
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 September 2016

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** ☒

On September 22, 2016, the registrant will be hosting an investor breakfast meeting in New York City beginning at 9:00 am EDT. At the meeting, the registrant will present updates about its corporate objectives, BL-8040 and business development activities. The foregoing presentations are filed as exhibits to this Report on Form 6-K as listed below:

Exhibit 1: Registrant's Corporate Presentation;

Exhibit 2: Registrant's BL-8040 Presentation; and

Exhibit 3: Registrant's Business Development Update

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 Financial and Operating Officer

Dated: September 22, 2016

Transforming Science Into Medicine

We advance early oncology and
immunology compounds into
valuable therapies for patients
with high unmet needs



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Transforming Science Into Medicine

Investor Breakfast Corporate Presentation

September 22, 2016

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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.

BioLineRx Snapshot



- Drug development company focused on oncology & immunology
 - NASDAQ/TASE traded; strong balance sheet
- Transforming science into medicine
 - Leverage selected early-stage programs through advanced clinical trials and registration
- Lead program is BL-8040 oncology platform for multiple indications
 - Best-in-class CXCR4 antagonist
- Significant collaborations with leading pharma companies
 - Strategic collaboration with **Novartis** for joint development of Israeli-sourced assets
 - Immunotherapy collaboration with **Genentech** in multiple oncology indications (BL-8040 & Atezolizumab)
 - Immunotherapy collaboration with **Merck** in pancreatic cancer (BL-8040 & Keytruda)
 - Out-licensing of European rights for BL-5010 to **Perrigo**





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Where are we at present?

Current Pipeline



Well Funded



- Cash position
 - ~\$42 million as of June 30, 2016
 - Funds operational capital through end of 2018/into 2019



- Capital structure
 - Traded on NASDAQ and TASE (Symbol: BLRX)
 - 56 million shares outstanding; 65 million fully diluted
 - US shareholders represent ~70% of investor base, including key life-sciences investors
 - Novartis is largest shareholder; holds ~9% of Company



- Other
 - ~50 employees, approximately 2/3 with advanced degrees
 - Analyst coverage: JMP Securities, Roth Capital, Maxim Group

Current Status Report



Program	Current status today	Looking forward into 2017
BL-8040 AML	<ul style="list-style-type: none"> • r/r AML - successful phase 2a • Consolidation AML phase 2b in full gear; understandings with EU agencies 	
BL-8040 Immunotherapy	<ul style="list-style-type: none"> • <u>Merck</u> agreement signed; phase 2a initiated • <u>Genentech</u> agreement signed 	
BL-8040 SC Mobilization	Phase 2 initiated; understandings with FDA	
BL-7010	<ul style="list-style-type: none"> • Device designation in EU • Progress on food supplement pathway, including new formulation, preps for GRAS designation and efficacy study 	
BL-5010	CE mark and product launch by Perrigo in Europe for initial OTC indication	
Novartis Collaboration	<ul style="list-style-type: none"> • Full alignment on screening process and therapeutic areas • Initiation of first projects under collaboration 	
iPharma JV in China	JV established and operating	



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Our future plans –
for 2017 and beyond

2017 Expected Achievements



Program	Current status today	Looking forward into 2017
BL-8040 AML	<ul style="list-style-type: none"> • r/r AML - successful phase 2a • Consolidation AML phase 2b in full gear; understandings with EU agencies 	<ul style="list-style-type: none"> • Consolidation AML study continues; LPI in study • Start of immunotherapy maintenance AML phase 1b
BL-8040 Immunotherapy	<ul style="list-style-type: none"> • <u>Merck</u> agreement signed; phase 2a initiated • <u>Genentech</u> agreement signed 	<ul style="list-style-type: none"> • Merck - partial results announced • Genentech - multiple phase 1b studies initiated and in full gear
BL-8040 SC Mobilization	Phase 2 initiated; understandings with FDA	Interim and final results
BL-7010	<ul style="list-style-type: none"> • Device designation in EU • Progress on food supplement pathway, including new formulation, preps for GRAS designation and efficacy study 	<ul style="list-style-type: none"> • GRAS designation • Start and completion of efficacy study • Initiation of BD process
BL-5010	CE mark and product launch by Perrigo in Europe for initial OTC indication	<ul style="list-style-type: none"> • Expansion of launch by Perrigo • Partnering deal for US market
Novartis Collaboration	<ul style="list-style-type: none"> • Full alignment on screening process and therapeutic areas • Initiation of first projects under collaboration 	<ul style="list-style-type: none"> • Progress on existing projects • 4-5 new projects added
iPharma JV in China	JV established and operating	New projects, high valuations, value-added exposure to Asia

2017 Expected Achievements (cont.)



- In addition to the above achievements, BioLineRx also expects to bring two additional IND-ready projects into the BLRX pipeline during 2017

Expected Pipeline at End of 2017



BioLineRx in Five Years



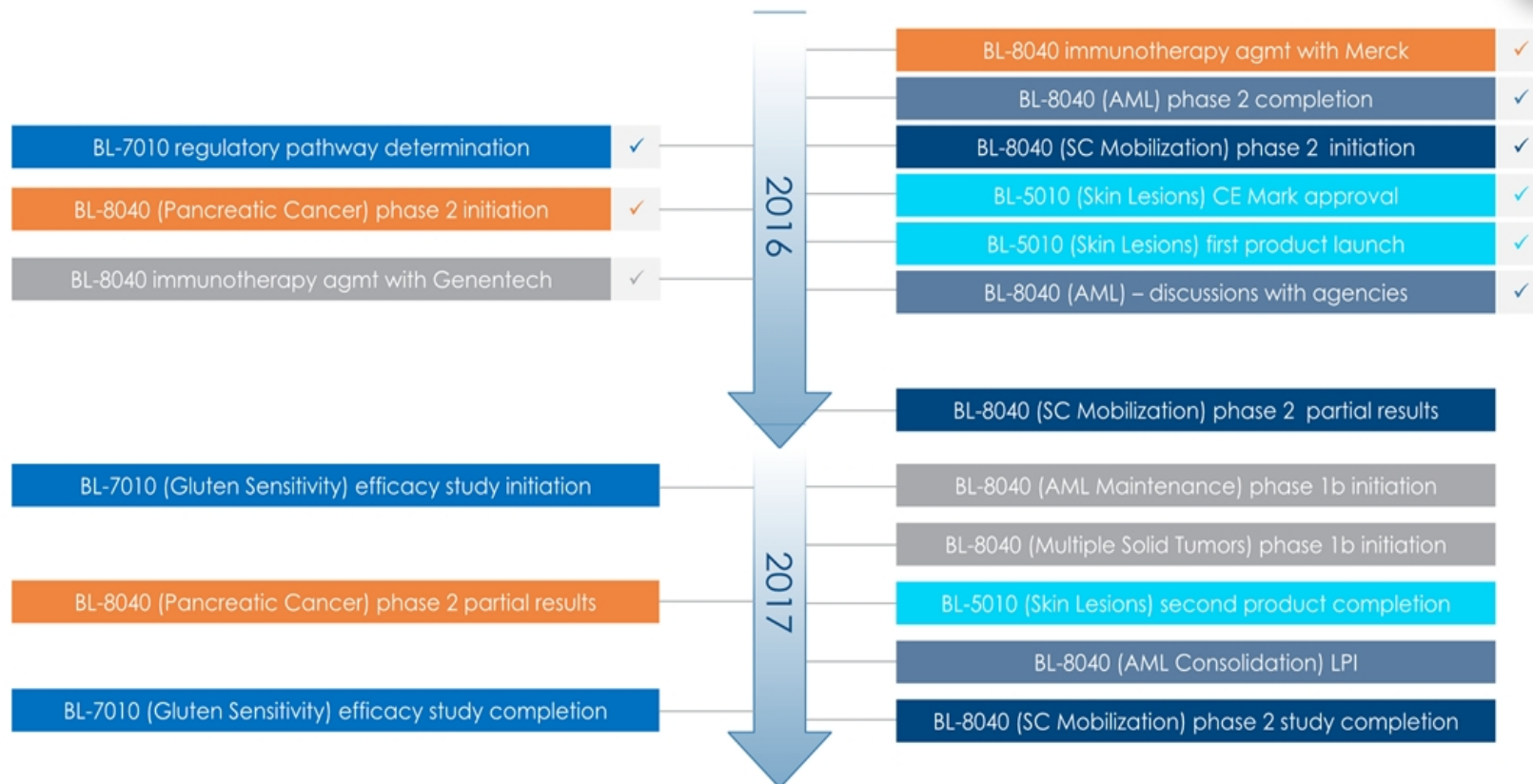
- Our plan is to become a significant player in the biotech industry
 - With critical mass of advanced projects in development
 - Alongside portfolio of revenue-generating assets
- We intend to achieve the following:
 - 2-3 products in the market, with material amount of sustainable revenues
 - Pipeline 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)



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Closing slides

Major Milestones – 2016 and 2017



BioLineRx in Five Years



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Thank You



Philip Serlin, CPA, MBA

Chief Executive Officer

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We advance early oncology and immunology compounds into valuable therapies for patients with high unmet needs



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BL-8040

Best-in-class CXCR4 antagonist for treatment of
multiple oncology indications

BL-8040 Highlights



- Platform Molecule: Multiple cancer and hematological indications
 - Received Orphan Designation from FDA for AML & SCM
- Mode of Action: Inhibits CXCR4 (a cell surface protein)
 - CXCR4 overexpressed in >70% of tumors; correlates with severity; well validated
 - Increases sensitivity to anti-cancer agents by affecting tumor microenvironment
 - Significant clinical superiority in immune cell mobilization
 - Potential synergy with multiple immuno-oncology platforms
 - Induces cancer cell death (apoptosis)
 - Multiple clinical studies ongoing or in final planning stages
 - Including immunotherapy collaborations with Genentech and Merck for multiple cancer indications



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BL-8040 MoA in Immuno-Oncology

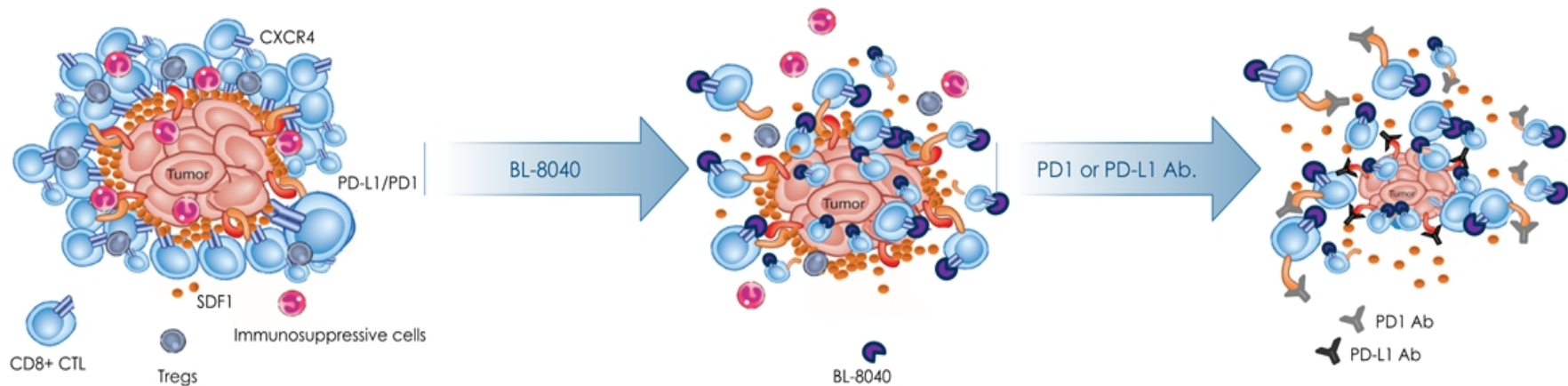
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BL-8040 Potential in Cancer Immunotherapy



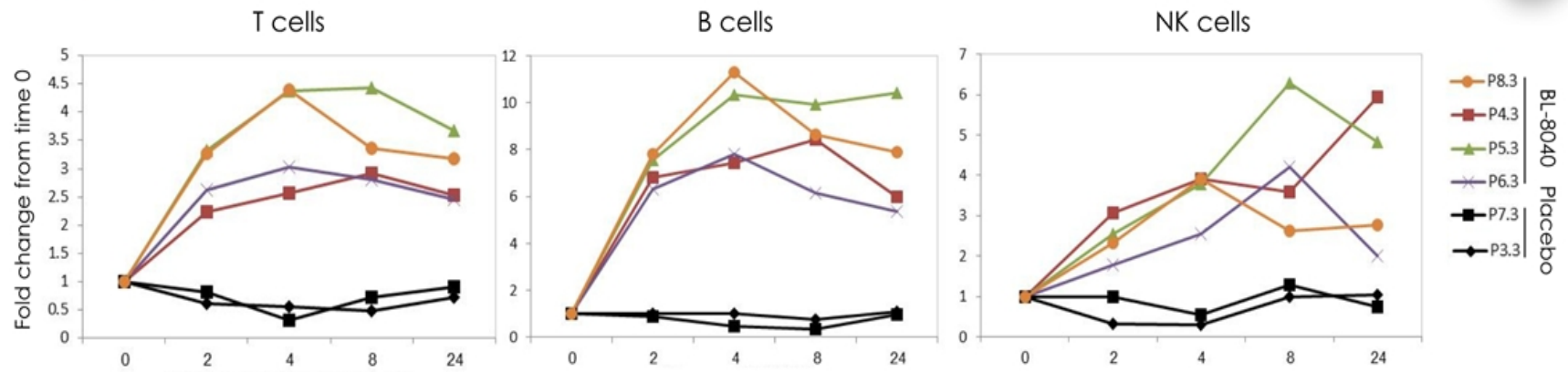
- **Immunostimulant** - BL-8040 is a powerful mobilizer of immune cells from the bone marrow and lymph nodes (T-cells, B-cells, immature Dendritic-cells and NK-cells)
- **Potentiator** - BL-8040 increases infiltration of immune cells into tumors (exhibiting a synergistic effect with anti PD1/PD-L1 immune checkpoint inhibitors)
- **Microenvironment modifier** - BL-8040 affects the tumor microenvironment by decreasing CXCR4-mediated migration of immune suppressor cells (i.e. MDSCs, Tregs)



BL-8040 is a powerful mobilizer of immune cells (clinical data)



Blood levels



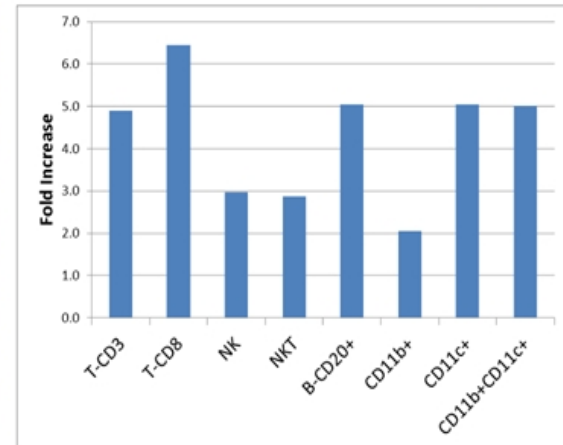
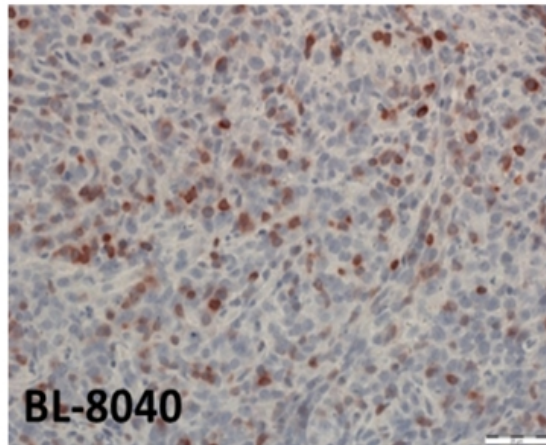
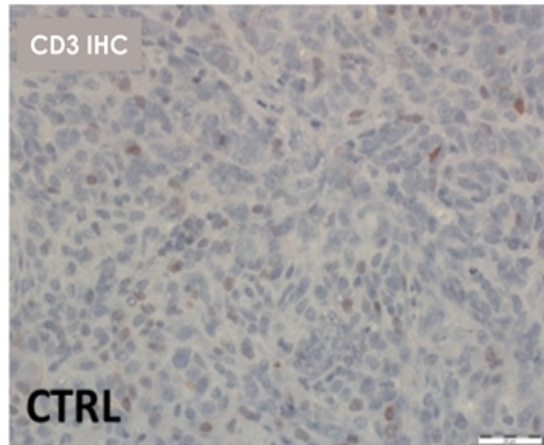
- Healthy volunteers treated with BL-8040 or placebo (clinical trial BL-8040.02)
- Single administration of BL-8040 (1 mg/kg) triggered substantial increase in T-cells, B-cells, NK-cells and Dendritic-cells in the blood
- Long receptor occupancy results in prolonged effect (≥ 24 hours)

BL-8040 Increases T-Cell Infiltration into Tumors (mice model)



- Model: Orthotropic syngeneic tumors in pancreas of C57BL/6 male mice
- Treatment with BL-8040 as single agent for 10 consecutive days

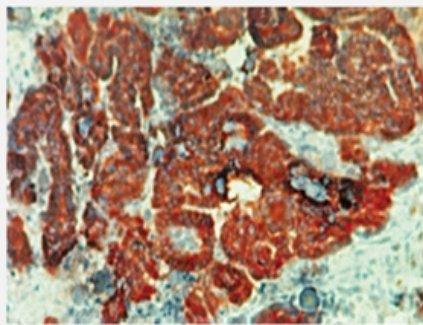
Treatment with BL-8040 induces accumulation of CD3+ T-cells in PDA tumors



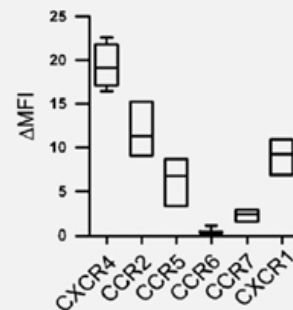
The immuno-suppressive role of CXCR4 in the tumor microenvironment



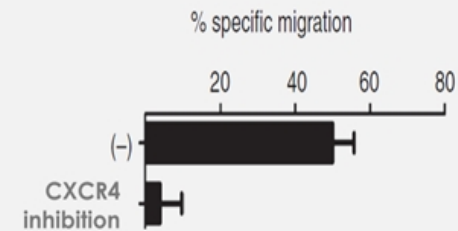
- CXCL12 expression is an independent predictor of poor survival
- CXCR4-CXCL12 axis is the key pathway mediating the attraction of immuno-suppressive cells (MDSCs, T-regs, pDCs) to the tumor microenvironment preventing local T-cell activation
 - CXCR4 inhibition selectively reduces intratumoral Tregs-cell infiltration
 - CXCR4 inhibition selectively inhibits the migration of MDSCs to the tumor



Ovarian epithelial carcinoma cells express functional SDF-1



High CXCR4 expression in cancer-isolated MDSCs



MDSCs migration is inhibited by CXCR4 blockade



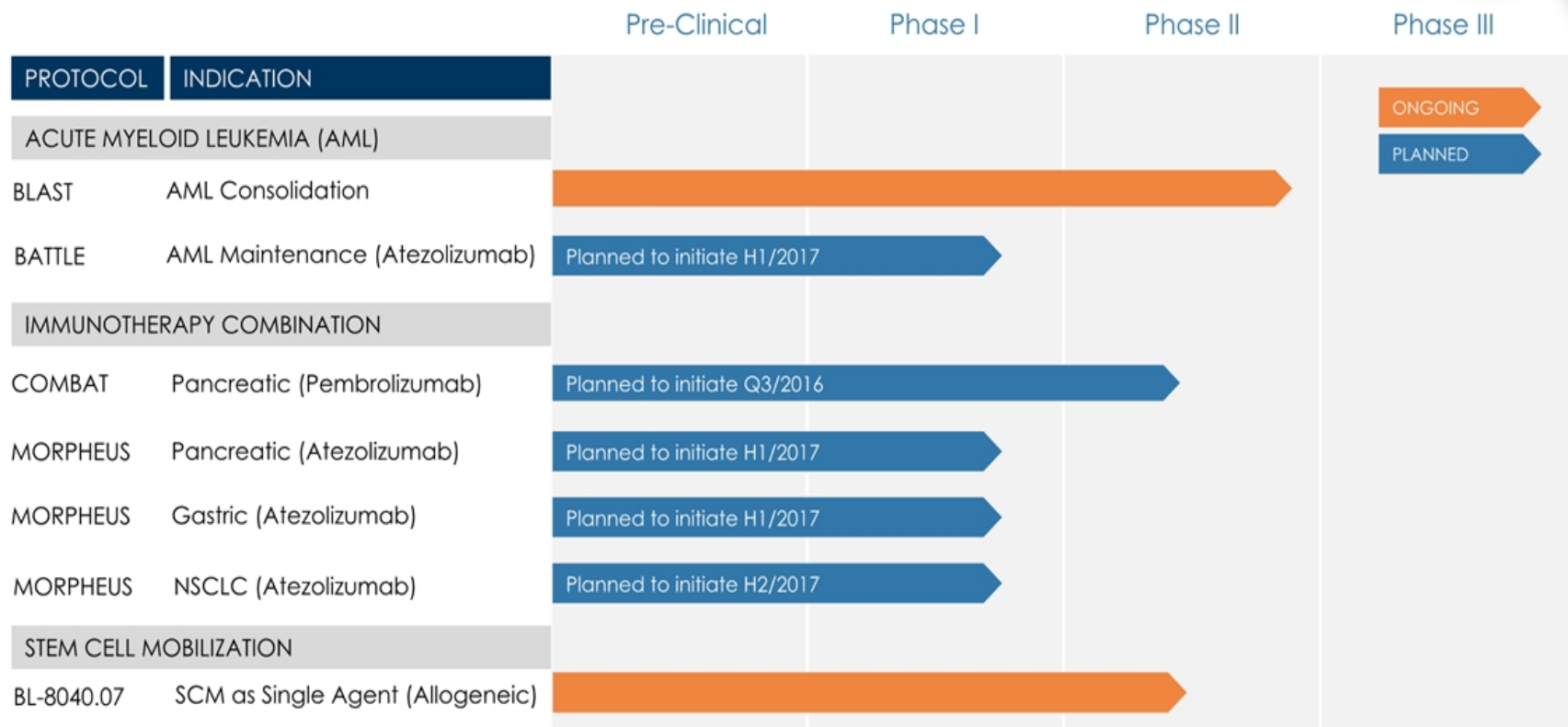
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BL-8040 Clinical Development Program

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BL-8040 Clinical Development Program



AML – Background and Direction



- Company conducted successful proof-of-concept phase 2a study in relapsed/refractory AML
 - 38% composite remission rate versus 20% historical benchmark
 - Showed longer than expected durability of remissions
 - Excellent safety and tolerability
 - Showed direct triple anti-leukemic activity: robust mobilization, induction of apoptosis and terminal differentiation of AML cells
- Results support accelerated development in AML space
 - BL-8040's high response rate indicates selective effect on chemotherapy resistant cells
 - BL-8040 showed direct anti-leukemic activity and bone marrow clearance by mediated robust mobilization suggesting potential elimination of minimal residual disease
 - Results encourage accelerated development of two specific AML treatment lines:
 - (i) consolidation and (ii) maintenance

AML – Clinical Development Status



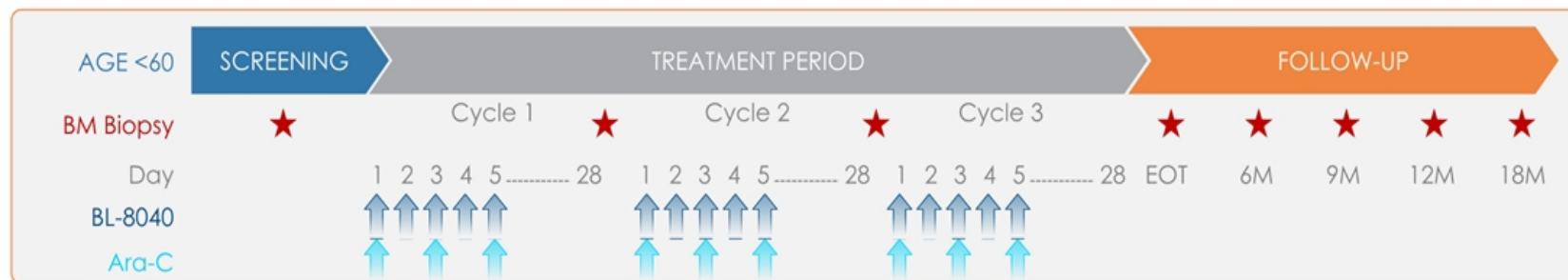
- Consolidation AML phase 2b study ongoing
 - 194 patients, double-blind, placebo controlled at ~25 sites in Germany
 - Enrollment ongoing
 - Interim results expected in 2018
- Maintenance AML phase 1b study (in collaboration with Genentech)
 - Combination study with Atezolizumab as maintenance therapy for high-risk elderly AML patients following induction treatment
 - Up to 60 patients, open label study at multiple leading sites in the US
 - In late planning stages, expected to commence in first half of 2017

Phase IIb - Consolidation Treatment for AML Patients



A Phase II, double-blind, placebo controlled, randomized, multicenter study to assess the efficacy of BL-8040 in AML patients in first complete remission

- Study Design
 - Double blind, placebo controlled, repeated administrations, multiple treatment cycles.
- Treatment
 - Two or three cycles (age based) of consolidation with high-dose Ara-C together with either BL-8040 or Placebo.
 - Ara-C 1 g/m² per dose for patients older than 60 years and 3 g/m² for patients younger than 60 years. Ara-C is administered IV twice a day (10 am and 10 pm) over 3 hours on day 1, 3 and 5.
 - Placebo or BL-8040 is administered SC at 8 a.m. on days 1, 2, 3, 4 and 5 of each consolidation cycle.
- Endpoints
 - To compare the Relapse Free Survival (RFS) 3, 6, 9, 12 and 18 months after randomization
 - To assess the toxicity, safety and tolerability of BL-8040 in combination with high-dose Ara-C
 - To assess MRD (by FACS/PCR) at time of enrollment and during the follow up period (3, 6, 9, 12 and 18 months)
 - To assess overall survival (OS) as an open label extension



Phase Ib - Combination with Immunotherapy as Maintenance Treatment for AML Patients



A Phase Ib, Multicenter, Single Arm, Open-label study, to Evaluate the Safety and Efficacy of BL-8040 and Atezolizumab combination for maintenance treatment in AML elderly High Risk patients

- Study Design

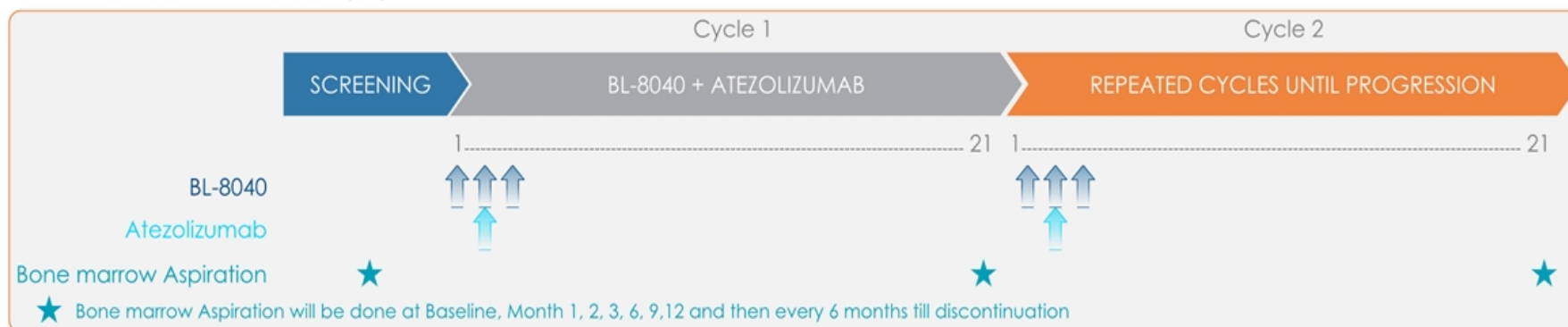
- Open label, repeated administrations, multiple treatment cycles. High risk AML patients unfit/not planned for transplant; Maintenance after consolidation for patients in CR1

- Treatment

- BL-8040 is administered SC on days 1-3 of each 21-day cycle
- Atezolizumab is administered IV on day 2 of each 21-day cycle

- Endpoints

- To assess Relapse Free survival assessed from the day of CR1 until relapse
- To assess the toxicity, safety and tolerability of BL-8040 in combination with Atezolizumab
- To assess MRD (by FACS) at time of enrollment and on treatment
- To assess overall survival (OS)



Immunotherapy Collaboration with Genentech



- Several phase 1b studies to investigate combination of BL-8040 with Genentech's Tecentriq™, (anti-PDL1 immune checkpoint inhibitor) in multiple cancer indications
 - Genentech to sponsor and conduct several phase 1b studies in multiple solid cancer indications (gastric, NSCLC, pancreatic)
 - BioLineRx to sponsor and conduct phase 1b study in (maintenance) AML
 - Open-label, multicenter, repeated administrations studies
- Study endpoints
 - Clinical response, safety and tolerability
 - Multiple pharmacodynamic parameters
- Studies are expected to commence H1 2017



Phase Ib - Combination with Tecentriq for Solid tumors



A basket phase Ib, multicenter, open-label study to Assess the Safety and Efficacy of BL-8040 in Combination with Atezolizumab in Patients with NSCLC, Gastric and Pancreatic Cancer

- Study Design
 - Open label, repeated administrations, multiple treatment cycles until progression
- Treatment
 - Daily SC BL-8040 injection as monotherapy for five consecutive days
 - Combination part - On day 8 start combination therapy consisting of SC BL-8040 TIW and IV of Atezolizumab E3W
 - The combination therapy will continue for up to two years, or until progression, clinical deterioration or early termination, whichever comes first
- Endpoints
 - To assess Objective Response Rate (ORR) according to RECIST 1.1 criteria.
 - Progression-free and Overall survival
 - Safety and tolerability of the combination
 - Multiple pharmacodynamic parameters



Immunotherapy Collaboration with Merck



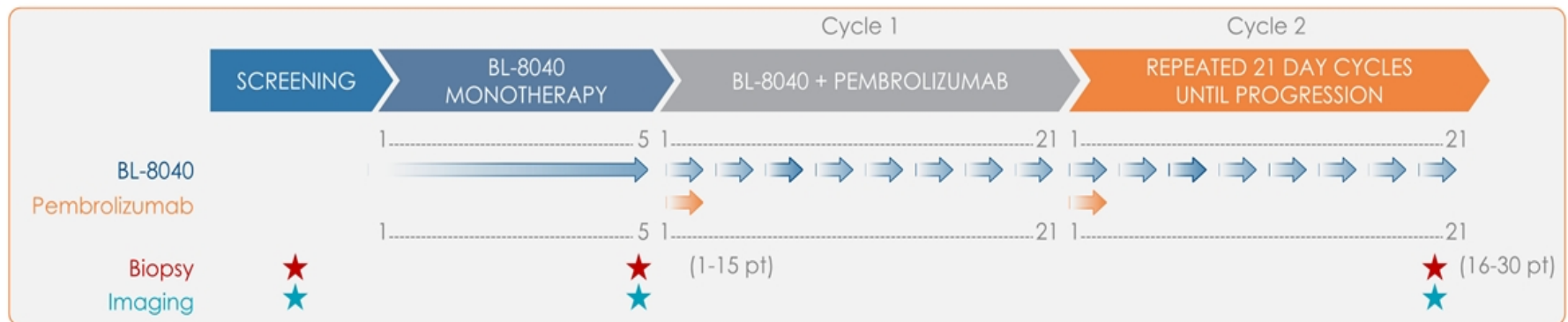
- Phase 2a study to examine combination of BL-8040 with Merck's Keytruda® (anti-PD1 immune checkpoint inhibitor) in pancreatic cancer
 - Up to 30 patients with metastatic pancreatic adenocarcinoma
 - Open-label, multicenter, single-arm trial
 - Sites in the US, Israel and South Korea
- Study endpoints
 - Clinical response, safety and tolerability
 - Multiple pharmacodynamic parameters, including ability to improve infiltration of T cells into tumor and their reactivity.
- Study will commence by end Q3 2016
 - All regulatory submissions were completed
 - Partial results expected H2 2017
 - Top-line results expected H2 2018



Phase IIa - Combination with Keytruda for PDAC



- A phase IIa, multicenter, open-label study to Assess the Safety and Efficacy of BL-8040 in Combination with Pembrolizumab in Patients with Advanced Pancreatic Cancer
- Study Design
 - Open label, repeated administrations, multiple treatment cycles until progression
- Treatment
 - Daily SC BL-8040 injection as monotherapy for five consecutive days
 - Combination part - On day 8 start combination therapy consisting of SC BL-8040 TIW and IV of Pembrolizumab E3W
 - The combination therapy will continue for up to two years, or until progression, clinical deterioration or early termination, whichever comes first
- Endpoints
 - To assess Objective Response Rate (ORR) according to RECIST 1.1 criteria.
 - Progression-free and Overall survival
 - Safety and tolerability of the combination
 - Multiple pharmacodynamics parameters



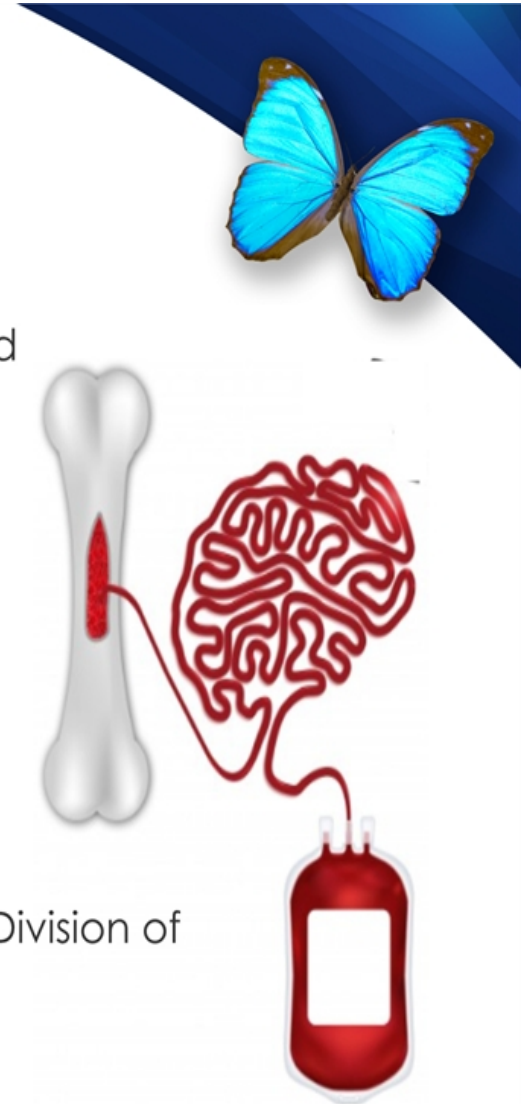


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BL-8040 Development and Commercialization Strategy in SCM

Stem Cell Mobilization for Transplantation

- G-CSF is current standard for stem cell mobilization
 - 4-6 daily injections of G-CSF, plus 1-4 apheresis sessions required
 - G-CSF is associated with bone pain and other side effects
 - G-CSF is not approved for allogeneic transplantation
 - No agents are approved for allogeneic transplantation
- Phase 1 results support BL-8040 as single agent one day collection regimen
- Type B meeting with the FDA held in October 2015
- Phase 2 study allogeneic transplantation ongoing
 - Collaboration with Washington University School of Medicine, Division of Hematology and Oncology
 - Partial results by end of 2016; topline results by end of 2017



BL-8040 Long Term Clinical Development Plan



- Development of BL-8040 for SCM for allogeneic stem cell transplantation
- The overall goal is to demonstrate that BL-8040 produces a similar quality of allograft as that produced by G-CSF
- Studies will likely demonstrate advantages:
 - Shorter duration of treatment prior to leukapheresis – single BL-8040 injection versus 4-5 injections of G-CSF with or without off label treatment with Plerixafor.
 - Reduction in the number of leukapheresis collections in order to obtain an adequate amount of cells for bone marrow transplant.
 - Overall donor treatment duration of 1-2 days.
- Development plan toward registration:
 - Single pivotal study
 - Total of 370 treated volunteers
 - Long-term follow up of healthy donors could be done in a post marketing setting
 - Company considers taking all the way toward commercialization, either with a partner or by itself

BL-8040 Long Term Clinical Development Strategy



		2016	2017	2018	2019	2020	2021	2022
SCM Allogeneic		Ongoing Ph2a		Long term follow up			Drug registration (NDA)	Commercialization
			Prep for Ph3		Phase 3			
AML Consolidation		Ongoing Ph2b BLAST study						Drug registration (NDA)
			Prep for Ph3	Potential Ph3 conducted by BioLineRx and/or partner				
Immuno-Oncology	MSD		Ph2a PDAC COMBAT study		Out licensing deal and/or Ph3 conducted by partner			
			Ph2a PDAC MDACC study					
	GENE		Ph2a AML BATTLE study			Out licensing deal and/or Ph3 conducted by partner		
			Ph2a solid tumors MORPHEUS study					

1. Phase 3 ready position
2. Initial input from open label immuno-oncology studies
3. AML consolidation interim results during 2018

1. Late stage SCM Phase 3 – NDA for SCM
2. Final data from immuno-oncology studies
3. Advanced stage of development for AML consolidation

Multiple value generating events in coming months with strong potential for partnership deal early in 2018

BL-8040 Summary



- BL-8040 is platform for multiple solid and liquid oncology indications
 - Focus on immunotherapy, AML and allogeneic stem-cell transplantation
- BL-8040 has demonstrated efficacy in several clinical studies
- BL-8040's MoA has been clinically validated
- CXCR4 is a validated target
- Collaborations with leading global pharma companies provide significant additional validation of program potential

Thank
You

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Investor Breakfast Business Development Update

September 22, 2016

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Focus on Two Main Initiatives

- Collaborations with top global pharma in cancer immuno-therapy
 - Rationale
 - Structure and details
- Strategic collaboration with Novartis
 - Status
 - Expectations for the next 12 months





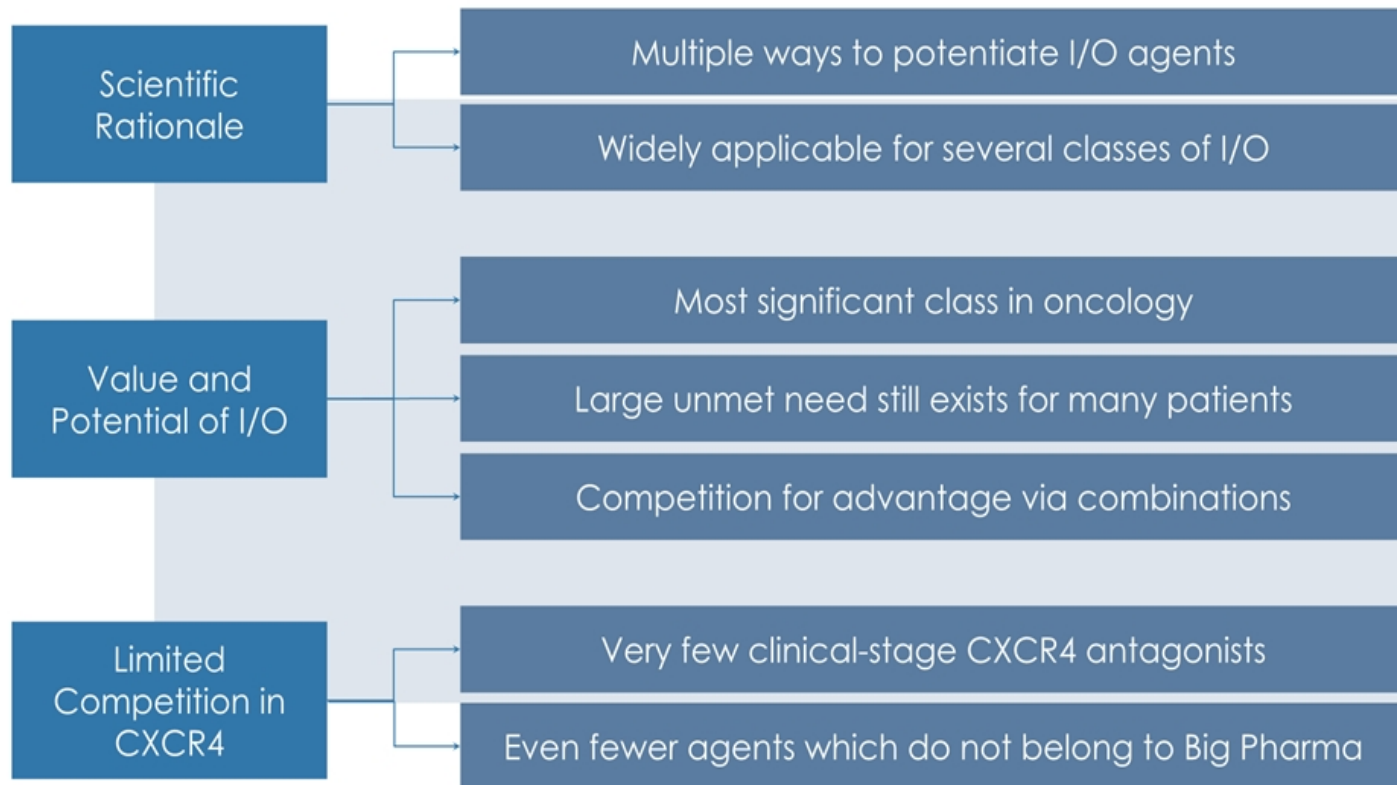
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BL-8040 In Immuno-oncology

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Why Do We Push BL-8040 in Immuno-oncology?



Merck Partnership Structure



- Explore combination with Keytruda, a PD-1 antagonist
 - One of leading I/O agents, blockbuster potential, applicability in multiple tumor types
- Phase 2a study in metastatic pancreatic cancer:
 - Keytruda single-agent has almost no effect
 - Clear scientific rationale for the combination with CXCR4 antagonist
 - Even a small clinical improvement would have clear significance
- BioLineRx is the sponsor of the clinical study
 - Merck provides Keytruda and performs some of the sample analysis
- Both parties have the right to continue to Phase 3 with access to the other party's compound

Genentech Partnership Structure



- Explore combination with Atezolizumab (Tecentriq), PD-L1 antagonist
 - Newly approved, blockbuster potential, applicability in multiple tumor types
- Large clinical program to explore the combination in multiple tumor types where:
 - There is a clear unmet need; Atezo single-agent activity leaves potential for improvement
 - Clear scientific rationale for the combination with CXCR4 antagonist
- BioLineRx is the sponsor of the clinical study in AML
 - An area where BioLineRx has significant expertise with BL-8040
- Genentech is the sponsor of all solid tumor studies
 - 1st wave (begin H1 2017): Gastric, NSCLC and potentially Pancreatic cancer
 - Potential to add an additional wave of up to 3 indications in H2 2017
- Both parties have the right to continue to Phase 3 with access to the other party's compound

Summary of Immuno-Oncology Collaborations



- Position BL-8040 as the leading independent CXCR4 antagonist for immuno-oncology combinations
 - Partnerships with 2 of the 3 leaders in immuno-oncology
- Partnerships allow to explore potential in various aspects, thus increasing value and probability-of-success:
 - Combination with both PD-1 and PD-L1 antagonists
 - Ability to compare combinations in one tumor (pancreatic cancer)
 - Explore combination in at least 4 different tumors, both solid and liquid
- Limited investment compared to large scale of the clinical program
- Retain flexibility for future steps
 - No exclusivity with a single partner
 - Can consider partnering or moving to registration depending on options



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Novartis alliance - status

Successful Strategic Collaboration with Novartis



- The first projects were in-licensed under the collaboration
- Current projects focus on NASH
 - Growing, high-potential therapeutic area
 - Aligned with our focus on also building an immunology franchise
 - Projects are first-in-class, potentially disease-modifying agents; close collaboration with Novartis on the development plan
- We expect to in-license an additional 4-5 projects under the collaboration during the next year
 - 1-2 additional projects to be in-licensed in 2016
 - Most projects would likely be aligned with our therapeutic area focus
- Continued commitment and strong collaboration on behalf of Novartis
 - Great validation for the company's scouting and development capabilities
 - Potential for repeated partnering with Novartis at a significantly reduced financial risk

Thank
You