# 2Q and Half Year Results 2010



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# 2Q and Half Year Results 2010

**David Brennan, CEO** 



### **Key Developments 1H 2010**

- Brilinta US FDA Advisory Committee
- US Court upholds US Crestor patent
- Progress on R&D change programme



## Senior leadership appointments in R&D



**Mene Pangalos**EVP, Innovative Medicines



Martin Mackay
President, Research
& Development



Anders Ekblom

EVP, Global Medicines

Development



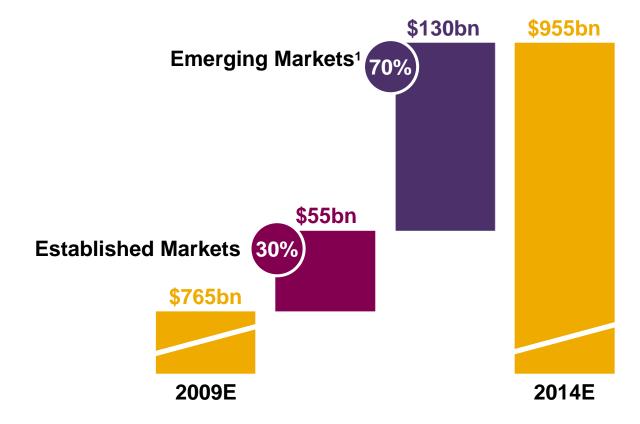
### **Key Developments 1H 2010**

- Brilinta US FDA Advisory Committee
- US Court upholds US Crestor patent
- Progress on R&D change programme
- Emerging Markets opportunity



## Emerging markets are forecast to contribute ~70% of pharma growth in the next 5 years

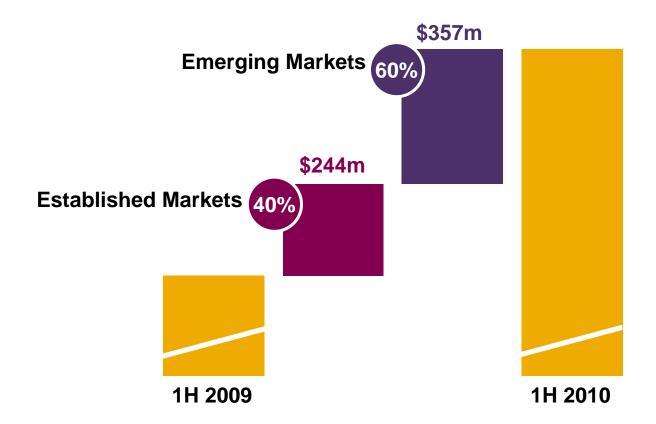
#### Worldwide pharmaceutical sales



Emerging markets projected to grow at a 12% CAGR from 2009-2014



#### AstraZeneca revenue 1H 2010





### **Key Developments 1H 2010**

- Brilinta US FDA Advisory Committee
- US Court upholds US Crestor patent
- Progress on R&D change programme
- Emerging Markets opportunity
- Healthcare reform in US and Europe
- Mid-term planning assumptions for revenue, Pre-R&D margins and cash generation & investment (2010-14)
- Dividend and share repurchases



#### **Headline results 1H 2010**

|   | 2010<br>\$m                                | 2009<br>\$m                                 | Actual growth | CER<br>growth |
|---|--|---|---------------|---------------|
| Sales   | 16,754                                     | 15,659                                      | +7%           | +4%           |
| Core Operating Profit   | 7,507                                      | 6,968                                       | +8%           | +5%           |
| Core EPS  Restructuring  MedImmune/Merck amortisation  Legal provisions | \$3.82<br>(\$0.30)<br>(\$0.14)<br>(\$0.01) | \$ 3.22<br>(\$0.13)<br>(\$0.13)<br>(\$0.30) | +19%          | +16%          |
| Reported EPS  | \$3.37                                     | \$ 2.66                                     | +27%          | +23%          |



### **Headline results 1H 2010**

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| Reported EPS          | \$3.37      | \$ 2.66     | +27%          | +23%          |
| Interim Dividend      | \$0.70      | \$ 0.59     |               |               |



# 2Q and Half Year Results 2010

Simon Lowth, Chief Financial Officer

## **Agenda**

- 2Q 2010 headline results
- Restructuring
- Cash flow and balance sheet
- Shareholder return programme
- Guidance update for FY 2010



### **Headline results 2Q 2010**

|   | 2010<br>\$m                                | 2009<br>\$m                                 | Actual growth | CER<br>growth |
|---|--|---|---------------|---------------|
| Revenue   | 8,178                                      | 7,958                                       | +3%           | +1%           |
| Core Operating Profit   | 3,650                                      | 3,606                                       | +1%           | -             |
| Core EPS  Restructuring MedImmune/Merck amortisation Legal provisions | \$1.79<br>(\$0.25)<br>(\$0.07)<br>(\$0.01) | \$ 1.64<br>(\$0.10)<br>(\$0.06)<br>(\$0.30) | +9%           | +9%           |
| Reported EPS  | \$1.46                                     | \$1.18                                      | +24%          | +22%          |



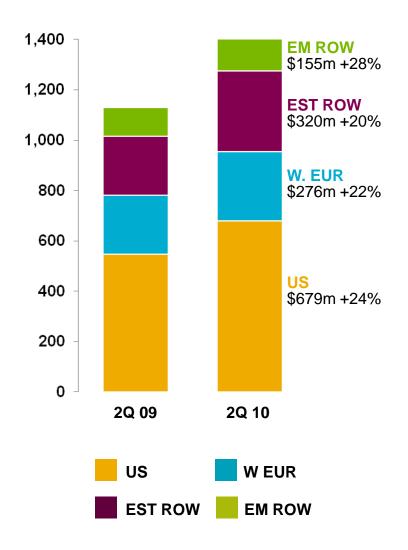
## Regional revenue performance 2Q 2010

|                  | 2010<br>\$m | CER<br>growth |
|------------------|-------------|---------------|
| Total Revenue    | 8,178       | +1%           |
|                  |             |               |
| US               | 3,396       | -4%           |
| Western Europe   | 2,213       | +1%           |
| Established ROW  | 1,277       | +4%           |
| Emerging Markets | 1,292       | +16%          |



#### **Crestor**

2Q10 Sales: \$1,430m +23%



#### US

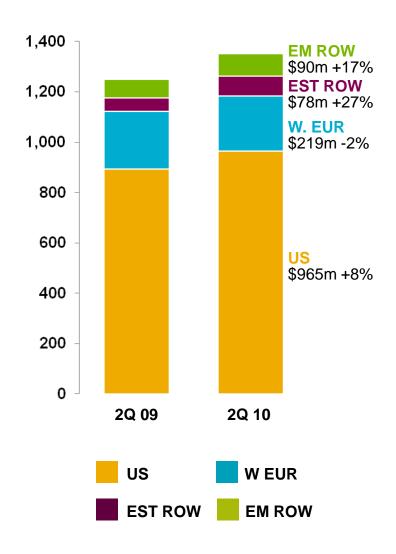
- US TRx +12%
  - 4 times statin market
- US TRx share 11.8% in June
- Dynamic share >16%
  - Second only to Simvastatin

- ROW sales \$751m +22%
- Volume growth 3 times statin market



## Seroquel

2Q10 Sales: \$1,352m +8%



- Seroquel IR: \$1,049m -5%
- Seroquel XR: \$303m +92%

#### US

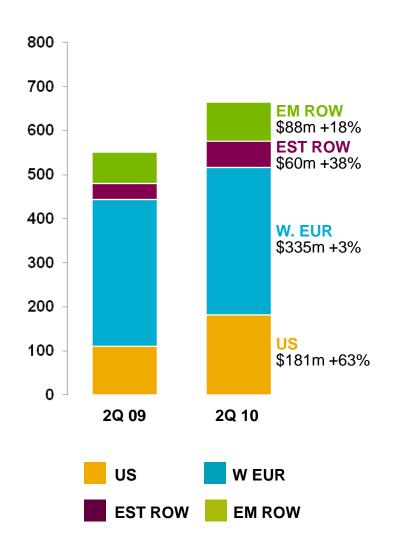
- TRx +70 basis points/market +120 bps
- Market leading TRx share 31%, -36 bps
- Seroquel XR now 15% of franchise TRx's

- Sales \$387m +6%
- Seroquel XR +51%
  - 1/3 of franchise sales
- EU approved for adjunct MDD shortly



## **Symbicort**

2Q10 Sales: \$664m +20%



#### US

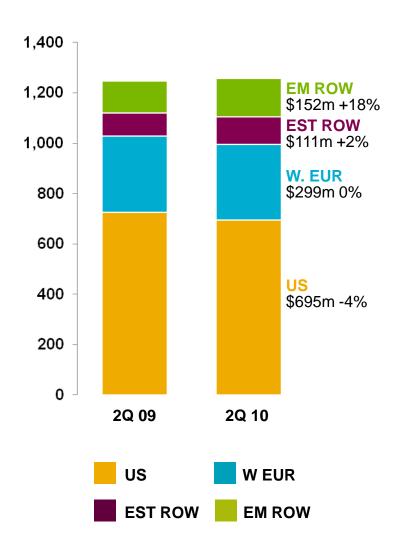
- TRx +57%
- NRx share 18.8%
  - Up ~5 pts vs June 09
- New Start share 27%

- Sales \$483m +9%
- Good launch in Japan



#### Nexium

2Q10 Sales: \$1,257m 0%



#### US

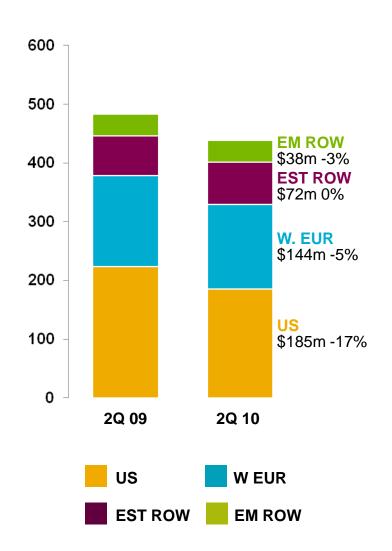
- Retail volume -5%
- Steady share of Dispensed Units
  - 6 bps vs Dec 2009
- Supported by new promotional channels
  - Customer service associates
  - Inside telephone sales
  - Digital
- Avg realised prices -6% Q1/flat Q2

- Sales \$562m +5%
- Timing of EU generics?
  - UK approval mid July



#### **Arimidex**

2Q10 Sales: \$439m -10%



#### US

- Multiple generics approved following 27 June patent expiry
- Q2 includes provision against pipeline inventory

- Sales extensions on completed Paediatric Investigation Plan (PIP)
  - Extends exclusivity to Feb 2011
  - 10 of 12 granted to date
    - France, Italy, UK



## Core margin: 2Q 2010

|                       | \$m     | CER<br>growth | % sales | Delta vs<br>PY CER |
|-----------------------|---------|---------------|---------|--------------------|
| Core Gross Margin     | 6,789   | +2%           | 83.0    | +80 bps            |
| Distribution          | (88)    | +26%          | 1.1     | <b>-20</b> bps     |
| Core SG&A             | (2,271) | +1%           | 27.8    | -                  |
| Core Other Income     | 186     | -47%          | 2.3     | -210 bps           |
| Core Pre-R&D Profit   | 4,616   | -2%           | 56.4    | -150 bps           |
| Core R&D              | (966)   | -9%           | 11.8    | +120 bps           |
|                       |         |               |         |                    |
| Core Operating Profit | 3,650   |               | 44.6    | -30 bps            |



## Restructuring programme 2010-2014

| Total Pr            | ogramme Cost<br>\$m | 2Q 2010<br>\$m | 1H 2010<br>\$m |
|---------------------|---------------------|----------------|----------------|
| Global Supply Chain | (340)               | (63)           | (91)           |
| SG&A                | (600)               | (53)           | (102)          |
| R&D                 | (1,060)             | (354)          | (372)          |
|                     |                     |                |                |



Annual Benefits
2014
\$m

Total
1,900



## Cash generation: 1H 2010

|                                    | 2010<br>\$m | 2009<br>\$m |
|------------------------------------|-------------|-------------|
| Opening net cash/(debt)            | 535         | (7,174)     |
| EBITDA*                            | 7,509       | 7,293       |
| Movement in working capital*       | (675)       | (172)       |
| Tax & interest paid*               | (1,235)     | (1,614)     |
| Other non-cash movements           | 32          | (173)       |
|                                    | 5,631       | 5,334       |
| Legal/Tax settlements*             | (864)       | -           |
| Net cash from operating activities | 4,767       | 5,334       |

**<sup>§</sup>** 

<sup>\*</sup> Adjusted for Legal/Tax settlements

## Cash generation: 1H 2010

|                                    | 2010<br>\$m | 2009<br>\$m |
|------------------------------------|-------------|-------------|
| Opening net cash/(debt)            | 535         | (7,174)     |
| Net cash from operating activities | 4,767       | 5,334       |
| Merck                              | (647)       | -           |
| Other capital expenditure          | (948)       | (507)       |
| Abraxane disposal                  | -           | 269         |
| Dividends/Net share buy-back       | (2,883)     | (2,084)     |
| Other movements                    | 79          | (4)         |
| Closing net cash/(debt)            | 903         | (4,166)     |
| Gross debt                         | (10,318)    | (11,661)    |
| Cash/Cash equivalents and STIs     | 11,221      | 7,495       |



#### **Shareholder returns**

- First interim dividend \$0.70
  - Aim to rebalance first interim dividend at around one third of prior year
  - Full year 2009 dividend \$2.30
- Share repurchases
  - Initial target: net \$1 billion in 2010
  - YTD \$516 million
  - New Target: net \$2 billion in 2010



## **Guidance for 2010 (Core basis)**

Revenue Low single-digit decline at CER

Gross Margin around the Q1 run rate of 81%

Core Pre-R&D Margin Near top of mid-term planning range

Net Finance Expense ~\$550m

Other Operating Income < FY2009

Tax Rate ~27%

**Core EPS** Range \$6.35 to \$6.65

## Development Update

Anders Ekblom, Executive Vice President Global Medicines Development

## **Agenda**

- Review of 1H 2010
- Key late stage projects
- 2H 2010 news flow



### Continued success in building global brands...

US

New product approved – Vimovo

Advisory Committee recommended *Brilinta* for approval in ACS



## **Brilinta / Brilique for ACS Positive FDA Advisory Committee**

- Mortality rates remain high with currently available treatment options for acute coronary syndromes (ACS)<sup>1</sup>
- Registry data indicates that up to 15% of patients die within the 1st year after their acute coronary event with current treatment<sup>2</sup>
  - This suggests a need exists for additional products to improve cardiovascular outcomes in ACS patients
- If approved, Brilinta could provide an alternative to Clopidogrel in patients with ACS
- Regulatory Status:
  - FDA PDUFA action date 16 September
  - 8 major regulatory filings to date (in addition to US)
  - EU decision expected in 1Q 2011



### Continued success in building global brands...

New product approved – Vimovo Advisory Committee recommended *Brilinta* US for approval in ACS New indication for *Crestor* based on JUPITER New indication for *Crestor* based on JUPITER EU New indication for Seroquel XR as add-on in MDD (CHMP) New higher dose (500mg) Faslodex approved in EU Nexium submitted for approval Japan Symbicort launched Faslodex and Nexium (PUB) approved in China **Emerging Markets** ONGLYZA submission in China



### ...tempered by some disappointments

Phase 3 results in recurrent Glioblastoma and Colorectal Recentin cancer not supportive of regulatory filing **Motavizumab** FDA Advisory committee not supportive of approval Complete response letter from FDA. Certriad Ongoing discussions to clarify requirements Complete response letter from FDA. Axanum Ongoing discussions to clarify requirements



## Dapagliflozin: a new approach to type 2 diabetes

| Attribute                | Dapagliflozin <sup>1-5</sup>   |
|--------------------------|--|
| Mechanism of action      | Potential first-in-class SGLT2 inhibitor   |
| Dosing                   | Once daily oral tablet   |
| Glycaemic efficacy       | <ul> <li>Significant reductions in HbA1c and fasting plasma glucose</li> <li>Decreased need for daily insulin dose in insulin-dependent patients</li> </ul>  |
| Other secondary benefits | <ul> <li>Meaningful reductions in body weight</li> <li>Reductions in systolic blood pressure without orthostatic hypotension</li> </ul>  |
| Safety & Tolerability    | <ul> <li>Low propensity for hypoglycaemia</li> <li>No renal safety signal</li> <li>No clinically significant changes in electrolytes</li> <li>Increased reports of signs and symptoms suggestive of urinary tract infections and genital infections</li> </ul> |

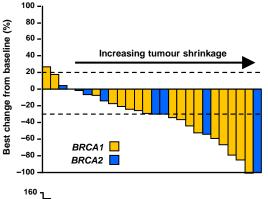


## Olaparib: a potential new therapy for breast and ovarian cancers

Positive Proof of Concept in Breast and Ovarian cancer

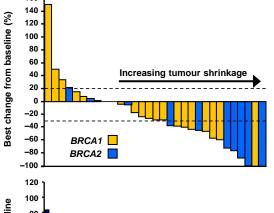
Phase 3 trial in BRCA Breast Cancer planned with a new tablet formulation

gBRCA Breast Cancer Olaparib

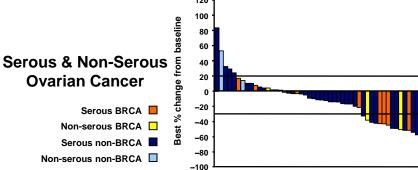


The start of Phase 3 is planned for 2011

gBRCA Ovarian Cancer Olaparib



1<sup>st</sup> regulatory filings expected in 2014



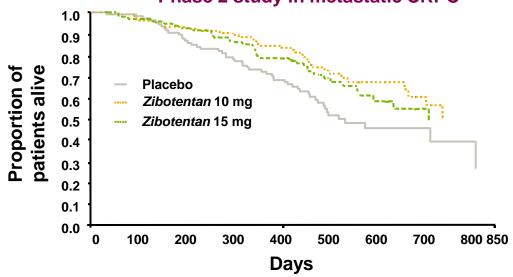


## Zibotentan: a potential new therapy in Castration Resistant Prostate Cancer

517,000 new cases of Prostate cancer each year<sup>1</sup>

~ 316,000 will develop CRPC<sup>1</sup> ~ 165,000 men will develop metastatic disease<sup>1</sup> 48% asymp. 52% symp<sup>2</sup>

#### Zibotentan improves Overall Survival in Phase 2 study in metastatic CRPC





## Zibotentan ENTHUSE Phase 3 programme covers the full spectrum of CRPC

#### Non Metastatic (M0)

Asymptomatic or mildly symptomatic for pain

152,000 Patients per year<sup>2</sup>

#### **Metastatic (M1)**

Asymptomatic or mildly symptomatic for pain

79,500 Patients per year<sup>2</sup>

### Metastatic (M1c) Symptomatic

85,500 Patients per year<sup>2</sup>

Study 15
Zibotentan vs
placebo
Co-primary
endpoints:

PFS & OS

(n=1500)

Recruiting Data expected 2013

Study 14
Zibotentan vs
placebo
Primary endpoint:
OS

Recruited Data expected 4Q 2010

(n=580)

Study 33
Zibotentan +
docetaxel vs
docetaxel alone
Primary endpoint:
OS

(n=1044)

Recruited
Data expected 2H 2011

**ENTHUSE Phase 3 Programme** 



## TC-5214: a new late stage opportunity in Major Depressive Disorder

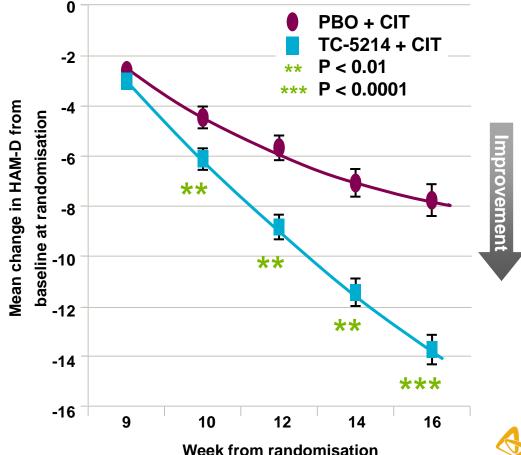
MDD affects many people and has a great impact on their lives

~ 42 million people in US, EU and Japan affected<sup>1</sup>

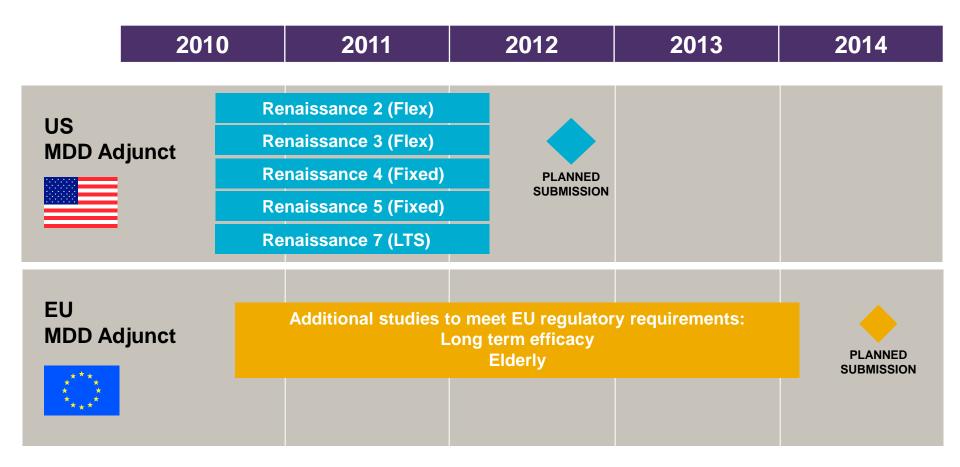
~18 million receive drug therapy1

>50% of patients fail to achieve remission with standard 1st line therapies<sup>2</sup>

TC-5214 is being developed as a new treatment option for patients with an inadequate response to first line SSRI/SNRI therapies TC-5214 adjunct Phase 2b study demonstrated a strong efficacy signal & was well tolerated in patients with an inadequate response to Citalopram



## TC-5214 clinical development programme for patients with inadequate response to SSRIs/SNRIs





Fixed = fixed dosing regime

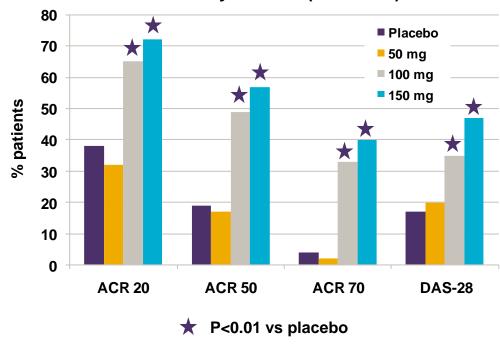
LTS = long term safety



# Fostamatinib disodium (FosD): a new oral approach for the treatment of Rheumatoid Arthritis (RA)

- RA is a systemic auto-immune inflammatory disease affecting approx. 1 in 100 people<sup>1</sup>
- FosD is being developed as a next generation oral RA therapy in adults who have failed to respond adequately to a traditional disease modifying anti-rheumatic drug (DMARD), such as Methotrexate
- A comprehensive Phase 2 programme has delivered impressive data
- Phase 3 planned to commence in 2H 2010

#### FosD Phase 2 Trial in RA – TASKi1 Efficacy Results (12 weeks)





#### 2H 2010 Newsflow

5 regulatory decisions

4 significant regulatory submissions

Key phase 3 data

Brilinta - US

Motavizumab - US

Faslodex 500 - US

ONGLYZA-metformin - US

Seroquel XR GAD - EU

Ceftaroline NME
Dapagliflozin NME
Vandetanib NME (orphan)
ONGLYZA-metformin
FDC in EU

Dapagliflozin Zibotentan



#### **Product references**

#### **Brilinta**

1. WHO; Cardiovascular disease: prevention and control 7/09. 2. Global Registry of Acute Coronary Events (GRACE registry).

#### **Dapagliflozin**

- 1. Ferrannini E et al. Diabetes Care 2010. 2. Strojek K et al, EASD 2010. 3. Bailey C et al. The Lancet 2010.
- 4. Nauck M et al. EASD 2010. 5. Wilding J et al. ADA 2010.

#### **Olaparib**

Advanced gBRCA breast cancer (Tutt et al): The Lancet 6 July 2010.

Advanced gBRCA ovarian cancer (Audeh et al): The Lancet 6 July 2010.

Serous and Non-serous ovarian cancer (Gelmon et al): ASCO 2010.

#### **Zibotentan**

1. Decision Resources (2009) - Global Prostate Cancer Incidence 2013 estimate. 2. Estimate based on Biovid patient record study in major markets (2009).

Ph 2 Study: James ND, Caty A, Borre M, et al. Safety and efficacy of the specific endothelin-A receptor antagonist ZD4054 in patients with hormone resistant prostate cancer and bone metastases who were pain free or mildly symptomatic: A double-blind, placebo-controlled, randomised, phase 2 trial. Eur Urol. 2009;55:1112\_1123.

#### TC-5214

1. Decision Resources. 2. Rush, JA, Trivedi MA, Wisniewski SR et al. Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR\*D Report. Am J Psychiatry 2006; 163:1905–1917.

#### Fostamatinib disodium (FosD)

1. Decision Resources.

Weinblatt ME, Kavanaugh A, Burgos-Vargas R, Dikranian AH, Medrano-Ramirez G, Morales-Torres JL, Murphy FT, Musser TK, Straniero N, Vicente-Gonzales AV, Grossbard E. Treatment of rheumatoid arthritis with a syk kinase inhibitor: A twelve-week, randomized, placebo-controlled trial. Arthritis Rheum. 2008 Nov;58(11):3309-18.

