

# AVEXA

## Company Update

April 2012



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# There is a clear market for ATC

- **ATC provides the best drug partner for all second line drugs**
  - Safe and well tolerated
  - Active against all the relevant resistance mutations seen in treatment experienced patients
  - Very few interactions with other drugs
  - Belongs to a familiar, well established class
  - Clear evidence that it would have clinical use and patient support
- **Independent analyses conducted identified a sizeable market for ATC**
  - Sales per annum range \$100M - ~\$400M+
  - Even as a niche twice-daily product



# Competitive Landscape for HIV

- **Top 10 HIV drug sales\***

	2009	2015 forecast
Once daily (QD)	US\$9.2Bn	US\$7.7Bn
Twice daily (BD)	US\$1.8Bn	US\$2.2Bn

- **QD dominates in first line patients**
  - Most HIV patients typically take 3 drugs a day
- **Sales of BD drugs are increasing and are forecast to be 21% of top ten HIV drugs in 2015**
- **Resistant/failing patients need drugs that work – irrespective of once or twice daily**
- **Most drugs used in resistant/failing patients are BD drugs**
- **FIVE of the existing QD drugs were initially approved (and sold) as BD drugs, and only later developed into QD drugs**
  - ATC can be expected to take a similar route

\* Sales figures are from Business Insights, *The HIV/AIDS Market Outlook to 2015*



# HIV drugs available

## used for treatment experienced, resistant patients

BD (twice daily) drugs			
Name	Target	Class*	Company
d4T	reverse transcriptase	Old NRTI	BMS
AZT	reverse transcriptase	Old NRTI	Various
etravirine	reverse transcriptase	NNRTI	Tibotec/J&J
darunavir	protease	PI	Tibotec/J&J
fosamprenavir	protease	PI	ViiV
lopinavir	protease	PI	Abbott
tipranavir	protease	PI	BI
enfuvirtide	gp41	EI	Trimeris/Roche
maraviroc	CCR5	EI	Pfizer
raltegravir	integrase	INI	Merck
dolutegravir	integrase	INI	ViiV (in phase 3 trials)
QD (once daily) drugs			
tenofovir	reverse transcriptase	NRTI	Gilead
abacavir	reverse transcriptase	NRTI	ViiV
didanosine	reverse transcriptase	Old NRTI	BMS
atazanavir	protease	PI	BMS

\*NRTI = nucleoside reverse transcriptase inhibitor; NNRTI = non-nucleoside reverse transcriptase inhibitor; PI = protease inhibitor; EI = entry inhibitor; INI = integrase inhibitor



# Where is the market opportunity for ATC?

- **All HIV patients (naïve or experienced) require 3 drugs**
- **The choice of drugs for experienced patients is often sub-optimal**
- **Current treatment options after first line failure include**
  - 2<sup>nd</sup> generation PI or NNRTI (some are poorly tolerated)
  - Integrase inhibitor (may develop resistance)
  - CCR5 inhibitor (only works in some patients and requires an expensive test)
  - Older NRTIs (poor safety / tolerability and possible resistance)
- **Some drugs cannot be used together because they interact**
- **Once approved ATC can be expected to be used with *any* of the drugs on the previous table to produce a more durable, safer and better tolerated regimen**



# Partnering Strategy (1)

## Traditional Co-Development model

- Typically many biotechs seek to fund expensive clinical trials by out-licensing at Phase I/ II
- Large high cost high risk clinical trials
- Out-license typically to big pharma
- Big pharma assumes high costs and risk of clinical trials and detailing drug for market launch
- Big pharma return on investment supported by long patent life and market exclusivity
- Licensor typically receives upfront / signing fees, milestones and royalties



# Partnering Strategy (2)

## Alternative Co-Marketing model

- **Avexa assumes remaining clinical development costs**
  - Significantly lower cost and risk following interactions with FDA and EMA
- **Avexa seeks co-marketing partner(s) who are responsible for sales and marketing**
- **Co-marketing partner(s) financial exposure substantially reduced**
- **Return on investment for co-marketing partner is supported by manufacturing patents, new IP, and data exclusivity laws (5 years in USA, and 10 years in EU)**
- **Avexa receives upfront and sign-on fees, milestone payments and higher royalties**





# Partnering Strategy (3)

- **Avexa now adopting co-marketing model**
- **Big pharma clearly unwilling to in-license even with reduced financial risk**
  - ATC highly likely to cannibalise big pharma's existing and future pipelines
- **Independent consultant confirmed big pharma reticence to traditional partnering model**
  - Looking for 'blockbuster' products with long patent life, not niche products in a known class
  - Focus on naïve patients where once daily dosing is preferred – not treatment experienced/resistant patients
  - In house competition from other 'blockbuster' drug areas e.g. cancer, immunology, neurology



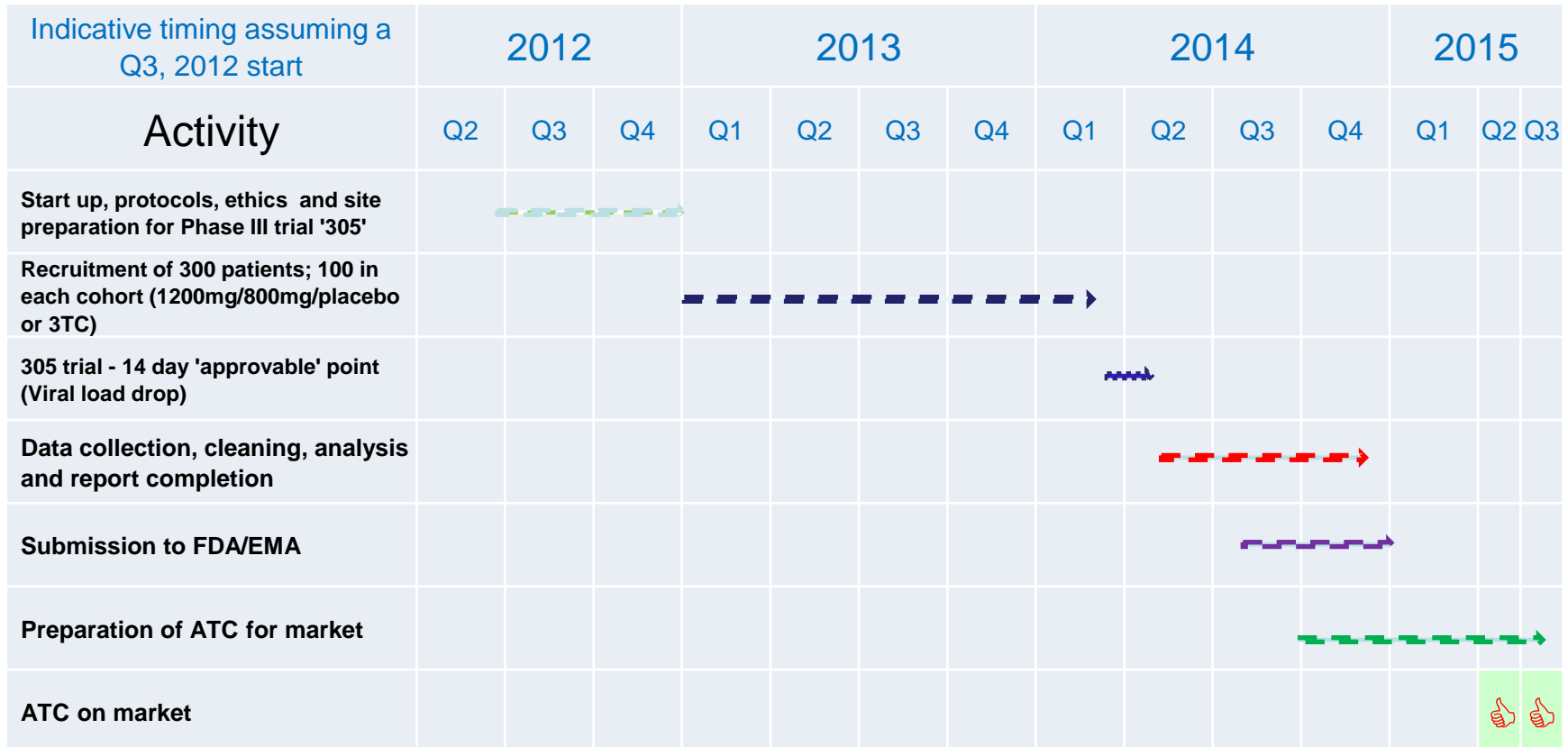
# ATC the path forward

- **Independent external consultants believe that the co-marketing partnering model represents the most appropriate avenue to realise the value of ATC**
- **Avexa is actively pursuing a co-marketing partnering strategy**
- **Seeking to secure one or more co-marketing partners**
- **Rights to ATC are being offered on a global or regional basis as appropriate**
- **Avexa reviewing funding options to complete remaining clinical development**
- **ATC “305” clinical development activity time line is shown in slide 11**



# ATC – Phase III trial (305)

*Schematic – for illustrative purposes only*



Note: The above schematic does not include the required carcinogenicity study (in rats) which will be run concurrently for approx. 12-24 months



# HIV Integrase Inhibitor, AVX15567

Out-licensed to Shanghai Institute of Organic Chemistry, SIOC  
(ASX release July 14, 2010)

- **AVX15567 was the lead HIV integrase inhibitor from an early discovery program**
  - This class of compound was superseded by later 2<sup>nd</sup> generation in house leads
- **The compound was out-licensed to SIOC for Chinese rights**
  - SIOC would fund the development of AVX15567 in China
- **Progress has been made in the area of chemical synthesis**
- **Political issues surrounding HIV incidence and treatment in China make this a problematic area**
  - Progress in obtaining funding has been slower than hoped



# Antibacterial AVX13616

Out-licensed to Valevia GmbH (ASX release Nov 18, 2010)

- **AVX13616 is an antibacterial agent with a novel mechanism of action**
- **All Avexa results have been confirmed and extended**
- **The lead compound AVX13616 continues to progress successfully**
- **Extension of therapeutic target studies have also been successful**
- **Development of AVX13616 is on schedule**



# HIV Integrase

Avexa's in-house HIV integrase inhibitor program

- **Integrase is a component of HIV that is essential for its ability to reproduce**
- **This program commenced in February 2011**
- **The program has identified a new chemical class of inhibitors, with different antiviral activities from those on market**
- **Started with a series of compounds that have very high potency**
  - The compounds are active against both normal and resistant HIV
  - However, their pharmacokinetic (drug-like) properties were poor
- **Over 40 specifically designed compounds have been made in the last 12 months**
  - Four have been chosen for further profiling
  - These have excellent potency and much improved drug-like qualities
- **Preclinical candidate to be chosen within 6 months**



# AVEXA

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