

Transforming science
into medicine



BIOLINERX

2 Forward-looking statements

This presentation contains “forward-looking statements.” These statements include words like “may,” “expects,” “believes,” “plans,” “scheduled,” and “intends,” and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

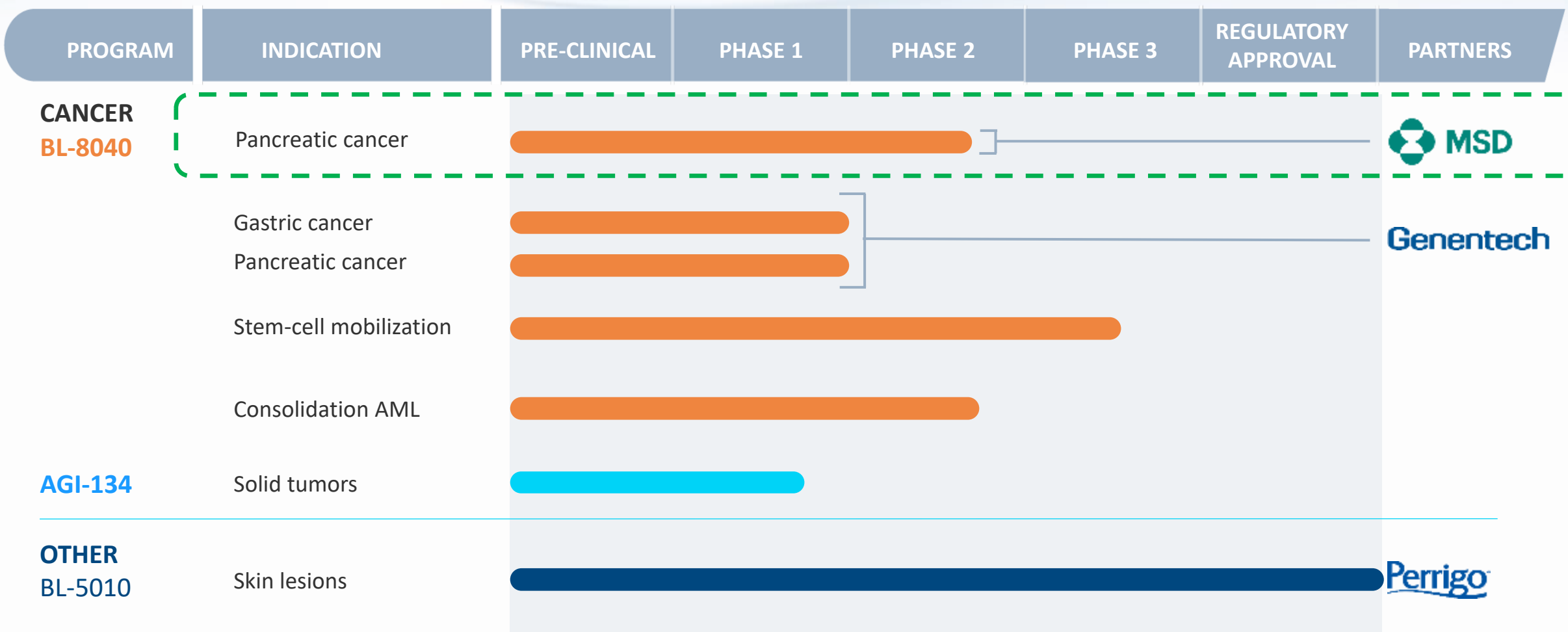
Agenda

- 7:45 – 8:10 Registration and breakfast
- 8:10 – 8:20 Introduction and short Company update
- 8:20 – 8:45 Keynote presentation: “New Approaches in Pancreatic Cancer”
- 8:45 – 9:05 Update on COMBAT triple combination study
- 9:05 – 9:10 Future milestones and closing remarks
- 9:10 – 9:30 Q&A

Our Mission

*Our mission is to become a leader in the development of novel
therapeutics for the treatment of cancer*

A Diverse Pipeline Targeting Multiple Oncology Indications



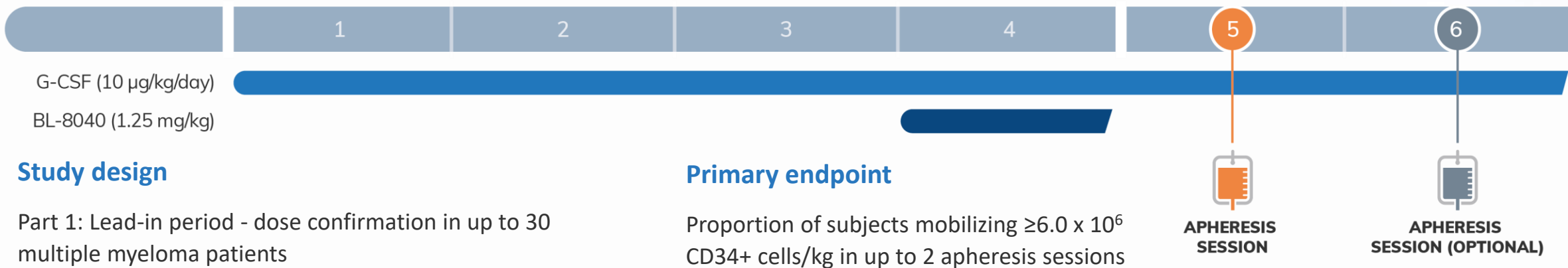
GENESIS Study: SCM for Autologous Transplantation in MM Patients

Initiated Q4 2017 - Phase 3 randomized, placebo-controlled, safety and efficacy study (n=177): NCT03246529

SCREENING

MOBILIZATION (DAYS)

COLLECTION (DAYS)



Study design

Part 1: Lead-in period - dose confirmation in up to 30 multiple myeloma patients

Part 2: Randomized placebo-controlled study in combination with G-CSF in 177 multiple myeloma patients

Primary endpoint

Proportion of subjects mobilizing $\geq 6.0 \times 10^6$ CD34+ cells/kg in up to 2 apheresis sessions

Lead-in period results (n=11)

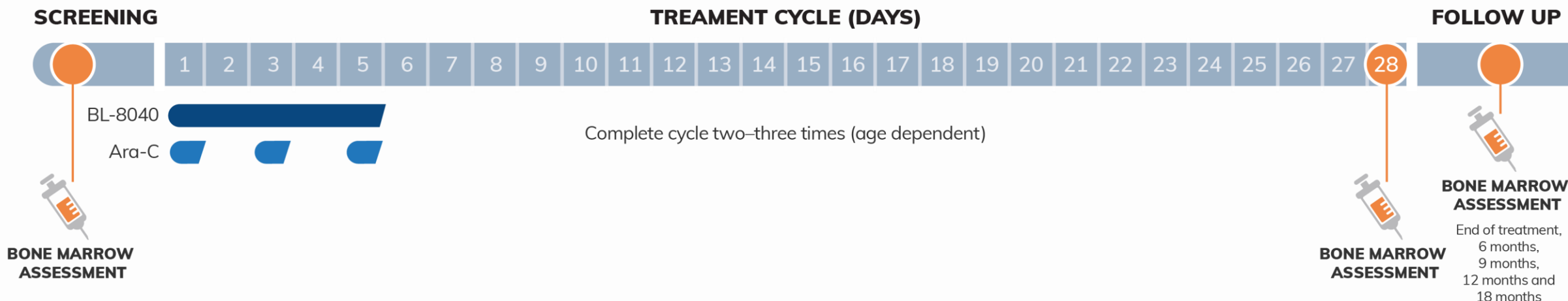
- BL-8040 in combination with G-CSF is safe and tolerable
- 82% of patients reached primary endpoint threshold of $\geq 6 \times 10^6$ CD34 cells/kg with one administration of BL-8040 and in up to 2 apheresis sessions; 64% reached the threshold in 1 apheresis session
- All patients mobilize $> 6 \times 10^6$ CD34 cells/kg in up to 4 aphereses
- DMC recommended early initiation of the double-blind, randomized, placebo-controlled part 2 of trial

Top-line results expected H2 2020

BLAST Study: Consolidation Therapy for AML Patients in 1st Remission

Phase 2b double-blind, multi-center placebo controlled study (n=194): NCT02502968 (in collaboration with German Leukemia Study Alliance)

Treatment: Two or three cycles (age-based) of high-dose Ara-C in combination with either BL-8040 or placebo



Endpoints

Relapse free survival (RFS)

Toxicity, safety and tolerability of BL-8040 in combination with high-dose Ara-C

Minimal residual disease (MRD)

Overall survival (OS)

BL-8040 potentially offers AML patients prolonged remission and increased overall survival

Interim results expected H1 2020



AGI-134 – High-Level Outline of Ongoing Phase 1/2a Clinical Study

Open-label study to evaluate the safety and tolerability of AGI-134 as monotherapy and in combination with checkpoint inhibitors, in unresectable metastatic solid tumors (NCT03593226)

PART 1

PART 2

Accelerated escalation monotherapy

Part 1 of study successfully completed - AGI-134 was found to be safe and well tolerated with no dose-limiting toxicities observed

Monotherapy basket

Combination - mCRC

Combination - HNSCC

Part 2 initial results expected H2 2020

Background to COMBAT/KEYNOTE-202 Triple Combo Data

- Collaboration with Merck signed beginning of 2016
- COMBAT/KEYNOTE-202 dual combo study initiated end of 2016; top-line results announced Q4 2018
- Merck collaboration expanded in Q3 2018 to add triple combo cohort to existing trial, with focus on second-line patients
- Preliminary triple combo data announced this morning based on ESMO IO abstract submission data cutoff date
- Additional triple combo data will be announced next week (based on updated data set to be included in oral presentation)
- Outstanding execution – have almost completed recruitment

Brand Name for BL-8040

- We recently received approval of a brand name for BL-8040
- The new brand name is:

MOTIXAFORTIDE

- We will gradually roll out this brand name beginning next year



Motixafortide (BL-8040)

**Oncology Combination Platform for
Solid and Hematological Cancers**

Focused on IO with Clinical POC in PDAC



Background & MoA

PDAC – High Unmet Need

PDAC – lowest survival rates across cancers

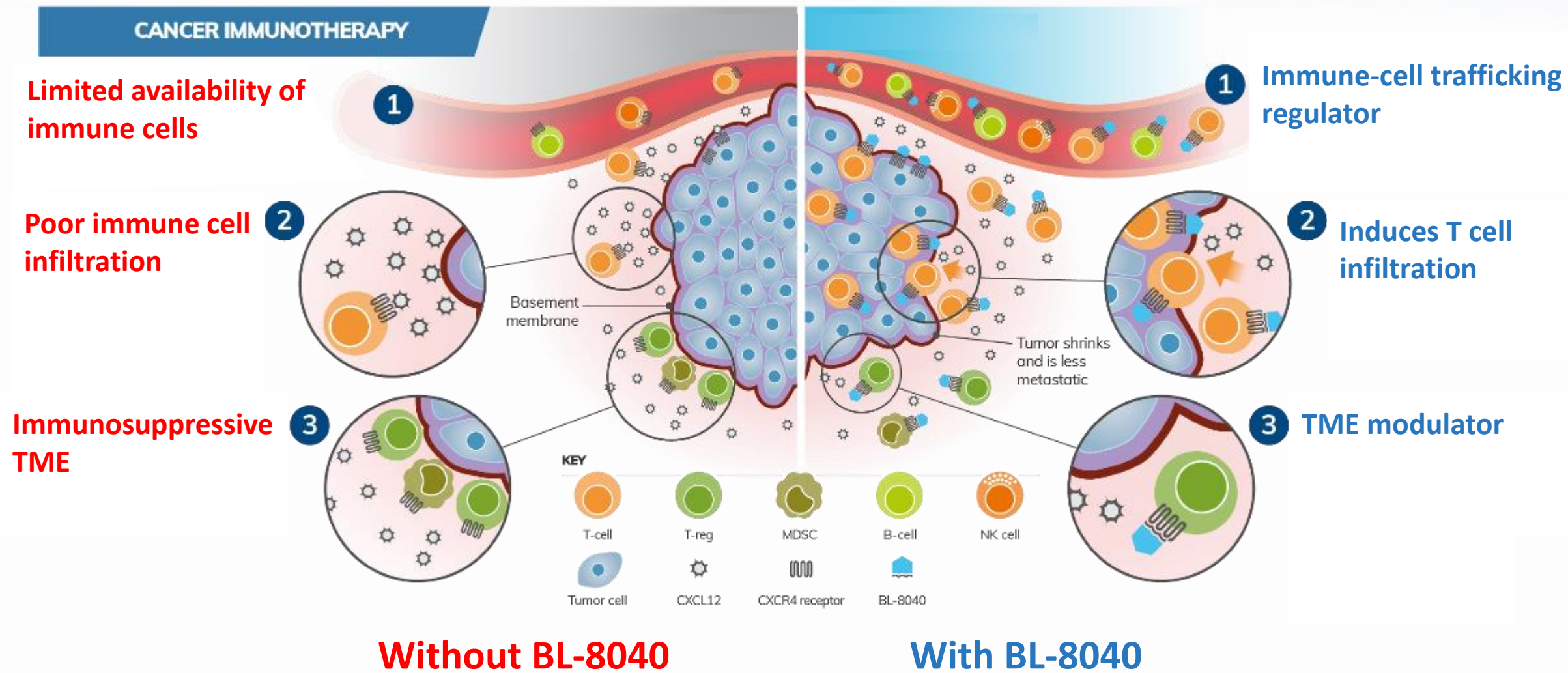
- Predicted 2nd leading cause of cancer deaths in U.S. by 2025
- Estimated 56,000 new cases and 45,000 deaths in the US in 2019
- SOC chemotherapy provides only modest benefit

Cold/immuno-suppressed tumors do not respond well to immune checkpoint inhibition (ICI) therapy

- Immunotherapy is effective in a number of solid tumours (melanoma, NSCLC, gastric cancer, genitourinary cancers, head and neck cancer and selected colorectal cancers)
- Pancreatic cancer has proved more of a challenge with disappointing results from early trials of single-agent immune checkpoint blockade; these therapies as single agents only remove the immune suppression, but do not provide a mechanism of immune activation

BL-8040 Unleashes CXCR4 Potential in Cancer Immunotherapy

*Targets the multiple immune “defects” in the PDAC TME**



* Zheng et al. J. Clin. Med. 2019, 8, 1472; doi:10.3390/jcm8091472

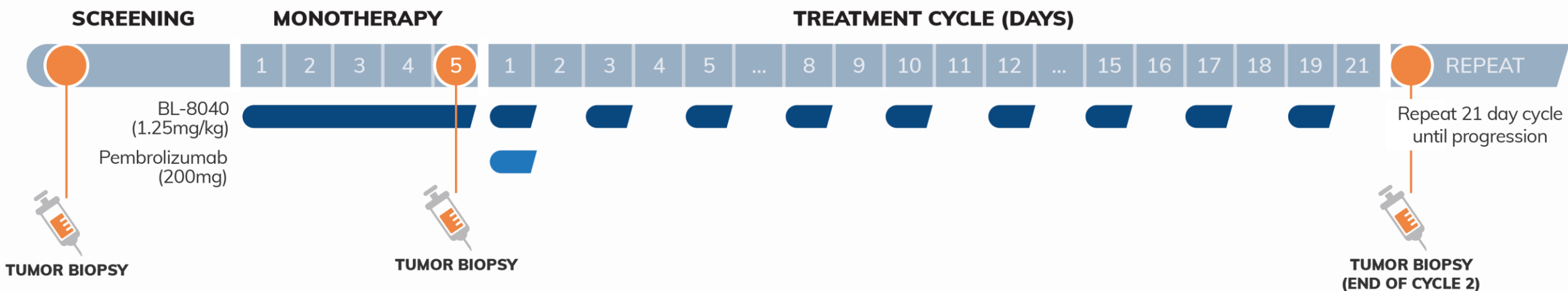


COMBAT/KEYNOTE-202 Study

**Dual Combination Results
(including PoM)**

BL-8040 + Pembro in PDAC: Dual Combo Study Design COMBAT/KEYNOTE-202 Phase 2a Study

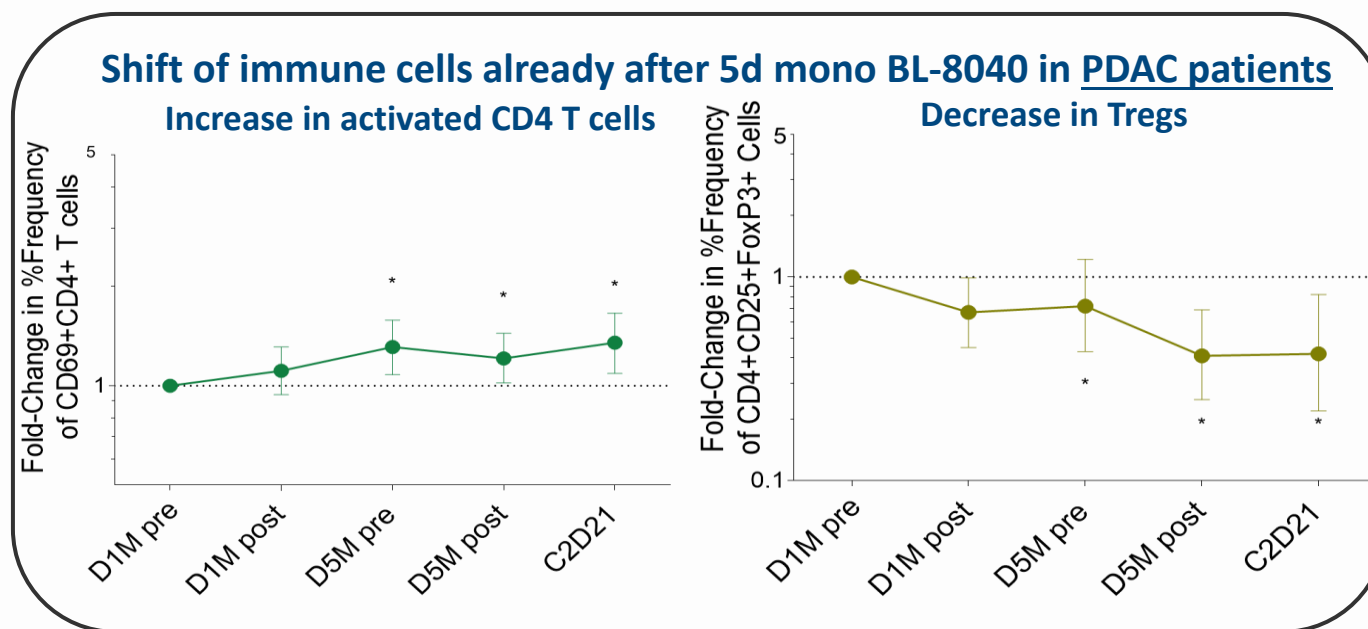
- Phase 2a, multicenter, open-label, single-arm study
- Assessing safety and efficacy of dual combo in PDAC



1. BL-8040: Powerful Immune Cell Trafficking Regulator

Quick (2h) and long lasting (>24h) monotherapy effect; effect maintained with combo

- **Induces trafficking** of immune cells from bone marrow and lymph nodes into the circulation
 - Similar trafficking shown in other indications (clinical - SCM Ph3 & multiple preclinical models)
- **Rebalances** peripheral immune cells in PDAC patients – significantly ↑ % of effector T cells, ↓ % of Tregs



Legend: **D1M**= Day 1 monotherapy, **D5M**=Day 5 monotherapy, **C2D21**=cycle 2 day 21 of combo (7w treatment)

2. BL-8040 ↑ TILs in the TME – After Only 5d Monotherapy

Inducing T cell inflamed TME – first time shown in PDAC patients

■ ↑ TIL with BL-8040 monotherapy and effect maintained with αPD1 combo in PDAC

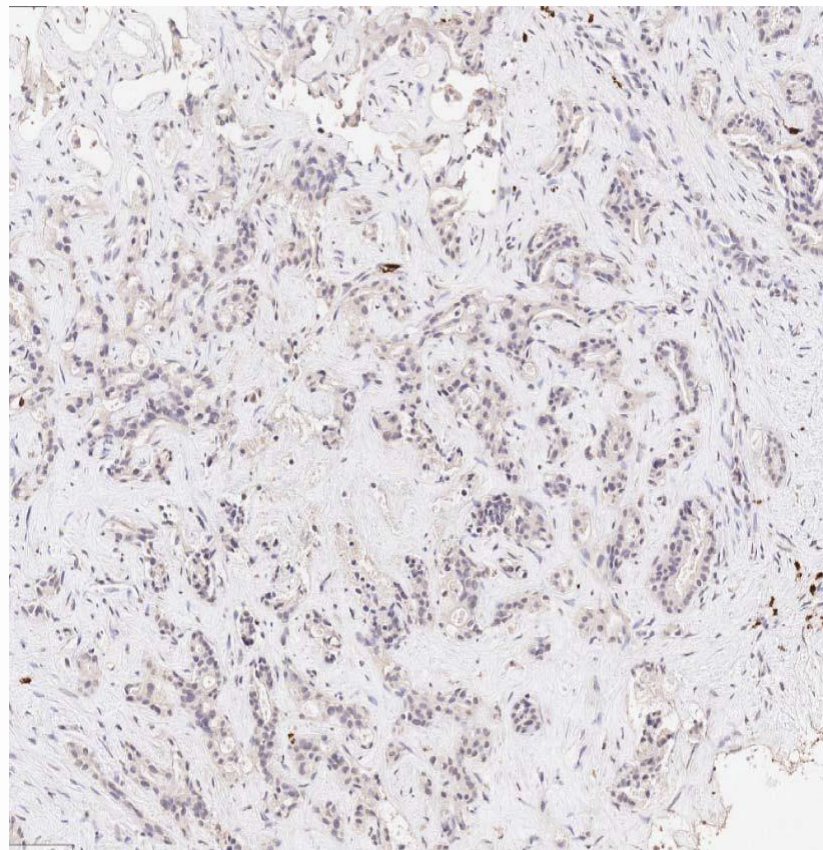
- By disrupting interaction between SDF1 (CXCL12) secreted by CAFs in the stroma and CXCR4 on T cells

■ Infiltration of CD3 and CD8 T cells in 80% (8/10) of evaluable PDAC patient biopsies

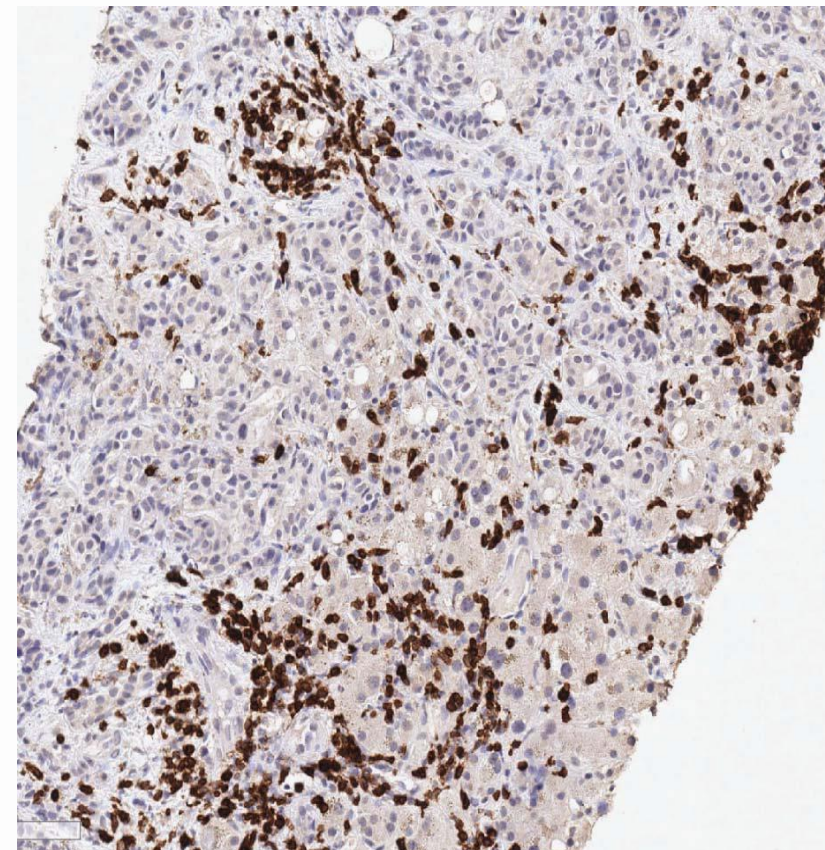
- up to 23-fold increase from baseline

αCD3 staining

Before BL-8040



After 5 days of BL-8040 Monotherapy

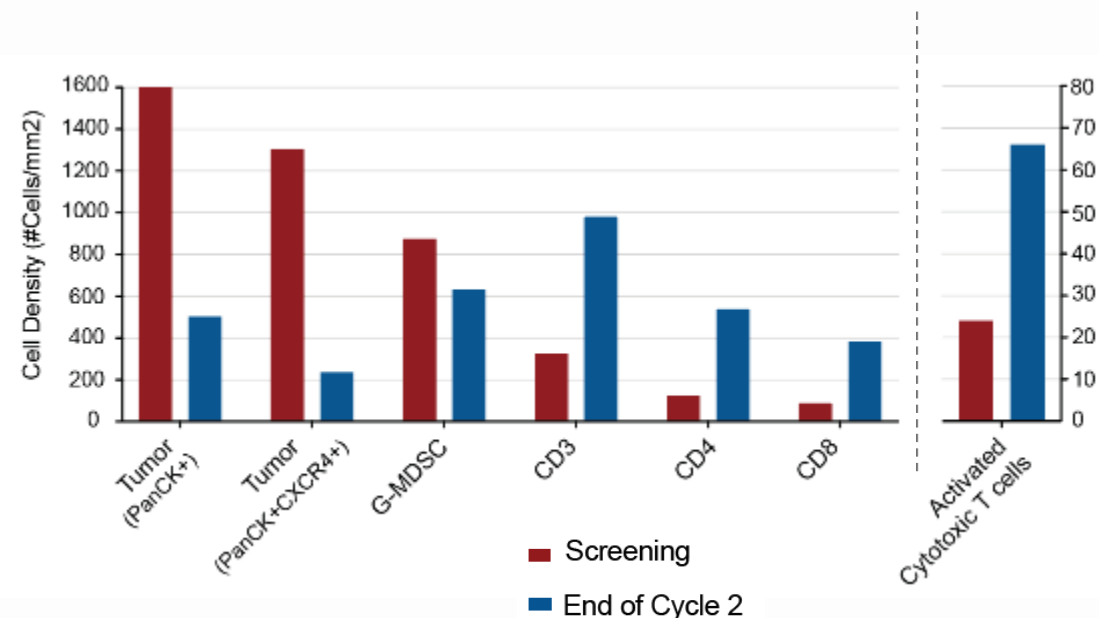
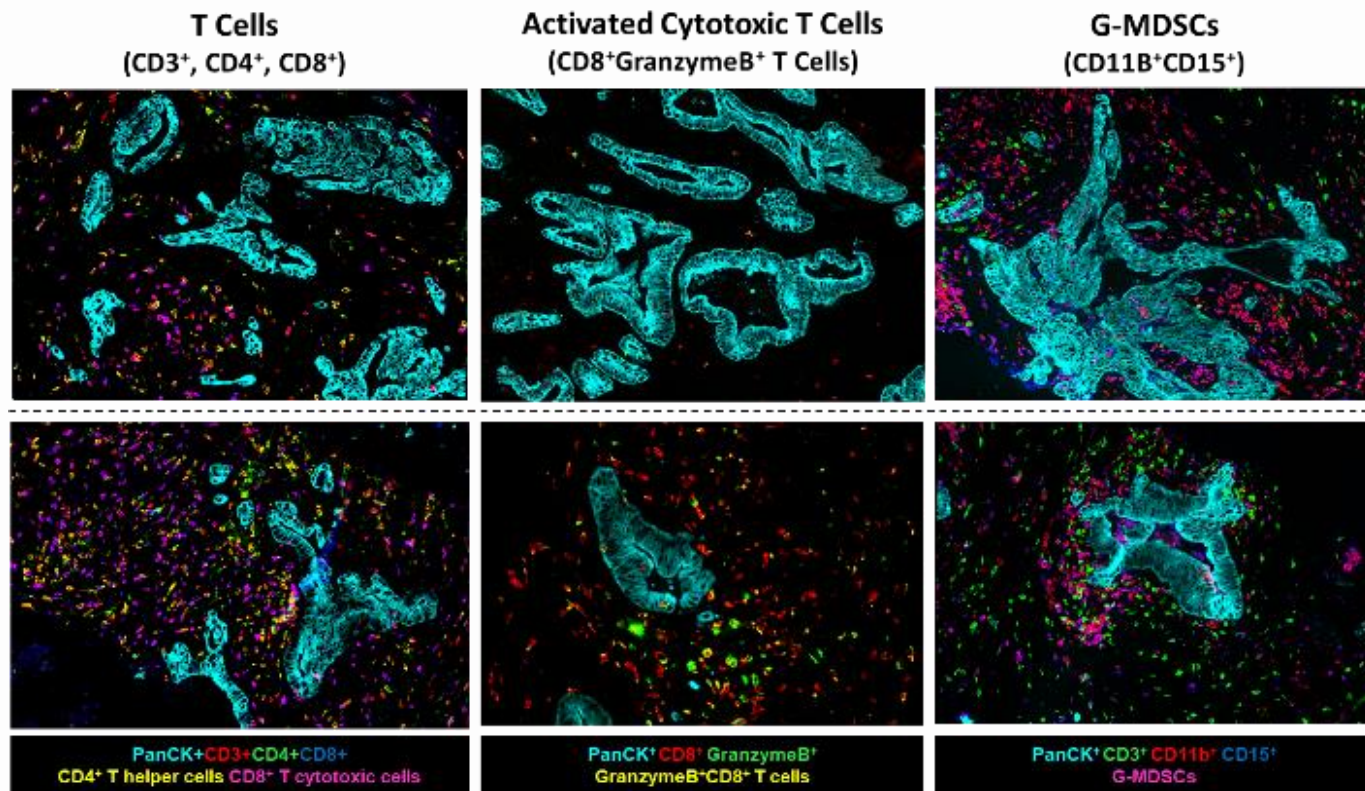


* picture is a sample from one patient

3. BL-8040 Modulates TME and Shifts TME Immuno-Phenotypes

↓MDSCs, ↓Tumor Cells, ↑T cells, ↑Activated CTLs - First Time in PDAC patients

Screening
End Cycle 2



Representative MultiOmyx™ data taken from a patient with SD and long treatment duration (11 combo cycles ~34 weeks)

Data shown before treatment vs. after ~7w of treatment (end of cycle 2)

COMBAT/KEYNOTE-202 – Dual Combination Results

Clinical activity and encouraging mOS in a non chemo-based treatment

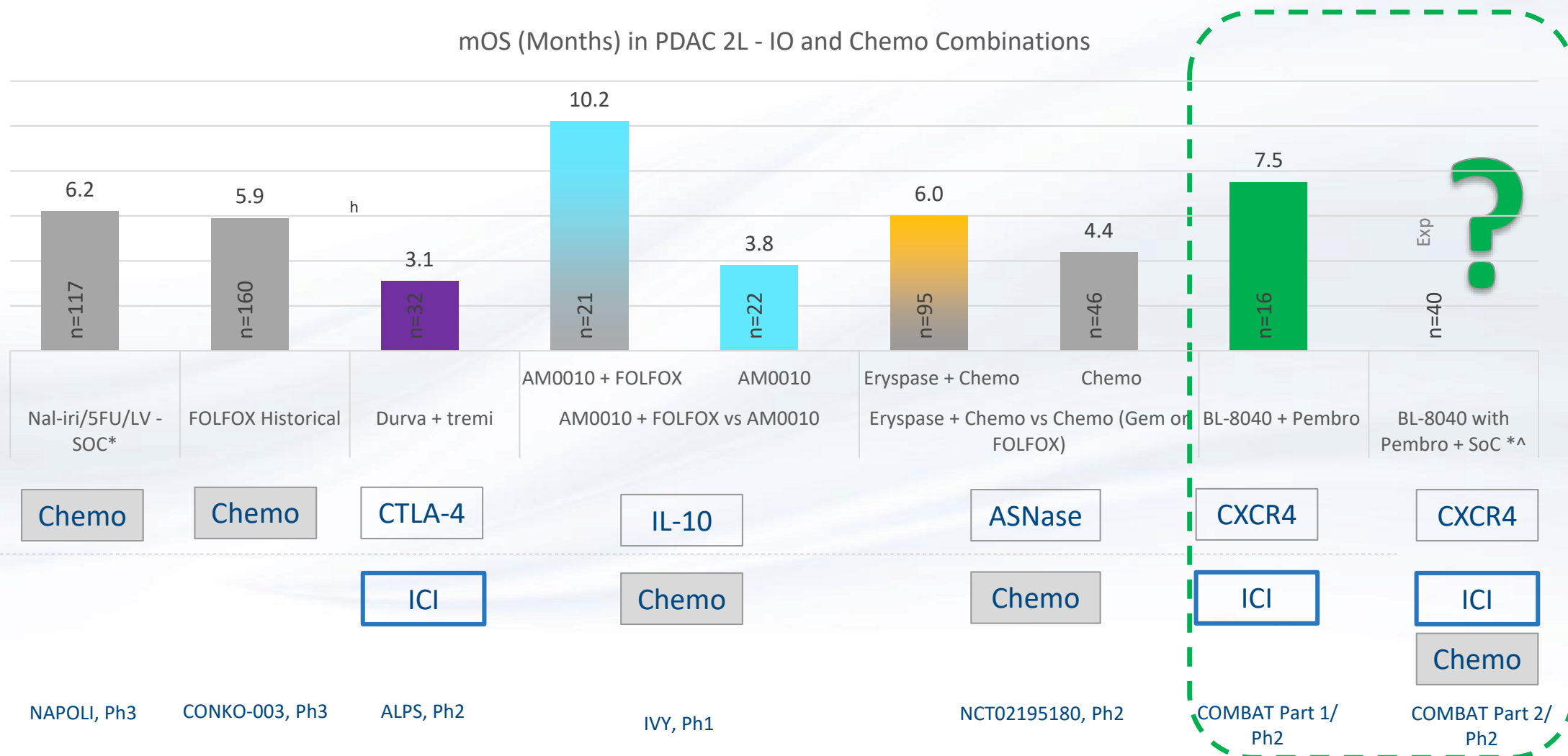
- **34.5%** for 29 evaluable patients showed **disease control** (response + SD):
 - **40% reduction in tumor burden** was seen in 1 patient with partial response
 - **1.5-13% reduction in tumor burden** was seen in 6 out of 9 patients with stable disease
- **34.4%** of patients in all lines of therapy (2L-5L) were still alive after 6 months (N=37), OS: 3.3 months
- **56.3%** of patients in 2L were still alive after 6 months (N=16) OS: 7.5 months
- Safety profile of each individual drug was not compromised by the combination, enabling it to serve as an immunotherapy platform for additional combinations

Encouraging results showing clinical activity, proof of MoA and good safety profile warrant addition of chemotherapy to further improve efficacy



Rationale for Triple Combination

Comparison of BL-8040/Keytruda Dual Combo Results with 2L PDAC SOC and Other Therapies in Development



What Do We See from this Comparison?

- Current approved chemotherapy for 2L metastatic PDAC has limited benefit
 - Onivyde/5FU/LV has mOS=6.2 months, with ORR=17%
- Single-agent immune checkpoint inhibitors have shown disappointing results in PDAC
- Combinations of immune checkpoint inhibitors and chemotherapy in PDAC have not shown any additional benefit to chemotherapy treatment alone
- Dual combination of BL-8040+Keytruda in PDAC showed:
 - Clinical activity
 - Proof of MoA
 - Good safety profile
 - Encouraging survival of immunotherapy regimen in 2L patients (mOS=7.5months, comparable to approved chemo)

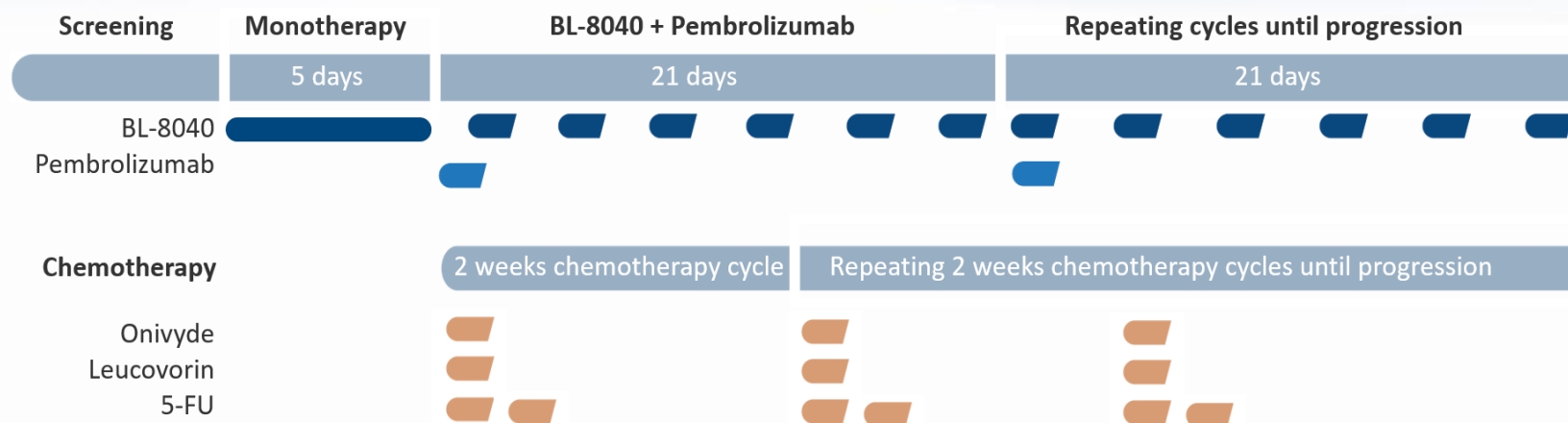
Specific Rationale for Addition of Chemotherapy

- Cytotoxic chemotherapy induces tumor death, reducing tumor burden
- Cytotoxic chemotherapy induces immunogenic cell death, leading to activation/expansion of new tumor-reactive T-cell clones
- BL-8040 induces immune cell trafficking, immune effector T cell infiltration, and TME modulation
- Pembrolizumab maintains/restores activity of T cells within tumor



COMBAT/KEYNOTE-202 Cohort 2 Triple Combination Preliminary Data

Design of Triple Combination Cohort (N=40)



Endpoints

- Objective response rate according to RECIST 1.1 criteria
- Disease control rate
- Progression-free and overall survival
- Safety and tolerability of the combination
- Multiple pharmacodynamic parameters

Response data (DCR, ORR) expected end-2019; Survival data (PFS, OS) expected mid-2020

Triple Combo Cohort – Background to Current Data Set

■ Patient population

- Metastatic PDAC (Stage IV) patients at first diagnosis
- Second-line – progressed after first-line gemcitabine-based treatment

■ Multi-center study conducted in the US, Spain and Israel

■ Data presented based on data cutoff date of September 30, 2019

■ As of data cutoff date:

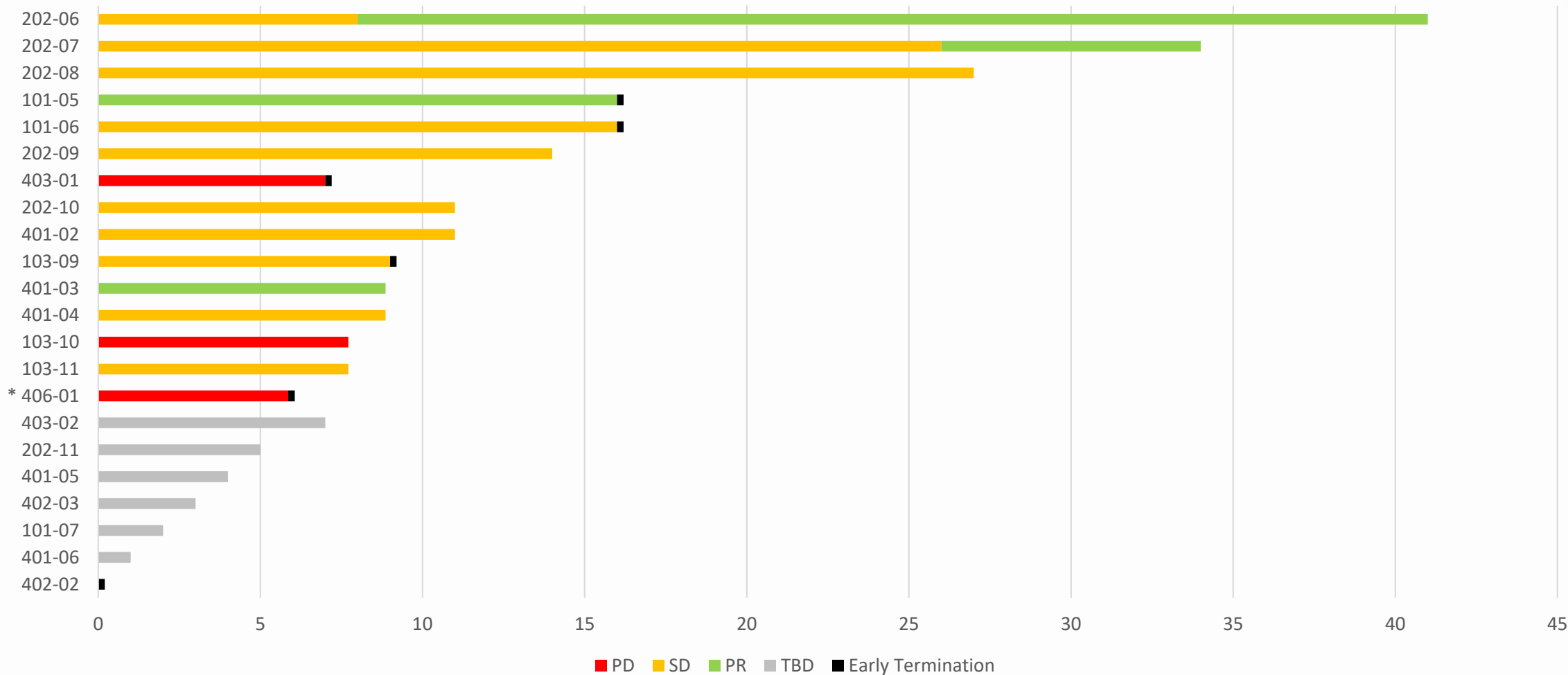
- Total enrolled patients: N=22
- Total evaluable patients*: N=15

■ Combination was generally well tolerated with safety profile consistent with the individual safety profile of each component alone

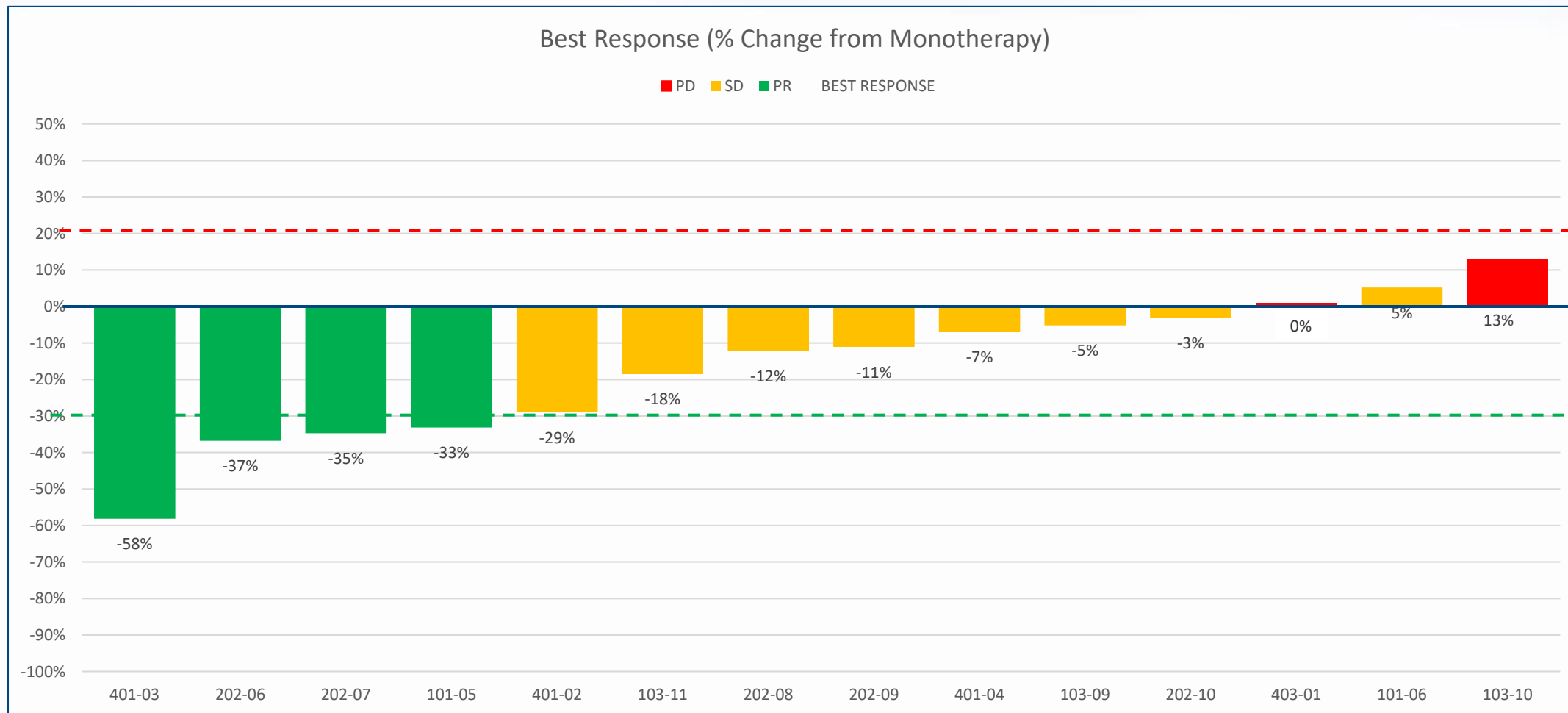
*No. of subjects treated with triple combination and that have a post baseline (D5 monotherapy) assessment or have clinical progression

COMBAT Cohort 2 - Individual Patient Data – Swimmer's Plot (n=22)

Time to Progression (Weeks)

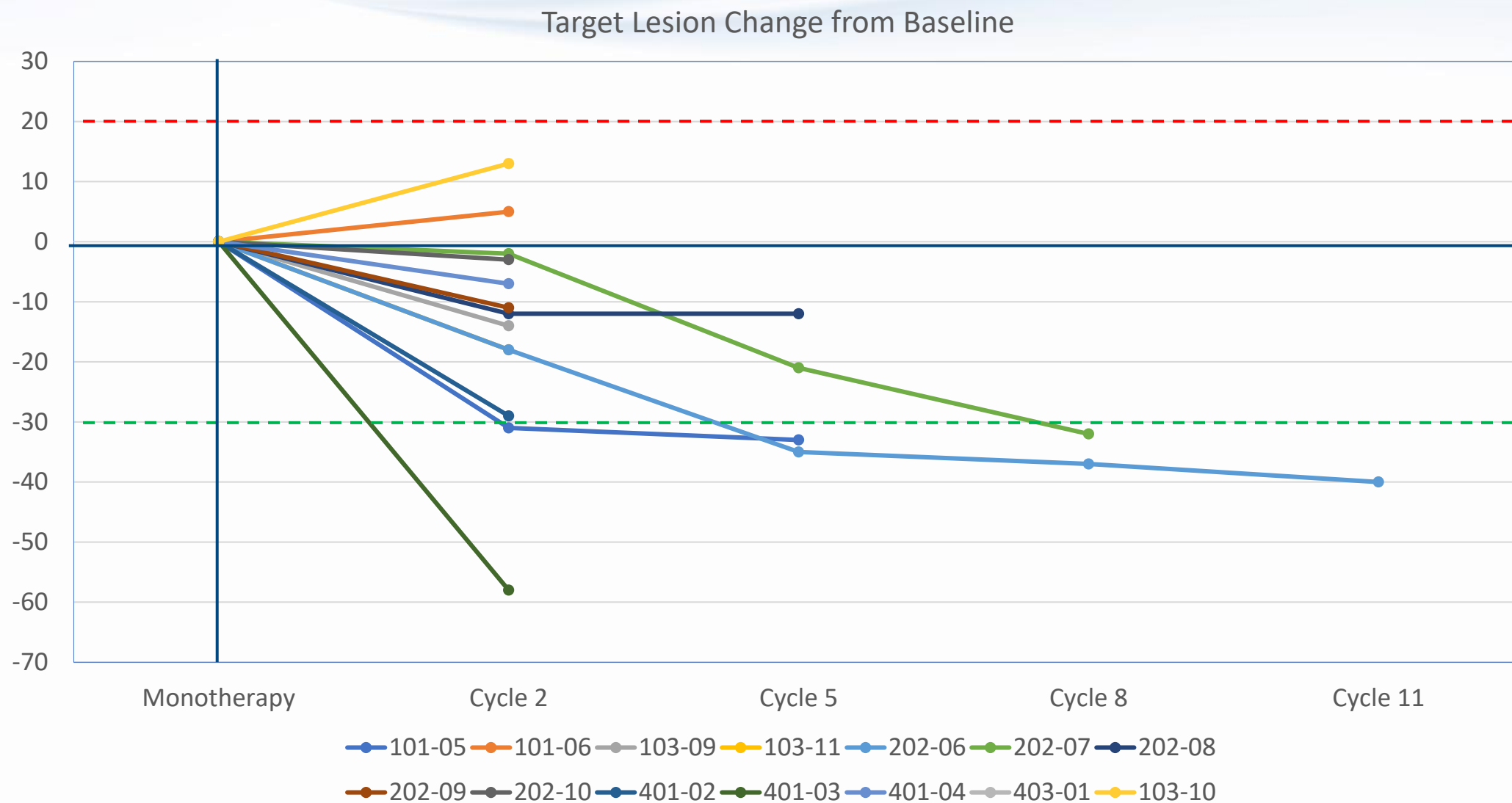


COMBAT Cohort 2 – Waterfall Plot – Change in Target Lesions (n=15*)



*Graph does not include one patient with clinical progression prior to CT scan

COMBAT Cohort 2 – Change in Target Lesions from Baseline (n=15*)



*Graph does not include one patient with clinical progression prior to CT scan

Summary of the Data and Next Steps

- As of today, only one therapy has been approved for second-line pancreatic patients (Onivyde/5FU/LV), with an ORR of ~17%, a DCR of 52% and mOS of 6.2 months
- Preliminary results of our study, **as per the abstract data cutoff of Sep 30, 2019:**
 - Combination was generally well tolerated with a safety profile consistent with the individual safety profile of each component alone
 - Out of 15 evaluable patients, 4 PRs and 8 SDs – resulting in DCR in 12/15 patients
 - Study is ongoing and data on median PFS and OS has not yet been reached
- Survival data remain on track for mid-2020
- Updated data will be presented next week at ESMO IO at an oral presentation



Thank you



Looking ahead

Upcoming Major 2019/2020 Milestones

Multiple opportunities for value creation

BL-8040	Preliminary response data from Phase 2 triple combo pancreatic cancer trial (under collaboration with Merck)	2H 2019	✓
BL-8040	Additional response data from Phase 2 triple combo pancreatic cancer trial	2H 2019	
BL-8040	Interim results from Phase 2b AML consolidation study	1H 2020	
BL-8040	Overall survival results from Phase 2 triple combo pancreatic cancer trial	Mid-2020	
BL-8040	Top-line results from Phase 3 registration trial in stem-cell mobilization	2H 2020	
AGI-134	Initial PoM and other efficacy results from part 2 of Phase 1/2a trial	2H 2020	

Thoughts for the Road

- Pancreatic cancer is a huge unmet medical need
- We are targeting an extremely tough population (i.e., second line) with a much lower benchmark, and we are excited with these excellent results seen so far
- This is the first readout from a triple combination trial in second line metastatic PDAC patients
- Pancreatic cancer is our initial step; we see opportunities in many other 'cold' tumors
- Recruitment almost finished and we eagerly await the duration of response and survival results that will come out mid next year.
- After this trial, we believe this combo would be ready for a pivotal registrational study
- Further development would be done under a collaboration



Q&A