

Majority-stake investment in Acerta Pharma

17 December 2015



Forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement:

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; effects of patent litigation in respect of IP rights; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing; the risks associated with manufacturing biologics; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; the risk that new products do not perform as we expect; failure to achieve strategic priorities or to meet targets or expectations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the risk of misuse of social media platforms and new technology; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the risks from pressures resulting from generic competition; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; economic, regulatory and political pressures to limit or reduce the cost of our products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.



Agenda

Overview

Pascal Soriot



Opportunity

Luke Miels



Clinical

Sean Bohan



Financials

Marc Dunoyer



Closing

Pascal Soriot



Overview

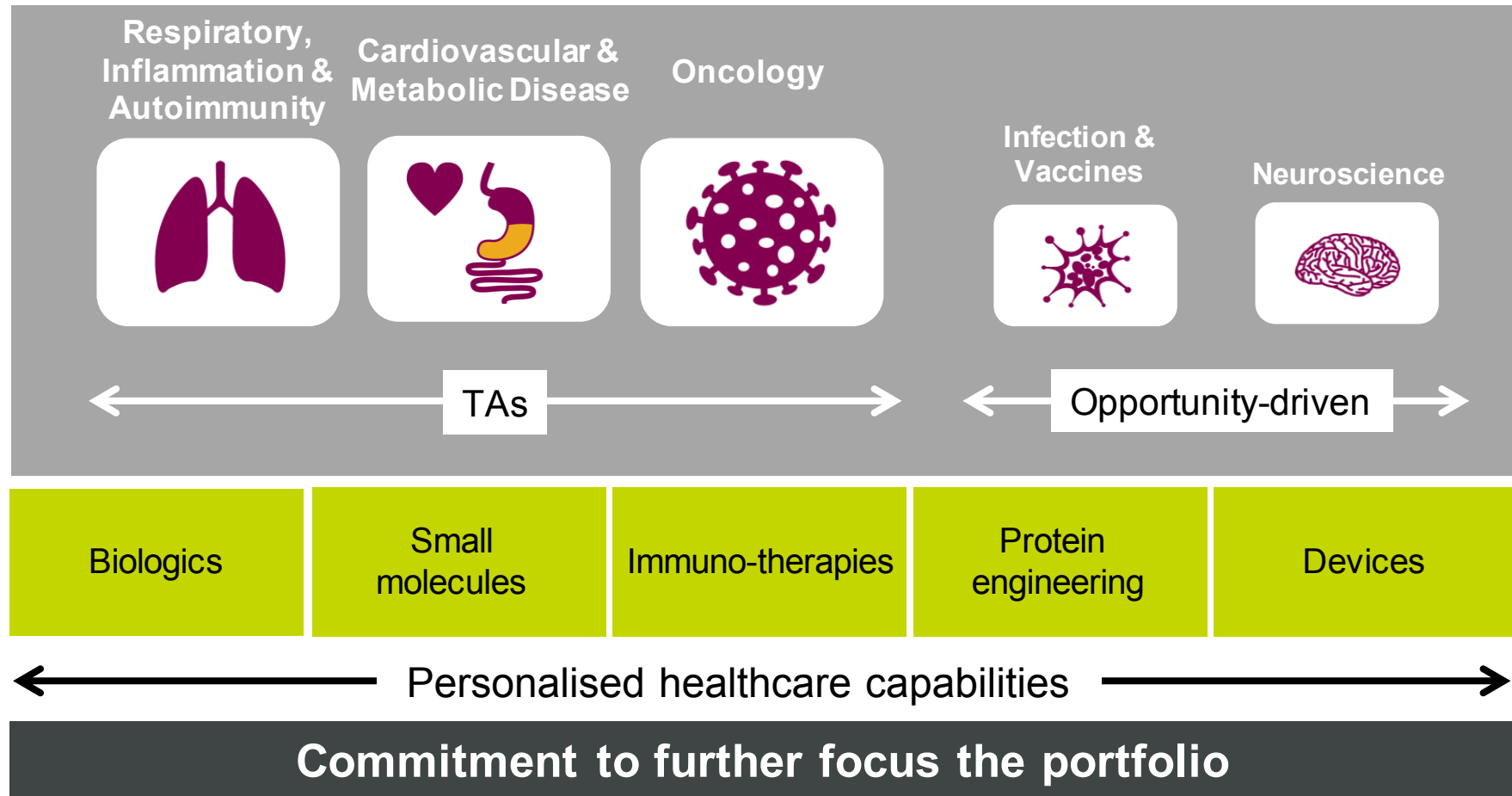
On-strategy, focused investment

- ACP-196 (acalabrutinib) potentially best-in-class Bruton's Tyrosine Kinase inhibitor (BTKi)
 - Global potential peak-year Product Sales in excess of \$5bn with opportunity for first regulatory submission in H2 2016
- 55% stake now (\$2.5bn + \$1.5bn deferred)
 - Option to acquire remainder (~\$3bn)
- Supports Return to Growth and completes AstraZeneca's transformation in Oncology
- Acerta to become AstraZeneca's 'Centre of Excellence' for haematology
- Synergistic with Celgene partnership



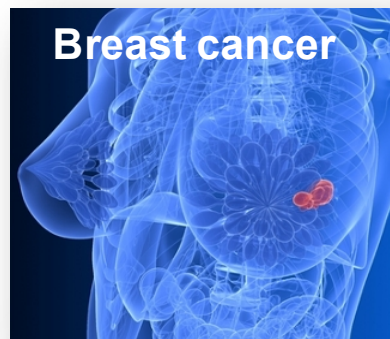
Achieve Scientific Leadership

R&D in three therapy areas (TAs) and across key platforms



Acerta: On-strategy investment for AstraZeneca

Completes AstraZeneca's transformation in Oncology



Faslodex,
pipeline



Lynparza,
cediranib, WEE-1



Tagrisso,
Iressa



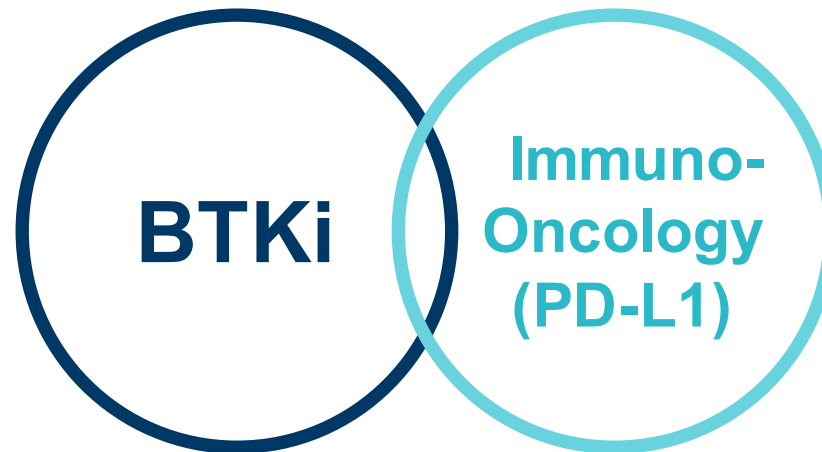
acalabrutinib

Immuno-Oncology

Four disease areas with first or best-in-class cornerstone medicines



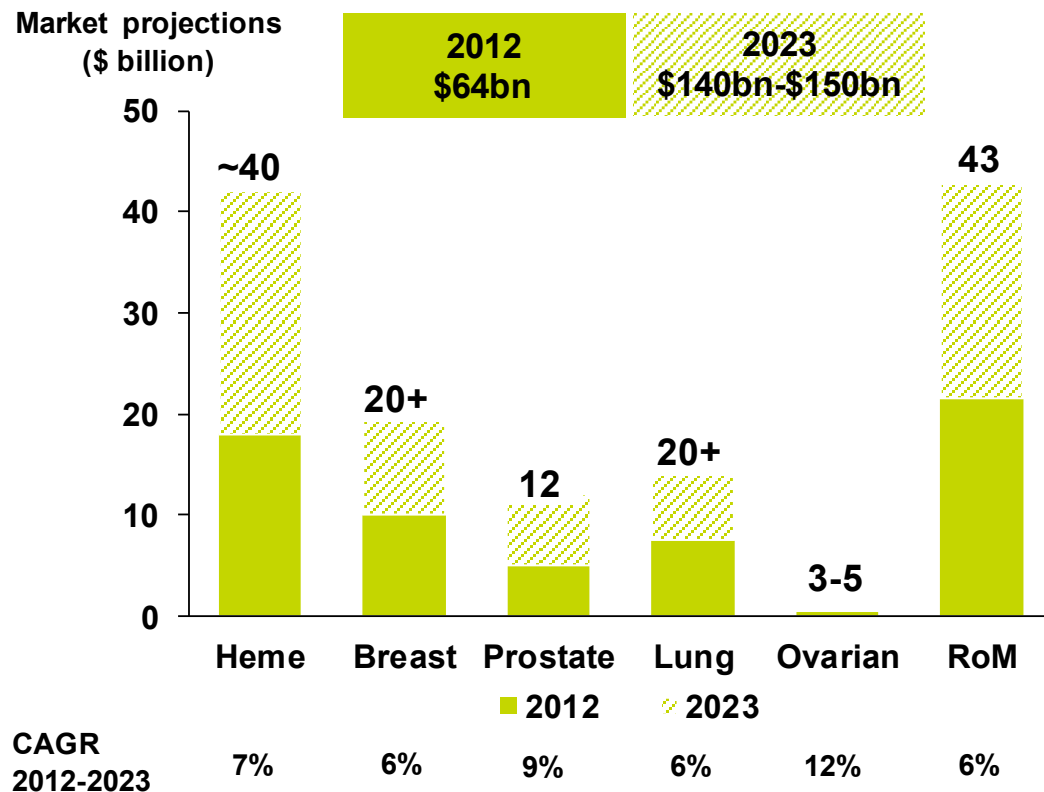
Two highly-attractive modes of action in one portfolio



Haematology: Significant growth market in Oncology

Accounts for ~1/3 of total Oncology market

Overall market size



Medicine	2014 sales (\$bn)	Indications*
Rituxan/MabThera	\$6.2	DLBCL, FL, CLL
Revlimid	\$5.0	MM, MDS, MCL
Gleevec	\$4.8	CML
Velcade	\$2.1	MM
Tasigna	\$1.5	CML
Treanda	\$0.8	CLL, FL
Imbruvica	\$0.5	CLL, MCL, WM

* DLBCL=Diffuse Large B-Cell Lymphoma; CLL=Chronic Lymphocytic Leukaemia; FL=Follicular Lymphoma; MDS=Myelodysplastic Syndromes; MCL=Mantle Cell Lymphoma; MM=Multiple Myeloma; WM=Waldenstrom Macroglobulinemia

Note: Chart data exclude sales of medicines used for supportive care in oncology

Source: Decision Resources, EvaluatePharma, Datamonitor, company reported sales, and IMS



The promise of targeted therapies in haematology

Example in CLL

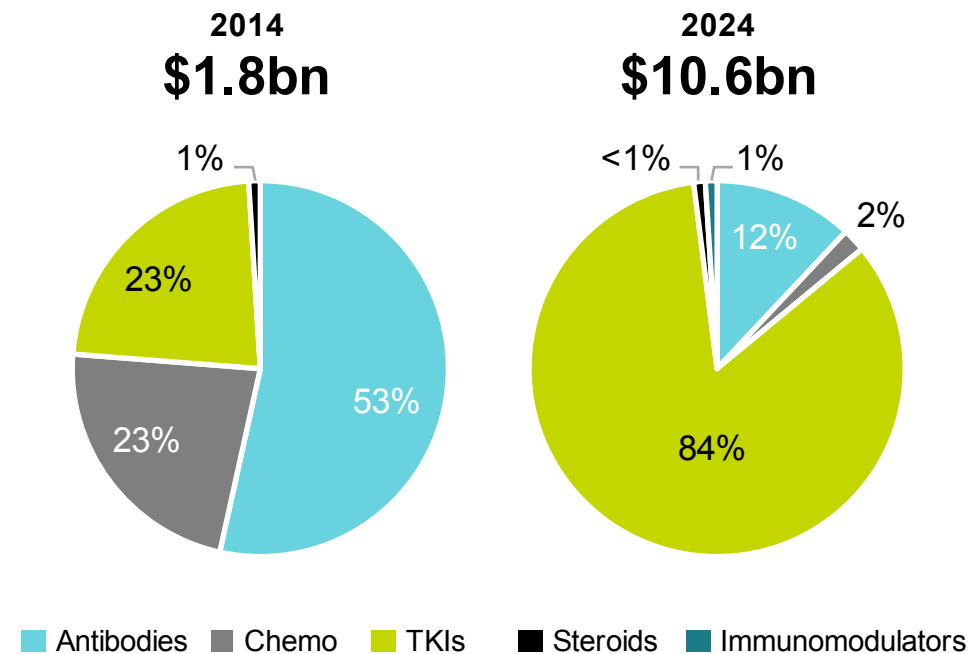
Medical need

- Median age of onset ~70 years old
- Majority of patients with existing comorbidities
- Requires highly efficacious treatment with good tolerability

BTKi class

- Highly efficacious; 3-5 years progression-free survival
- Convenient oral administration
- Chemo-free regimen with potential for improved tolerability
- Long duration of treatment

Projected G7 market

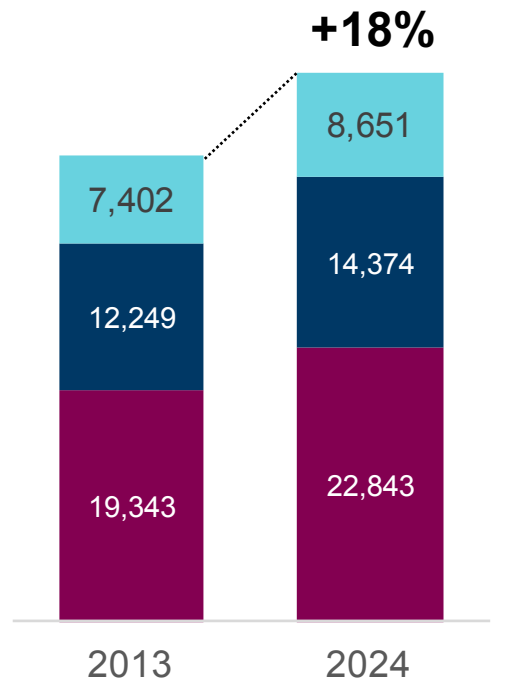


Source: Decision Resources, NHL, November 2015



CLL market growth underpinned by aging population and longer treatment duration

Medicine-treated population



■ 1st Line ■ 2nd Line ■ 3rd Line+

Treatment duration*

CD20, e.g. rituximab + chemo-containing regimen

5.5 months

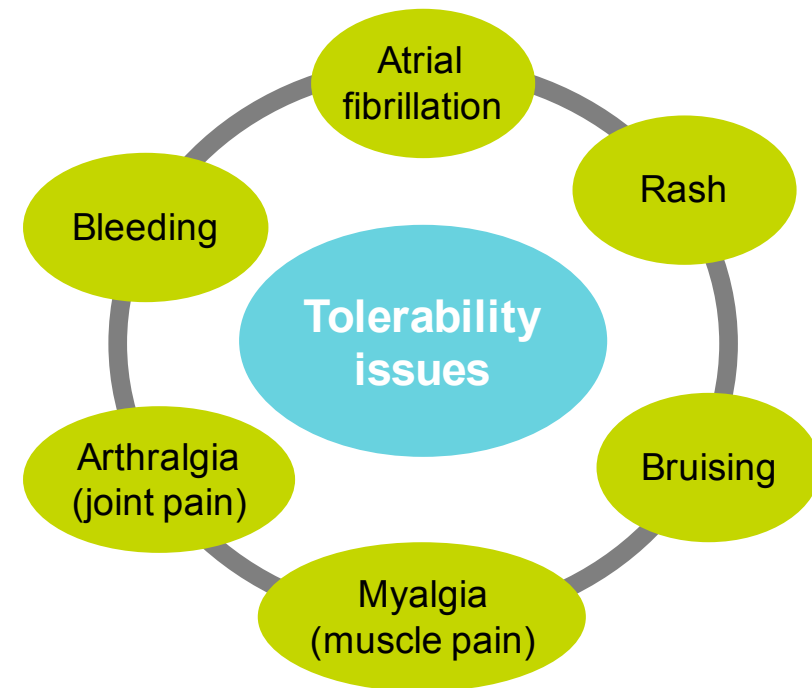
BTKi regimen

35 months



BTK inhibition requires continuous target suppression

- Long duration of treatment
- Maintaining response requires continuous dosing
- Interruptions or dose reductions can lead to fast disease progression or resistance
- In NHL, combinations are needed for superior efficacy and tolerability is critical



Source: Jain, P. (2015). Outcomes of patients with chronic lymphocytic leukemia after discontinuing ibrutinib. *Blood*. 125(13):2062-2067

11 Maddocks, K.J. (2014). Etiology of Ibrutinib Therapy Discontinuation and Outcomes in Patients With Chronic Lymphocytic Leukemia. *JAMA Oncol*. doi:10.1001/jamaoncol.2014.218

Farooqui, M. (2015). Atrial Fibrillation in CLL/SLL Patients on Ibrutinib; *ASH Abstract# 2933*

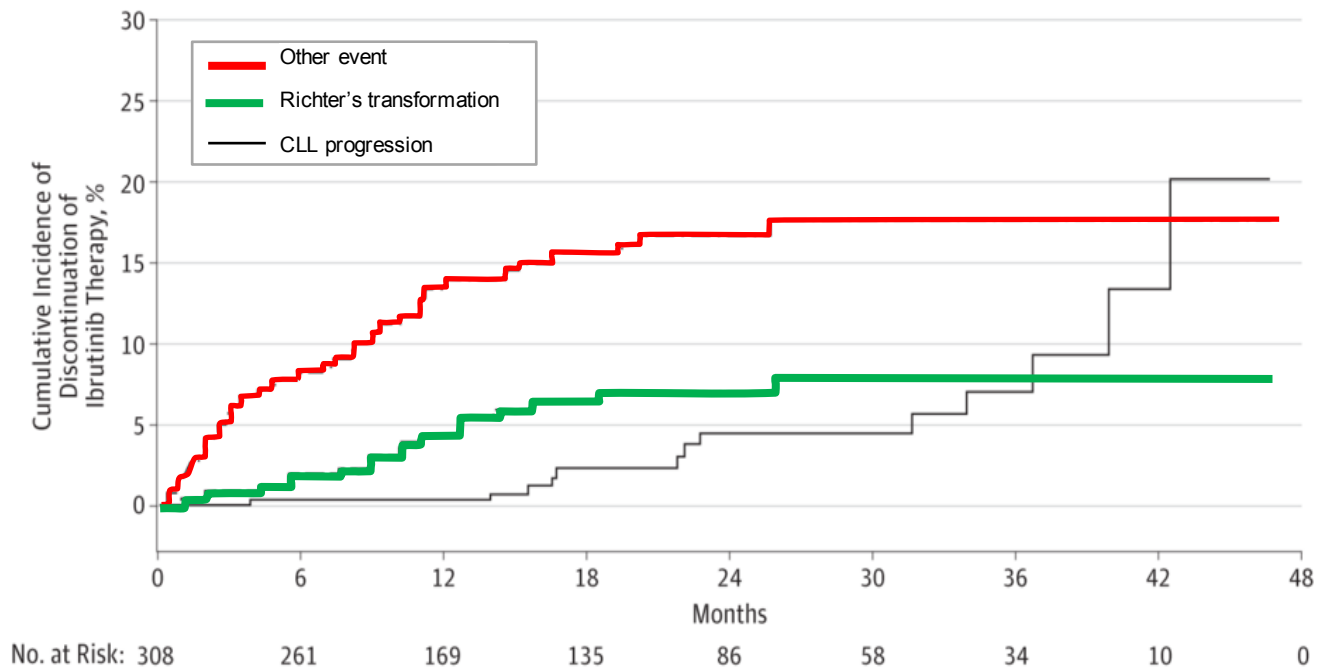


First-generation BTK inhibitor

Discontinuations from multiple factors

Original Investigation

Etiology of Ibrutinib Therapy Discontinuation and Outcomes in Patients With Chronic Lymphocytic Leukemia



Richter's transformation: A transformation which occurs in some patients with CLL into a fast-growing diffuse large B cell lymphoma, a variety of non-Hodgkin lymphoma which usually carries a worse prognosis.

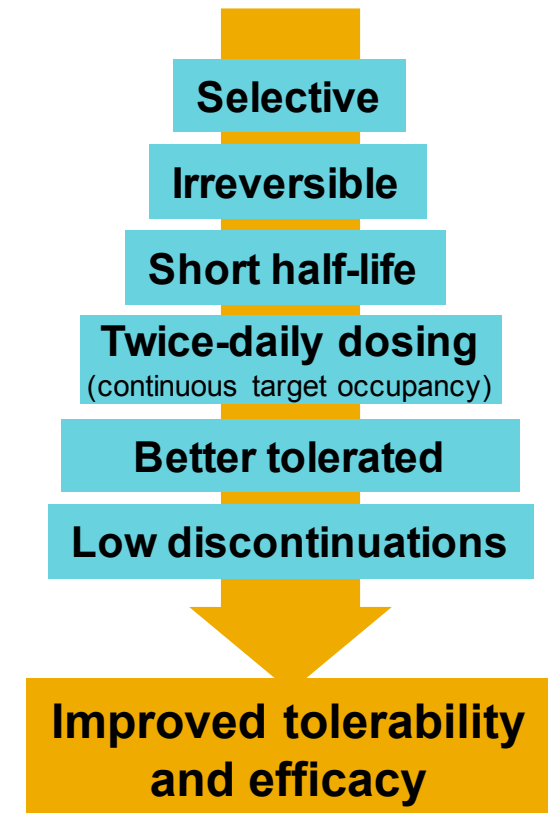
JAMA Oncol. doi:10.1001/jamaoncol.2014.218
Published online February 26, 2015.



Acalabrutinib: The molecule

Second-generation BTKi with best-in-class potential

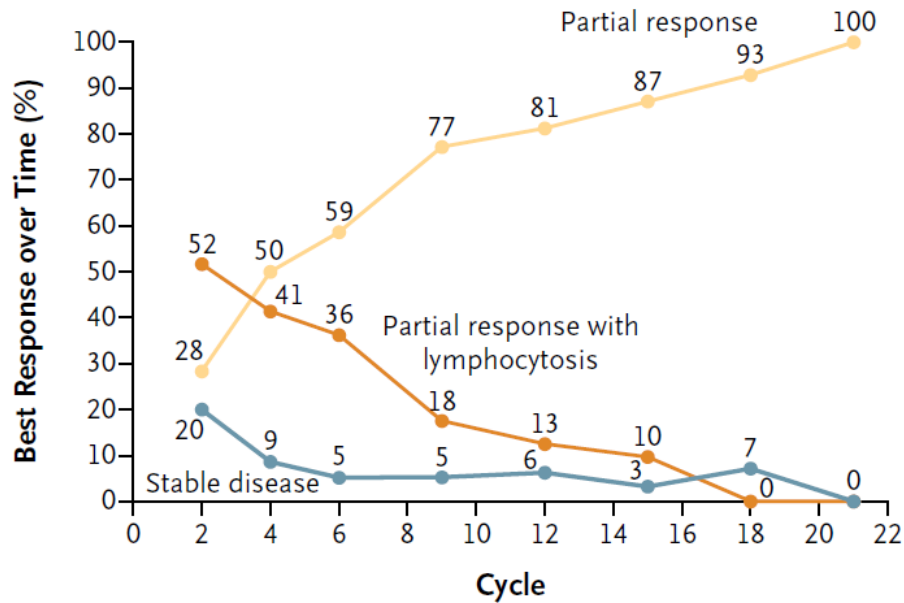
- Approximately 1,000 patients treated to date; more than 600 as monotherapy
- Better overall tolerability
- Lower rate of discontinuations



Acalabrutinib: Remarkable efficacy

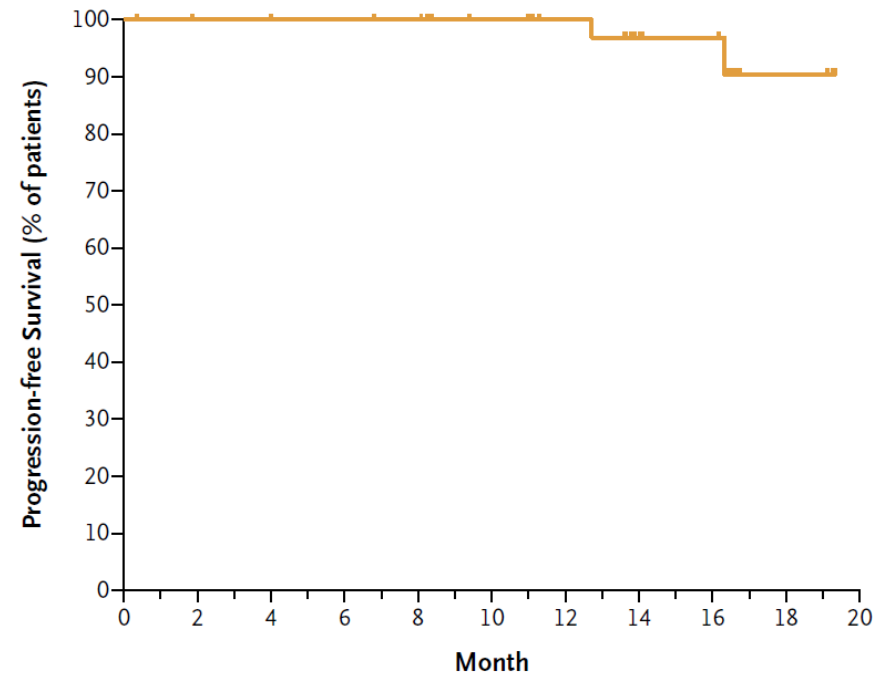
Phase I in relapsed/refractory (R/R) CLL

Best response per 28-day cycle



No. of Patients: 60, 58, 58, 57, 48, 31, 14, 3

Progression-Free Survival



No. at Risk: 61, 60, 59, 59, 59, 58, 58, 57, 57, 49, 48, 48, 32, 31, 20, 16, 16, 3, 3, 3



Acalabrutinib: Haematology development

Regulatory submission possible from H2 2016

Indication	Trial design and line of therapy	Phase
CLL/SLL	acalabrutinib vs. ibrutinib R/R CLL	III
	acalabrutinib + obinutuzumab vs. obinutuzumab + chlorambucil vs. acalabrutinib TN CLL	III
	acalabrutinib, First in human study R/R CLL, including ibrutinib-intolerant	I/II
	acalabrutinib Ibrutinib-intolerant CLL patients	II
	acalabrutinib + ACP-319 (PI3K delta) R/R CLL	I
	acalabrutinib + obinutuzumab TN, R/R CLL/SLL/PLL	Ib
DLBCL	acalabrutinib open label R/R de novo ABC DLBCL	Ib
FL	acalabrutinib open label R/R FL	Ib
MCL	acalabrutinib open label R/R MCL	II
MM	acalabrutinib open label R/R MM	Ib
WM	acalabrutinib open label R/R WM	Ib/II
NHL	acalabrutinib + ACP-319 (PI3K delta) R/R NHL	I/II
	acalabrutinib + pembrolizumab R/R NHL	Ib/II



Acalabrutinib: Solid cancers and inflammation

Pancreatic 1L

- acalabrutinib + G/A vs. G/A
- Phase II trial
 - N = 120
 - ORR primary endpoint

Pancreatic 2L

- acalabrutinib + P vs. acalabrutinib
- Phase II trial
 - N = 76
 - DCR primary endpoint

Bladder

- acalabrutinib + P vs. P
- Phase II trial
 - N = 74
 - ORR primary endpoint

SCCHN

- acalabrutinib + P vs. P
- Phase II trial
 - N = 74
 - ORR primary endpoint

NSCLC

- acalabrutinib + P vs. P
- Phase II trial
 - N = 74
 - ORR primary endpoint

Ovarian

- acalabrutinib + P vs. acalabrutinib
- Phase II trial
 - N = 76
 - ORR primary endpoint

Rheumatoid Arthritis

- acalabrutinib + MTX
- Phase II trial
 - N = 70
 - DAS28-CRP primary endpoint

G = gemcitabine; A = nab-paclitaxel; P = pembrolizumab; MTX = methotrexate; SCCHN = squamous cell cancer of the head and neck; NSCLC = Non-Small Cell Lung Cancer; DCR = Disease Control Rate; ORR = Objective Response Rate;



Acalabrutinib: Development summary

- Approximately 1,000 patients treated so far across multiple indications, including ibrutinib-intolerant patients
 - More than 600 patients on monotherapy; almost 400 patients on combinations
- Tolerability and initial efficacy data indicate best-in-class BTKi
- Multiple registration approaches included in the development plan
- Initial data in solid cancers expected in 2016
- Initial regulatory submission planned for H2 2016



Financial terms

AstraZeneca to acquire 55% equity stake

- Initial payment of \$2.5bn
- Deferred payment of \$1.5bn; earlier of US approval or 31 December 2018

Options for Acerta shareholders to sell, and AstraZeneca to buy the remaining 45% for an additional ~\$3bn

Completion expected by end of Q1 2016, subject to customary closing conditions

- Transaction to be accounted for as business combination
- Funded by cash and debt



Financial terms

Long-term value creation potential

- Late-stage development medicine with expected 2017 launch and potential peak-year Product Sales in excess of \$5bn

Near and medium-term commitments maintained

- Moderately dilutive to Core EPS in near term
- Progressive dividend policy
- FY 2016 guidance on 4 February 2016 with FY 2015 results



Summary

On-strategy, focused investment

- ACP-196 (acalabrutinib) potentially best-in-class Bruton's Tyrosine Kinase inhibitor (BTKi)
 - Global potential peak-year Product Sales in excess of \$5bn with opportunity for first regulatory submission in H2 2016
- 55% stake now (\$2.5bn + \$1.5bn deferred)
 - Option to acquire remainder (~\$3bn)
- Supports Return to Growth and completes AstraZeneca's transformation in Oncology
- Acerta to become AstraZeneca's 'Centre of Excellence' for haematology
- Synergistic with Celgene partnership



Q&A

Please press *1 on your phone to indicate that you wish to ask a question

