# 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**

***For the month of February 2019***

## 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 1934:

**Yes** ☐ **No** ☒

**Item 7.01. Regulation FD Disclosure**

A copy of the Management Presentation of BioLineRx Ltd. (the "Company") is furnished as Exhibit 99.1 to this Item 7.01.

The information contained in Item 7.01 of this report and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On February 4, 2019, the Company issued a press release announcing that it has commenced an underwritten offering of American Depositary Shares ("ADSs"), each representing one of its ordinary shares, par value NIS 0.10 per share with each ADS to be sold together in a fixed combination with a warrant to purchase ADSs. pursuant to a preliminary prospectus supplement, dated February 4, 2019 to the Company's prospectus dated January 19, 2018, filed as part of its effective shelf registration statement on Form F-3 (File No. 333-222332) previously filed with, and declared effective by, the Securities and Exchange Commission.

The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering. A copy of the press release is furnished as Exhibit 99.2.

This Current Report on Form 6-K shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities described above in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following Exhibits are filed as part of this report:

| Exhibit No. | Description of Exhibit |
|---|---|
| 99.1 | Company Presentation |
| 99.2 | Press Release dated February 4, 2019 |

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: February 4, 2019

Exhibit 99.1

# Transforming science into medicine

BIOLINERX

## 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.

## Offering Summary

| | |
|---|---|
| Issuer | BioLineRx Ltd. (NASDAQ:BLRX; TASE:BLRX) |
| Offering size | $15 million |
| Offering type | Confidentially marketed public offering (CMPO) |
| Securities offered | American depositary shares (1 ADS = 1 ordinary share) and warrants to purchase ADSs |
| Use of proceeds | • BL-8040 – complete phase 3 in SCM; complete phase 2 trial in consolidation AML; complete phase 2 trials in pancreatic cancer and gastric cancer<br>• AGI-134 – complete phase 1/2a in solid tumors (monotherapy and combo arms) |
| Expected pricing | February 5, 2019 (before market opens) |
| Sole bookrunner | Oppenheimer & Co. Inc. |

# Our Mission

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

## Who are We?

| Ticker / Exchange | BLRX (NASDAQ) |
|---|---|
| Headquarters | Tel Aviv, Israel |
| Market cap | ~$70 million (25-Jan-19) |
| Shares outstanding | ~115 million |
| Cash | ~$35 million (30-Sep-18) |
| Cash runway | Through 1H 2020 |
| Employees | 45 (35 in R&D) |

## Investment Highlights

| | |
|---|---|
| **Singular focus on novel oncology compounds** | ➢ Large-market indications with unmet medical needs<br>➢ BL-8040 program in phase 3 for SCM; phase 2 for AML, pancreatic cancer/other solid tumors<br>➢ AGI-134 program in phase 1/2a for solid tumors |
| **Multiple opportunities for value creation** | ➢ 8 mid-to-late stage clinical studies ongoing<br>➢ 3-4 data readouts over next 12 months<br>➢ Phase 3 registrational topline data expected in 2020 |
| **Validation via significant pharma collaborations** | ➢ Merck/MSD (established Jan 2016; expanded Jul 2018)<br>➢ Genentech (established Sep 2016) |
| **Compelling valuation** | ➢ ~$70 million market cap<br>➢ ~$35 million cash as of 3Q 2018<br>➢ Cash runway through 1H 2020 |

SCM – stem cell mobilization; AML – acute myeloid leukemia

# A Diverse Pipeline Targeting Multiple Oncology Indications

# BL-8040 – Best-In-Class CXCR4 Antagonist for Multiple Oncology and Hematology Indications

For treatment of solid tumors, AML and indications requiring hematopoietic stem cell transplantation

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# BL-8040 – A Best-in-Class CXCR4 Antagonist Targeting Multiple Indications

- A 14-amino acid synthetic cyclic peptide, high-affinity CXCR4 antagonist with long receptor occupancy (>48 hours)
- CXCR4 is over-expressed in more than 70% of cancers and its high expression levels correlate with disease severity
- CXCR4 and its ligand CXCL12 (SDF-1) play a critical role in the trafficking of CXCR4 expressing cells such as HSPCs, immune cells and cancer cells

## Phase 3

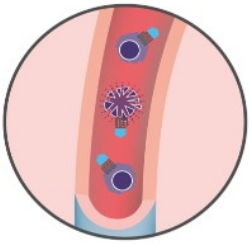
### Stem Cell Mobilization for Multiple Myeloma

*Robust mobilization of HSPCs cells for transplant*

## Phase 2

### Acute Myeloid Leukemia

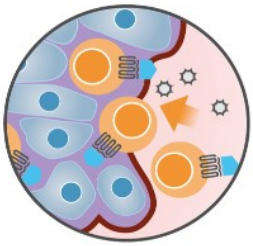
*Mobilization of leukemic cells from bone-marrow protective niche, sensitization to anti-cancer treatment and induction of apoptosis*



## Phase 1 & 2

### Cancer Immunotherapy for Solid Tumors

*Mobilization of immune cells to peripheral blood; infiltration of immune T cells into tumor; reduction of immunosuppression in tumor microenvironment*




HSPC – Hematopoietic stem and progenitor cell

# BL-8040 in Stem Cell Mobilization

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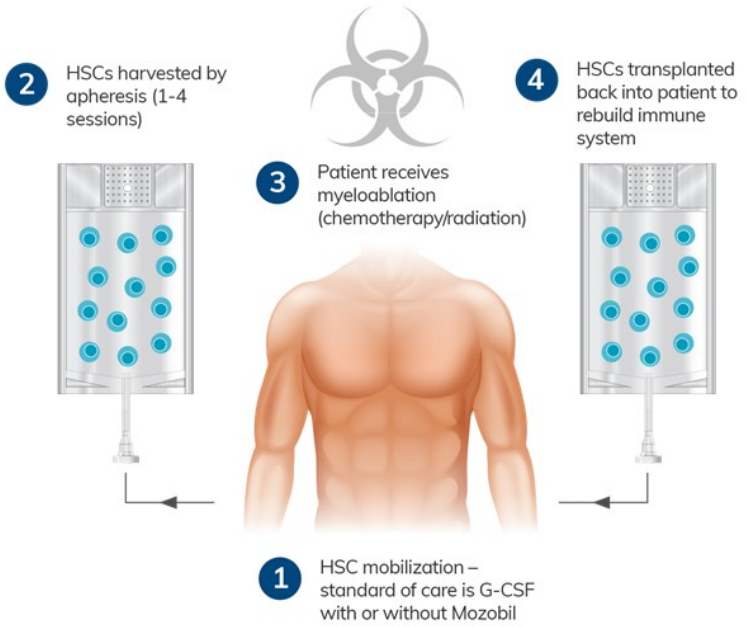
# Stem-Cell Mobilization or Patients Undergoing Autologous Hematopoietic Stem Cell Transplantation

**Patients with hematological malignancies often require HSC transplant after treatment to restore their immune system**

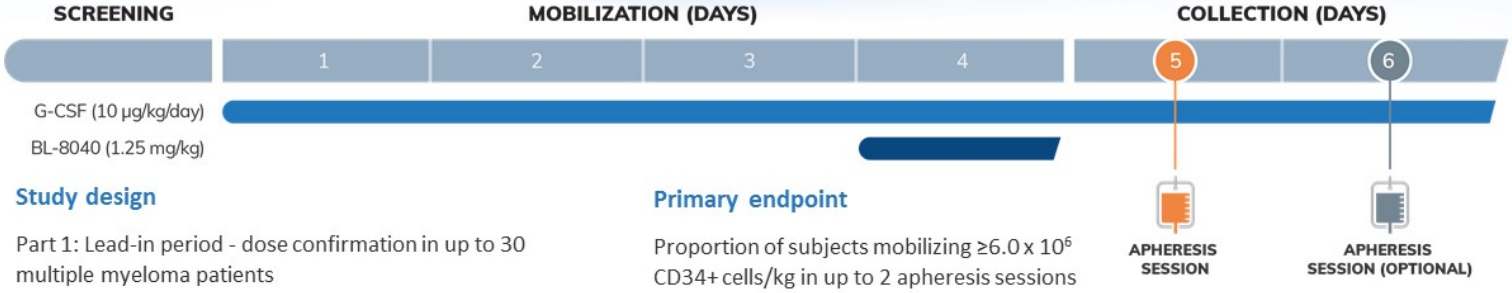



- **Significant unmet medical need in SCM**
  - Multiple apheresis sessions required
  - 50-70% of patients are poor mobilizers
  - For poor mobilizers, 1-4 daily injections of Mozobil on top of G-CSF are required
- **BL-8040 potentially offers a more effective and convenient mobilization option for patients**
  - Robust HSC mobilization
  - Single administration on top of SOC
  - No more than 1-2 apheresis sessions


HSC – hematopoietic stem cell; SCM – stem cell mobilization

# GENESIS Phase 3 Study: Mobilization of HSCs for Autologous Transplantation in Multiple Myeloma Patients

Initiated 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

## Primary endpoint

Proportion of subjects mobilizing ≥6.0 x $10^6$ 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 ≥6x$10^6$ 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 >6x$10^6$ CD34 cells/kg in up to 4 apheresis***
- **DMC recommended early initiation of the double-blind, randomized, placebo-controlled part 2 of trial**

***Our goal is for BL-8040 on top of G-CSF to become the new standard-of-care in this field***

# BL-8040 in AML

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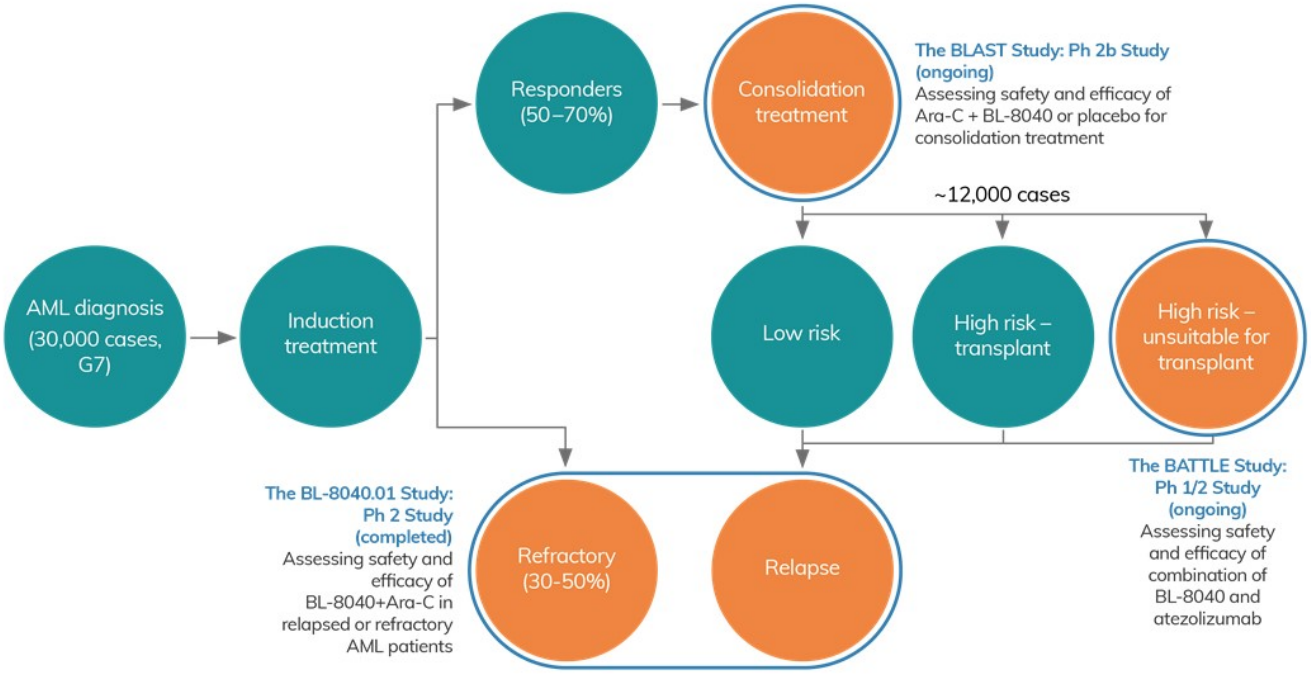
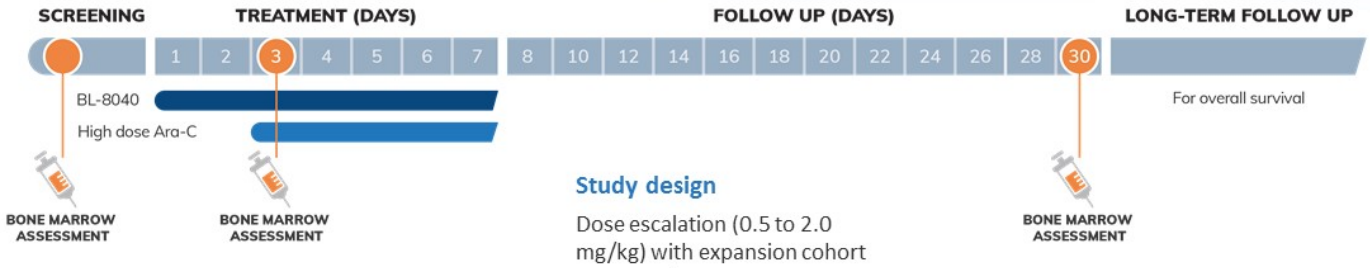
# BL-8040's Potential Role in AML Treatment Landscape



# BL-8040.01 Phase 1/2a Study: 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

**Efficacy Results for dose selected for expansion (n=23, 1.5 mg/kg)**

1. **39% composite CR (CR+CRi)**
2. **10.7 months median OS, as compared to historical data* of 6.1 months for patients treated only with high-dose Ara-C**
3. **Correlation between response and: (i) mobilization of AML blasts from bone marrow to peripheral blood; (ii) frequency of granulocytes in bone marrow**

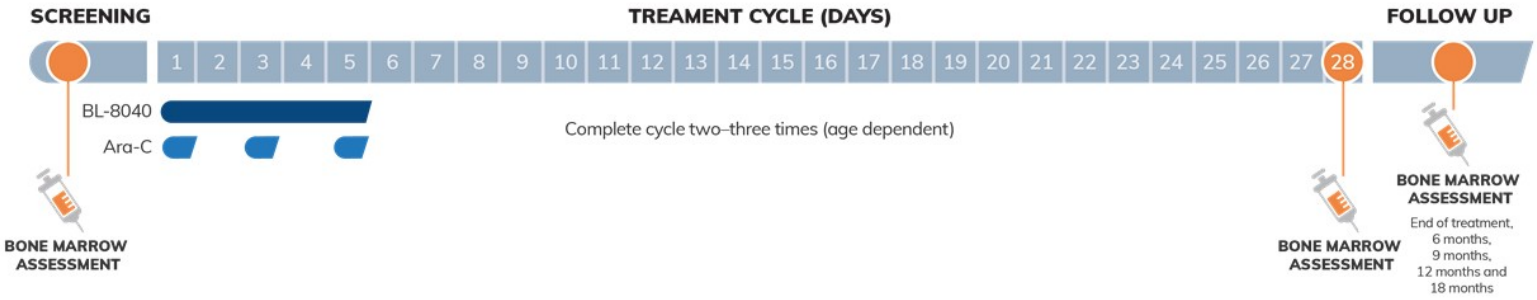
* Ravandi F, *The Lancet Oncology*, 2015;16 (9):1025–1036.

CR, complete response; CRi, complete response with incomplete hematological recovery

# BLAST Phase 2b Study: Consolidation Therapy for AML Patients in First 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**

SAL Studienallianz Leukämie

# BL-8040 in Cancer Immunotherapy

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# BL-8040 – Addressing Unmet Needs in Cancer Immunotherapy

**Despite significant advances in cancer immunotherapy, material unmet needs remain:**

- Improving 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-PDL1 antibodies

**BL-8040 addresses these needs by:**

- Mobilizing immune cells to peripheral blood circulation
- Increasing immune cell infiltration into tumors
- Reducing immunosuppression in tumor microenvironment

# Ongoing Collaborations with Global Pharma Companies Validate BL-8040's Novel Mechanism of Action

NCT02826484, NCT03193190, NCT03281369, NCT03154827

## MERCK

- COMBAT Phase 2a study for BL-8040 + pembrolizumab (Keytruda®)
  - Study in metastatic pancreatic cancer
- Open-label multi-center study
- Commenced Sep-16; top-line results of BL-8040-Keytruda combination announced Oct-18
- **Collaboration expanded in July 2018 to include additional cohort with triple combo of BL-8040, Keytruda + chemotherapy**

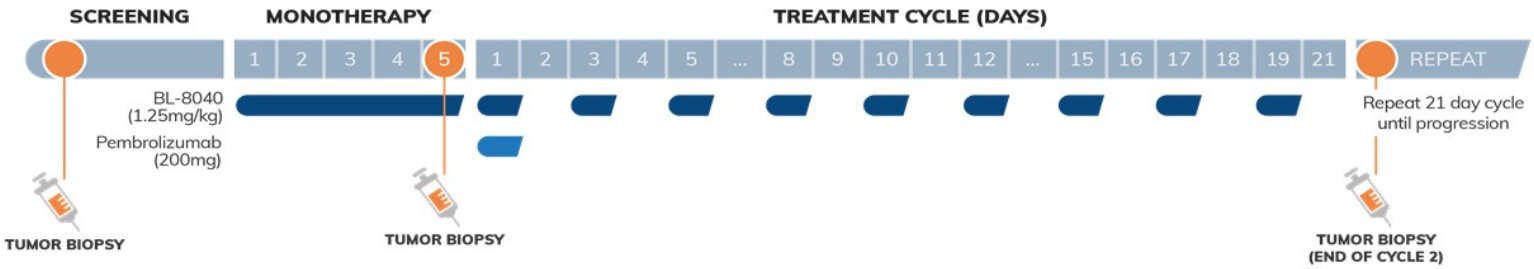
## Genentech

- Four phase 1/2 studies planned for BL-8040 + atezolizumab (Tecentriq®)
  - 3 studies in solid tumors (pancreatic, gastric, NSCLC)
  - 1 study in AML
- Open-label multi-center single arm studies
- Pancreatic and gastric studies commenced H2 2017

# COMBAT/KEYNOTE-202 Phase 2a Study in Advanced Pancreatic Cancer

**Phase 2a open-label, multi-center study in combination with pembrolizumab (n=37): NCT02826486**

To assess the safety and efficacy of BL-8040 in combination with pembrolizumab (Keytruda) in patients with advanced pancreatic cancer




## 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

MERCK

RECIST - Response Evaluation Criteria in Solid Tumors

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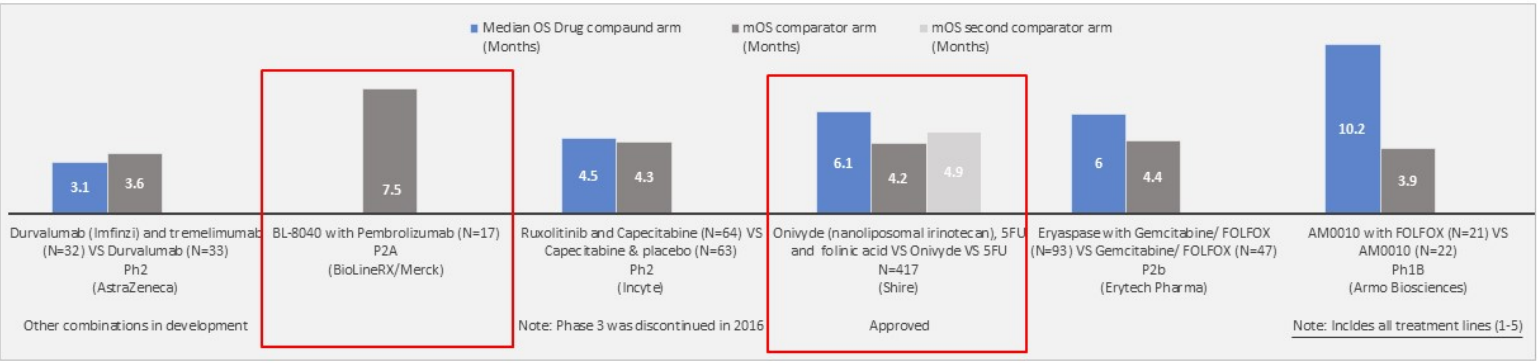
## COMBAT/KEYNOTE-202 Phase 2a Study – Dual Combination Results

- **34.5%** for 29 evaluable patients showed **disease control activity** (response + stable disease):
  - **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)
- **51.1%** of patients in 2L were still alive after 6 months (N=17) 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
- Mechanism of action demonstrated by the combination:
  - Increased activated cytotoxic T cells
  - Decreased myeloid derived suppressor cells in tumor microenvironment
  - Reduction in tumor cell numbers

# Encouraging Results – Comparison with Other Second Line Treatments

- In a number of clinical studies, Keytruda alone has not demonstrated any activity in PDAC
- The COMBAT results show extended disease control and survival for combination of BL-8040+Keytruda, with a very good safety and tolerability profile

## Overall survival results of second-line in COMBAT vs other trials in PDAC

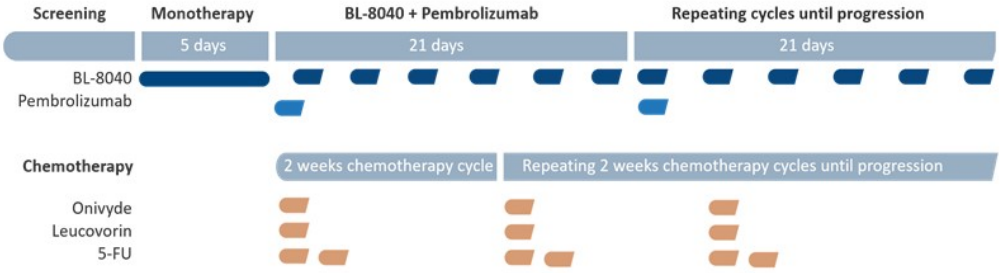



**BL-8040+Keytruda, as non-chemo combination, showed better OS than the only approved second-line chemotherapy, as well as other chemo monotherapy treatments seen in a number of clinical trials**

# Addition of Chemotherapy – Rationale and Design

- 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 facilitates infiltration of T cells into tumor core
- Pembrolizumab maintains/restores activity of T cells within tumor

## Design of additional cohort:




### 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

# AGI-134 – Cancer Immunotherapy

A universal anti-cancer vaccine with a unique mechanism of action

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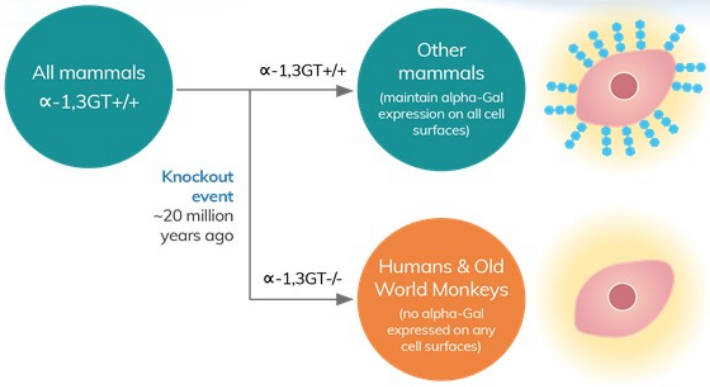
# What is the Alpha-Gal and Anti-Gal story?



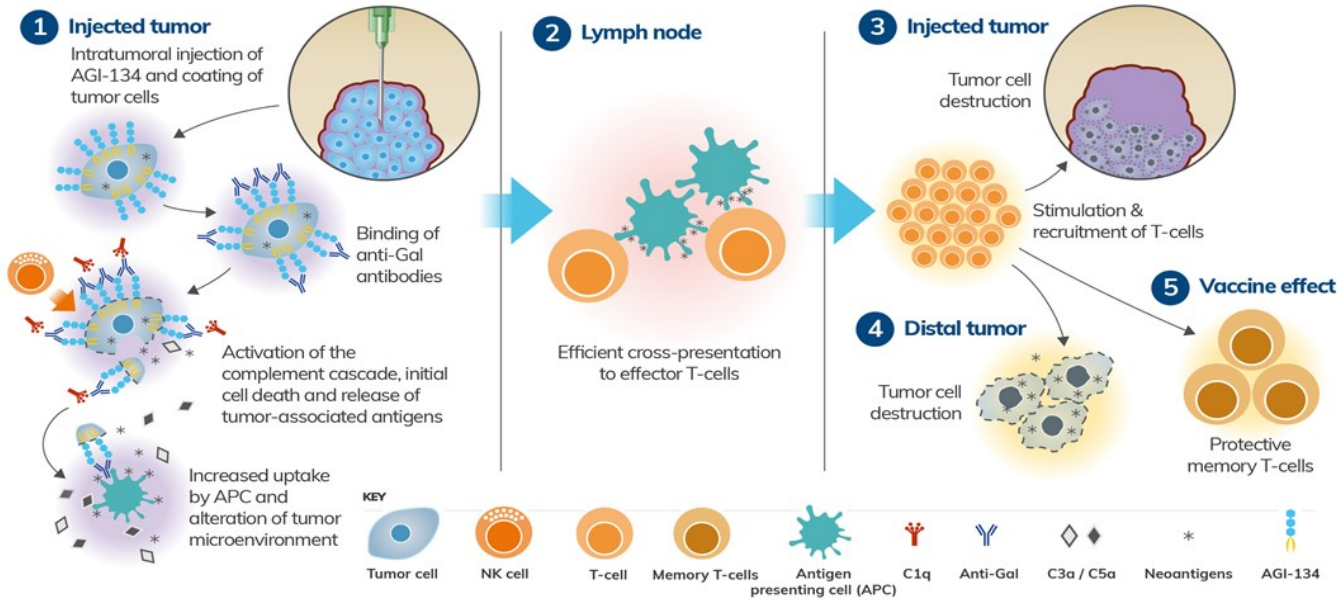


Xenotransplantation experiments in the 1980's-90's found that, when introduced to humans, the alpha-Gal-positive tissue was bound by **pre-existing** human anti-Gal antibodies, which were the main cause of the rejection of porcine heart valves

**AGI-134 coats tumor cells with alpha-Gal to make them look like foreign tissue and harness the pre-existing immune machinery, to evoke an immune response against the tumor**

**AGI-134: a fully synthetic alpha-Gal glycolipid for IT injection**

# AGI-134 – Mechanism of Action




**AGI-134 directs pre-existing anti-Gal antibodies to the tumor and induces activation of multiple immune system effector arms against the patient's own neoantigens**

# AGI-134: A unique MOA Among Intratumoral Agents

| | Oncolytic viruses (e.g.: T-Vec) | PAMPs (e.g.:TLR-9 and STING agonists) | AGI-134 |
|---|---|---|---|
| Injected tumor cells identified by **naturally occurring pre-existing antibodies** | | | ✓ |
| Antibody-bound tumor cells **destroyed by activated CDC and ADCC** | | | ✓ |
| Tumor **neoantigens release** by tumor cell lysis | ✓ | | ✓ |
| Generation of **IgG-tagged immune complexes,** which activate antigen presenting cells (APCs) | | | ✓ |
| The antibody-activated complement system creates **pro-inflammatory milieu in the tumor microenvironment** | | | ✓ |
| Complement **chemo-attractants** recruit immune cells to the tumor | | | ✓ |
| Activation of antigen presenting cells and increased **uptake of tumor antigens** | ✓ | ✓ | ✓ |
| APCs induce a follow-on systemic immune response by the **stimulation and clonal expansion of T cells** | ✓ | ✓ | ✓ |

**Intratumoral immunotherapies have validated proof of concept**

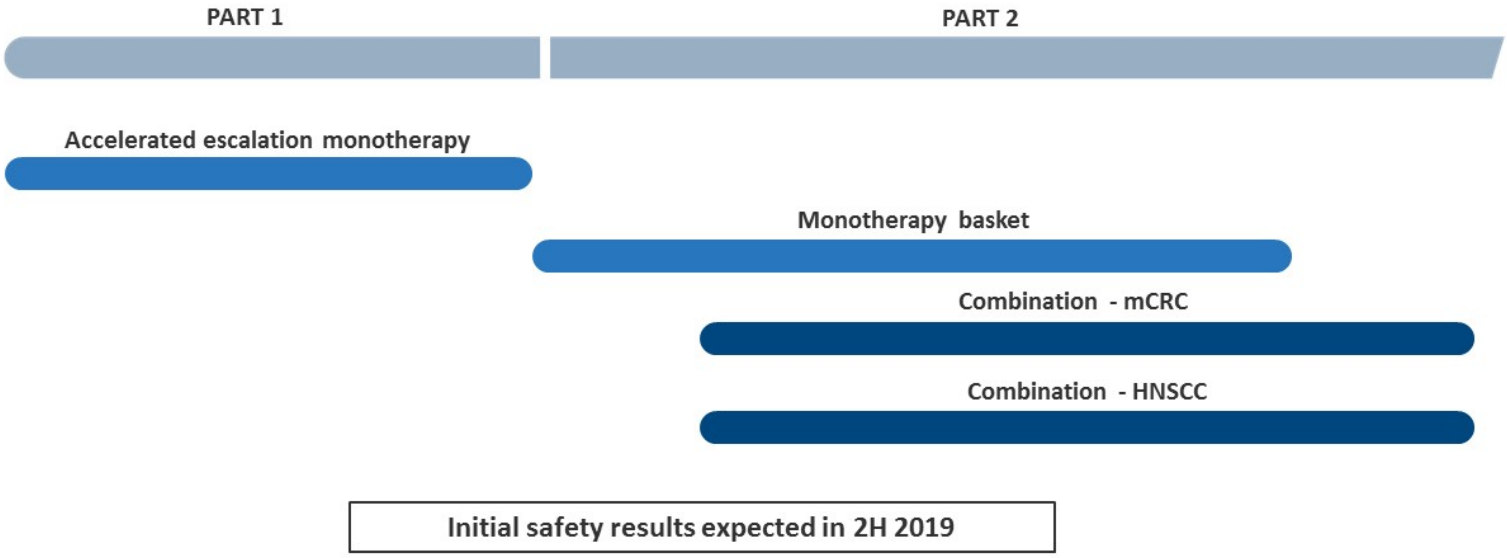
PAMPs =Pathogen-associated molecular pattern
TME = Tumor Microenvironment

# Current Status - High Level Outline of Ongoing Phase 1/2a Clinical Study

AGI-134

AGI-134+ICI

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




**Initial safety results expected in 2H 2019**

mCRC= metastatic colorectal cancer
HNSCC= head & neck squamous cell carcinoma
ICI= immune checkpoint inhibitor

# Looking ahead

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# Recent Accomplishments and Upcoming Milestones

**Multiple opportunities for value creation**

| | | | |
|---|---|---|---|
| ✓ | BL-8040 | Partial results from Phase 2a COMBAT pancreatic cancer study (with Merck) | 1Q 2018 |
| ✓ | BL-8040 | Top-line results from Phase 2 allogenic stem cell mobilization (Auto SCM) study | 2Q 2018 |
| ✓ | AGI-134 | Initiation of Phase 1/2a trial in solid tumors | 3Q 2018 |
| ✓ | BL-8040 | Lead-in results from Phase 3 GENESIS Auto SCM study | 3Q 2018 |
| ✓ | BL-8040 | Top-line results from dual combo Phase 2a pancreatic cancer study (with Merck) | 4Q 2018 |
| ✓ | BL-8040 | Initiation of Phase 2a triple combo pancreatic cancer trial (with Merck) | 4Q 2018 |
| | BL-8040 | Top-line results from Phase 2 study in pancreatic cancer (with MDACC) | 1H 2019 |
| | BL-8040 | Interim results from Phase 2b AML consolidation study | 2H 2019 |
| | AGI-134 | Initial safety results from Phase 1/2a solid tumor study | 2H 2019 |
| | BL-8040 | Top-line results from Phase 1b/2 pancreatic cancer trial (with Genentech) | 2H 2019 |
| | BL-8040 | Top-line results from Phase 2 triple combo pancreatic cancer trial (with Merck) | 2H 2019 |

# Key Takeaways

| | |
|---|---|
| **Singular focus on novel oncology compounds** | ➢ Large-market indications with unmet medical needs<br>➢ BL-8040 program in phase 3 for SCM; phase 2 for AML, pancreatic cancer/other solid tumors<br>➢ AGI-134 program in phase 1/2a for solid tumors |
| **Multiple opportunities for value creation** | ➢ 8 mid-to-late stage clinical studies ongoing<br>➢ 3-4 data readouts over next 12 months<br>➢ Phase 3 registrational topline data expected in 2020 |
| **Validation via significant pharma collaborations** | ➢ Merck/MSD (established Jan 2016; expanded Jul 2018)<br>➢ Genentech (established Sep 2016) |
| **Compelling valuation** | ➢ ~$70 million market cap<br>➢ ~$35 million cash as of 3Q 2018<br>➢ Cash runway through 1H 2020 |

SCM – stem cell mobilization; AML – acute myeloid leukemia

**Exhibit 99.2**

**For Immediate Release**

**BioLineRx Announces Proposed Underwritten Public Offering of its American Depositary Shares and Warrants**

Tel Aviv, Israel – February 4, 2019 - BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today announced that it has commenced an underwritten public offering of American Depositary Shares ("ADSs"), each representing one of its ordinary shares with each ADS to be sold together in a fixed combination with a warrant to purchase ADSs. All of the securities in the offering are to be sold by BioLineRx. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

BioLineRx anticipates using the net proceeds from the proposed offering for general corporate purposes, which may include, but are not limited to, working capital and funding clinical trials.

Oppenheimer & Co. Inc. is acting as sole book-running manager for the offering.

The securities described above will be issued pursuant to a shelf registration statement (File No. 333-222332) that was previously filed with, and declared effective by, the Securities and Exchange Commission ("SEC"). Any offer, if at all, will be made only by means of a prospectus supplement and accompanying prospectus forming a part of the effective registration statement. A preliminary prospectus supplement and accompanying prospectus related to the offering will be filed with the SEC and will be available on the SEC's website located at www.sec.gov. Copies of the preliminary prospectus supplement and accompanying prospectus may also be obtained, when available, from Oppenheimer & Co. Inc., Attention: Syndicate Prospectus Department, 85 Broad Street, 26th Floor, New York, New York 10004, by telephone at 212-667-8055, or by email at EquityProspectus@opco.com .

This press release does not constitute an offer to sell or a solicitation of an offer to buy nor shall there be any sale of these securities in any state or 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 jurisdiction.

**About BioLineRx**

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. The Company in-licenses novel compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory acute myeloid leukemia ("AML") and is in the midst of a Phase 2b study as an AML consolidation treatment and has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated a Phase 1/2a study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD (known as Merck in the United States and Canada), on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), and a collaboration agreement with Genentech Inc., a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

*Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," 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. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 6, 2018 and BioLineRx's other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.*

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