



# **33<sup>rd</sup> Annual J.P. Morgan Healthcare Conference**

January 2015

# Forward-looking Statements

This presentation contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause Clovis Oncology's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences are discussed in Clovis Oncology's filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made, and Clovis Oncology undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

# Clovis Investment Highlights

- Three targeted oncology therapeutics in advanced clinical development
- Very encouraging monotherapy activity for all three agents
  - 50 percent or greater overall response rate (ORR) for each agent
- Largely unpartnered assets
- Multiple NDA and sNDA submissions planned over next three years
- IP protection to 2030 or beyond for each program
- Proven capability of developing targeted oncology drugs with companion diagnostics
- Strong balance sheet with nearly \$500 million cash

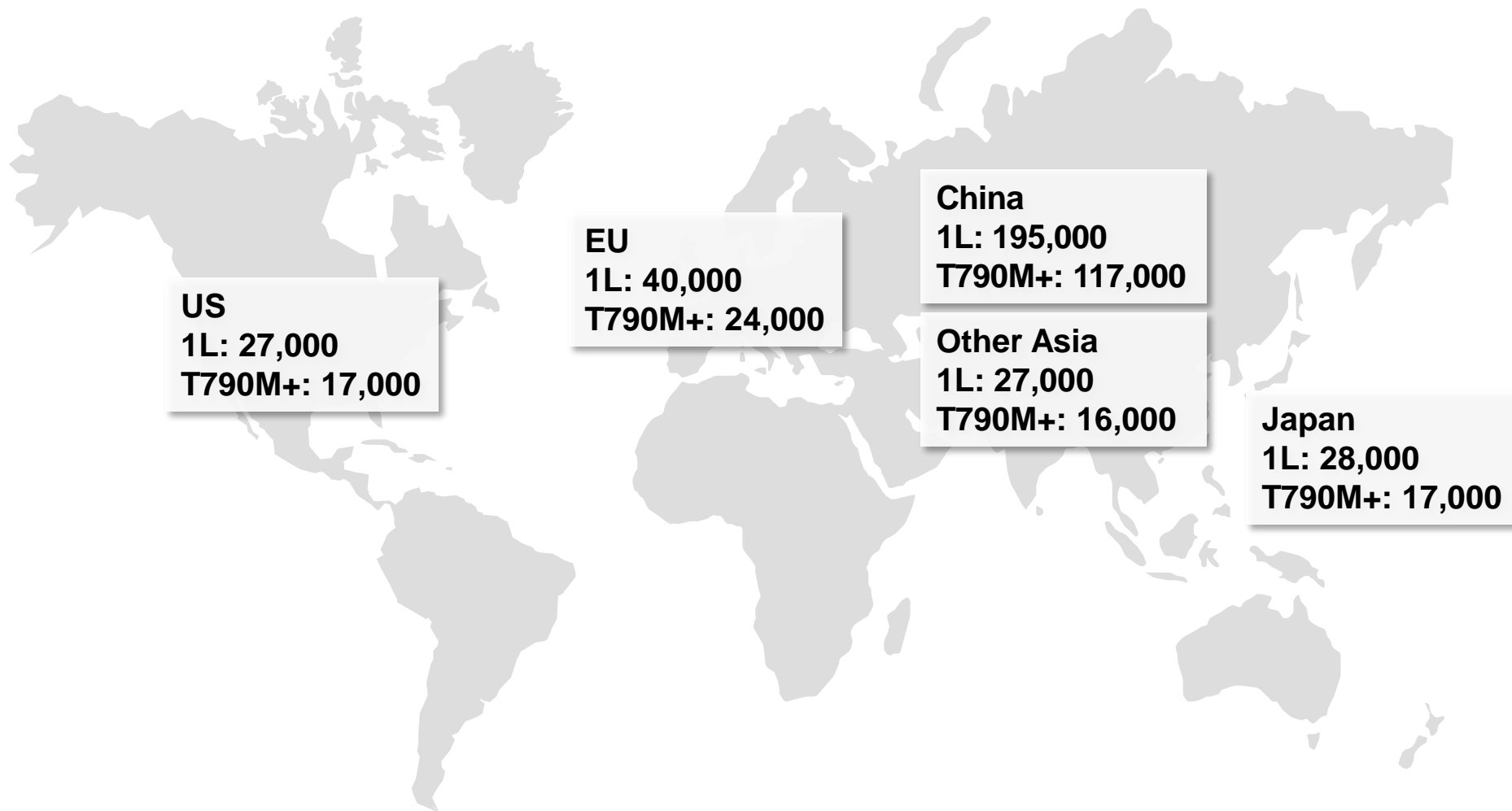
# 2015: A Transformational Year for Clovis

- Rociletinib in mutant EGFR lung cancer:
  - FDA Breakthrough Therapy Designation granted in T790M+ patients
  - Fully-enrolled NDA submission population Q4 2014
  - NDA and MAA submissions planned for mid-2015
  - Front-line and combination studies underway
  - Potential U.S. launch Q4 2015
- Rucaparib in ovarian cancer:
  - Expanded ARIEL2 into registration study; NDA planned for 2016
  - Enrollment of ARIEL3 maintenance study to complete within next 12 months
  - Unique BRCAness signature enables broad program in ovarian cancer and other tumor types
- Lucitanib in FGF-aberrant breast and lung cancer:
  - Targeted Phase 2 program underway in breast and lung cancers
  - First data from breast cancer study expected by YE 2015

# Rociletinib Overview

- Novel, oral, mutant selective covalent inhibitor of EGFR in NSCLC
  - Inhibits key EGFR activating and T790M resistance mutations
  - Only EGFR inhibitor in clinical development to spare wild-type (normal) receptor signaling
  - Initial focus on second-line therapy; front-line study underway
- Compelling and durable clinical activity and progression-free survival (PFS) data reported in T790M+ and T790M- patients at ENA in November 2014
- NDA and MAA submissions planned for mid-2015
  - QIAGEN to concurrently submit U.S. PMA for companion diagnostic
- Multiple combination studies to initiate in 2015
- Global rights held by Clovis
- IP through 2033

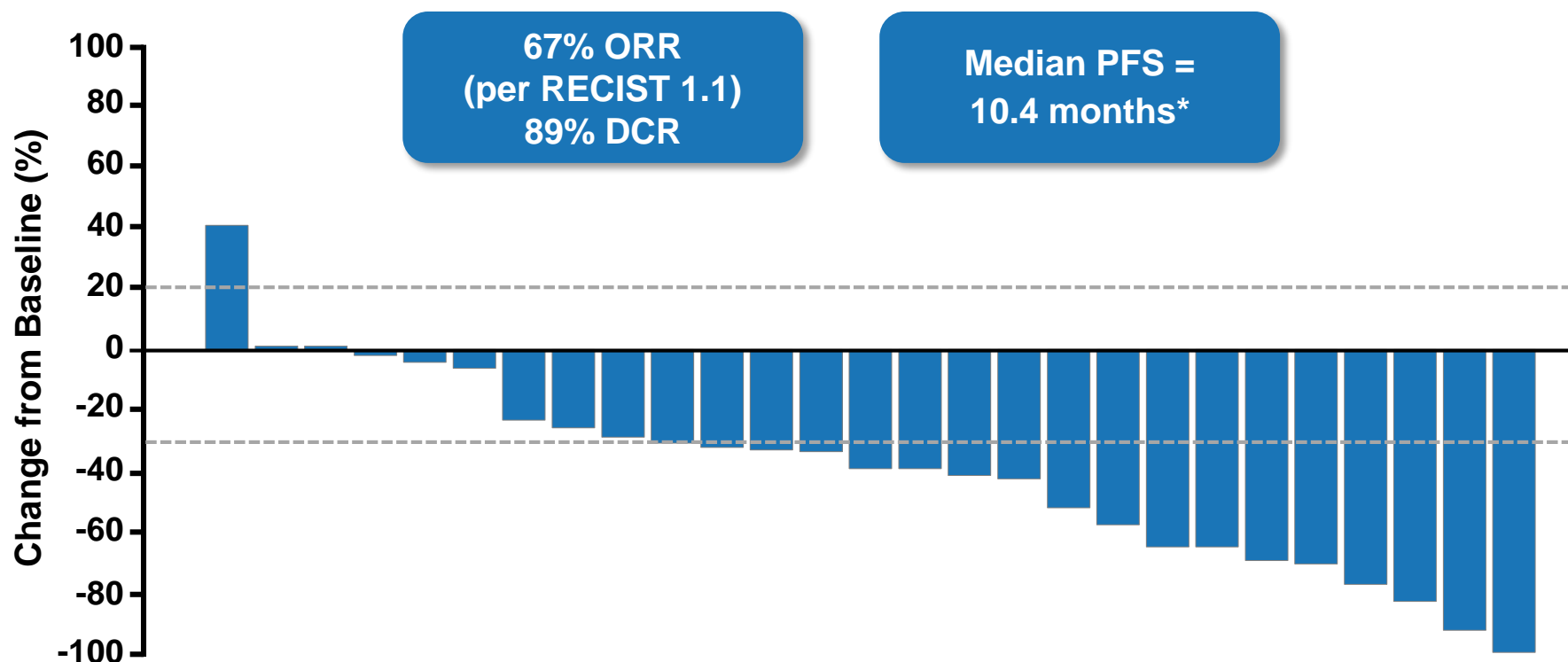
# Mutant EGFR NSCLC is a Common Disease: Much Higher Incidence in Asian Territories



Sources: estimated annual incidence of EGFR+ NSCLC; Globocan 2012; Clovis Oncology estimates

# Compelling Activity in Patients with EGFR-mutant NSCLC with T790M Mutation

## Best Response for Evaluable T790M+ Patients



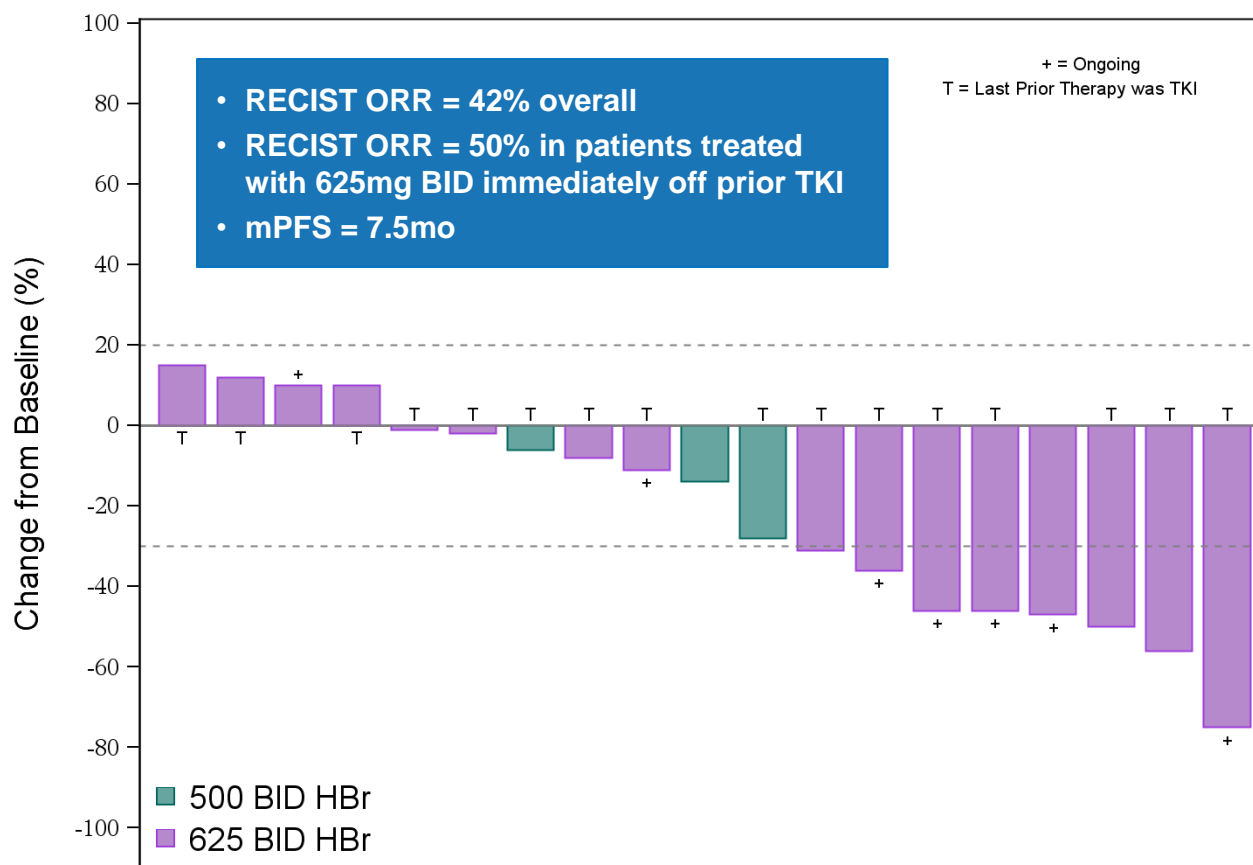
*Includes patients treated with 625mg or 500mg BID (clinical dose group)*

*\*Data as of 25 September 2014 reflecting 31% data maturity*

*Source: Data from Soria et al, ENA 2014*

# Striking Activity in T790M-negative Patients

## Best Response for Target Lesions Centrally Confirmed T790M Negative 1686-008 Pts at 500 or 625mg BID (Clinical Dose Group)



\*Database as of January 2<sup>nd</sup> 2015



# Why Is a Targeted Therapy Active in an Off-Target Population?

- Tumor heterogeneity?
- Extensive preclinical evidence that IGF1R is a driver of acquired resistance to EGFR TKIs
- New data from patients show IGF1R pathway important in acquired EGFR TKI resistance (*Science*, December 2014)
- Rociletinib metabolite inhibits IGF1R and insulin receptor
- Clovis now actively developing rociletinib in T790M negative patients
  - T790M negative patients represent a significant unmet medical need
  - Rociletinib may possess a unique competitive advantage

# Comprehensive Monotherapy Development Program



**TIGER**

**Find the TIGER trial  
that's right for you**

## **TIGER-X (Ph 2)**

- Single arm – expansion cohorts
- $\geq 2$ nd-line mutant EGFR NSCLC, T790M+

## **TIGER-1 (Ph 2/3)**

- Randomized rociletinib vs erlotinib
- 1st-line, treatment-naïve

## **TIGER-2 (Ph 2)**

- Single-arm
- 2nd-line mutant EGFR NSCLC, T790M+
- Patients progressing on 1st-line EGFR TKI
- Now adding T790M– cohort

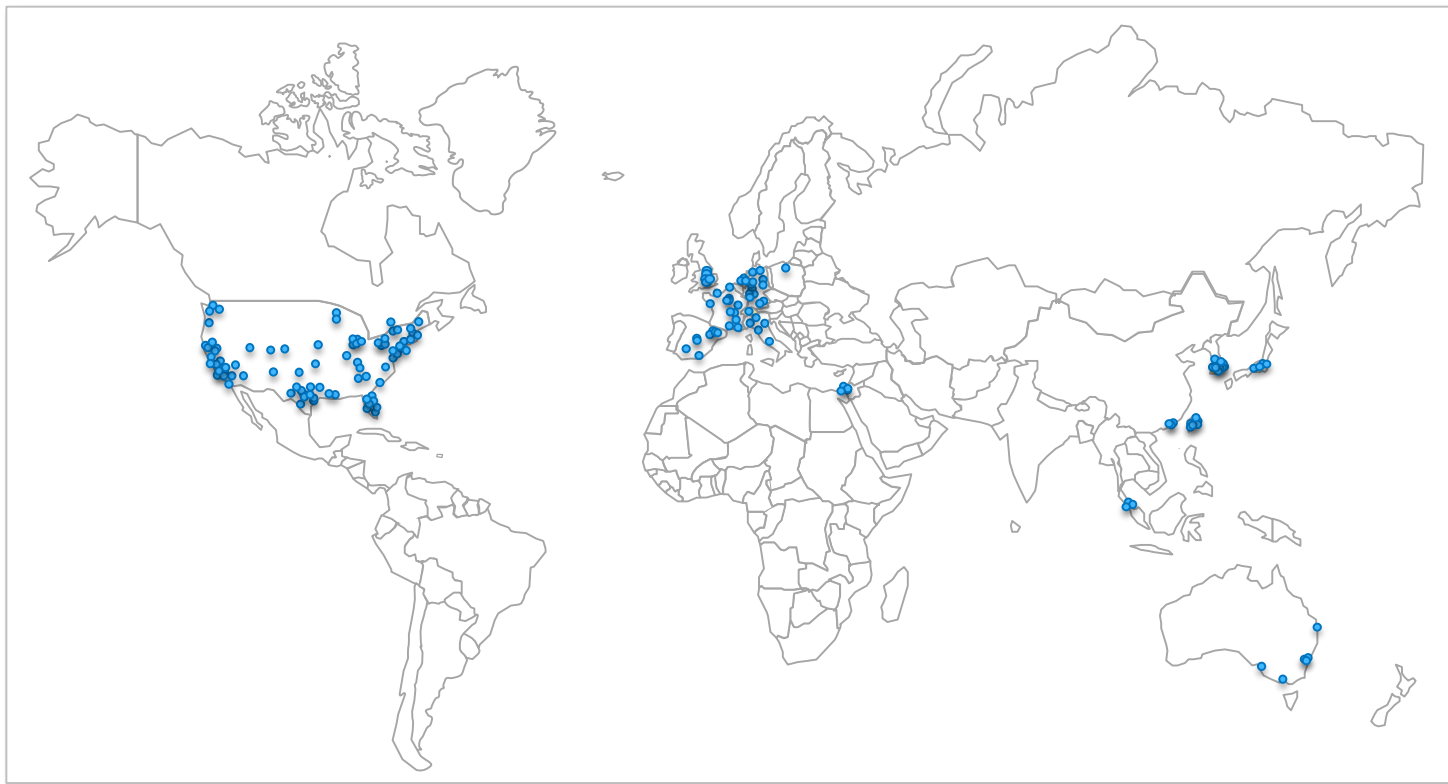
## **TIGER-3 (Ph 3)**

- Randomized rociletinib vs chemotherapy
- $> 2$ nd-line mutant EGFR NSCLC, T790M+ and T790M– (sequential analysis)

# Global TIGER program: More than 150 Sites Across Four Continents

**TIGER**

Find the TIGER trial  
that's right for you



# Rociletinib: Backbone of mEGFR Combination Therapy

- Highly active and well-tolerated monotherapy
- Combinations may build on existing strong efficacy and durability of benefit
  - Potential to overcome additional mechanisms of resistance
- Initial combination studies with:

Target	Drug
PDL1	mAb
PD1	Pembrolizumab (Merck)
MEK	Trametinib (GSK)
Aurora kinase	small molecule inhibitor

- Additional combinations expected in 2015

# Rociletinib Global Expanded Use Program

- Provides access to rociletinib for patients not eligible for the TIGER program
- Expected to initiate in the U.S. and Europe in Q2 2015
- U.S. Expanded Access Protocol
  - Broad U.S. geographic distribution
- Global Access Program
  - Initial focus in Europe
  - Reimbursement expected

# Initiating Robust U.S. Launch Plan in 2015

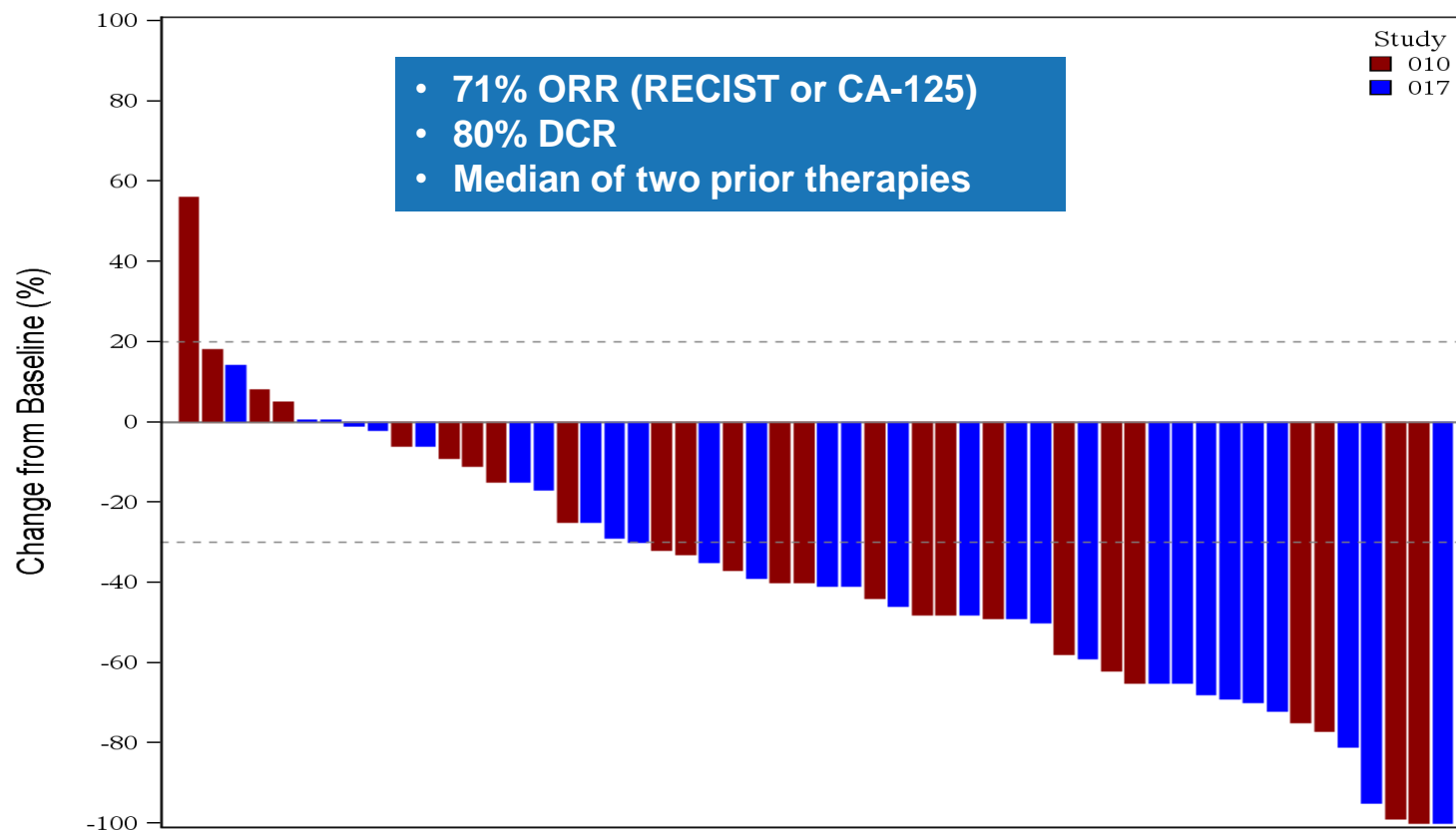
- Senior commercial and medical affairs leadership teams are now in place
  - U.S. MSL team to be fielded Q1 2015
  - Marketing, Market Access and Sales leadership in place
- U.S. disease education campaign launched
  - Impact on patients of wild-type EGFR inhibition
  - Role of T790M in resistance
- U.S. launch plan being implemented
  - Sales force planning
  - Market access strategy
  - Launch campaign being developed

# Rucaparib Overview

- Potent oral inhibitor of PARP-1 and PARP-2
- Striking activity in mutant BRCA ovarian cancer
  - 71% overall response rate (ORR)
- Unique focus beyond BRCA to patients with other DNA repair deficiencies (BRCAness) in ARIEL2 treatment study
  - 40% ORR in BRCAness ovarian cancer patients
  - Significant therapeutic potential in other tumor types
- Expanded ARIEL2 into registration study
  - Ovarian cancer patients who have failed three prior therapies
  - Three hundred mutant BRCA and BRCAness patients
  - NDA planned for 2016
- ARIEL3 maintenance study to complete enrollment in next 12 months
- Global rights held by Clovis
- IP through 2035

# Rucaparib: Highly Active in Women with mutant BRCA Ovarian Cancer and Prior Chemotherapy

**Best target lesion response to rucaparib 600mg BID – both germline and somatic BRCA mutations included**

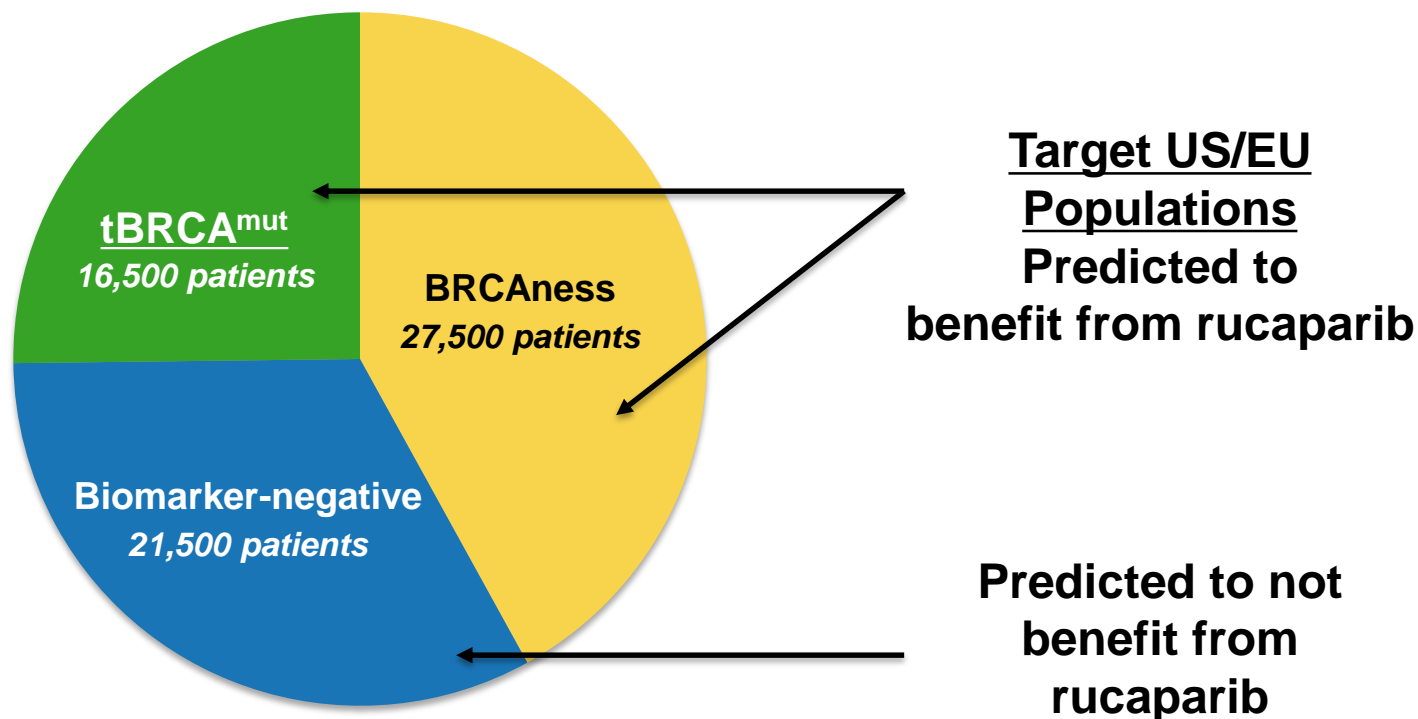


Source: Company data



# Ovarian Cancer Patients whose Tumors have BRCA Mutations or BRCAness Both Benefit from Rucaparib

**BRCAness: a significant additional opportunity**

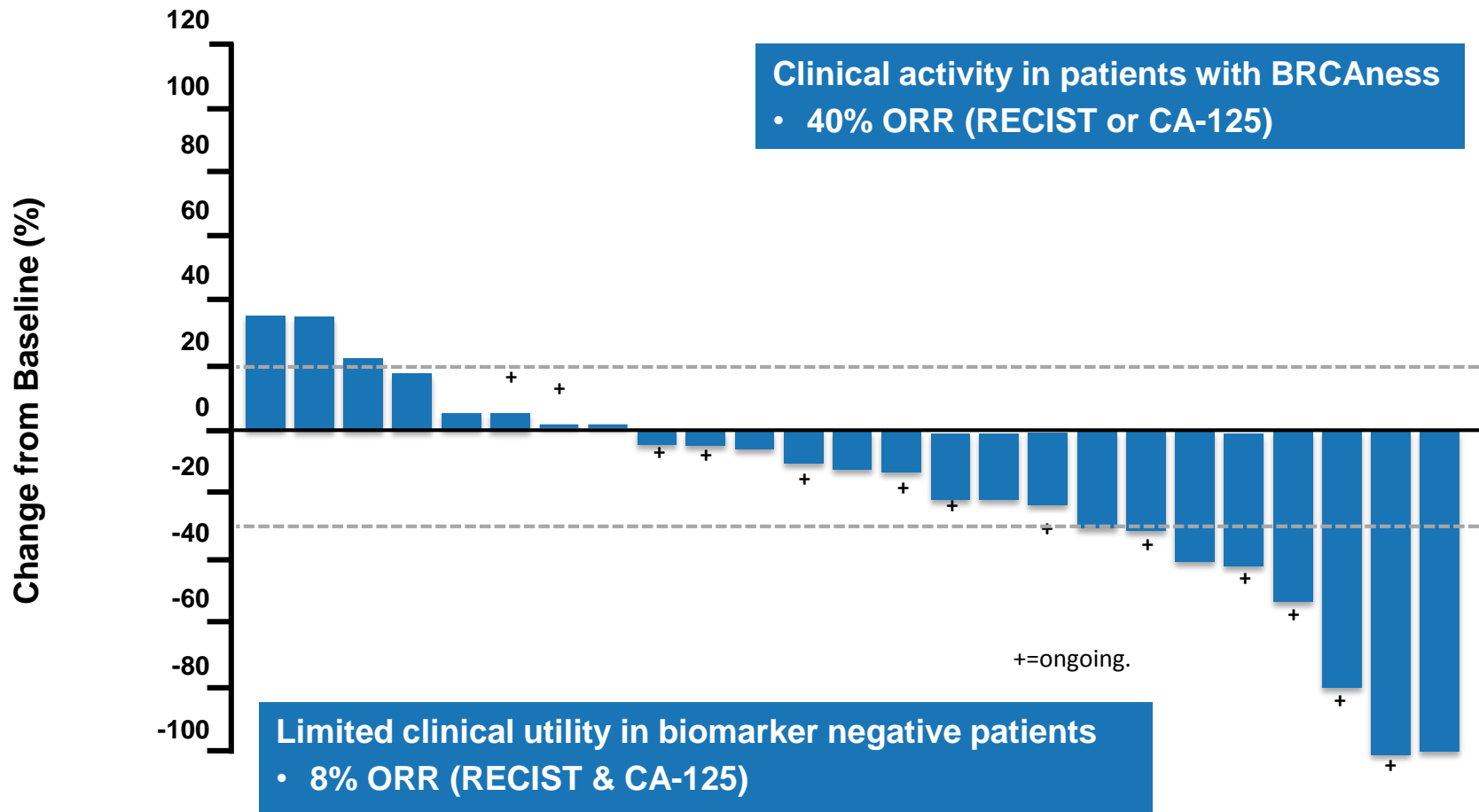


*tBRCA: tissue BRCA, incorporating both germline BRCA and somatic BRCA*

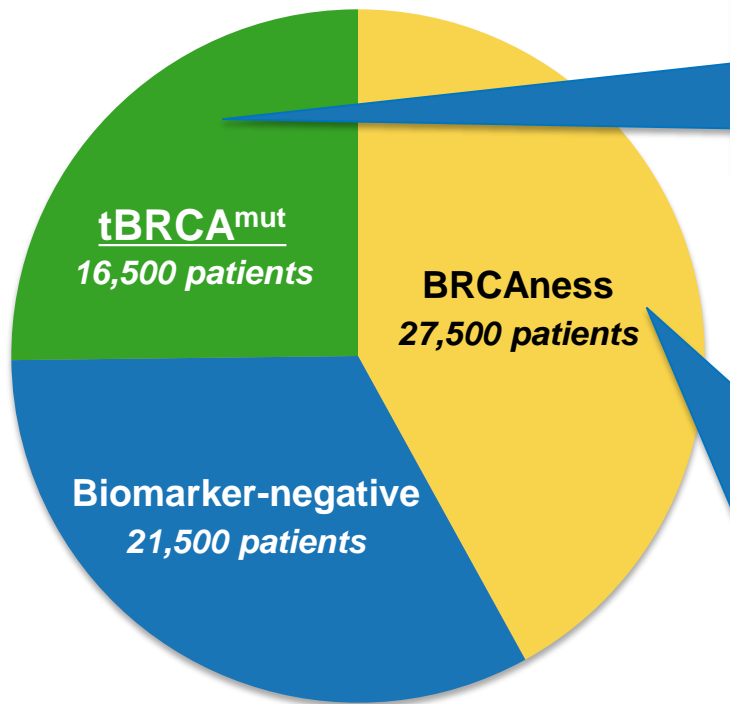
*Sources: Estimated annual incidence of ovarian cancer for US and EU is 65,500; Globocan 2012; Clovis Oncology estimates*

## Differential Rucaparib Activity Seen in Patients with BRCA-ness Signature

## Best Target Lesion Response



# The optimal companion diagnostic in ovarian cancer looks beyond gBRCA mutations



- Patients with germ-line (17%) and somatic (8%) BRCA mutations respond equally to rucaparib
- Tissue test (not blood) required to identify somatic mutations

- Tissue test also required to detect BRCAness (42%)
- Clovis developed a proprietary BRCAness signature
- Signature prospectively and successfully applied in an interim look at 200-patient ARIEL2 study
- Signature allows analysis of archival or fresh tissue – interesting differences observed
- Signature being applied prospectively in ARIEL3
- Foundation Medicine a key collaborator

*tBRCA: tissue BRCA, incorporating both germline BRCA and somatic BRCA*

*Sources: Estimated annual incidence of ovarian cancer for US and EU is 65,500; Globocan 2012; Clovis Oncology estimates*

# Ovarian Cancer Development Program



## Study 10 (Ph 2)

- Single arm
- Platinum-sensitive relapsed OC w/gBRCA mutation

## ARIEL2 (Ph 2)

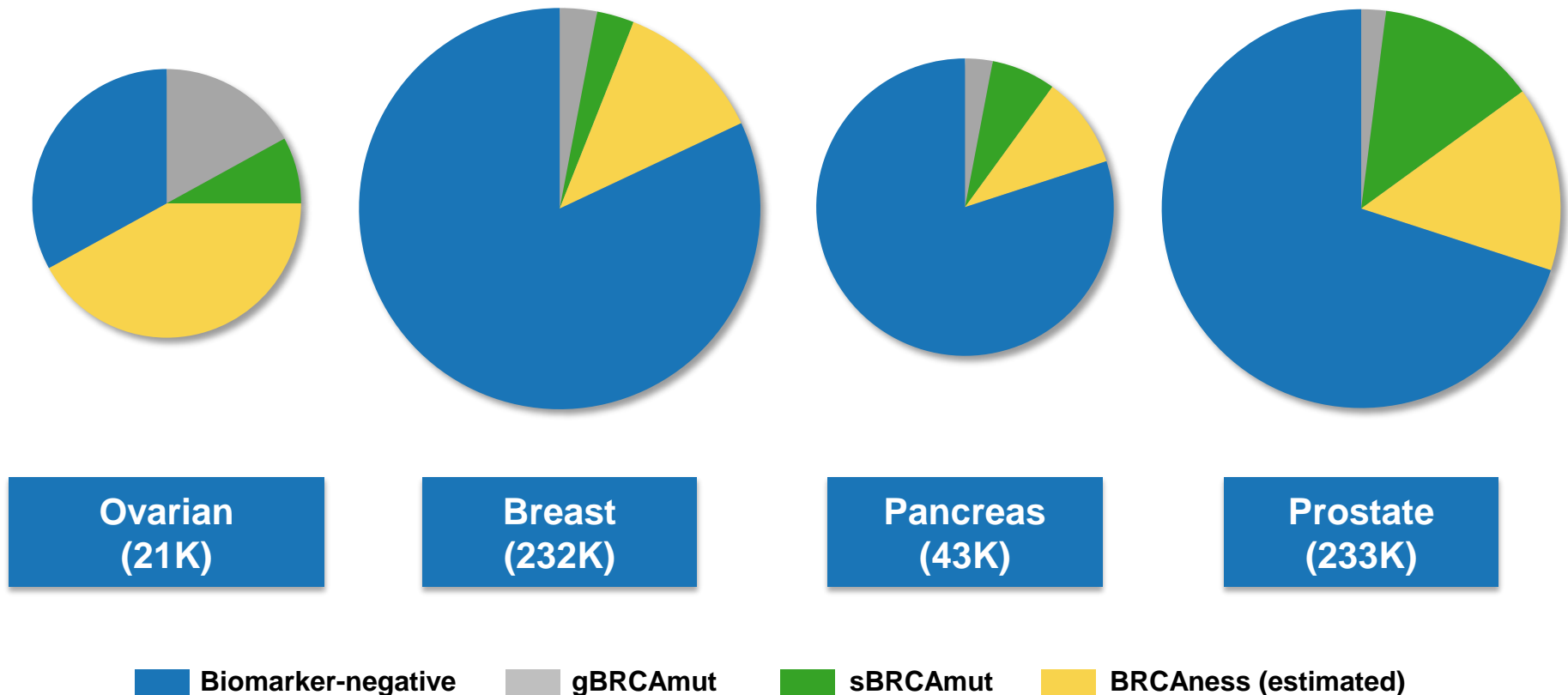
- Single arm registration study
- Treatment in relapsed OC
- Efficacy in prespecified HRD subgroups
- NDA planned for 2016

## ARIEL3 (Ph 3)

- Randomized placebo vs. rucaparib
- Switch-maintenance in platinum-sensitive OC
- Efficacy (PFS) in prospectively defined HRD subgroup

Exploration in other tumor types with BRCA and BRCAness:  
breast, gastroesophageal, pancreatic

## Other solid tumors are more common than ovarian, and have substantial BRCA and BRCAness populations



Source: US incidence, Globocan 2012; data from TCGA, ICGC, Genome Res. 2011 21:47-55, Eur Urol (2012)  
<http://dx.doi.org/10.1016/j.euro.2012.08.053>. Clovis estimates of size of BRCA and BRCAness populations.

# Treating BRCAness in Breast Cancer: The RUBY Study

- BRCA mutation and BRCAness seen widely in breast cancer
- Large French cooperative group, Unicancer, expressed interest in initiating study after viewing ENA data in November 2014
- RUBY: a single arm, open-label, Phase 2 study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic signature
  - Study to include HER2 negative, ER/PR positive patients
- Unicancer will sponsor the trial in 25 sites across France
- Study expected to initiate in Q2 2015

# Lucitanib Overview

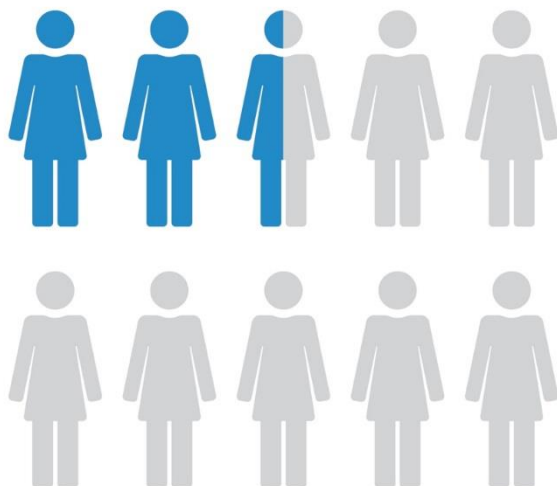
- Oral TKI targeting FGFR 1-3; VEGFR 1-3; and PDGFR  $\alpha/\beta$
- 50% ORR in heavily pre-treated FGF-aberrant breast cancer patients
- Clovis holds exclusive rights for lucitanib in the U.S. and Japan
  - Rights in Europe and ROW markets sub-licensed to Servier
  - Servier to fund initial €80 million global research and development program
- Three Phase 2 monotherapy trials of lucitanib are underway
  - Initial focus on breast and lung cancer
- Preliminary U.S. breast cancer data expected 2H 2015
- Potential Phase 3 breast cancer study to initiate 2016
- IP through 2030

*Source: Soria et al ASCO 2014*

# Lucitanib may address two of the most common cancers

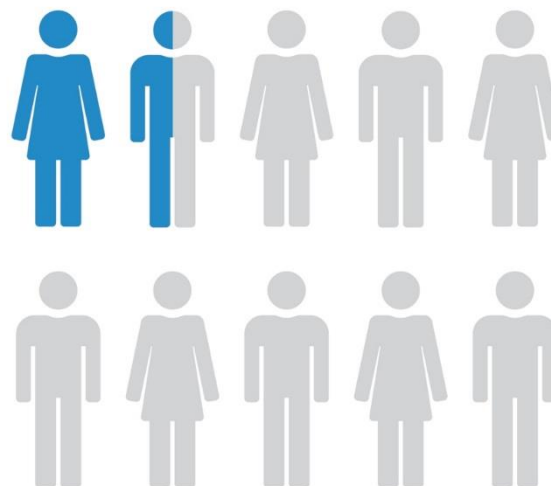
## Breast Cancer

~25% of breast cancer  
is FGF aberrant



## Lung Cancer

~15% of lung cancer is  
FGF aberrant





# 2015: A Transformational Year for Clovis

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  - Fully-enrolled NDA submission population Q4 2014
  - NDA and MAA submissions planned mid-2015
  - Planning for commercial launch Q4 2015
  - Initiating multiple combination studies
- Rucaparib – global registration studies underway in ovarian cancer
  - ARIEL2 expanded into registration study in mBRCA and BRCAness patients; NDA planned for 2016
  - Enrollment of ARIEL3 maintenance study to complete in next 12 months
  - Unique BRCAness signature enables broad program in ovarian cancer and other tumor types
- Lucitanib – Targeted Phase 2 program underway in breast and lung cancers
  - First data from breast cancer study expected by YE 2015
- Strong balance sheet with nearly \$500 million cash