters		Total N=96
Age, median (range)	Median (Range)	61.0 (30-78)
Gender n (%)	Male	66 (68.8)
	Female	30 (31.3)
ECOG, n (%) / 0	0	13 (13.5)
	1	83 (86.5)
Stage at diagnosis n (%)	III	3 (3.1)
	IV	93 (96.9)
PD-L1 status n (%)	CPS <1	32 (82.1)*
	CPS ⩾1	7 (17.9)*
	unknown	57
Number of prior lines of therapy n (%)	2	72 (75.0)
	⩾3	24 (25.0)

ESMO LBA Oral: LBL-024 in later-Line EP-NEC with Favorable Safety, Low-Grade and Transient Liver Enzyme Elevation

LBL-024 Phase IIb Study: 3L+ EP-NEC, NCT05170958 | Data Cutoff: August 16, 2026

- Favorable overall safety: grade ⩾3 TRAEs 28.1% (27/96); no new safety signals.
- Excellent hepatic safety: increased ALT/AST mainly grade 1-2 and transient; grade ⩾3 increased ALT and AST 0% and 2.1%, respectively.

TRAEs (≥15%)		
Preferred term, n (%)	**Any grade**	**Grade ≥3**
Anemia	39 (40.6)	6 (6.3)
AST increased	**31 (32.3)**	**2 (2.1)**
ALT increased	**30 (31.3)**	**0**
White blood cell count decreased	20 (20.8)	4 (4.2)
Gamma-glutamyl transferase increased	**18 (18.8)**	**4 (4.2)**
Platelet count decreased	18 (18.8)	3 (3.1)
Proteinuria	18 (18.8)	0
Blood creatine phosphokinase increased	17 (17.7)	2 (2.1)

TRAEs (≥15%)		
Preferred term, n (%)	**Any grade**	**Grade ≥3**
Lymphocyte count decreased	16 (16.7)	3 (3.1)
Hypothyroidism	16 (16.7)	0
Hypercholesterolemia	16 (16.7)	0
Hypertriglyceridemia	16 (16.7)	1 (1.0)
Neutrophil count decreased	15 (15.6)	3 (3.1)
Hyponatremia	15 (15.6)	1 (1.0)
Decreased appetite	15 (15.6)	0

TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; AST, aspartate aminotransferase; ALT, alanine aminotransferase.

ESMO Proffered Oral: LBL-024 in 1L EP-NEC Achieves 18-Month OS Rate of 55.7%

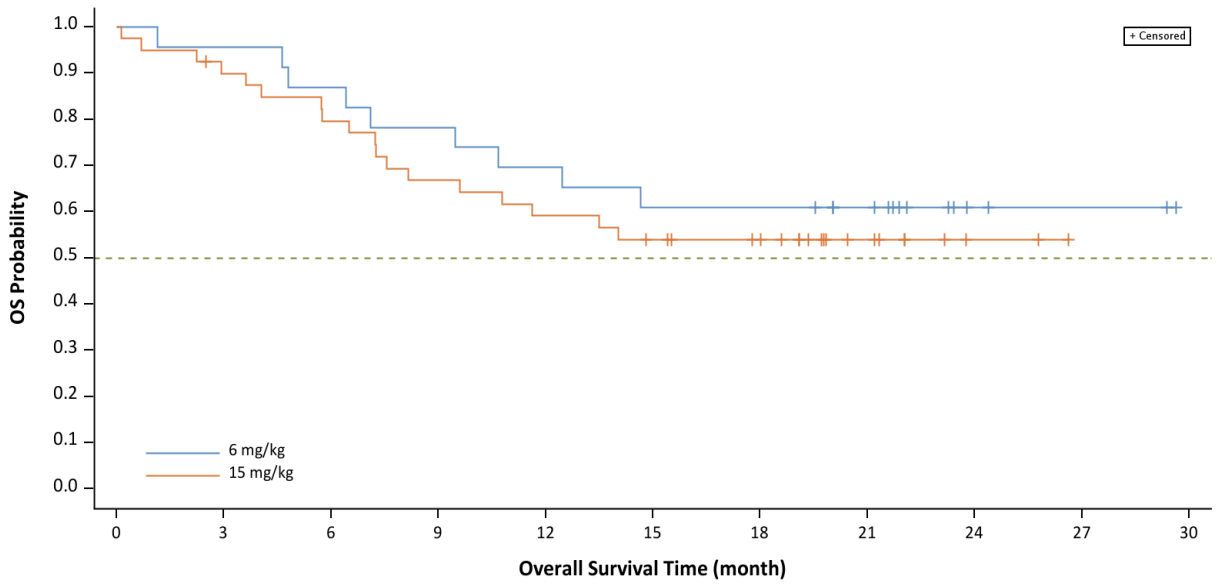
LBL-024 Phase Ib/II Study: 1L EPNEC, NCT06157827 | Data Cutoff: June 30, 2026

- Median follow-up 21.2 mo; mOS not mature; 18-mo OS rate 55.7% (historical mOS ⩽12 mo)
- **OS confirms strong immunotherapeutic benefit; final mOS expected to substantially exceed historical benchmarks**
- Consistent benefit in PD-L1-negative/positive populations: 18-mo OS rates 50.1% and 66.0%

55.7%

18-mo OS rate

Overall survival KM curve



No. at Risk (No. censored)

6 mg/kg	23 (0)	22 (0)	20 (0)	18 (0)	16 (0)	14 (0)	14 (0)	11 (3)	3 (11)	2 (12)	0 (14)
15 mg/kg	40 (0)	35 (1)	31 (1)	26 (1)	23 (1)	20 (2)	17 (5)	8 (14)	2 (20)	0 (22)	

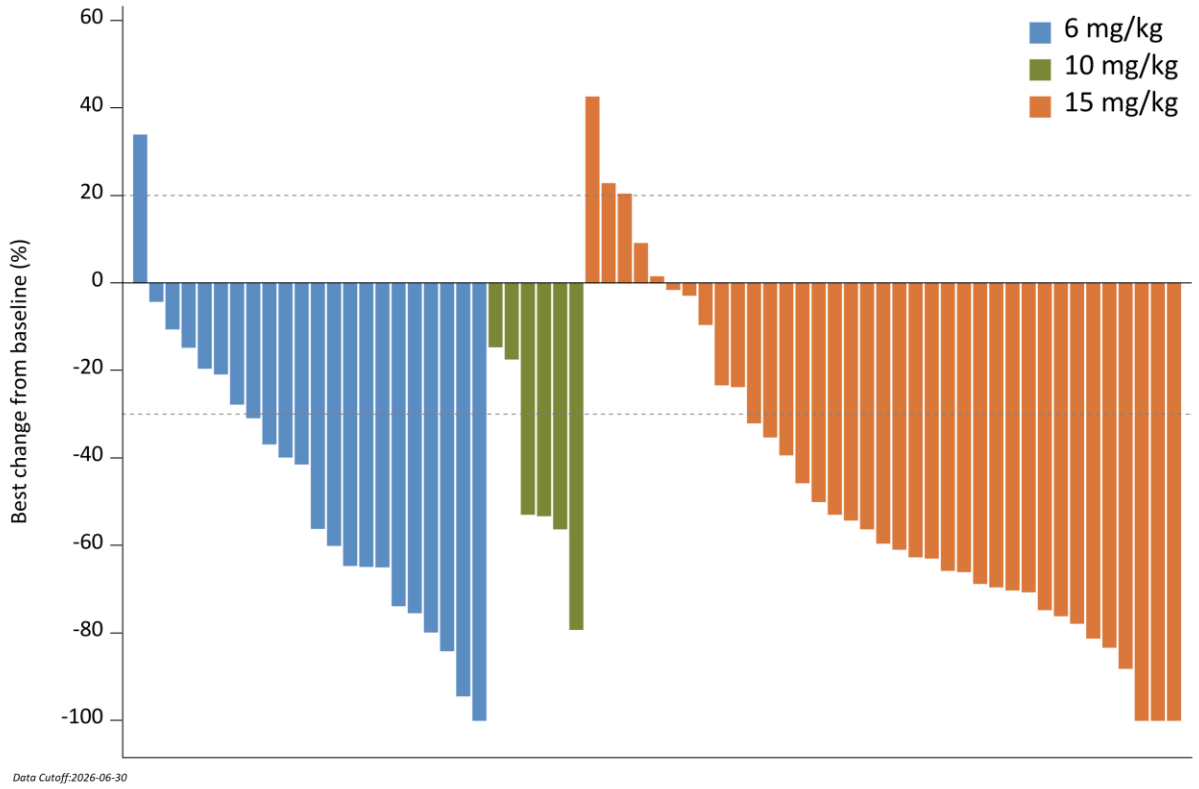
cutoff date: 2026-06-30

vs 1L therapy	Indication	mOS (mo)
LBL-024 + etoposide/cisplatin (EP) or etoposide/carboplatin (EC)	1L EP-NEC	NE (18-mo OS rate 55.7%)
Etoposide/cisplatin (EP)	NEC	12.5
	Hepatobiliary/pancreatic poorly differentiated NEC	5.8
Etoposide/carboplatin (EC)	NEC	11.5

ESMO Proffered Oral: LBL-024 in 1L EP-NEC with Durable Responses, mDoR of 10.2 Months, Highlighting the Unique Advantage of Immunotherapy

LBL-024 Phase Ib/II Study: 1L EPNEC, NCT06157827 | Data Cutoff: June 30, 2026

- Among 65 evaluable pts, ORR 69.2%, cORR 60.0%, DCR 90.8%
- **DoR markedly longer than PFS: mDoR 10.2 mo vs mPFS 5.7 mo; durable benefit in responders drives OS benefit, demonstrating the unique advantage of immunotherapy**



10.2 mo

Median DoR

Cutoff date: June 30, 2026.

ESMO Proffered Oral: Baseline Characteristics of LBL-024 in 1L EP-NEC Consistent with Real-World Trends

LBL-024 Phase Ib/II Study: 1L EPNEC, NCT06157827 | Data Cutoff: June 30, 2026

- 97.1% stage IV; 98.6% with metastases (61.8% liver)
- 94.2% Ki-67 ⩾50%, highly aggressive; 71.0% PD-L1-negative (CPS <1)

Parameters		Phase Ib/II			Total
		6 mg/kg	10 mg/kg	15 mg/kg	
		N=23	N=6	N=40	N=69
Ki-67 n (%)	<50%	1 (4.3)	0	3 (7.5)	4 (5.8)
	⩾50%	22 (95.7)	6 (100.0)	37 (92.5)	65 (94.2)
PD-L1 status n (%)	CPS <1	14 (60.9)	3 (50.0)	32 (80.0)	49 (71.0)
	CPS ⩾1	6 (26.1)	3 (50.0)	6 (15.0)	15 (21.7)
	Unknown	3 (13.0)	0	2 (5.0)	5 (7.2)
Stage at diagnosis n (%)	III	0	0	2 (5.0)	2 (2.8)
	IV	23 (100.0)	6 (100.0)	38 (95.0)	67 (97.1)
Presence of metastatic lesion n (%)	Yes	22 (95.7)	6 (100.0)	40 (100.0)	68 (98.6)
	No	1 (4.3)	0	0	1 (1.4)
Metastatic site n (%)	Lymphnode	20 (90.9)	5 (83.3)	34 (85.0)	59 (86.8)
	Liver	14 (63.6)	5 (83.3)	23 (57.5)	42 (61.8)
	Lung	6 (27.3)	2 (33.3)	9 (22.5)	17 (25.0)
	Bone	2 (9.1)	2 (33.3)	8 (20.0)	12 (17.6)
	Others	8 (36.4)	4 (66.7)	16 (40.0)	28 (41.2)

PD-L1, programmed death-ligand 1; CPS, combined positive score.
Cutoff date: June 30, 2026.

ESMO Proffered Oral: LBL-024 plus Chemotherapy in 1L EP-NEC with Excellent Safety

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LBL-024 Phase Ib/II Study: 1L EPNEC, NCT06157827 | Data Cutoff: June 30, 2026

- Manageable safety with low immune-related toxicity.
- Most common TRAEs were WBC count decreased, neutrophil count decreased and anemia, mostly chemo-related.
- Liver enzyme abnormalities mainly grade 1-2 and transient.

	6 mg/kg, n (%) (n=23)	10 mg/kg, n (%) (n=6)	15 mg/kg, n (%) (n=40)	EP-NEC total, n (%) (N=69)
Any TEAEs	23 (100.0)	6 (100.0)	40 (100.0)	69 (100.0)
Treatment-related	22 (95.7)	6 (100.0)	40 (100.0)	68 (98.6)
⩾Grade 3 TEAEs	22 (95.7)	5 (83.3)	34 (85.0)	61 (88.4)
Treatment-related	20 (87.0)	5 (83.3)	30 (75.0)	55 (79.7)
SAEs	16 (69.6)	3 (50.0)	25 (62.5)	44 (63.8)
Treatment-related	13 (56.5)	3 (50.0)	15 (37.5)	31 (44.9)
irAEs	11 (47.8)	2 (33.3)	13 (32.5)	26 (37.7)
⩾Grade 3	4 (17.4)	2 (33.3)	6 (15.0)	12 (17.4)
TRAEs leading to opamtistomig treatment discontinuation#	1 (4.3)	0 (0.0)	3 (7.5)	4 (5.8)
TRAEs leading to death*	0 (0.0)	0 (0.0)	2 (5.0)	2 (2.9)

 # 1 grade 3 immune-mediated myocarditis, 1 grade 2 pulmonary infection, 1 grade 3 hearing impairment with grade 3 bilateral lower-limb myasthenia, and 1 grade 3 neurological injury.

** 1 respiratory failure, septic shock and pulmonary embolism; 1 cardiopulmonary arrest. Per sponsor assessment, none were considered related to LBL-024; causes of death were mainly advanced tumor progression, baseline comorbidities, infection and poor baseline condition.*

TEAE, treatment-emergent adverse event; SAE, serious adverse event; irAE, immune-related adverse event; TRAE, treatment-related adverse event. TRAEs include all study drugs.

Any TRAE	Total, n=69	
	Any grade	Grade ⩾3
Decrease white blood cell count	57 (82.6)	25 (36.2)
Decreased neutrophil count	56 (81.2)	43 (62.3)
Anemia	55 (79.7)	15 (21.7)
Decreased platelet count	45 (65.2)	17 (24.6)
Nausea	31 (44.9)	1 (1.4)
Increased AST	24 (34.8)	3 (4.3)
Alopecia	23 (33.3)	0
Increased ALT	22 (31.9)	2 (2.9)
Decreased appetite	21 (30.4)	0
Asthenia	21 (30.4)	1 (1.4)
Proteinuria	21 (30.4)	0
Decreased body weight	14 (20.3)	1 (1.4)
Hypothyroidism	13 (18.8)	1 (1.4)
Hypoalbumenia	12 (17.4)	0
Hyponatremia	12 (17.4)	1 (1.4)

irAE	Grade ⩾3	irAE	Grade ⩾3
Diabetes mellitus	2 (2.9)	Immune-mediated myositis	1 (1.4)
Immune-mediated myocarditis	2 (2.9)	Adrenal insufficiency	1 (1.4)
Hyperglycaemia	1 (1.4)	Hypothyroidism	1 (1.4)
Blood creatinine increased	1 (1.4)	Cytokine release syndrome	1 (1.4)
Platelet count decreased	1 (1.4)	Acute kidney injury	1 (1.4)
Muscular weakness	1 (1.4)	Pneumonitis	1 (1.4)

LBL-024 plus Chemotherapy in 1L BTC: Robust Efficacy and FDA Fast Track Designation (FTD)

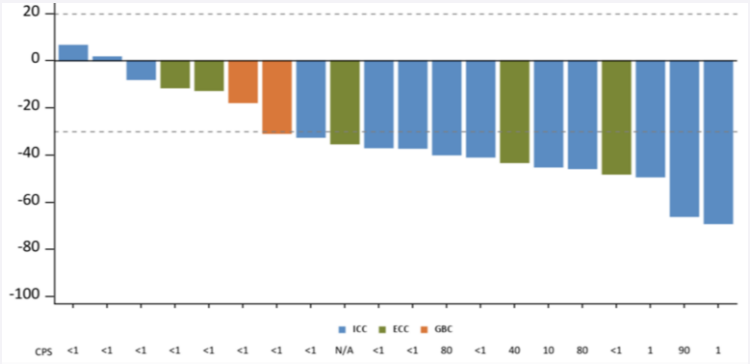
LBL-024 Phase II Study: 1L BTC, NCT07111546 | Data Cutoff: Sept 1, 2026

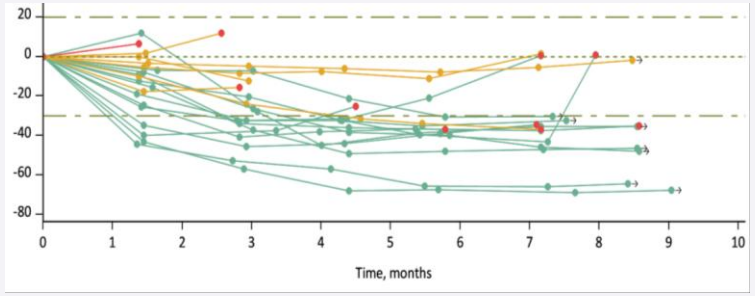
- First pt dosed Oct 2025; safety lead-in of 20 pts completed Jan 2026. First expansion pt dosed late Mar 2026; all 50 expansion pts enrolled by Jul 2026.
- In 1L Biliary Tract Cancer (a cold tumor), LBL-024 achieved ORR up to 70%, markedly above current first-generation IO SOC (20-30%).
- FDA FTD granted only 9 days after submission. Plan to submit a Phase III clinical study communication request in H1 2027*.

Marked and durable tumor shrinkage

All-comers: ORR 70% (14/20), DCR 95% (19/20)

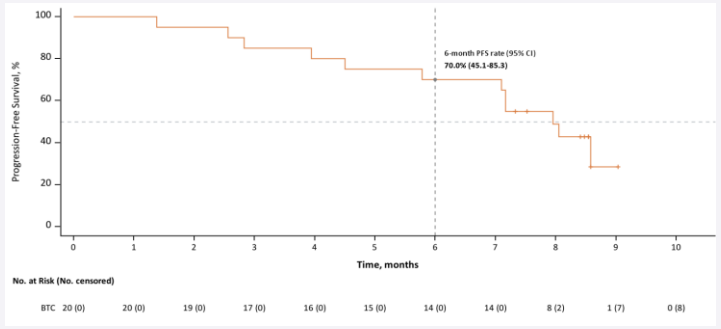
- PD-L1-positive: ORR 100% (7/7), DCR 100% (7/7)





PFS numerically superior to historical data

	Total (n=20)	CPS ⩾1 (n=7)
Events, n (%)	12 (60.0)	3 (42.9)
Median PFS (mo)	8.0	NE
6-mo PFS rate (%)	70.0	85.7

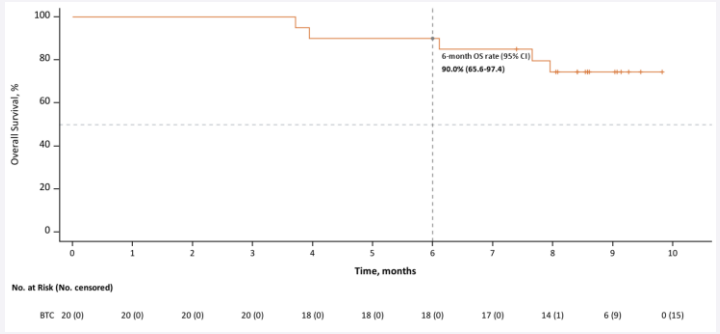


1L BTC standard of care

	ORR (%)	DCR (%)	PFS (mo)	OS (mo)
Durvalumab + chemotherapy	26.7%	85.3%	7.2	12.9
Pembrolizumab + chemotherapy	28.7%	83.0%	6.5	12.7

Promising OS Benefit

	Total (n=20)	CPS ⩾1 (n=7)
Events, n (%)	5 (25.0)	1 (14.3)
6-mo OS rate (%)	90.0	100.0



Data cutoff: Sept 1, 2026; median follow-up 8.6 mo; comparable studies have not reported data in PD-L1-negative pts. * FDA FTD granted only 9 days after submission. Phase III filing planned for H1 2027. FDA also advised early communication on the registrational plan for LBL-024 plus chemotherapy in BTC.

LBL-024 plus Chemotherapy in 1L BTC: Favorable Safety and Tolerability, No New Safety Signals

LBL-024 Phase II Study: 1L BTC, NCT07111546 | Data Cutoff: Sept 1, 2026

As of Sept 1, 2026; median follow-up 8.6 mo.

- Baseline PD-L1-negative (CPS <1) pts accounted for 60%, vs typically <30% in comparable 1L BTC studies. Disease subtype distribution matched the real world.
- Favorable safety and tolerability: TEAEs mainly chemo-related hematologic toxicity; hepatotoxicity mostly grade 1-2; no TRAE-related deaths; no new safety signals. Liver abnormalities mostly grade 1-2; grade 3-4 events rare.

Baseline characteristics

	Total (n=20)	CPS <1 (n=12)	CPS ⩾1 (n=7)
Median age, yr	61.0 (43-75)	62.5 (46-75)	57.0 (43-69)
Age <65, n (%)	14 (70.0)	9 (75.0)	5 (71.4)
Male, n (%)	14 (70.0)	8 (66.7)	5 (71.4)
ECOG PS 1, n (%)	11 (55.0)	7 (58.3)	3 (42.9)
Disease subtype, n (%)			
Gallbladder cancer	2 (10.0)	2 (16.7)	0
Intrahepatic CCA	13 (65.0)	7 (58.3)	6 (85.7)
Extrahepatic CCA	5 (25.0)	3 (25.0)	1 (14.3)
Disease status, n (%)			
Locally advanced	3 (15.0)	1 (8.3)	1 (14.3)
Metastatic	17 (85.0)	11 (91.7)	6 (85.7)

Safety

	TEAEs (n=20)	TRAEs (n=20)
Any grade	20 (100.0)	20 (100.0)
Grade ⩾3	16 (80.0) *	16 (80.0) *
SAE	6 (30.0)	5 (25.0)
Led to discontinuation of any treatment	3 (15.0)	3 (15.0)
Led to discontinuation of opamtistomig	1 (5.0)	1 (5.0)
Led to death	1 (5.0) #	0
irAEs, n (%)		
Any grade	6 (30.0)	
Grade ⩾3	1 (5.0)	

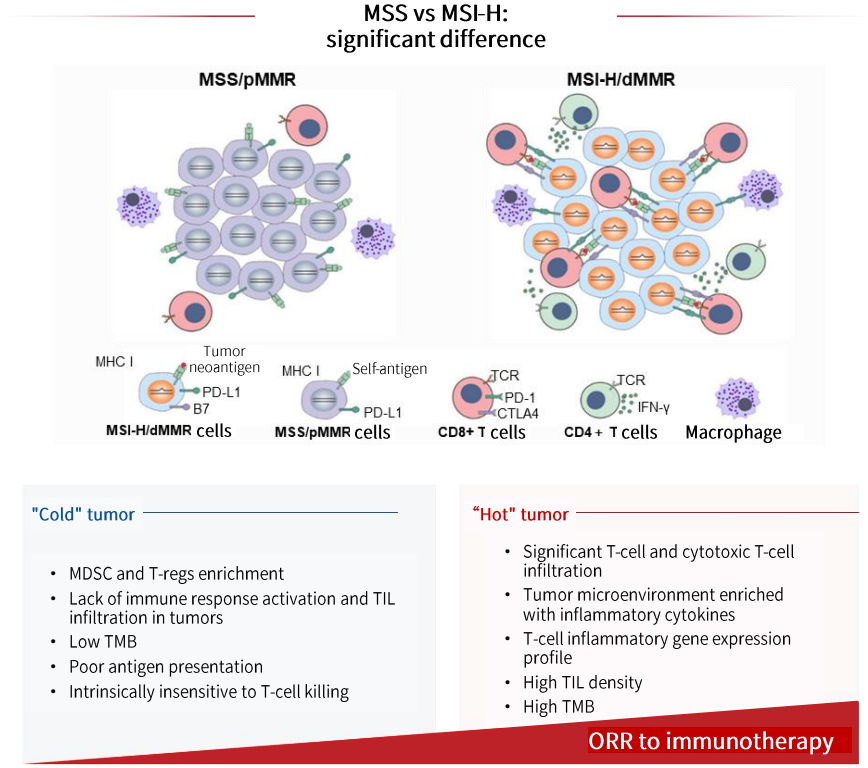
As of Sept 1, 2026; median follow-up 8.6 mo.
1 fatal TEAE due to acute kidney injury, unrelated to study treatment.
* AEs were largely chemo-related. TRAEs include all study drugs.

LBL-024 in MSS CRC Preclinical Study: Background and Methods

LBL-024 Preclinical Translational Research in MSS CRC

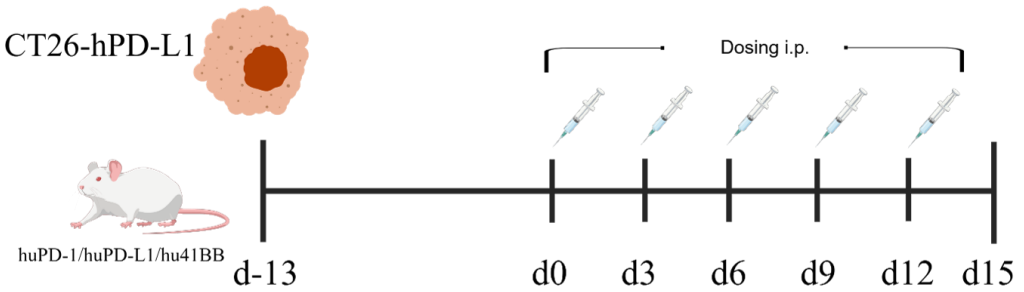
- Approximately 95% of CRC cases are of the MSS/pMMR subtype. Their tumor microenvironment lacks effector T cells and is enriched with immunosuppressive cells, making them intrinsically resistant to PD-1/PD-L1 monoclonal antibodies; these are typical immune "cold" tumors.
- Reversing immune "cold" tumors into "hot" tumors represents one of the largest and most significant unmet needs in tumor immunotherapy.

Advanced CRC is predominantly immune-tolerant



Advanced CRC is predominantly immune-tolerant

Group	Dose
PBS	-
LBL-024	2 / 8 / 30 mg/kg
Pembrolizumab	5 mg/kg



Treatment Groups

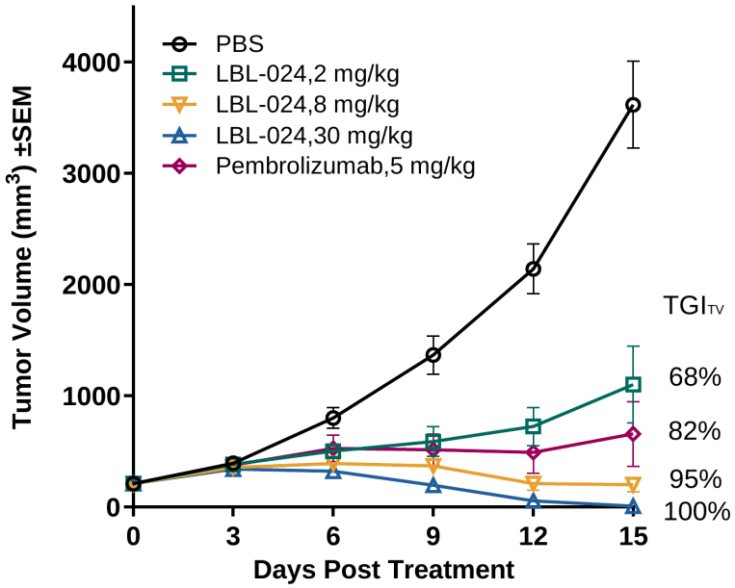
1.PBS
2.LBL-024 (2mg/kg)
3. LBL-024 (8mg/kg)
4. LBL-024 (30mg/kg)
5.Pembrolizumab (5mg/kg)

LBL-024 in MSS CRC Preclinical Study: Marked Tumor Inhibition and Cold-to-Hot TME Remodeling

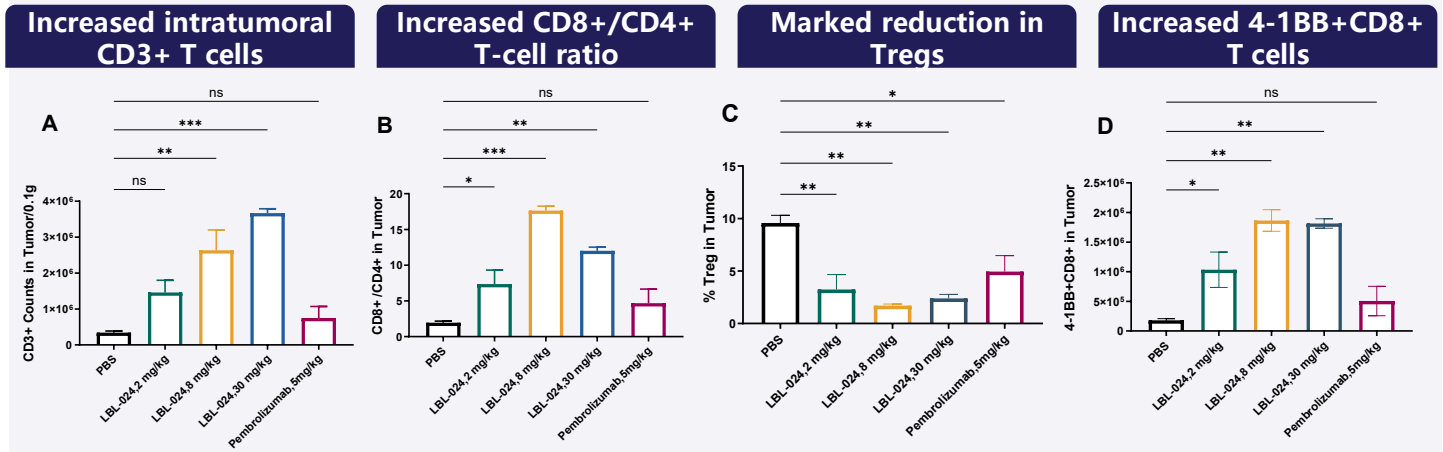
LBL-024 Preclinical Translational Research in MSS CRC

Marked tumor inhibition vs pembrolizumab

- Significant tumor growth inhibition (TGI) at all LBL-024 doses
- 100% TGI at 30 mg/kg
- At 8 and 30 mg/kg, LBL-024 showed sustained tumor inhibition superior to pembrolizumab.



Remodeling of the tumor immune microenvironment



- LBL-024 conditionally activates intratumoral CD8+ T cells and remodels the immunosuppressive TME, converting immune "cold" tumors into "hot" tumors.
- A Phase Ib/II study in MSS/pMMR CRC is ongoing (NCT07791758).

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1. ESMO Data Highlights

2. LBL-024 (PD-L1/4-1BB)

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3. LBL-034 (GPRC5D/CD3)

4. Q&A



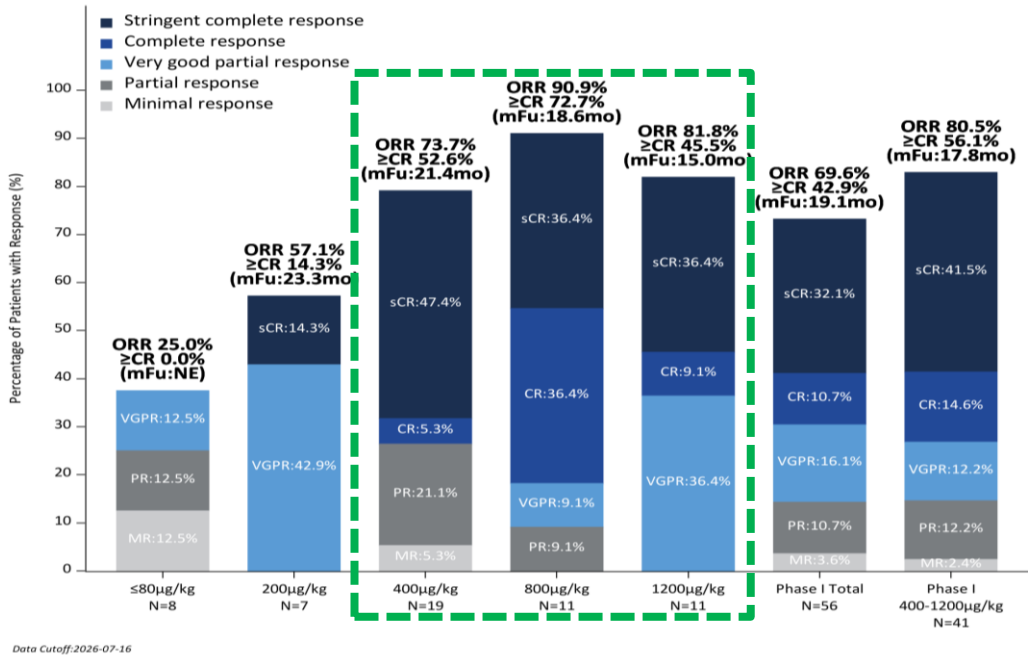
ESMO Proffered Oral: Efficacy Overview - Deep and Durable Responses with Sustained Benefit

LBL-034 Phase I Study: RRMM, NCT06049290 | Data Cutoff: Jul 16, 2026

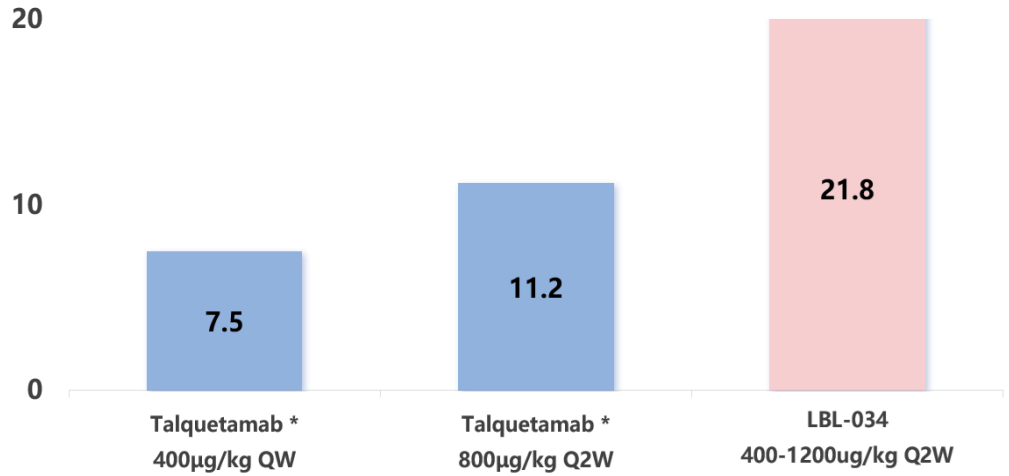
400-1200 μg/kg cohort (N=41) Median follow-up 17.8 mo

80.5%	21.8 mo	Not reached	54.8%
ORR (≥CR rate 56.1%)	mPFS (immature)	mDoR	18-mo PFS rate

Depth of response: deep responses



Durability: sustained responses, sustained benefit



RRMM pts treated with LBL-034 show a clear trend of prolonged median PFS

Cutoff date: July 16, 2026.
ORR, overall response rate; CR, complete response; mPFS, median progression-free survival; mDoR, median duration of response.
** MonumenTAL-1 Study.*

Refractory Subgroups: Responses Observed in Both Extramedullary Disease and Prior BCMA-Treated Populations

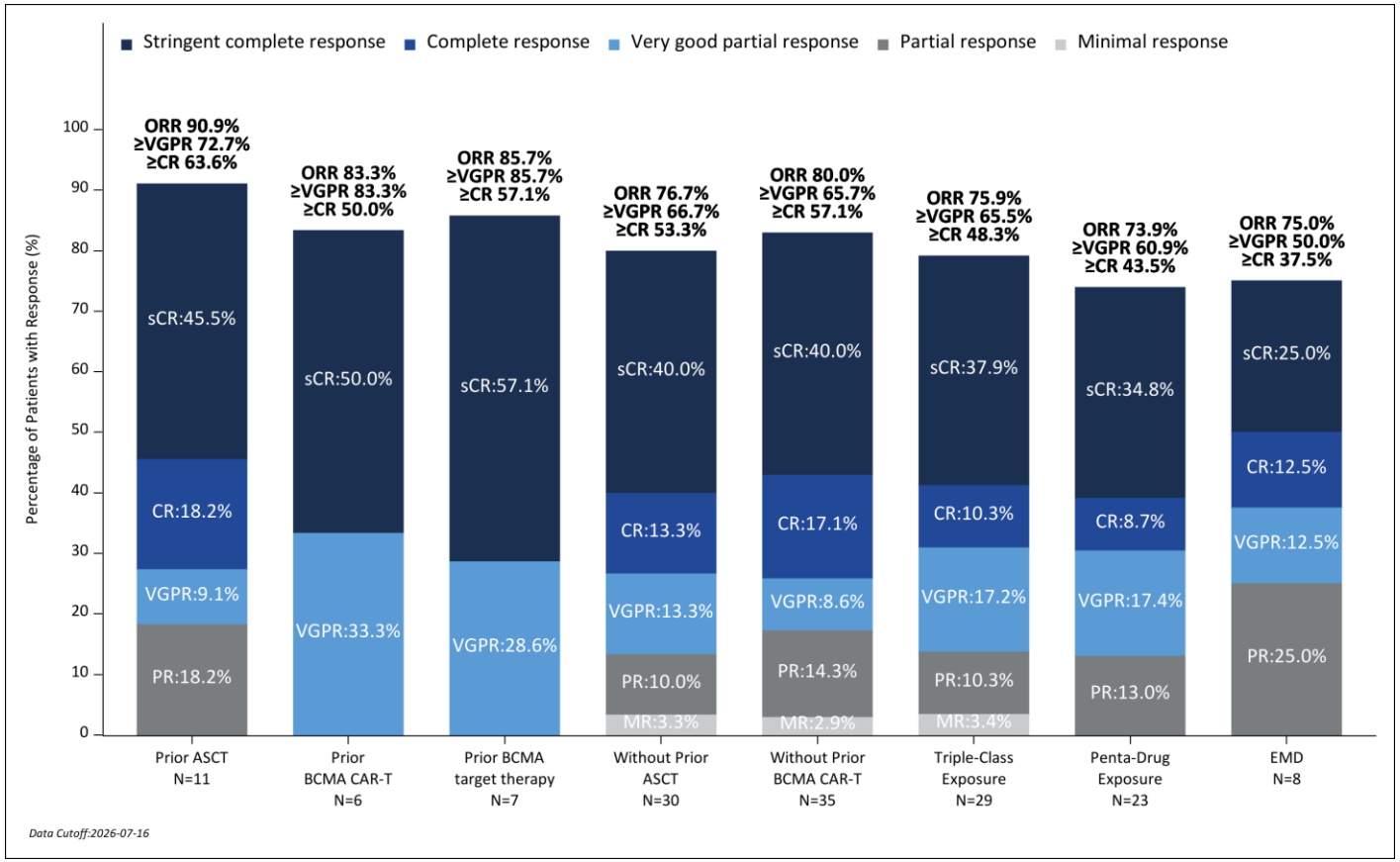
LBL-034 Phase I Study: RRMM, NCT06049290 | Data Cutoff: Jul 16, 2026

400-1200 μg/kg cohort: Subgroup results support broader clinical coverage potential

Refractory subgroup	n	ORR	sCR rate
EMD	n=8	75.0%	25.0%*
Prior BCMA-targeted therapy	n=7	85.7%	57.1%
Penta-drug exposed	n=23	73.9%	34.8%

Sustained antitumor activity in high-risk refractory populations, supporting later-line and post-BCMA sequential therapy

Subgroup efficacy summary



* 2 sCRs in the EMD subgroup. ORR, overall response rate; sCR, stringent complete response; EMD, extramedullary disease. * 1200 μg/kg cohort (n=3): ORR 100%, with rapid regression of extramedullary lesions.

Baseline and Overall Safety: Favorable Safety in Heavily Pretreated Patients

LBL-034 Phase I Study: RRMM, NCT06049290 | Data Cutoff: Jul 16, 2026

Baseline: Multiple prior failures with high-risk features

4.5 lines
Median prior therapy

94.6%
Refractory to later line

57.1%
Penta-drug exposed

64.3%
High-risk cytogenetics

23.2%
With EMD

16.1%
Prior BCMA CAR-T

Heavily pretreated, multi-drug exposed, high-risk population of clinical reference value.

Overall safety:

AEs (N=56)	Any grade, n (%)
TEAE	56 (100.0)
LBL-034-related TEAE	55 (98.2)
SAE	30 (53.6)
Grade ⩾3 TEAE	52 (92.9)
Grade ⩾3 LBL-034-related TEAE	46 (82.1)
LBL-034-related death	0
LBL-034-related permanent discontinuation	1 (1.8)

AEs were mainly expected events such as hematologic toxicity; no LBL-034-related deaths.

TEAE, treatment-emergent adverse event; SAE, serious adverse event; EMD, extramedullary disease.

Safety Profile: AEs Concentrated in Step-Up Dosing and Cycle 1; CRS Mostly Low Grade; Low Drug-Related Discontinuation

LBL-034 Phase I Study: RRMM, NCT06049290 | Data Cutoff: Jul 16, 2026

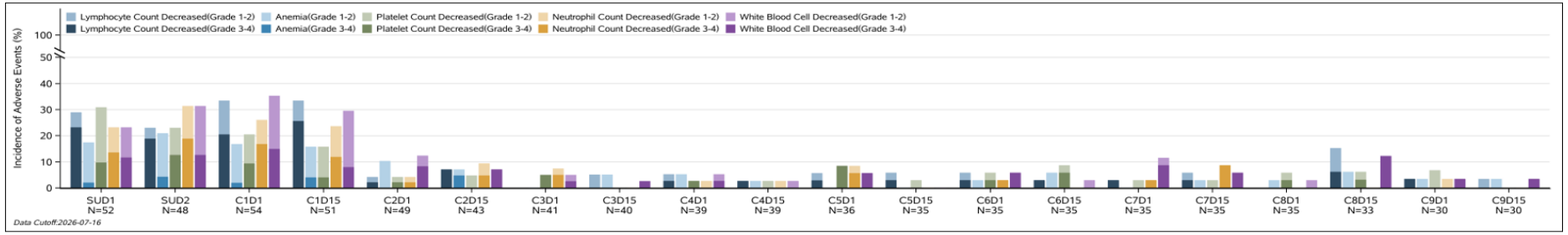
1.8%
Grade ≥3 CRS (1/56)

2 cases
ICANS (1 grade 2, 1 grade 4; both fully recovered)

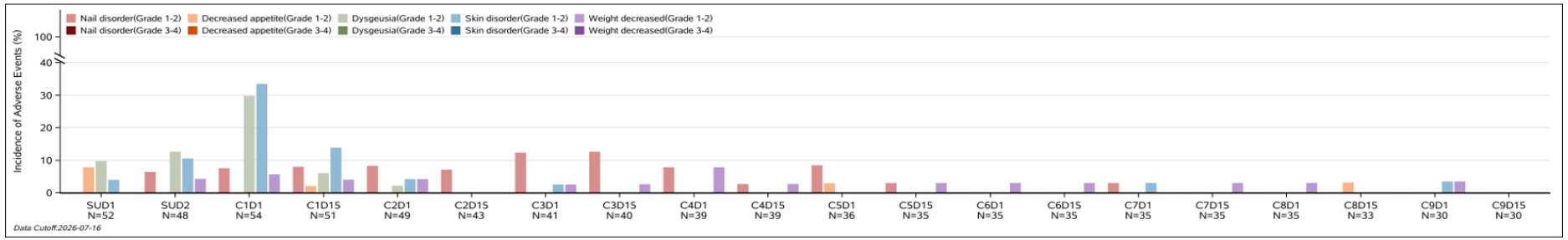
0
Motor dysfunction or ataxia

0
LBL-034-related deaths

Hematologic TEAEs: incidence by treatment cycle



Non-Hematologic TEAEs: incidence by treatment cycle



Most TEAEs occurred during step-up dosing and cycle 1; incidence declined in subsequent cycles, supporting focused monitoring during dosing and long-term management.

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LBL-024 Supporting Appendix: Dose Selection of LBL-024 for First-Line Treatment of EP-NEC

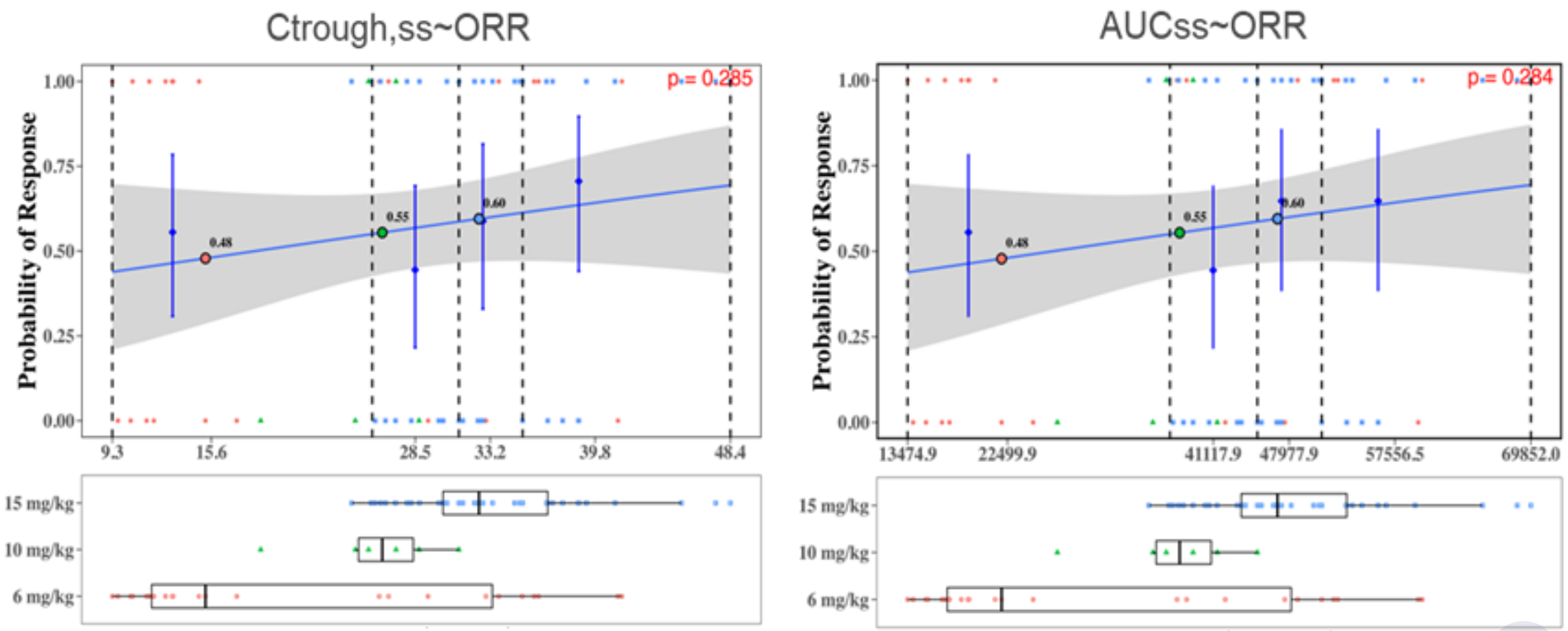
1. The 15 mg/kg dose was selected based on a comprehensive analysis of the full development program, incorporating multiple factors including E-R analysis, tumor tissue origin, baseline levels, prior treatment history (e.g., whether lymph node dissection was performed), and overall tumor control. Based on this integrated analysis, 15 mg was determined to be superior to 6 mg.
2. This dose was recommended through a joint decision by the Leading PI and all investigators.
3. This dosing regimen was reviewed and approved by regulatory authorities.

LBL-024 Supporting Appendix: Dose Selection of LBL-024 for First-Line Treatment of EP-NEC

E-R analysis confirmed that higher exposure was associated with better tumor shrinkage and response, while the safety profile remained stable.

Exposure–response (E-R) analysis showed that, within the 6–15 mg/kg dose range, LBL-024 demonstrated a positive trend of increasing objective response rate and depth of tumor shrinkage with higher systemic exposure, with no significant exposure-related increase in toxicity observed. The positive exposure–response trend observed supports the selection of 15 mg/kg and serves as a core basis for establishing the recommended Phase II dose (RP2D).

E-R analysis



Some 6 mg/kg pts had low exposure; escalating to 15 mg/kg may bring more pts into an adequate exposure range, increasing the probability of response.

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