#### SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

#### FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

THE SECURITIES EXCHANGE ACT OF 1934
For the month of December 2017
BioLineRx Ltd.
(Translation of registrant's name into English)
2 HaMa'ayan Street
Modi'in 7177871, Israel
(Address of Principal Executive Offices)
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:
Form 20-F ⊠ Form 40-F □
Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 193
Yes □ No ⊠

On December 5, 2017, the registrant will be hosting an investor breakfast meeting in New York City beginning at 9:00 am EST. At the meeting, the registrant will present updates about its main therapeutic candidates and corporate objectives. The presentation to be made to investors is filed as Exhibit 1 to this Report on Form 6-K

This Form 6-K, including all exhibits hereto, is hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

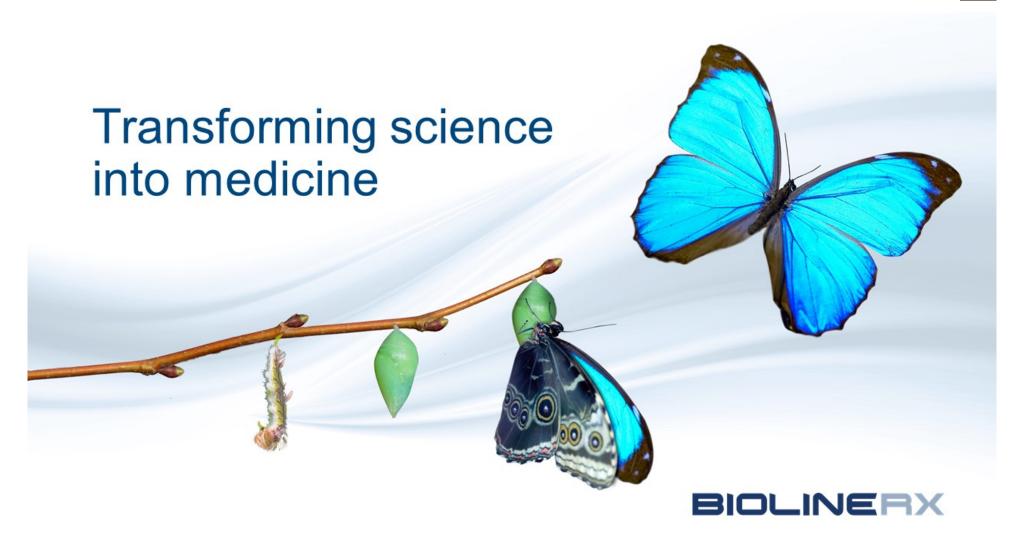
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### BioLineRx Ltd.

By: /s/ Philip Serlin

Philip Serlin Chief Executive Officer

Dated: December 5, 2017



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.





Who are we?

NASDAQ: BLRX

# Oncology and immunology focus

## Lead oncology assets:

- BL-8040
- AGI-134

Immunology franchise with Novartis

## Significant pharma collaborations







## Attractive investment case

## Strong balance sheet

\$55 million (end Q3 2017)

## Significant upcoming milestones:

- Top line combination results from phase 2 COMBAT study in pancreatic cancer
- Results from initial lead-in period of phase 3 GENESIS study in SCM
- Interim analysis from phase 2b BLAST study in consolidation AML
  BIOLINERX





# 2017 achievements

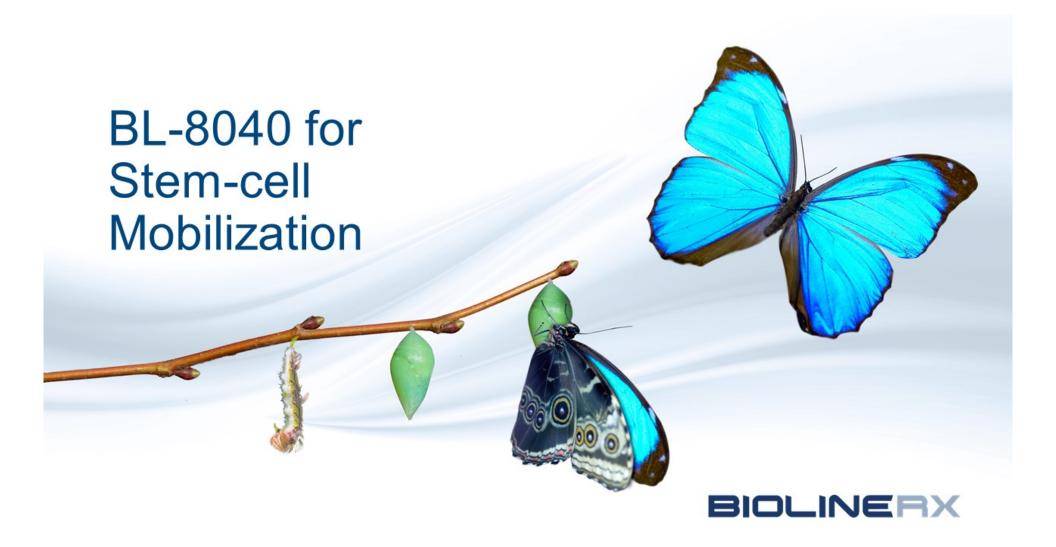


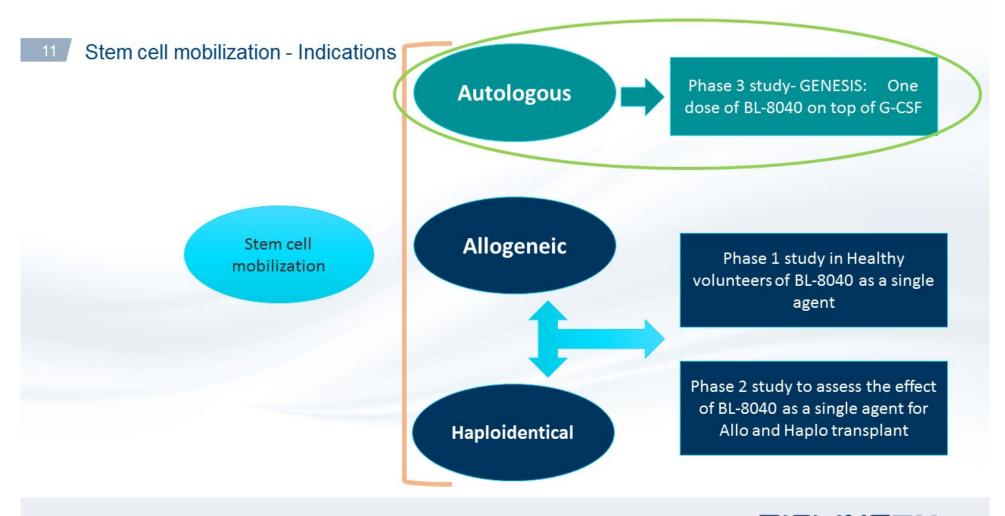
- Completed recruitment for phase 2a COMBAT study in pancreatic cancer (Merck collaboration)
- 3 phase 1b/2 studies initiated under the Genentech collaboration (pancreatic, gastric and AML)
- Reached understandings with FDA on phase 3 registrational study in autologous SCM
- Acquired highly innovative immuno-oncology asset AGI-134 via Agalimmune acquisition
- Continued long-term follow-up for phase 2a study in r/r AML reporting highly encouraging OS data
- Reported successful partial results on phase 2 study in allogeneic SCM
- Presented encouraging data at several top-tier scientific conferences
- Strengthened balance sheet and brought new leading fundamental life science investors to cap table













## GENESIS Phase 3 - Mobilization of SC for autologous transplant in Multiple Myeloma patients

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

#### 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

## **BL-8040** potentially offers patients

- Robust HSC mobilization
- · Single administration on top of SOC
- No more than two apheresis sessions

G-CSF, granulocyte-colony stimulating factor Clinicaltrials.gov. NCT0346529



## GENESIS Study: Phase 3 SCM in Multiple Myeloma patients

Objectives	To demonstrate that the combination of BL-8040 + G-CSF is superior to G-CSF alone in
Primary	The ability of mobilize ≥ 6M CD34+ cells in up to 2 apheresis
Secondary	The ability to mobilize ≥ 2M CD34+ cells in 1 apheresis
Safety and Tolerability	Is safe and tolerable

Other Objectives	The combination will also be tested with regard to:
	Time to engraftment of neutrophils and platelets
	Durability of engraftment





# BL-8040 – Solid Tumors

Mobilizing and promoting infiltration of immune cells and reducing immunosuppression in the tumor microenvironment



# Despite significant advances in cancer immunotherapy, material needs remain:

- Improving the efficacy of immunotherapy in "cold" tumors, such as pancreatic cancer
- Increasing rates and durability of response to existing therapies such as anti-PD1 and anti-PDI 1 antibodies

## BL-8040 may address these needs by:

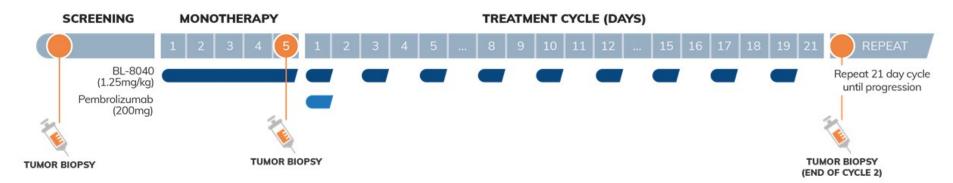
- Mobilization of immune cells into circulation
- Increasing immune cell infiltration into tumors
- Reducing immunosuppression in tumor microenvironment



## COMBAT study: Advanced Pancreatic Cancer

Phase 2a open-label study in combination with Pembrolizumab (n=30): NCT02826484

A Phase 2a, multi-center, open-label study to assess the safety and efficacy of BL-8040 in combination with Pembrolizumab (Keytruda) in patients with advanced pancreatic cancer







## **COMBAT-Objectives**

A phase 2a, multicenter, open-label study to assess the safety and efficacy of BL-8040 in combination with Pembrolizumab (Keytruda) in patients with advanced pancreatic cancer

Objectives	To demonstrate that the combination of BL-8040 and Pembrolizumab			
Primary	Induces responses assessed as <u>overall response</u> (CR+PR)			
Secondary	Prolongs the <u>progression free survival</u> (PFS)			
	Prolongs the <u>overall survival</u> (OS)			
Safety and Tolerability	Is safe and tolerable			

Other Objectives	Assessment of
	Disease control assessment (CR+PR+SD)
	Biomarkers for monotherapy and combination treatment
	Biopsy assessment for infiltration
	Immunophenotyping

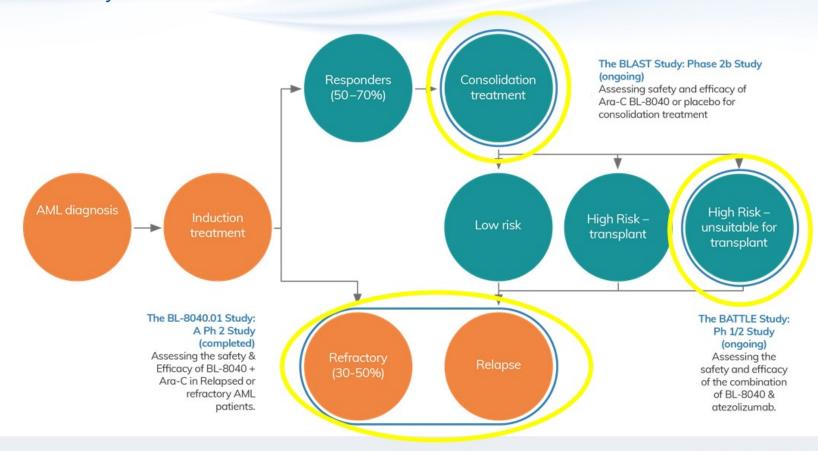


## Participating Sites and PIs

Site	City/Country	PI	Patients enrolled
Beth Israel Deaconess MC	Boston/US	M – study PI-	6
Rambam MC	Haifa/Israel	aum	5
Tel Aviv Sourasky MC	Tel Aviv/Israel	nt Geva	4
Sheba MC	Ramat Gan/ Israe	Talia Golan	4
Rabin MC	Petach Tik	Solomon Shtemer	4
Dana Farber Cancer Institute	Bos CO	Brian Wolpin	4
Washington University of St Louis	N	Katrina Pedersen	2
Honor Health Research Institute	r Izona/US	Erkut Borazanci	3
Samsung MC	Tel Aviv/ Israel Ramat Gan/ Israel Petach Tile Boe Arizona/US Seoul/ South Korea Arizona/US	Joon Oh Park	2
Mayo Clinics	Arizona/US	Mitesh Borad/ Ramesh Ramanathan	2
Ochsner MC	New Orleans/LA	Robert Ramirez	1
Massachusetts General Hospital	Boston/US	David Ryan	0
Baylor Charles A. Sammons Cancer Center	Dallas/US	Carlos Becerra	NER



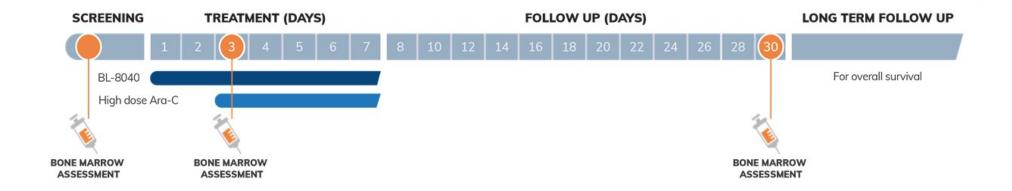
## Acute Myeloid leukemia-Treatment Lines





## Study BL-8040.01: Encouraging results in patients with relapsed/refractory AML

Phase 1/2a dose escalation/expansion study (n=42): NCT01838395



## Study design

Dose escalation (0.5 to 2.0 mg/kg) with expansion cohort at 1.5mg/kg

CR, complete response; CRi, complete response with incomplete hematological recovery; AML, Acute Myeloid Leukemia



## BL-8040.01 for Relapse/Refractory AML-Key Findings

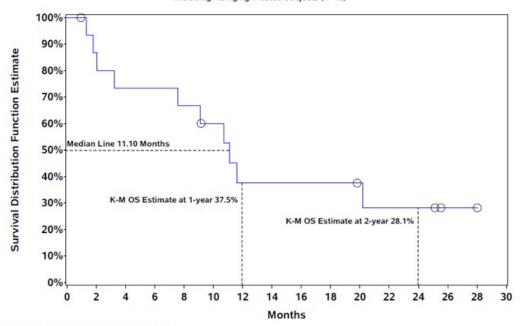
Population	Relapsed or refractory AML patients including patients after allogeneic transplantation				
Primary Endpoint	Safety and Tolerability	BL-8040 was found to be safe and well tolerated in combination with high dose cytarabine			
Secondary endpoint	Composite Response rate of 38% in subjects receiving BL-8040 dose ≥1.0 mg/kg (n=39), compared to 16.3 % with cytarabine according to historical data*				
Exploratory endpoint	BL-8040 was found to be pro-apoptotic as a single agent				
	BI-8040 was found to mobilize blasts to the peripheral blood				

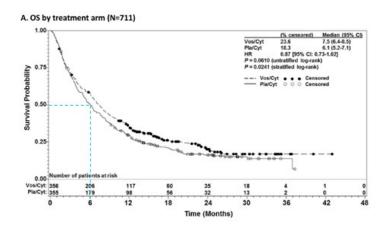
<sup>\*</sup>VALOR Study, Ravandi et al.



## BL-8040.01- Overall Survival in R/R AML patients treated with BL-8040 +HiDAC

#### Overall Survival (OS) in BL-8040.01 – rrAML study Kaplan-Meier (K-M) Methodology Including 1.5mg/kg Treated Subjects (N=16)





Ravandi et al.

Circles displayed identify censoring pattern



24

**BONE MARROW** 

ASSESSMENT

## BLAST study: Consolidation therapy in AML patients in first remission

Phase 2b double-blind, placebo controlled study (n=194): NCT02502968

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

TREAMENT CYCLE (DAYS)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

PL 9040

BL-8040
Ara-C

Complete cycle two-three times (age dependant)

ASSESSMENT
End of treatment,
6 months,
9 months,

**ASSESSMENT** 

12 months and 18 months

**BONE MARROW** 

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





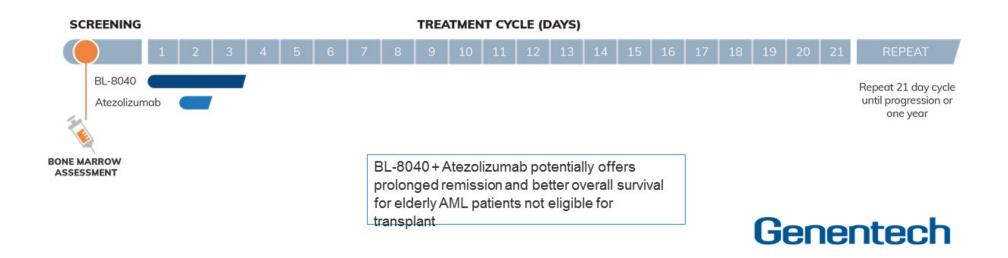
Objectives	To demonstrate that the combination of BL-8040 High Dose Cytarabine (HiDAC)
Primary	Prolongs the Relapse free survival
Secondary	Reduces the minimal residual disease (MRD)
	Prolongs the Overall survival
Safety and Tolerability	Is safe and tolerable.



## BATTLE study – Combination of BL-8040 and Atezolizumab in AML patients at a high risk of relapse

Phase 1b/2 single arm, open-label study (n=60): NCT03154827

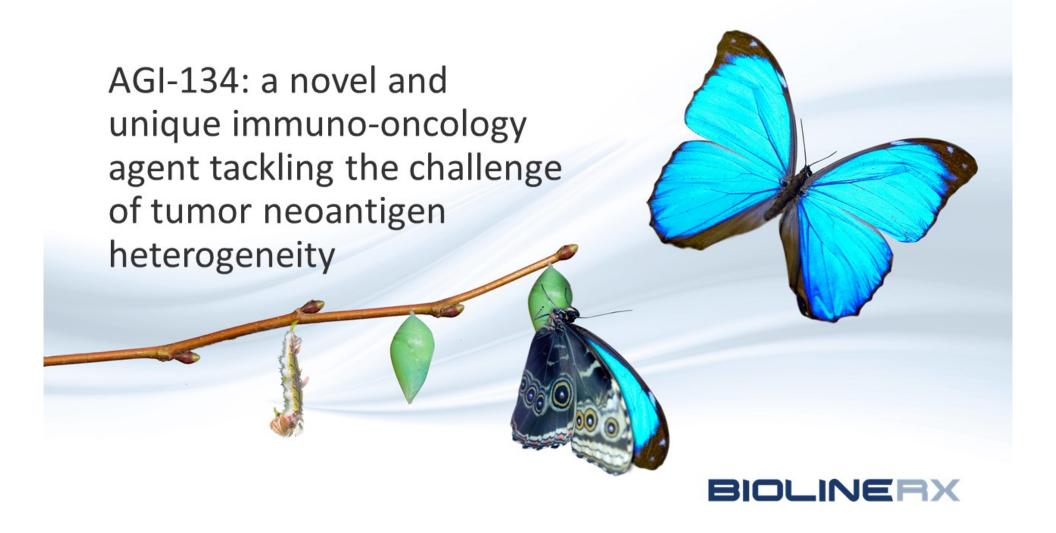
A Phase 1b/2, multi-center, single arm, open-label study, to evaluate the safety and efficacy of BL-8040 in combination with Atezolizumab for maintenance treatment in AML patients of 60 years or older that are not fit for transplant



BIOLINERX

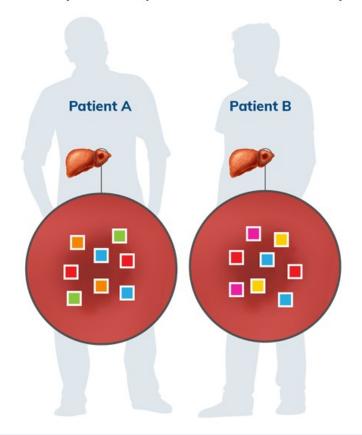
Objectives	To demonstrate that the combination of BL-8040 and Atezolizumab				
Primary	Prolongs the relapse free survival (RFS) time as compared to historical data.				
Secondary	Reduces the minimal residual disease (MRD)				
	Prolongs the Overall Survival (OS) time as compared to historical data.				
	Prolongs the time to first relapse as compared to historical data.				
Safety and Tolerability	Is safe and tolerable.				





## AGI-134 – Harnessing pre-existing immunity to deliver a patient-specific anti-tumor response

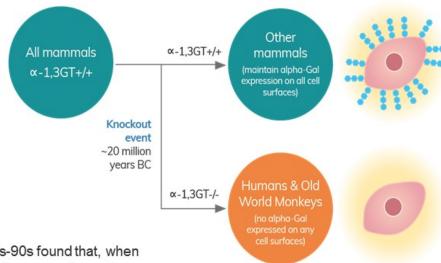
- Tumors vary from patient to patient in their neoantigen load and identity
- AGI-134 is a universal drug that evokes a vaccine effect via a unique, hyperacute, multi-arm mechanism that targets patient-specific neoantigens





## alpha-Gal and anti-Gal

- The alpha-Gal epitope is abundantly synthesized on glycolipids of nonprimates
- Due to constant exposure to this antigen (expressed by gut flora) humans develop and maintain high levels of anti-Gal Abs



Xenotransplantation experiments in the 1980s-90s found that, when introduced to humans, the alpha-Gal-positive tissue was bound by pre-existing human anti-Gal antibodies, which were the main cause of the rejection, e.g. of porcine heart valves

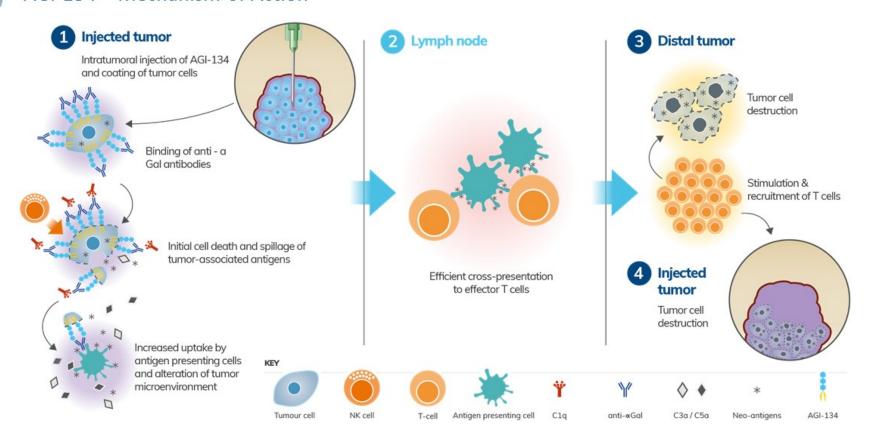


A fully synthetic a-Gal glycolipid molecule for intratumoral injection into solid tumors, to induce an immune response against a patient's own neoantigens





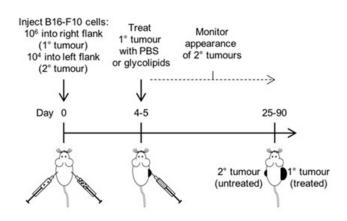
## AGI-134 - Mechanism of Action

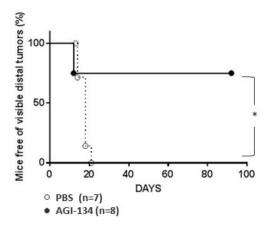


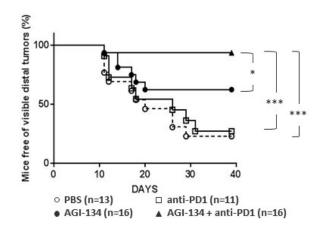


## Compelling Pre-Clinical Data Supports Phase I Study due 1H 2018

- A single dose of AGI-134 into a primary tumor protected mice from secondary tumor development for more than 90 days
- Combination of AGI-134 with an immune checkpoint inhibitor (anti-PD-1) resulted in increased efficacy over either agent's monotherapy effect







AACR 2017 poster 616 ASCO 2016 poster 3083 AACR 2016 poster 4862



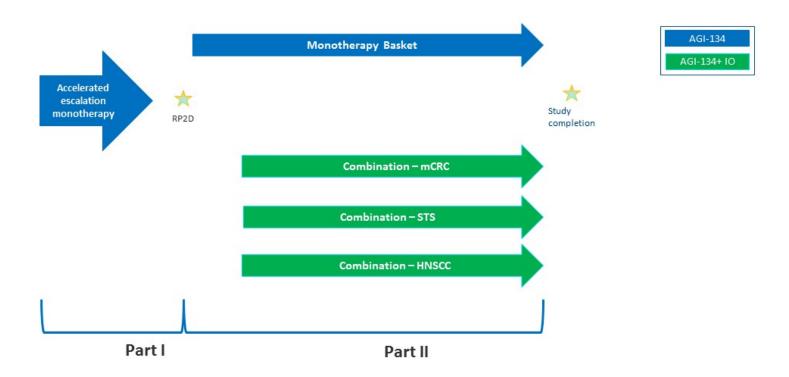
## How is AGI-134 differentiated from competitors?

Pa	Yearlink Gene	Personality 1	ILR ODONISTS INC.	Oncolytic Alice	, ses
Evokes <b>personalized</b> anti-tumor immunity	<b>✓</b>		✓	✓	<b>✓</b>
Targets a multitude of patient-specific neoantigens	✓			✓	✓
Does not require <b>complex ex vivo processing</b> or computer modelling	✓			✓	
Harnesses pre-existing antibodies	<b>✓</b>	✓			
Directly labels the treated tumor for destruction	<b>✓</b>				
Activates the <b>complement cascade</b> , creating a <b>proinflammatory TME</b>	✓				

<sup>\*</sup>NewLink Genetics were developing a whole-cell cancer vaccine using alpha-Gal to boost immunogenicity. As whole-cell cancer vaccines do not target patient-specific neoantigens and do not alter the TME, they failed in Ph 3



## High level outline of Phase 1/2a clinical study



RP2D = Recommended Phase 2 Dose

STS = Soft Tissue Sarcoma

mCRC = Metastatic Colorectal Cancer

HNSCC = Head and Neck Squamous Cell Carcinoma



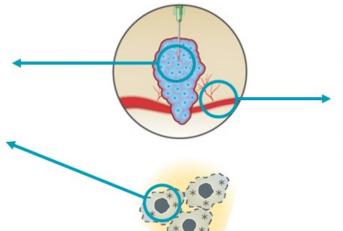
## AGI-134 - Immune monitoring strategy

A comprehensive immune monitoring strategy that aims to:

- Assess how immune status at baseline affects response to treatment
- Assess how immune status changes in response to treatment
- · Identify markers that are predictive of patient response to treatment

#### Treated and distal tumors:

- Level and composition of immune infiltrate & change with treatment
- Changes in infiltrating T cell repertoire
- Changes in inflammatory signature



#### Peripheral blood:

- Anti-Gal antibody titer and change with treatment
- · Changes in circulating T cell repertoire
- Changes in pro-inflammatory mediators

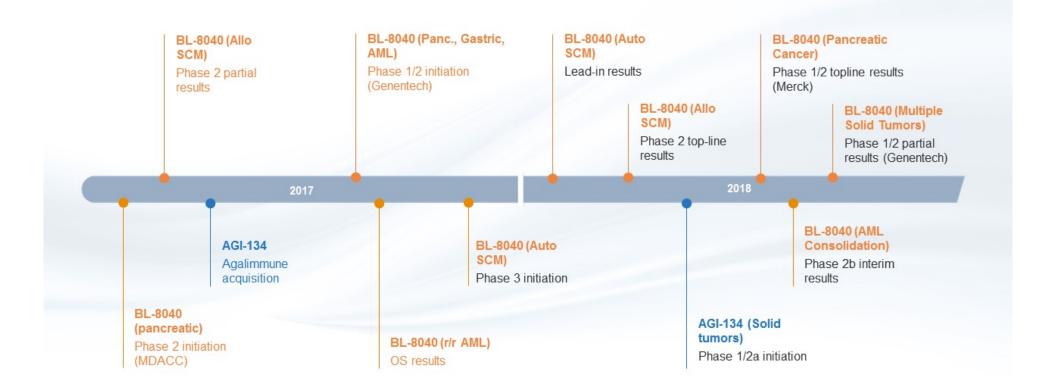




# Looking ahead

BIOLINERX

## Principal Milestones for 2017/2018





## Looking into the upcoming year

- Multiple read-outs during 2018: COMBAT top line results, Phase 3 lead-in results and potential BLAST interim results
- Continue to lay foundations for future events: Phase 3 in SCM, AGI-134 initiation
- Company expecting to meet previously-stated timelines
- Expecting continued collaborations with leading global pharma companies in 2018





# Long-term vision



#### BioLineRx in Five Years

Our plan is to become a significant player in the biotech industry

- With critical mass of advanced projects in development
- Alongside portfolio of revenue-generating assets

We intend to achieve the following:

- 2-3 products in the market, with material amount of sustainable revenues
- Pipeline of 3-5 clinical stage assets
- Full infrastructure to advance assets through registration and market launch
- Expansion of strategic collaborations with global pharma companies, with direct access to cutting edge technologies
- One or more significant out-licensing deals with global pharma company
- Execute strategic transactions as opportunities arise (in addition to traditional in-licensing model)

