BeyondSpring

DUBLIN-3 (BPI-2358-103):

A Global Phase 3 Trial with the Plinabulin/Docetaxel combination vs. Doc in 2nd/3rd Line NSCLC Patients with EGFR-wild type Progressing on a Prior Platinum-Based Regimen (NCT02504489)

September 2021 | NASDAQ: BYSI

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Company Highlights (NASDAQ Ticker – BYSI)

Committed to raising the standard of care for cancer patients with first-in-class treatments that improve lives and clinical outcomes for millions of patients in need

Headquarter	New York, NY
Lead Asset	Plinabulin for CIN, US NDA PDUFA November 30, 2021 Plinabulin for NSCLC, est. NDA filing 1H 2022
Partnerships:	Plinabulin in Greater China – Co-development & Commercial Partnership with Hengrui Subsidiary SEED Therapeutics (proprietary TPD Platform) $800M partnership with Eli Lilly
Cash position	$76.3 million as of June 30, 2021 + $45 M from Hengrui upfront and investment

Lead Asset Plinabulin: "A Pipeline in a Drug"

CIN

- Plinabulin + G-CSF for CIN Prevention Indication
- Breakthrough Designation (BTD) and NDA accepted with Priority Review from US and China FDA

NSCLC

- DUBLN-3: Plinabulin + Docetaxel for 2nd/3rd line NSCLC, EGFR wild type
- Positive Topline Final phase 3 OS data reported in August 2021
- Late-breaking oral presentation of DUBLIN-3 data at ESMO on 9/20/2021

IO

- Triple I/O combo in multiple cancer indications in early development, including 7 cancers at MD Anderson
- Efficacy data for phase 1 SCLC at ASCO 2021

Dublin-3 Study Investigator and Speaker at ESMO

Dr. Trevor Feinstein

Dr. Trevor Feinstein is board certified in medical oncology and hematology by the American Board of Internal Medicine. Dr. Feinstein graduated from University of Illinois medical school and completed his residence and fellowships at the University of Pittsburgh. He joined Piedmont Cancer Institute in 2011. He is a certified member of MD Anderson Cancer Network. He is a co-investigator on several peer-reviewed research projects and actively involved in clinical trials focusing on improved therapies for various cancers. He is director of research at Piedmont Fayette Hospital. Dr. Feinstein has authored numerous publications and abstracts in Hematology and Oncology.

BACKGROUND

Severely Unmet Medical Need – 2nd/3rd Line NSCLC, EGFR Wild Type

- **Phase 1A (study 100, dose escalation, n=38): NCT00322608**

plinabulin monotherapy in various cancer (day 1, 8, 15 in 28 day per cycle), plinabulin 30 mg/m2 was selected;

- **Phase 1B (study 101, phase 1B part, 2nd/3rd line NSCLC, n=13): NCT00630110**

plinabulin (13.5 mg/m2, 20 mg/m2, or 30 mg/m2 on day 1 and 8) + docetaxel (75 mg/m2 on day 1) in 21 day per cycle.

✓ Plinabulin dose was selected to be 30 mg/m2 for RP2D;

- **Phase 2 (study 101, 2nd/3rd line NSCLC, n=172): NCT00630110**

plinabulin (2 doses at 20 mg/m2 or 30 mg/m2 on day 1 and 8) + docetaxel (75 mg/m2 on day 1) vs docetaxel (75 mg/m2, day 1) in 21 day per cycle, in 2nd/3rd line NSCLC.

✓ 30 mg/m2 plinabulin had better efficacy than 20 mg/m2.

✓ Superior Duration of response (DOR) in DP (30 mg/m2) vs D ($p<0.05$).

- ❑ Large patient population with limited treatment options
  - EGFR wild type: ~85% western NSCLC and ~70% of Asian NSCLC patients
  - With immunotherapies moved to first line, Docetaxel-based therapies are the mainstay therapy
  - TKIs are worse than docetaxel[1]
- ❑ Docetaxel-based Therapies (SOC)[2]
  - Limited efficacy
  - >40% severe neutropenia

Since nivolumab was approved 6 years ago, no new agent with novel mechanism has been approved in this indication.

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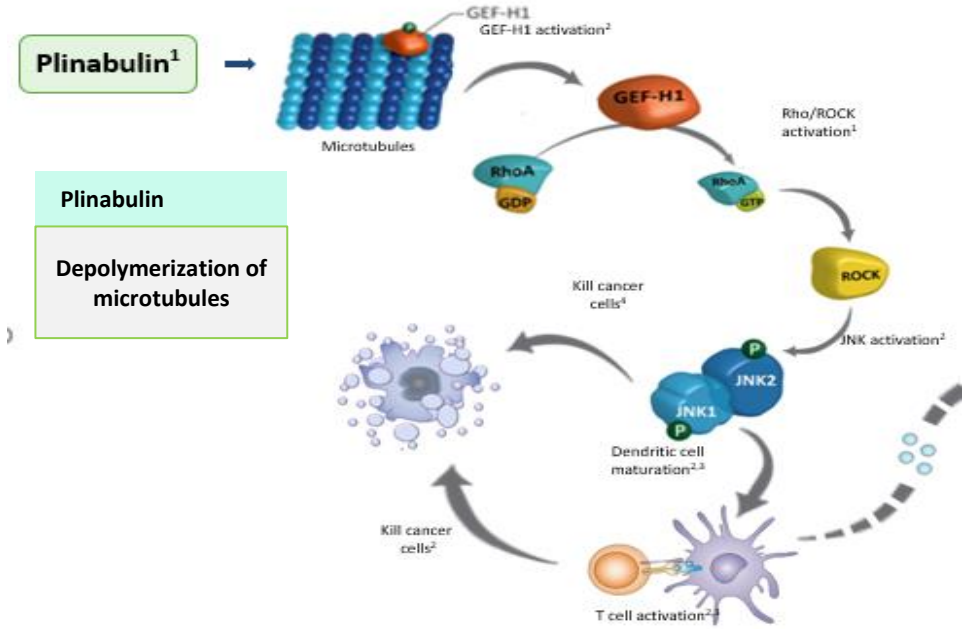
[1] Lancet Oncol. 2013 Sep;14(10):981-8. 2. [1] Lancet 384 (9944): 665-673 (2014).

PLINABULIN : Durable Anticancer Activity MOA

Plinabulin: First-in-Class, Selective Immunomodulating Microtubule-Binding Agent (SIMBA)

- Plinabulin Induces Dendritic Cell Maturation (the most potent APC), a Key Step in Initiating Anti-Cancer Durable Response

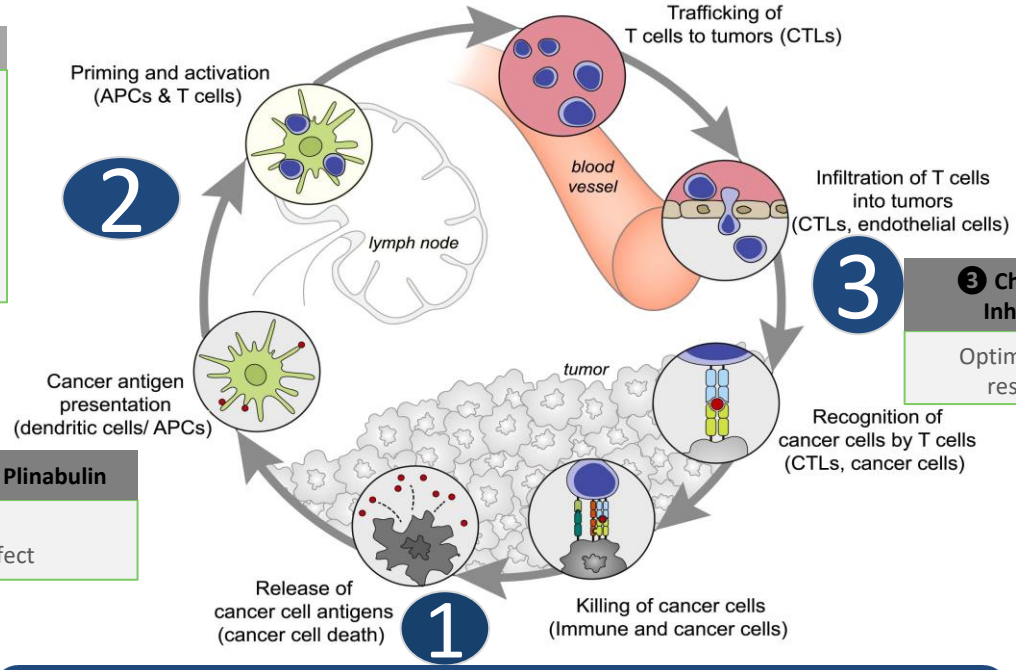


Plinabulin

Depolymerization of microtubules

❷ Plinabulin

Stimulate maturation of dendritic cells to increase antigen presentation.
Dendritic cells are the most important antigen-presenting cells



❸ Checkpoint Inhibitors

Optimize T cell response

❶ Radiation/Chemotherapy/ Plinabulin

Release Tumor Antigens
For more potent anti-cancer effect

Plinabulin Novel Target: Immune Defense Protein GEF-H1

❶ + ❷ + ❸ → Optimal Immuno-Oncology Response

Note: [1] La Sala et al., 2019 Chem. [2] Kashyap et al., 2019 Cell Reports. [3] Zhang et al., 2005 Mol Cell Biol. [4] Singh et al., 2011 Blood. [5] Suwa et al., 2000 Am J Physiol Heart Circ Physiol; Ghosh et al., 2018 ACR Annual Conference; Blayney et al., Society of Leukocyte Biology. [6] Asensi et al., 2004 Infection and Immunity.

DUBLIN -3 STUDY OVERVIEW

Plinabulin/Docetaxel combination vs. Docetaxel (NCT02504489)

DUBLIN - 3

- Non-squamous or squamous NSCLC
- Stage IIIb/IV
- ECOG performance status ≤ 2
- Progression during or after treatment with one or two treatment regimen containing platinum
- Must have at least one measurable lung lesion
- Prior checkpoint inhibitor therapy allowed
- Written consent

Randomized 1:1
21-day cycle
(n=559)

Docetaxel + Plinabulin (N=278)

All Cycles:

Day 1:Docetaxel 75 mg/m2 + Plinabulin 30mg/m2

Day 8: Plinabulin 30mg/m2

→ PD

Docetaxel + Placebo (N=281)

All Cycles:

Day1: Docetaxel 75 mg/m2 + Placebo

Day 8:Placebo

→ PD

- ✓ **Primary endpoint**: Overall Survival (OS)
- ✓ **Secondary endpoints:** ORR, PFS , Percent of patients with grade 4 neutropenia on C1D8, Month 24 OS rate, Month 36 OS rate , DoR , Q-TWiST, QoL, % patients who received docetaxel >8 cycles, >10 cycles, and >12 cycles

Statistical Considerations

- **Primary Endpoint:** OS from randomization based on ITT population

- **Planned Sample Size:** Approximate 439 death events (approximately 554 patients to be enrolled) to provide 85% power to detect a treatment difference at two-sided significance level of 0.05 with two planned interim analyses (see below).

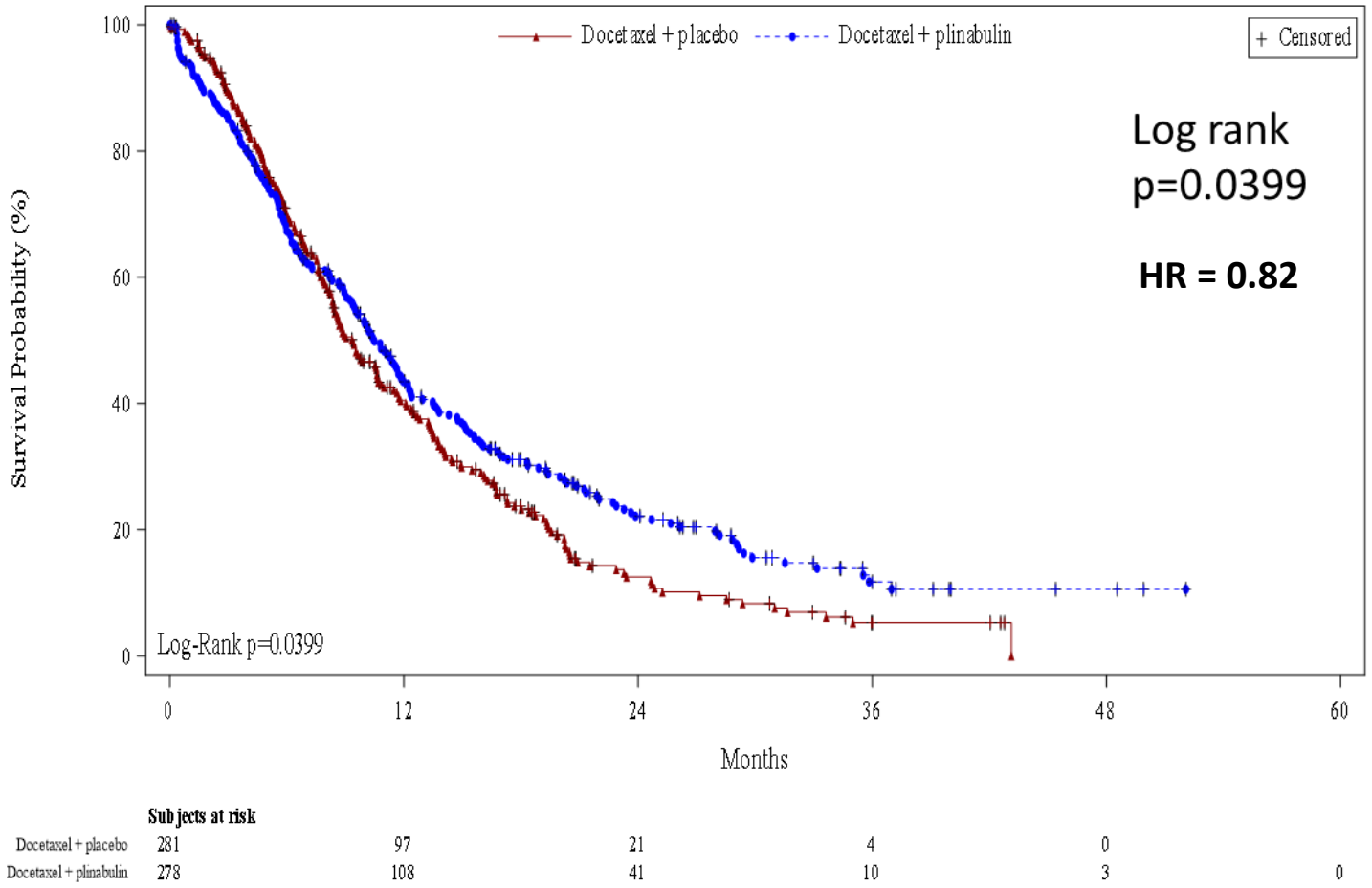
- **Two Planned Interim Analyses**: Two interim analyses were planned.
  - 1st: at 33% of death events (about 150 events) and 2nd: at 67% of death events (about 300 events).

- **Planned Final Analyses**: 439 death events reached.
  - Log rank 2-sided nominal p value (based on K-M OS curve) < 0.046 to be statistically significant;
  - Mean OS: restricted mean survival time method. 2-sided nominal p value < 0.05 to be statistically significant.

Baseline Characteristics

	Docetaxel + placebo (N=281)	Docetaxel + Plinabulin (N=278)	Total (N=559)
Age (years)			
Median	60	61	61
Range	25,85	37,82	25,85
Sex, n(%)			
Male	207 (73.7%)	199 (71.6%)	406 (72.6%)
Tumor histology, n (%)			
Non-Squamous	178 (63.3%)	153 (55.0%)	331 (59.2%)
Squamous	100 (35.6%)	120 (43.2%)	220 (39.4%)
Missing	3 (1.1%)	5 (1.8%)	8 (1.4%)
ECOG, n(%)			
0	44 (15.7%)	40 (14.4%)	84 (15.0%)
1	225 (80.1%)	229 (82.4%)	454 (81.2%)
2	11 (3.9%)	9 (3.2%)	20 (3.6%)
Missing	1 (0.4%)	0 (0.0%)	1 (0.2%)
Line of prior therapy, n (%)			
First Line	216 (76.9%)	204 (73.4%)	420 (75.1%)
Second Line	65 (23.1%)	74 (26.6%)	139 (24.9%)
Geographic region, n(%)			
China	245 (87.2%)	243 (87.4%)	488 (87.3%)
ROW	36 (12.8%)	35 (12.6%)	71 (12.7%)

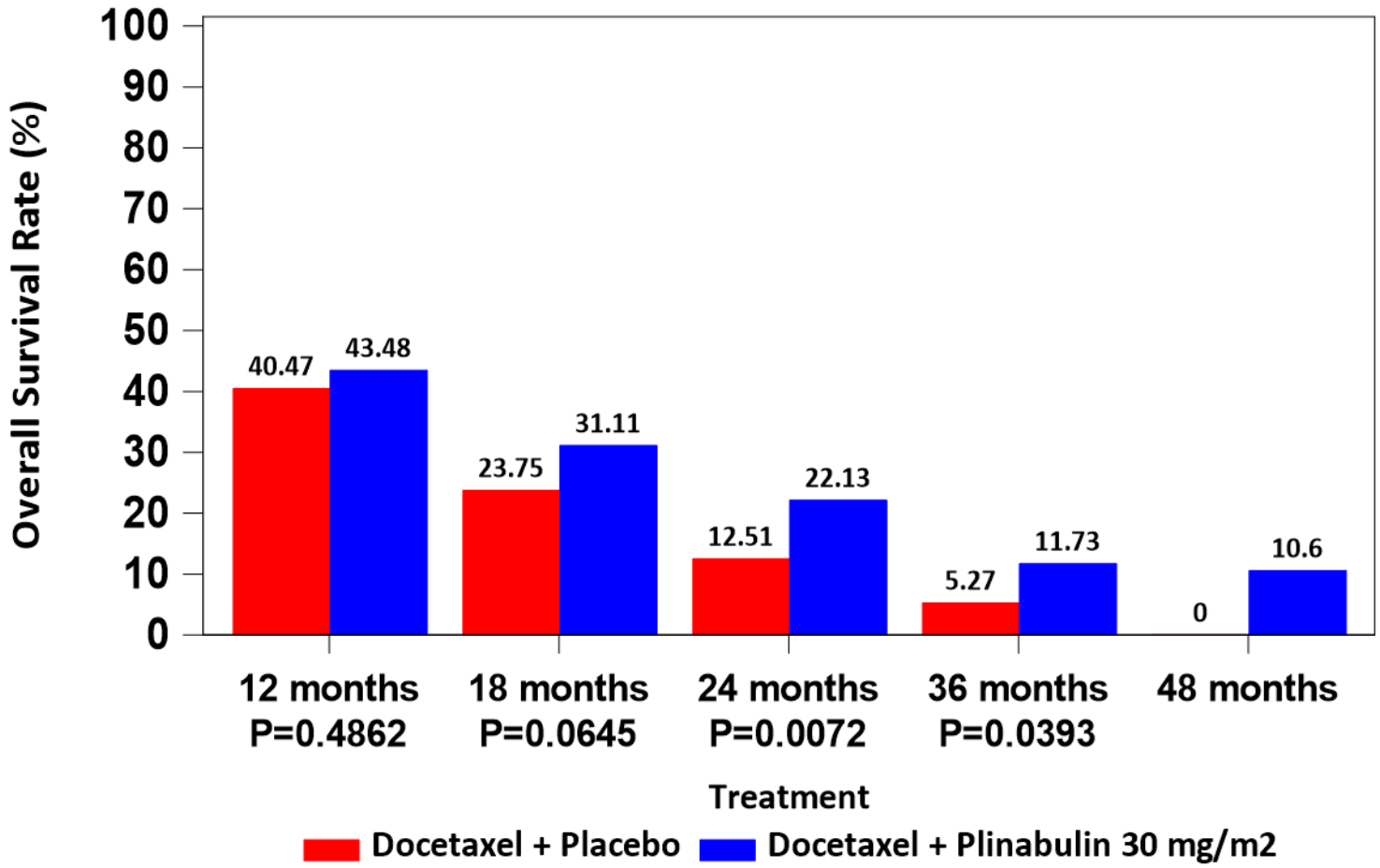
Met Primary Study Objective in Overall Survival (OS)



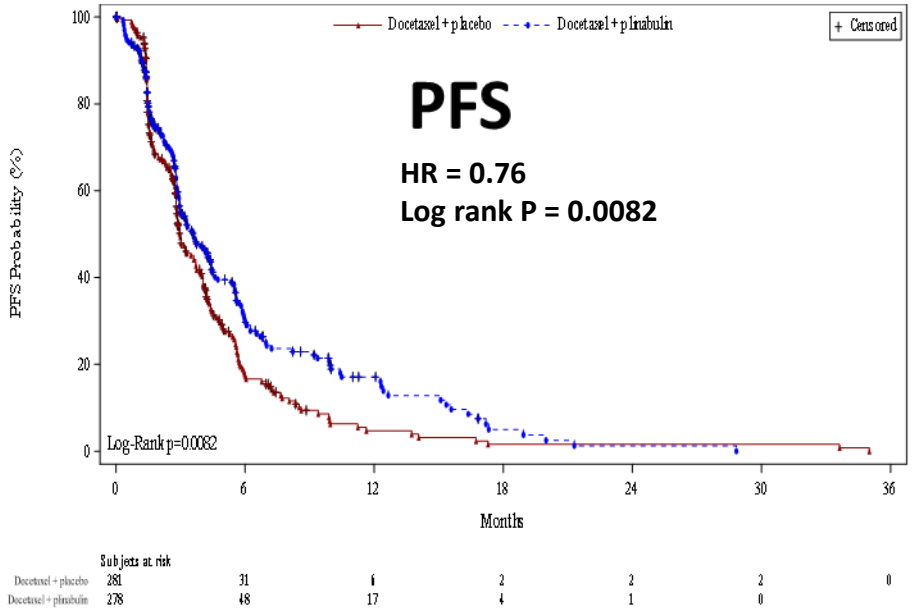
ITT population	Docetaxel (75 mg/m2) N=281	Plinabulin (30 mg/m2) + Docetaxel (75 mg/m2) N=278
OS (Months)	Mean OS (SE): 12.77 (0.676) Median OS (95% CI): 9.4 (8.4, 10.7)	Mean OS (SE): 15.08 (0.848), p=0.0332 Median OS (95% CI): 10.5 (9.3, 11.9) Log-rank p=0.0399; HR = 0.82 (0.68,0.99)

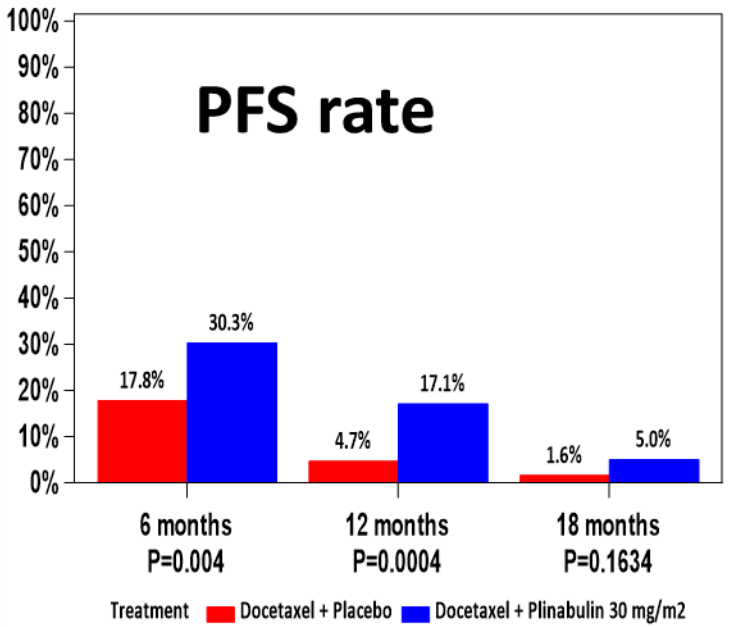
Met Primary Study Objective in Overall Survival (OS)

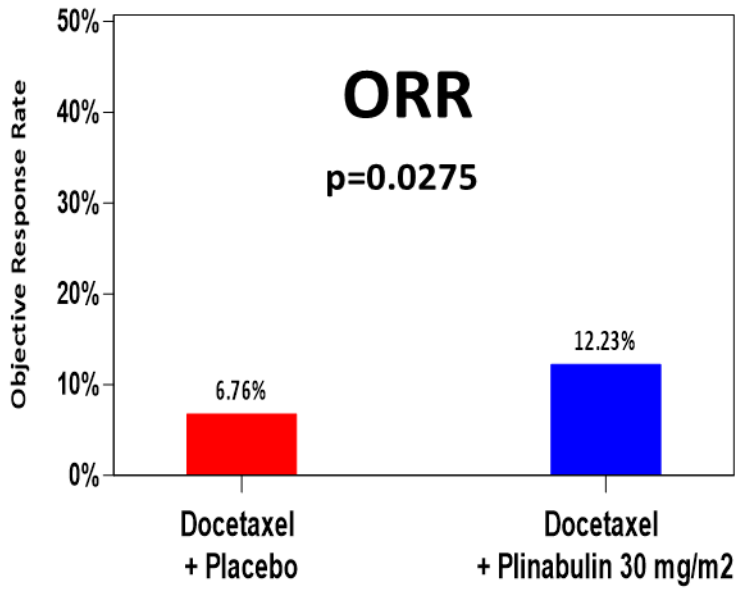
Doubling of OS rate in 24 M, 36 M, and 48 M OS rate in DP (10.6%) vs. D (0%)



Significant Improvement in PFS, Double ORR with Plinabulin







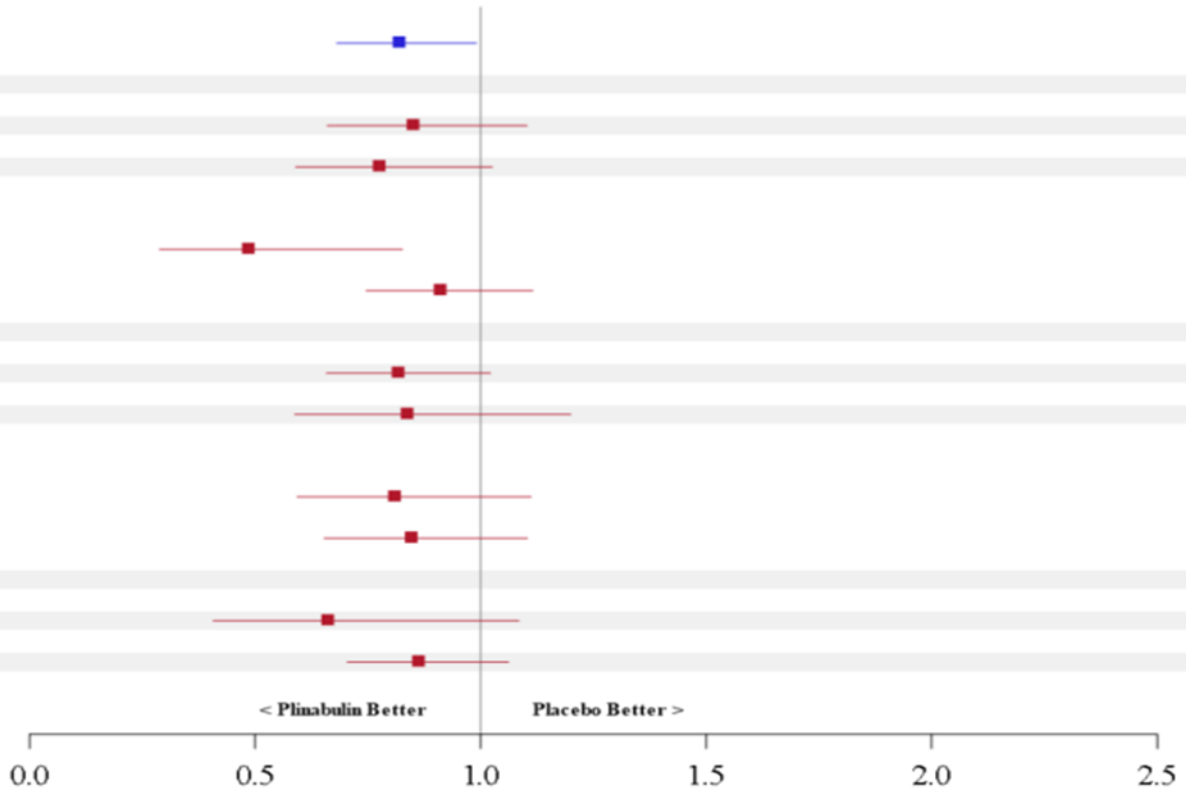
Secondary Endpoint (ITT population)	Docetaxel(75 mg/m2) N=281	Plinabulin (30 mg/m2) + Docetaxel (75 mg/m2) N=278
PFS* (months or M)	Mean PFS (SE): 4.4 (0.3)	Mean PFS (SE): 6.0 (0.4); p=0.0062
	Median PFS (95% CI): 3.0 (2.8, 3.7)	Median PFS (95% CI): 3.6 (3.0, 4.4), Log-rank p=0.0082; HR=0.76 (0.63, 0.93)

*Investigator-Assessed

FOREST PLOT

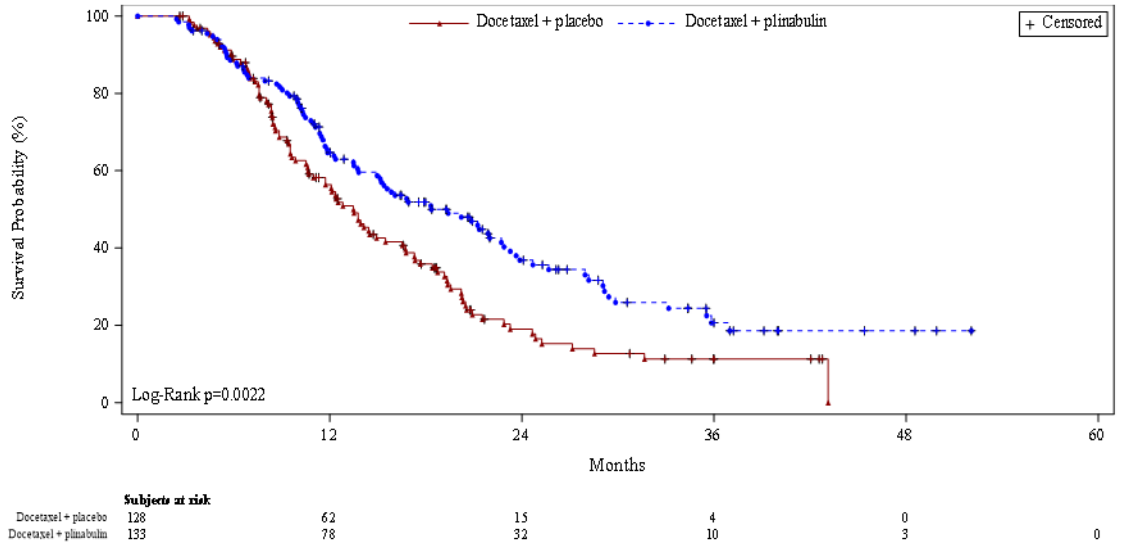
Subgroup Analysis of Overall Survival - ITT Population

Subgroup	No.of Patients		Hazard Ratio	95% CI of Hazard Ratio		
	D	DP		HR	Low	High
Overall	281	278		0.822	0.681	0.991
Age						
<=Median age(61 years)	158	144		0.853	0.66	1.103
>Median age(61 years)	123	134		0.778	0.59	1.026
ECOG group						
0	44	40		0.488	0.288	0.827
1-2	236	238		0.913	0.746	1.116
Gender						
Men	207	199		0.82	0.658	1.022
Women	74	79		0.84	0.588	1.2
Smoking status						
Non-smoker	98	94		0.812	0.593	1.112
Smoker	146	151		0.849	0.653	1.104
Tumor stage						
IIIB	41	50		0.664	0.407	1.085
IV	236	224		0.865	0.704	1.062



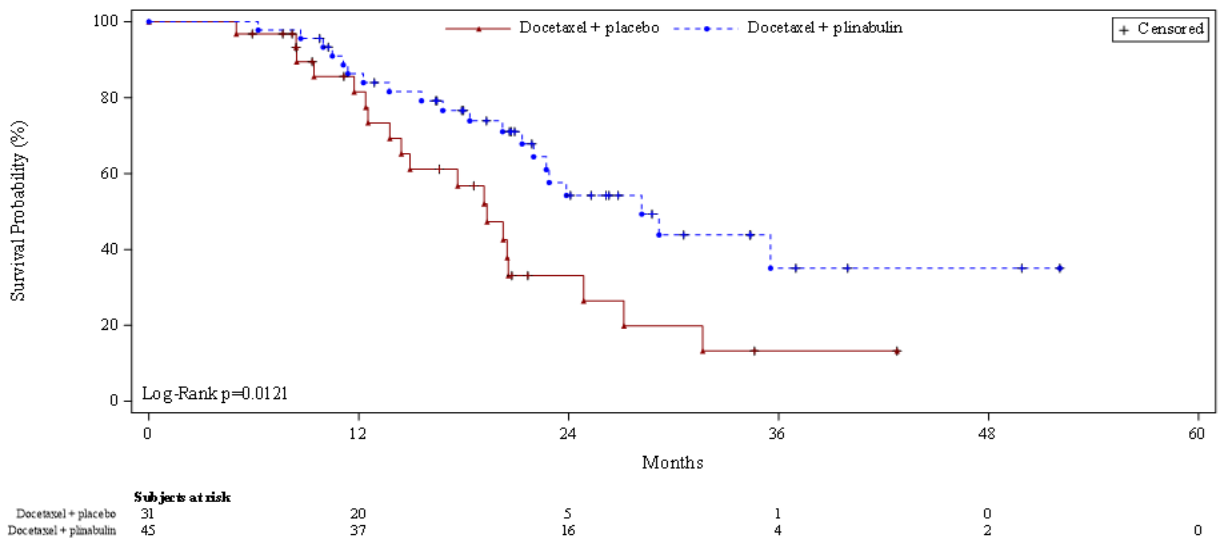
Overall Survival for patients with ≥4 or ≥8 cycles

OS K-M Graph for treatment cycles >= 4 cycles



	Median OS	p value
D (n= 128)	13.5(10.68,16.54)	
DP (n= 133)	18.3(14.96,22.88)	HR=0.634; P = 0.0022

OS K-M Graph for treatment cycles >= 8 cycles



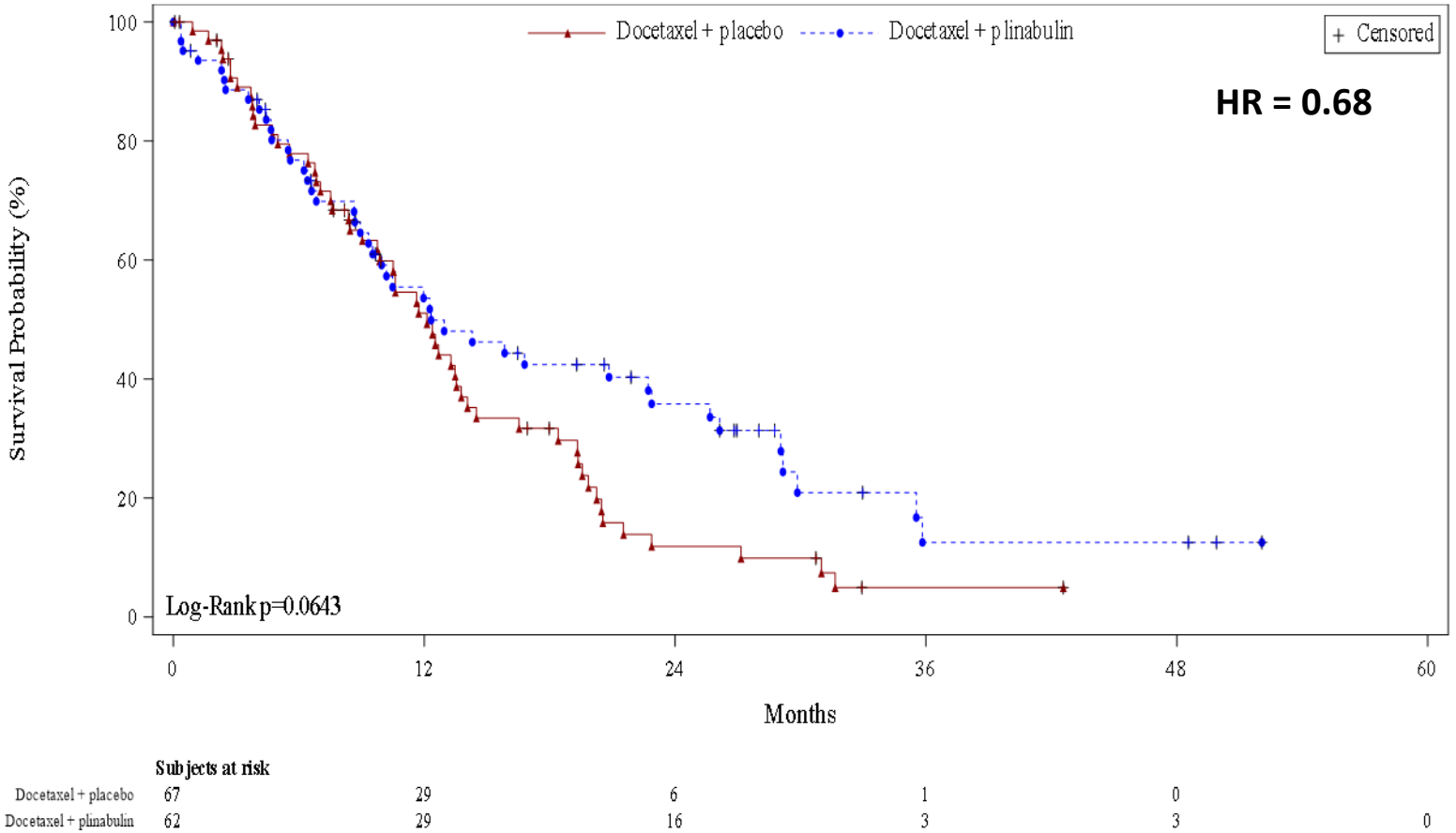
	Median OS	p value
D (n= 31)	19.3(13.77,24.85)	
DP (n= 45)	28.2(21.99,NA)	HR=0.453; P = 0.0121

Baseline Characteristics for PD-1/PD-L1 Exposed Patients

	Docetaxel + placebo (N=67)	Docetaxel + Plinabulin (N=62)	Total (N=129)
Age (years)			
Median	60	64	61
Range	28,85	45,82	28,85
Sex, n(%)			
Male	38 (56.7%)	42 (67.7%)	80 (62.0%)
Tumor histology, n (%)			
Non-Squamous	48 (71.6%)	33 (53.2%)	81 (62.8%)
Squamous	19 (28.4%)	29(46.8%)	48 (37.2%)
ECOG, n(%)			
0	10 (14.9%)	11 (17.7%)	21 (16.3%)
1	53 (79.1%)	47 (75.8%)	100 (77.5%)
2	4 (6.0%)	4 (6.5%)	8 (6.2%)
Line of prior therapy, n (%)			
First Line	33 (49.3%)	26 (41.9%)	59 (45.7%)
Second Line	34 (50.7%)	36 (58.1%)	70 (54.3%)
Geographic region, n(%)			
China	34 (50.7%)	34 (54.8%)	68 (52.7%)
ROW	33 (49.3%)	28 (45.2%)	61 (47.3%)

Beneficial Long Term Trend in PD-1/PD-L1 Exposed Patients

K-M Overall Survival - PD-1/PD-L1 Exposed – DUBLIN-3*

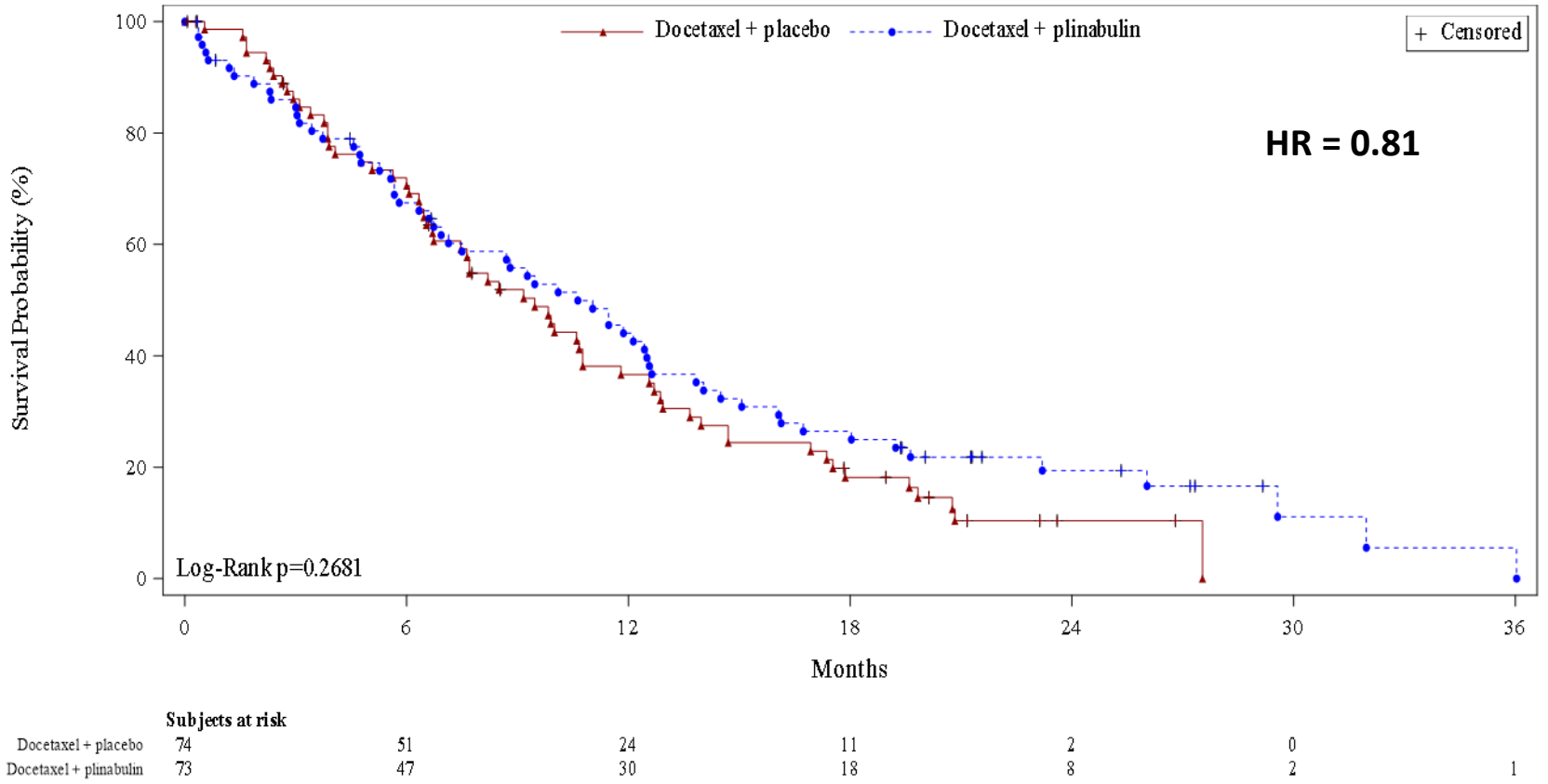


	Docetaxel (75 mg/m2) (n= 67)	Plinabulin (30 mg/m2) + Docetaxel (75 mg/m2) (n= 62)
Median OS (95% CI)	12.1(9.76,13.77)	12.3(9.34,22.88)
P-Value (Log-Rank Test)		0.0643
Hazard Ratio (95%CI)		0.682(0.454,1.025)
P-Value		0.0620
Mean (Months) (SE)	13.97(1.320)	18.33(1.909)
P-Value (RMST Test of Equality)		0.0602
Month 24 Survival Rate (%, 95% CI)	11.88(3.13,20.63)	35.82(22.90,48.75)
Month 24 P-value		0.0026
Month 36 Survival Rate (%, 95% CI)	4.95(-1.37,11.27)	12.54(0.71,24.37)
Month 36 P-value		0.2676
Month 48 Survival Rate (%, 95% CI)	0.00(NA,NA)	12.54(0.71,24.37)
Month 48 P-value		NA

* DUBLIN-3 – 103 Study with NSCLC (NCT02504489)

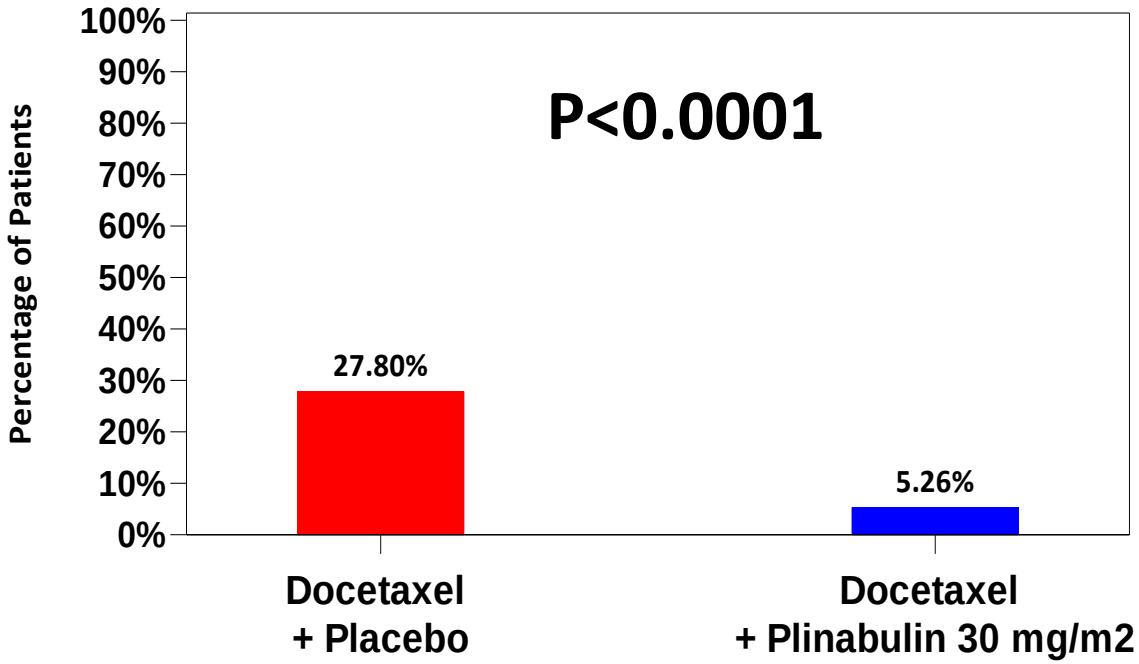
Consistent Long Term Survival Benefit in Western pts vs ITT

K-M Overall Survival in Western patients - Pooled 101 and DUBLIN-3 study, in the Same Target Population

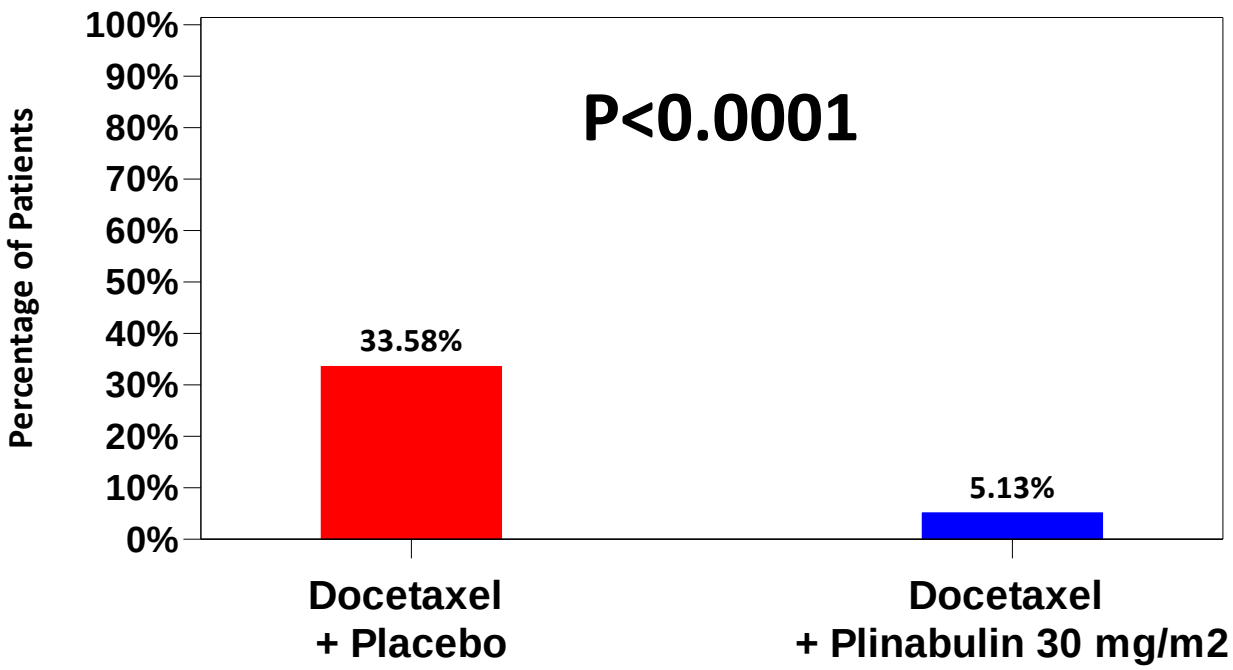


Significant Reduction in Grade 4 Neutropenia
Cycle 1 Day 8 and All Cycles Day 8

Grade 4 neutropenia, Cycle 1 Day 8



Grade 4 neutropenia, All Cycles Day 8



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Safety: Well Tolerated and Lower Grade 3/4 AE Per Cycle

Safety: Treatment Related Adverse Events Reported >=10% Patients

	Docetaxel + Placebo (N=278) ; n (%)		Docetaxel+Plinabulin (30 mg/m^2) (N=274) ; n (%)	
Preferred term	All Grade	Grade 3/4	All Grade	Grade 3/4
White blood cell count decreased	183(65.8%)	130(46.8%)	156(56.9%)	75(27.4%)
Neutrophil count decreased	186(66.9%)	144(51.8%)	134(48.9%)	81(29.6%)
Nausea	63(22.7%)	0	93(33.9%)	3(1.1%)
Diarrhea	47(16.9%)	2(0.7%)	101(36.9%)	23(8.4%)
Hypertension	9(3.2%)	3(1.1%)	85(31.0%)	47(17.2%)

Grade 3/4 Events per Patients per Year AE Analysis Adjusted for Cycle Number

Statistic	Docetaxel + Placebo	Docetaxel + Plinabulin
Total N	278	274
Number of Patients with Events, n(%)	215 (77.3)	204 (74.5)
Total number of Years	71.65	83.43
Total number of Events	791	824
Observed Event Rate per Year	11.04	9.88
Estimated Event Rate per Patient per Year (95% CI)	11.04 (10.30, 11.84)	9.88 (9.22, 10.57)
Rate Ratio vs Docetaxel + Placebo (95% CI)		0.89 (0.81, 0.99)
P-value vs Docetaxel + Placebo		0.0253

Q-Twist - Quality-adjusted Time Without Symptoms of Disease and Toxicity

Quality of Life was assessed with validated tools (EORTC QLQ C30 and QLQ-LC13), and the Q-TWiST analysis integrating Efficacy, Safety and Quality of Life inputs (including EQ-5D HU QoL)

Q-TWiST - EQ-5D HU

Health State	Health State Utility	Docetaxel Restricted Mean	Docetaxe + Plinabulin Restricted Mean	Restricted Mean Difference	RM P-Value	Docetaxel + Placebo	Docetaxel + Plinabulin	Difference	P-Value
						281	278		
TOX	0.8267 (0.8187 to 0.8346)	0.86	0.81	0.05 (-0.20 to 0.30)	0.6973	0.71 (0.54 to 0.89)	0.67 (0.50 to 0.85)	0.04 (-0.17 to 0.25)	0.6974
TWIST	0.8533 (0.8467 to 0.8599)	3.56	5.14	-1.58 (-2.55 to -0.60)	0.0015	3.04 (2.50 to 3.57)	4.38 (3.64 to 5.12)	-1.35 (-2.18 to -0.52)	0.0015
REL	0.8051 (0.7724 to 0.8379)	8.35	9.13	-0.78 (-2.64 to 1.08)	0.4113	6.72 (5.65 to 7.79)	7.35 (6.09 to 8.61)	-0.63 (-2.13 to 0.87)	0.4118
QTWiST						10.47 (9.34 to 11.63)	12.40 (10.99 to 13.83)	-1.93 (-3.63 to -0.23)	0.0263

Q-TWiST Gain	Relative Gain to OS Restricted Mean	Relative Gain to Q-TWiST
1.93	15.11%	18.43%
	(1.72% to 30.63%)	(2.07% to 37.20%)
	p-value=0.0396	p-value=0.0393

Improvement >18% in Q-Twist, which is clinically meaningful.

Dublin-3: Superior Efficacy (OS, PFS, ORR) and Significant Reduction in Grade 4 CIN (DP vs. D)

Primary Endpoint	Docetaxel (75 mg/m2) N=281	Plinabulin (30 mg/m2) + Docetaxel (75 mg/m2) N=278
OS (months)	Mean 12.77 (0.676) Median 9.4 (8.4, 10.7)	15.08 (0.848); p=0.03 10.5 (9.3, 11.9), Log-rank p=0.0399 HR = 0.82 (0.68 – 0.99)
Secondary Endpoint - Hierarchy Order		
ORR (%)	6.76%	12.23%; p=0.0275
PFS (months)	Mean 4.4 (0.3) Median 3.0 (2.8, 3.7)	6.0 (0.4); p=0.006 3.6 (3.0, 4.4), Log-rank p=0.008 HR = 0.76 (0.63, 0.93)
Grade 4 neutropenia, cycle 1 Day 8 (%)	27.8%	5.3%; p<0.0001
24 Month OS Rate (%)	12.5%	22.1%; p = 0.0072
36 Month OS Rate (%)	5.3%	11.7%; p = 0.0393
48 Month OS Rate (%) - exploratory	0%	10.6%; p value cannot be calculated
Q-TWiST • Relative Gain to Q-TWiST	10.47 M (9.34, 11.63)	12.40 M (10.99, 13.83) 18.43% (2.07%, 37.20%); p=0.0393

CONCLUSION

- Dublin-3 study met OS primary endpoint and key secondary endpoints: PFS and ORR.
- Plinabulin showed durable anti-cancer benefit in doubling 24 M, 36 M OS rate in Plinabulin + Docetaxel (DP) vs Docetaxel (D). OS rate at 48 M for DP at 10.6% vs D at 0%.
- DP is well tolerated, with lower grade 4 and grade 3/4 AE per patient per year in comparison to D arm. In addition, plinabulin protected bone marrow by significantly reducing grade 4 neutropenia of Docetaxel (28% to 5%, $p<0.0001$).
- Improvement >18% Q-twist (time with good QoL),which is clinically meaningful.

Plinabulin + Docetaxel has a favorable benefit/risk ratio,
and has the potential of preferred 2nd/3rd line treatment for NSCLC with EGFR wild type.

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Potential "Cornerstone" for IO Combos

PD-1/PD-L1 Inhibitors
- $30 B global annual sales

Potential to greatly expand the addressable market

Current Severe Unmet Medical Needs

- PD-1/PD-L1 resistant patients need later line therapies
- PD-1 + chemo double efficacy of PD-1, but with CIN risk
- PD-1 or PD-1+CTLA-4 with high ir-SAE
- PD-1/PD-L1 non-responsive tumor;
- Patients who cannot use PD-1/PD-L1

+"Easy-to-use" APC Inducer

Plinabulin Clinical Development

- Plinabulin + I/O + chemo/radiation
- Plinabulin is developed as a CIN prevention agent (pan cancer, pan chemo)
- Plinabulin+PD-1+CTLA-4 in SCLC
- Plinabulin+ I/O + chemo/radiation
- Plinabulin + chemo

Triple I/O Combo Development for Multiple Cancers

	Indication / Target	Program	Trial Name / Collaborator	Commercial Rights	Status
Triple Combo IO (IIT)	SCLC Checkpoint naïve and checkpoint refractory patients	Plinabulin + Nivolumab (PD-1) + Ipilimumab (CTLA-4)	7 US sites, including Rutgers University as lead center (Big Ten)	Global	Phase 1 completed, Presenting at ASCO June 2021
	SCLC Checkpoint refractory patients	Plinabulin + Nivolumab (PD-1) + Ipilimumab (CTLA-4)	Big Ten Study	Global	Initiating Phase 2
	7 Cancers* PD-1/PDL1 failed pts	Plinabulin + PD-1/PD-L1 + radiation	MD Anderson	Global	First patient dosed in 06/2021

*NSCLC, SCLC, Renal Cell, Bladder, Merkel Cell, Melanoma, Cancers with high levels of microsatellite instability

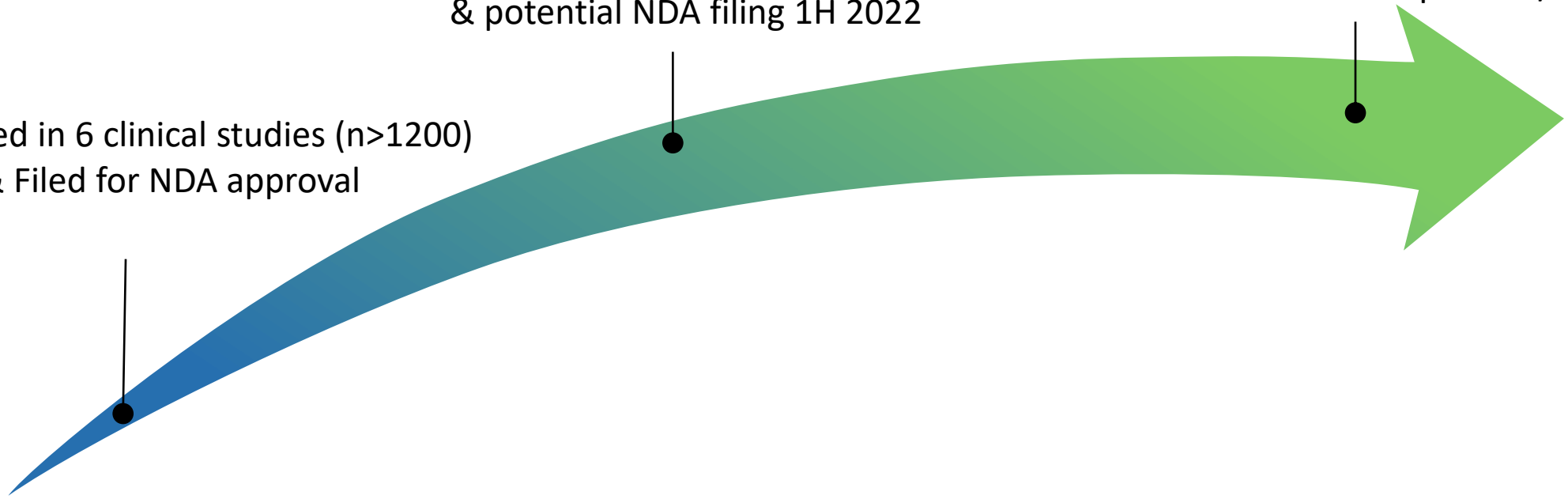
Plinabulin Franchise: "Pipeline in a Drug"

Clinical Confirmation → **Expand** → **Transform**

Confirmed in 6 clinical studies (n>1200)
& Filed for NDA approval

Positive Phase 3 Topline OS data (n=559)
& potential NDA filing 1H 2022

Promising early clinical efficacy data
– 7 different cancers in phase 1/2 study



CIN (BTD & Priority Review)
Superior Regimen vs. SOC
PDUFA 11/30/2021

NSCLC
Strong MOA Rationale &
Successful DUBLIN-3 phase 3 Study

Multiple Cancers (I/O Combo)
Synergistic MOA with Checkpoint Inhibitors & Promising Preclinical & Early Clinical Efficacy Data

thank you!

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