

# Developing first-in-class drugs to treat aggressive cancer

4th June 2018

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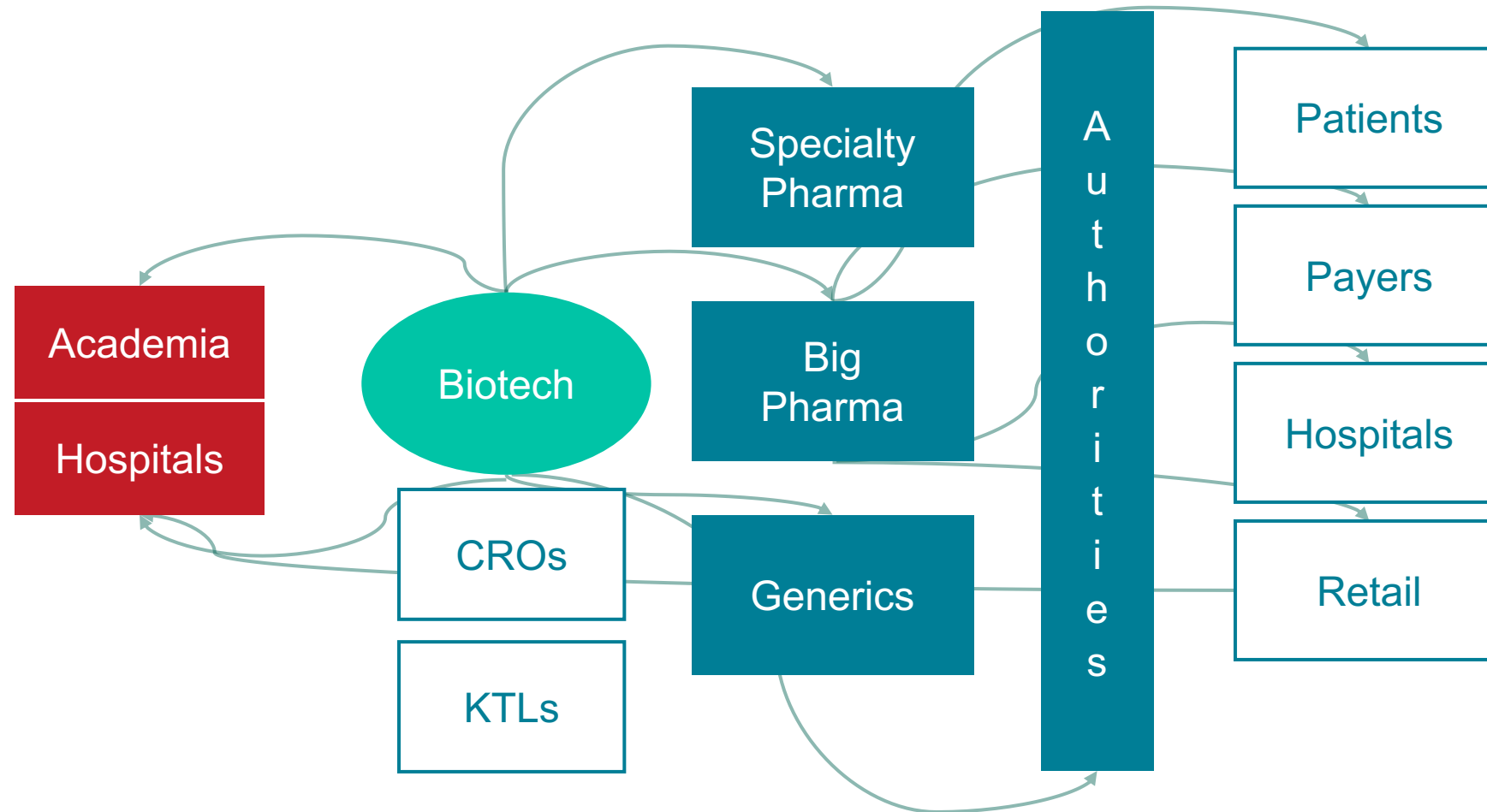
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A photograph of a modern, multi-story building interior. The image shows several levels with glass railings and concrete balustrades. Warm, yellowish light is visible through the glass, suggesting an interior space with modern decor. The architecture is clean and contemporary, with a focus on open space and natural light. The text is overlaid on a white rectangular background in the upper right portion of the image.

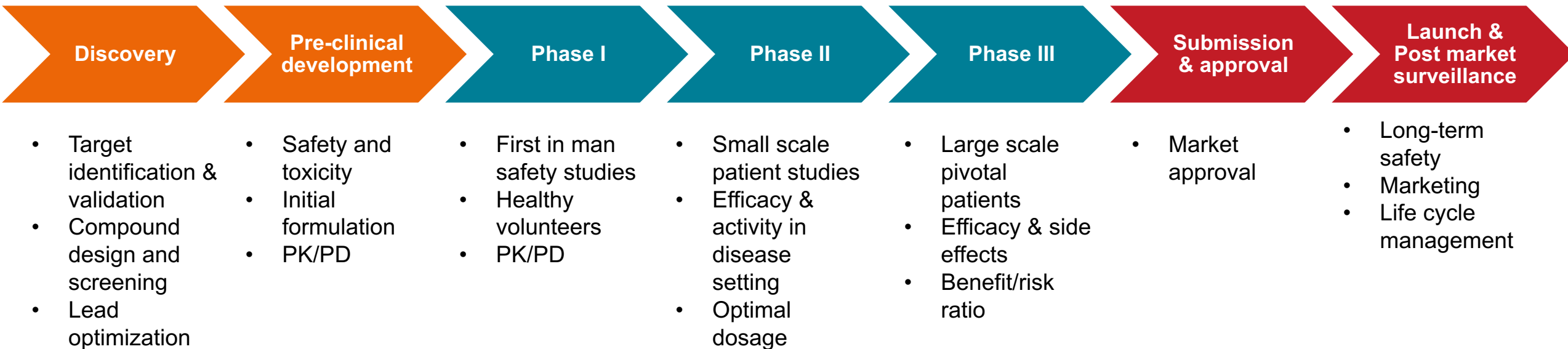
BerGenBio (OSE:BGBIO) is a clinical stage biopharmaceutical company developing innovative drugs for aggressive diseases, including immune evasive, drug resistant and metastatic cancers.

# Where does Biotech fit into the food chain?





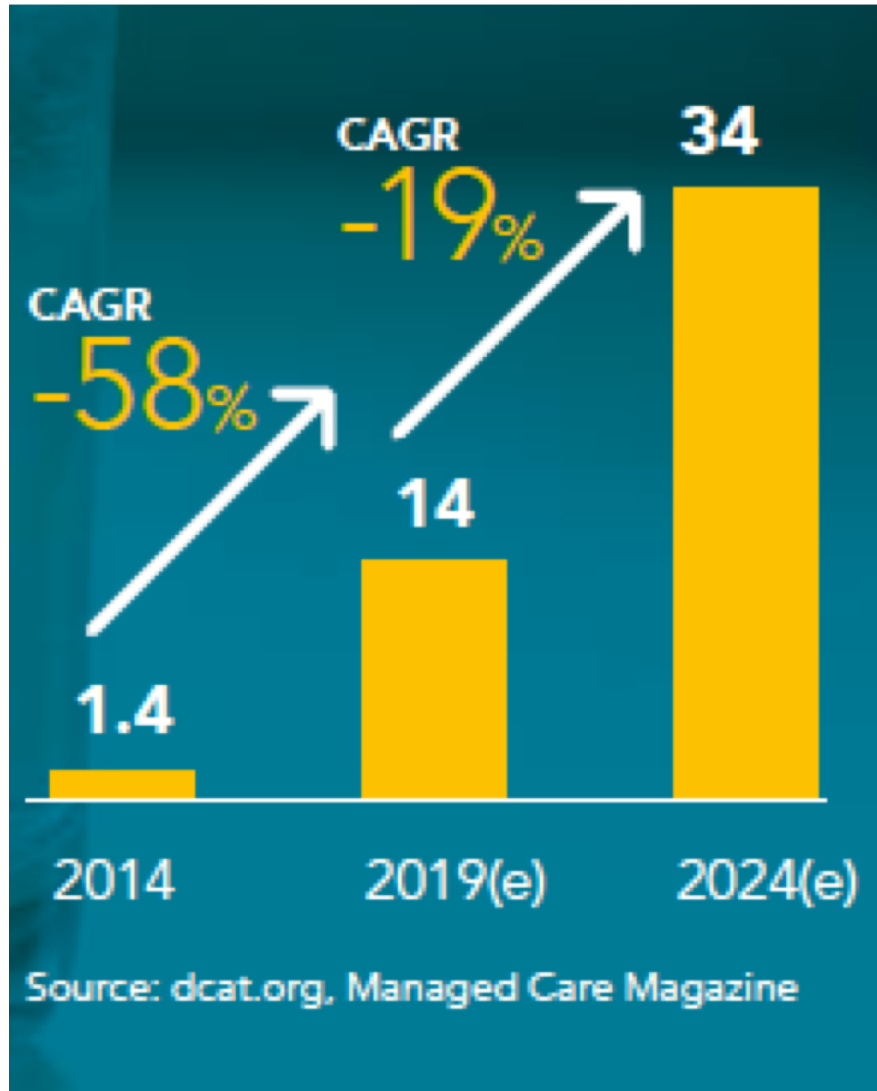
# The drug development value chain



# Global cancer burden

- In 2018, cancer accounts for about one in seven deaths worldwide and by 2030<sup>1</sup>
- the American Cancer Society expects the global cancer burden to grow to 22 million new cases per year with 13 million cancer deaths due to growth and aging of the population<sup>1</sup>
- The global oncology market reached USD 121 billion in 2017 and is expected to grow with a compound aggregate growth rate (“CAGR”) of 7.4% to reach USD 173 billion by 2022<sup>1</sup>
- Immunotherapy is one of the fastest growing areas within oncology R&D<sup>2</sup>

# Immuno-oncology market development



“ The cost of oncology drugs will exceed \$150 billion by 2020 (...) especially **immunotherapies** – will drive much of this growth ”

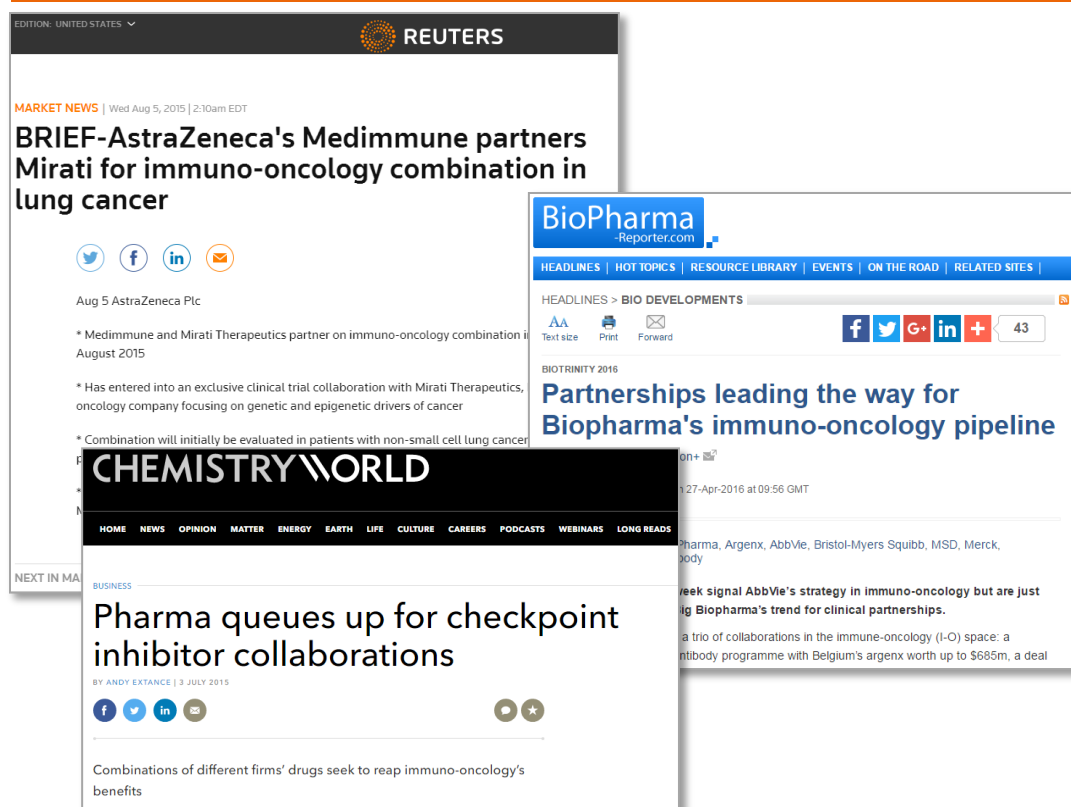
- IMS Institute, Global Oncology Trend Report

Sales within the CPI drug category alone are forecasted to increase significantly over the ten-year period from 2014 to 2024 (aggregated figures for the seven major markets US, France, Germany, Italy, Spain, the UK and Japan):



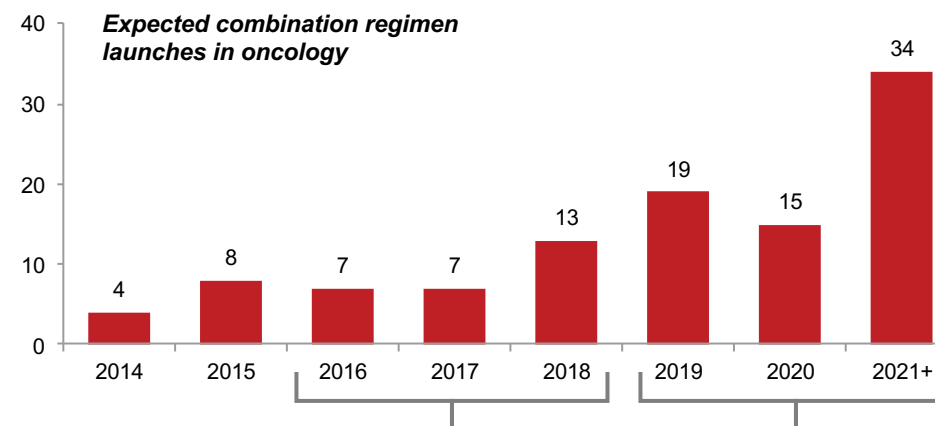
# Combination treatments are driving clinical benefit & commercial opportunity

Multiple examples of potentially high value partnerships; trend particularly prominent within immune-oncology



Expected new combination regimen launches

"Combination treatments are becoming the treatment of choice"



"Breast and haematology combos will predominate in the early years"

"After 2018, combos targeting solid tumours, especially lung cancer and melanoma, will increase dramatically"

✓ Growth expected in indications targeted by BerGenBio

# Corporate Snapshot

## Background



**Leaders in developing selective AXL inhibitors:** innovative drugs for aggressive diseases, including immune evasive, drug resistant and metastatic cancers

**Diversified pipeline,** lead drug is tested in several indications of high unmet medical need and large market potential

**Promising efficacy** with sustained treatment benefit and confirmed favourable safety

**Companion diagnostic**

## Bemcentinib (BGB324)



**First-in-class highly selective oral AXL inhibitor**

Broad phase II clinical programme in NSCLC, TNBC, AML/MDS, melanoma

## Pipeline



Bemcentinib (BGB324)

AXL antibody

AXL ADC (partnered)

Immunomodulatory small molecules

## OSE:BGBIO



Cash runway through to 2020

Included in the OSEBX index from 1<sup>st</sup> June 2018

+138% year to date share price increase (30 May)

## Corporate



35 staff

Headquarters and research in Bergen, Norway; Clinical Trial Management in Oxford, UK

# Key events in BerGenBio history

2008 - 2010	2011	2012	2013	2014	2015	2016	2017	2018
<ul style="list-style-type: none"> <li>• UiB Spin- out</li> <li>• Seed funding</li> <li>• Patents filed</li> </ul>	<ul style="list-style-type: none"> <li>• NOK 54m equity issue</li> <li>• In license BGB324</li> </ul>	<ul style="list-style-type: none"> <li>• Grant NOK 12m</li> <li>• Preclinical</li> </ul>	<ul style="list-style-type: none"> <li>• Phase I</li> <li>• NOK 37m equity issue</li> <li>• Wellcome Trust investment</li> </ul>	<ul style="list-style-type: none"> <li>• Phase Ib</li> <li>• NOK 165m equity issue</li> <li>• Grants NOK24m</li> <li>• Out-License ADC program</li> <li>• Orphan designation</li> </ul>	<ul style="list-style-type: none"> <li>• Grant NOK 13m</li> <li>• UK office Oxford</li> </ul>	<ul style="list-style-type: none"> <li>• Phase II</li> <li>• NOK 212m capital raise</li> <li>• Grant NOK 15m</li> </ul>	<ul style="list-style-type: none"> <li>• IPO NOK400m</li> <li>• Merck collaboration</li> <li>• IFU Grant NOK 24m</li> </ul>	<ul style="list-style-type: none"> <li>• BGB324 named bemcentinib</li> <li>• PIPE NOK 187,5m</li> <li>• Included in OSEBX</li> <li>• Interim data announced at ASCO</li> </ul>

## Key Partners



M D Anderson



*Meteva AS*





# AXL and bemcentinib

Overview and clinical development

# AXL's role in cancer

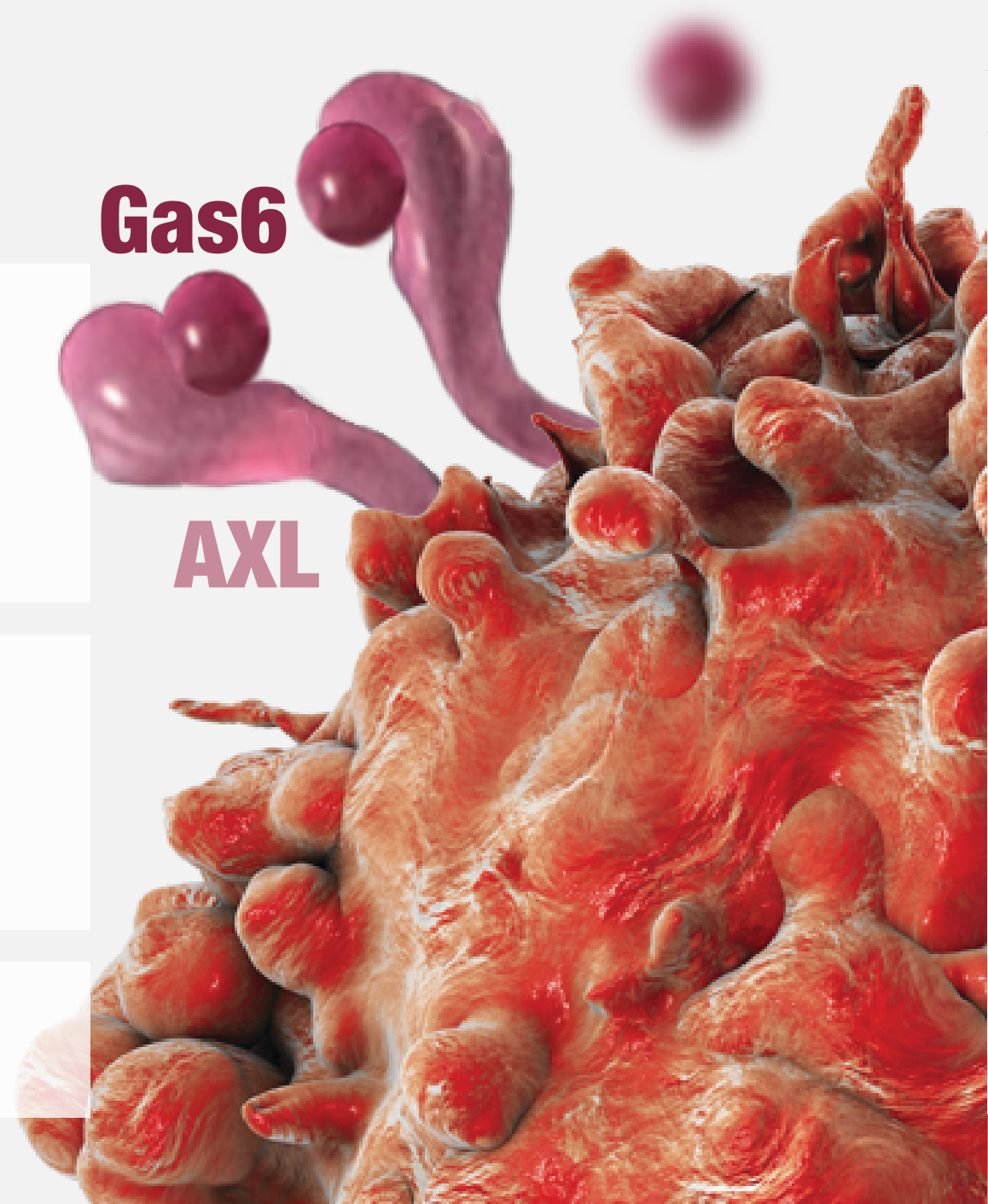
**90%** of cancer deaths result from tumors spreading, becoming immune evasive and drug resistant

**AXL** is a key mediator of these traits in most cancers

The **AXL** receptor has an important role in:

- Cancer cell survival
- Drug resistance
- Immune suppression / evasion
- Metastasis

Interest in **AXL** as a key target for aggressive disease is increasing rapidly



# Bemcentinib, first in class highly selective AXL inhibitor



**Most advanced  
selective, orally  
bioavailable, small  
molecule AXL kinase  
inhibitor in phase II  
clinical development**

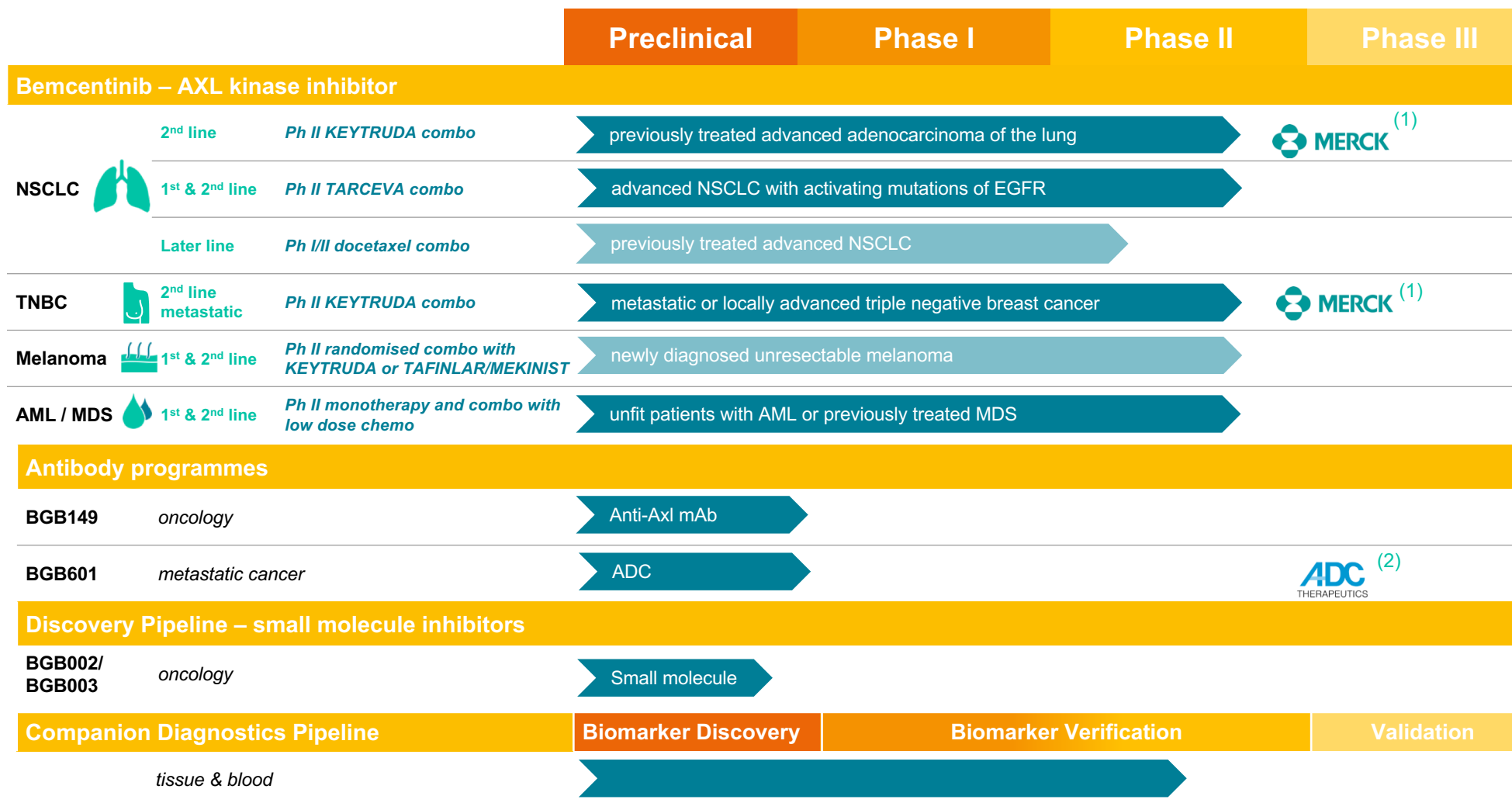
**Once daily dosing**

**Well tolerated**

**Safely combined with chemo,  
targeted and IO drugs**



# Pipeline of innovative AXL inhibitors



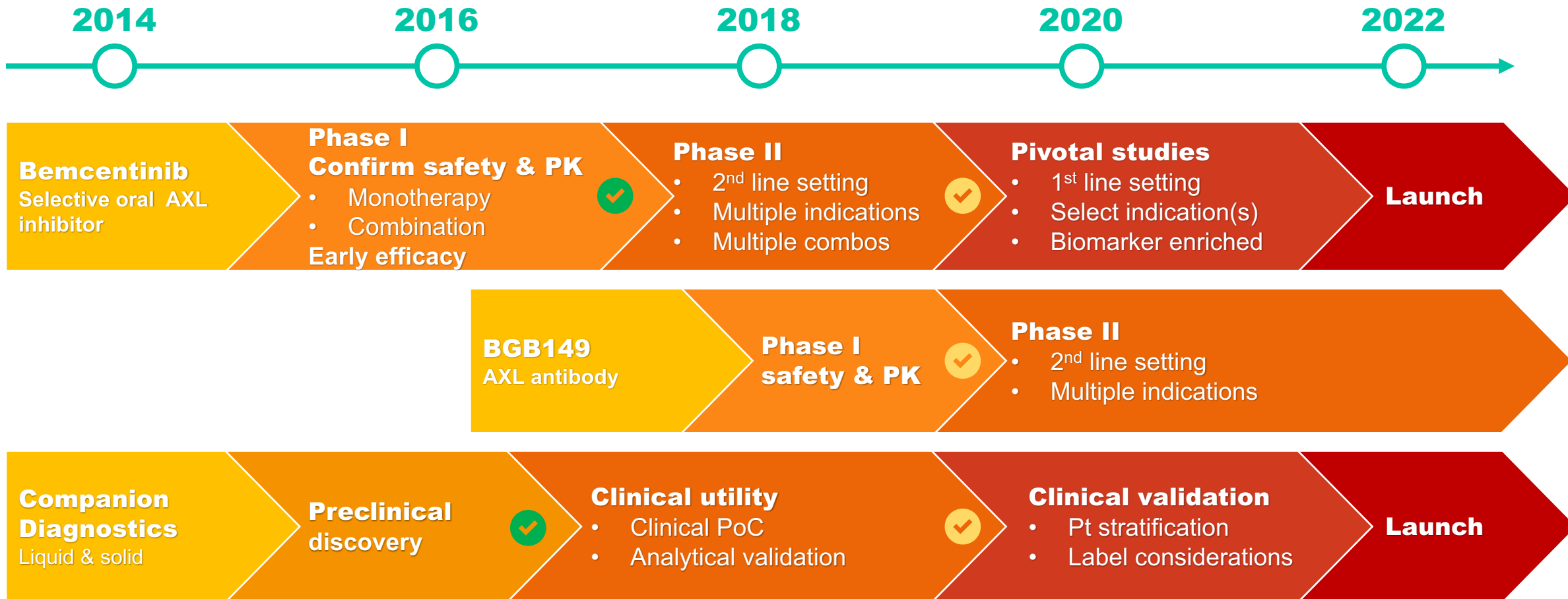
Patients:  
**>350**

Sites in Europe  
and North  
America:

**50**

Key read-outs:  
**2018**

# Clinical Development Strategy



# Bemcentinib: Most advanced selective AXL inhibitor





# Partnership with Merck Sharp & Dohme B.V. (MSD): Clinical trial collaboration bemcentinib + KEYTRUDA

The 24th of November 2016, **BerGenBio** and **MSD** entered a collaboration with **BerGenBio** as sponsor of two Phase II clinical trials for a combination of **bemcentinib** with MSD 's antibody **pembrolizumab** (Keytruda TM):

- In patients with previously treated advanced adenocarcinoma of the lung (**NSCLC**)
- In patients with previously treated, locally advanced and unresectable or metastatic **TNBC** or Triple Negative Inflammatory Breast Cancer

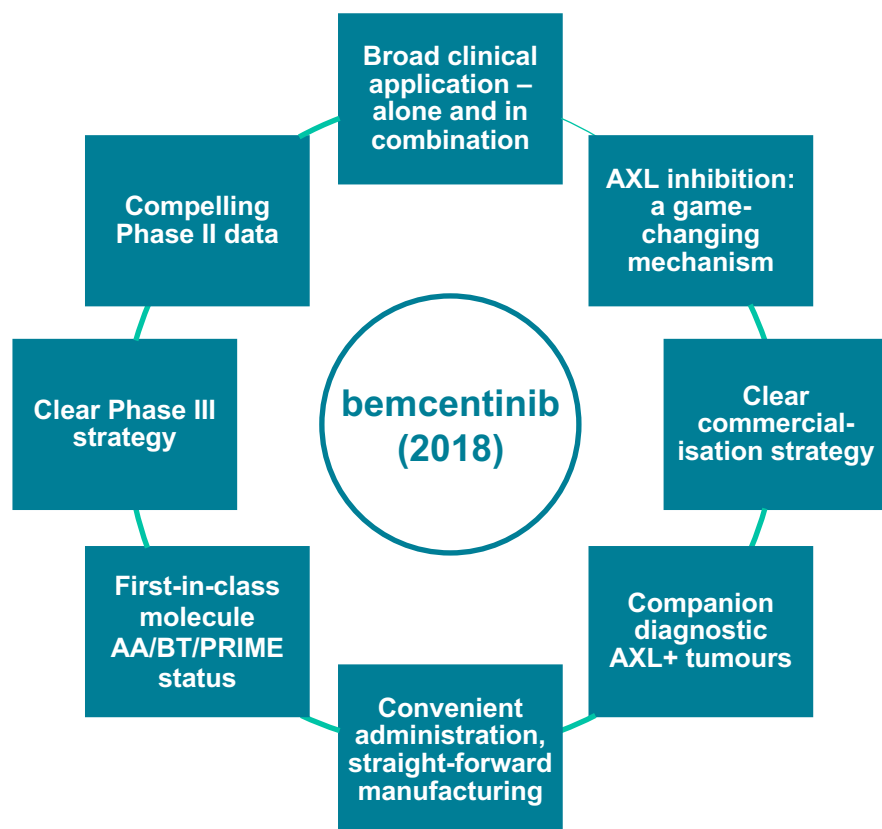
Each party has access to all data generated and after study completion either party can propose a Phase III registration study (or other subsequent study) for the combination.

**Merck has no preferential rights to bemcentinib**



# Bemcentinib – Set to become a highly attractive and valuable asset

Late stage, first-in-class assets will be highly sought after



BerGenBio retains full strategic flexibility



Progress bemcentinib clinical trials

Clear go to market opportunities

First-in-class selective drug with broad clinical application potentially triggering interest from bigger pharma

# Successful IPO, PIPE and broadened shareholder base

## Listing on OSE

- IPO completed 7 April 2017, (OSE:BGBIO)
  - Raised NOK 400 million in gross proceeds
- Private placement completed 13 April 2018
  - Raised NOK 187,5 million in gross proceeds
  - Adding institutional investors in US specialising in the biotechnology industry

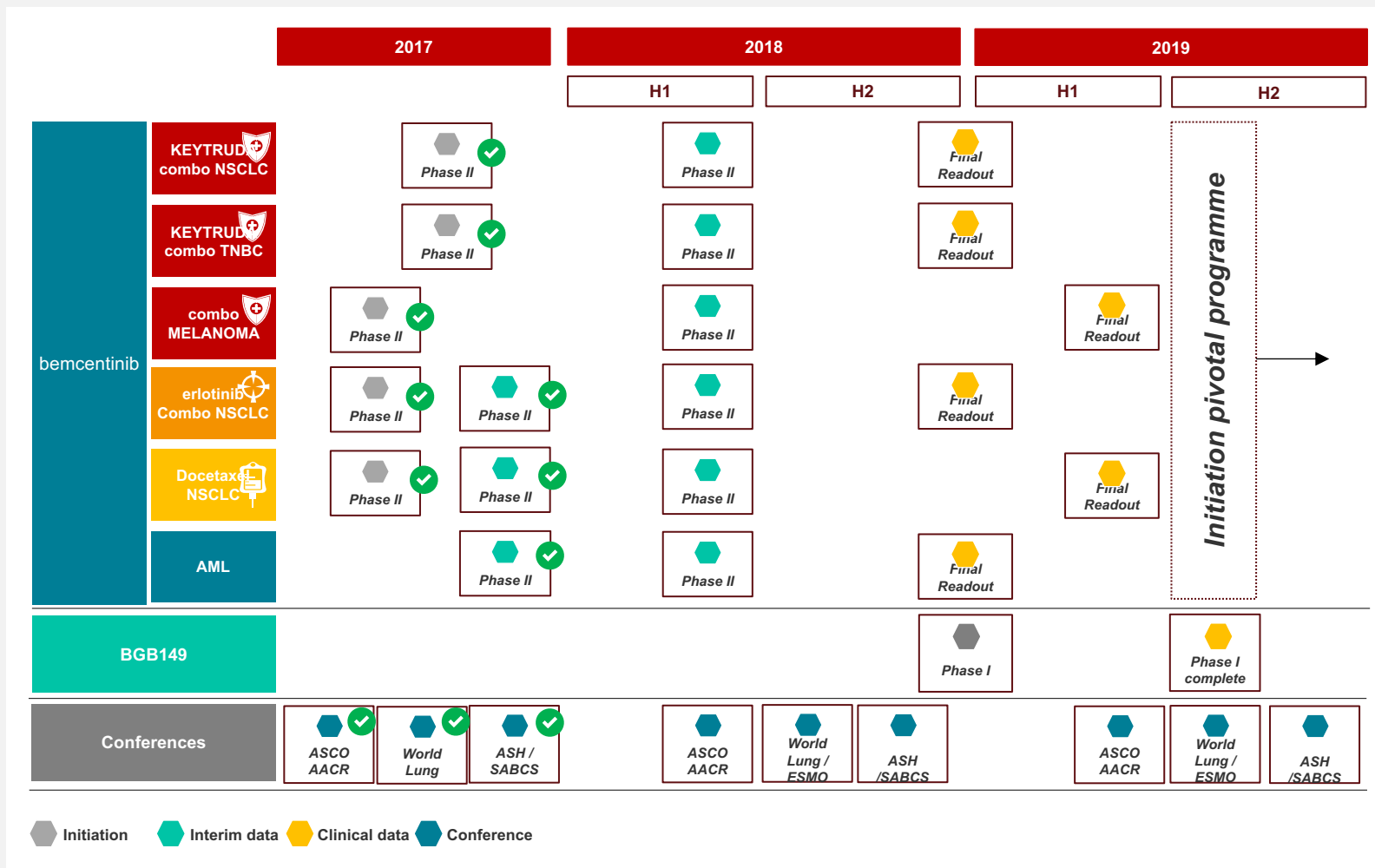


## Share facts

Currency	NOK
Market	Oslo (NOK)
ISIN code	NO0010650013
Ticker code	BGBIO
Industry	Biotechnology
Market Capitalization	NOK 2.7 bn
Number of Shares	54,711,446
Number of shareholders	2,779

- Included in the OSEBX index from 1 June 2018
- Share price increase 138% YTD (30 May)

# Significant milestones expected in 2018 & 2019



## Significant milestones expected over the next 12 months:

### Bemcentinib

- Interim clinical data from 6 phase II trials at ASCO
- Final readout from 4 phase 2 trials in H2

### BGB149

- Initiation of AXL antibody BGB149 clinical trials in H2

# ASCO 2018 - HIGHLIGHTS

ASCO poster # 385  
June 4 8 AM CT

## Biomarker programme

- ✓ AXL IHC: AXL expression shows promising early correlation with patient benefit in KEYTRUDA combo study
- ✓ Liquid biopsy: Soluble AXL is predictive of patient benefit in AML/MDS

ASCO poster # 292,  
June 4 8 AM CT

## Bemcentinib + KEYTRUDA: NSCLC

- ✓ 8 of 15 pts radiographically evaluated to date had tumour shrinkage, including 3PRs
- ✓ Correlation with AXL expression: 5 of 6 pts found to be AXL positive, 4 of those had clinical benefit

ASCO poster # 80,  
June 4 8 AM CT

## Bemcentinib monotherapy: AML/MDS

- ✓ chosen for poster discussion: Monday June 4 11:30 AM
- ✓ Plasma soluble AXL found predictive of patient benefit

ASCO poster # 375,  
June 4 1:15 PM CT

## Bemcentinib + EGFR inhibition: NSCLC

- ✓ 5 of 6 pts receiving bemcentinib + TARCEVA first line and radiographically evaluated to date showed tumour shrinkage incl 1 PR
- ✓ Durable responses and meaningful clinical benefit observed in second line both as monotherapy and in combo with TARCEVA

## Bemcentinib + KEYTRUDA & TAF/MEK: Melanoma

- ✓ 15 of 19 pts radiographically evaluated to date showed tumour shrinkage incl. CRs, 8 PRs and 6 SDs
- ✓ All combos well tolerated

## Bemcentinib + docetaxel: NSCLC

- ✓ 3 of 7 pts radiographically evaluated to date showed PRs in a disease setting that normally sees response rates < 10%
- ✓ Soluble predictive biomarker candidates identified



# Thank you.

For further information please visit [www.bergenbio.com](http://www.bergenbio.com)

*Developing first-in-class drugs to treat  
aggressive cancer*



# Glossary

AA	Accelerated approval
ADC	Antibody drug conjugate
ALK	Alkaline phosphatase
AML	Acute myeloid leukemia
BLA	Biologic license application
BT	Breakthrough therapy
CAB	Clinical advisory board
CBR	Clinical benefit rate
CDx	Companion diagnostic
CLIA	Clinical Laboratory Improvement Amendments
CLL	Chronic lymphocytic leukemia
CPI	Checkpoint inhibitor
CR	Complete response
CTL	Cytotoxic T-lymphocytes
ECG	Electrocardiogram
EGFR	Epidermal growth factor receptor
ELISA	Enzyme-linked immunosorbent assay
EMT	Epithelial-to-mesenchymal transition
EU5	France, Germany, Italy, Spain, United Kingdom

FDA	US Food and Drug Administration
GLP	Good Laboratory Practice
IHC	Immunohistochemistry
mAb	Monoclonal antibody
MDS	Myeloid dysplastic syndrome
NDA	New drug application
NSCLC	Non-small cell lung cancer
pAxl	Phosphorylated Axl (activated Axl)
PD	Progressive disease
PR	Partial response
RCC	Renal carcinoma
RP2D	Recommended Phase II Dose
RTK	Receptor tyrosine kinase
TAM	Tyro, Axl, Mer (family of kinases)
TNBC	Triple negative breast cancer
sAxl	Soluble Axl
SD	Stable disease
SoC	Standard of Care
QTcF	QT interval, a measure of time in the heart's electrical cycle