TaiMed Biologics, Inc.

April, 2018

History

- Concept of TaiMed started by a group of advisors to Taiwan's National Science Council
- Founders
  - David Ho, MD —— Director and CEO, Aaron Diamond AIDS Research Center
  - Ing-wen Tsai, PhD —— current Taiwan President
- TaiMed Biologics was formed in September 2007
  - Originally, built around the licensing of ibalizumab (TMB-355) from Genentech

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Financial Status

- TaiMed has been a publicly traded company on the Taipei Exchange Emerging Stock Market (stock code: 4147) since 2010.
- IPO on Nov 23, 2015 and traded on the Taipei Exchange Market (OTC)
- Current market cap is approximately USD$1.5B

  MSCI standard index from May, 2016
- Ruentex hold ~17% of TaiMed

  National Development Fund hold ~16% of TaiMed
- Shareholders exceed 28,000 (April, 2017).

Fundraising History

- Raised a total of USD$208M through four fundrasing rounds :
  - First round (2007-2008) —— USD$30M
  - Second round (2010) —— USD$22M
  - Third round (2014) —— USD$46M
  - Forth round for IPO (2015) —— USD$110M
- Cash in hand as of 12/31/2017 : USD$120M
- Total shares outstanding : 250M

Corporate Structure

- TaiMed Biologics, Inc. in Taipei, Taiwan
  - Corporate Headquarter
  - Finance/Accounting
  - Collaborative Discovery Research
  - Preclinical Development

- TaiMed Biologics USA in Irvine, CA, USA
  - Clinical
  - Business Development

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Marketing Environmental Analysis (I)

HIV Patients Distribution-Worldwide

Over 35 million people infected with HIV worldwide, and less than 30% receive treatment

WHO(2013)

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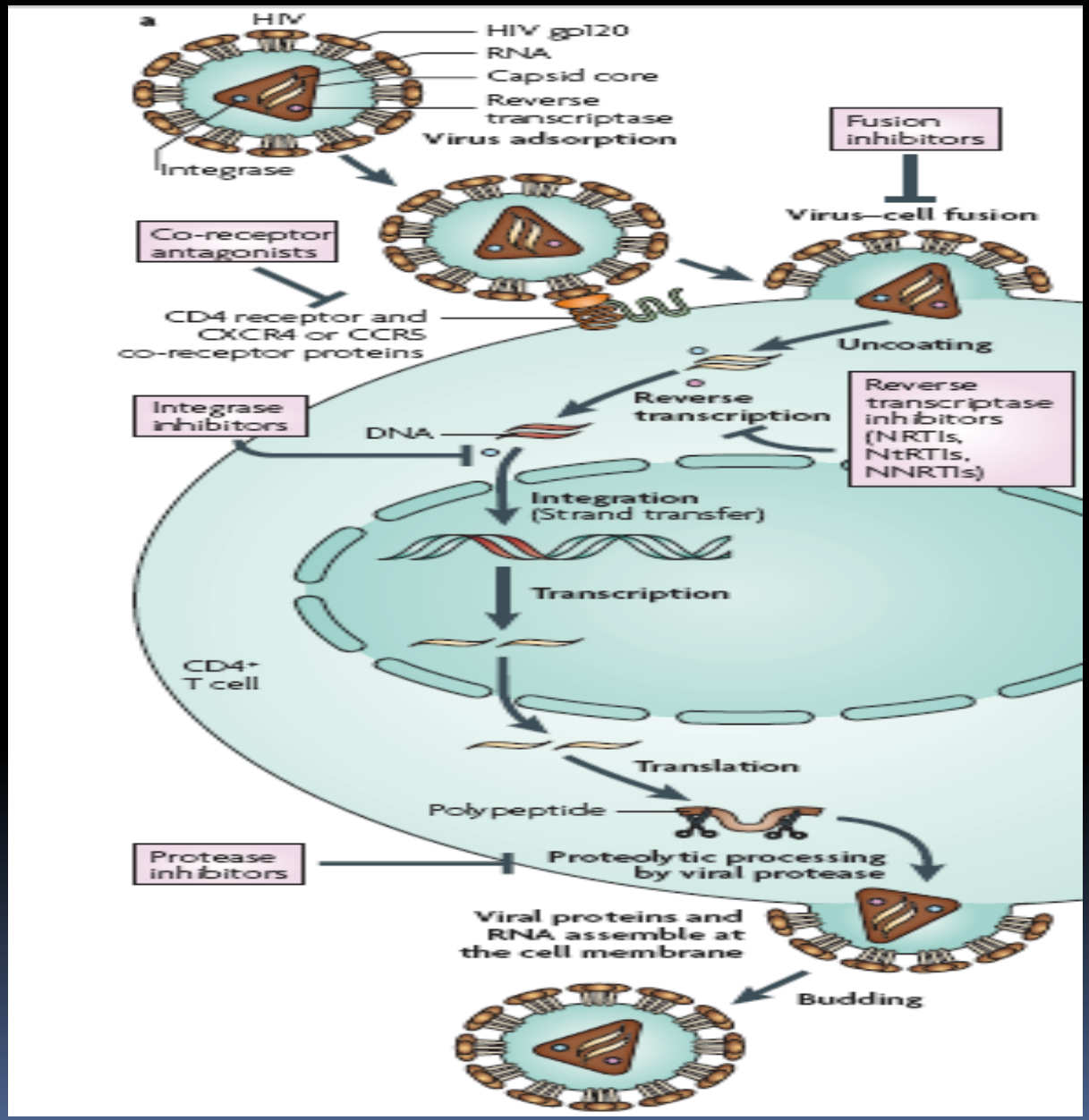
Marketing Environmental Analysis (II)

Anti-HIV Drugs Market Distribution

- Worldwide market is around 16 billion and the annual growth rate is around 7%.
- US is the major market due to no price control, and the 5 countries in western Europe are the second major market.
- At least 30 drugs within 5 distinct mechanistic classes were approved by FDA up to date.
  - Nucleoside reverse transcriptase inhibitors (NRTI)、
  - Non-nucleoside reverse transcriptase inhibitors (NNRTI)、
  - Protease inhibitors (PI)、
  - Entry Inhibitors、
  - Integrase Inhibitors
- FDA approved only 3 new drugs in the past 5 years. The industrial pipeline is fruitless.
- Long-acting injectable drugs have brought people to attention.

HIV Replication Cycle



Nature Reviews Drug Discovery 2007 , 6, 1001

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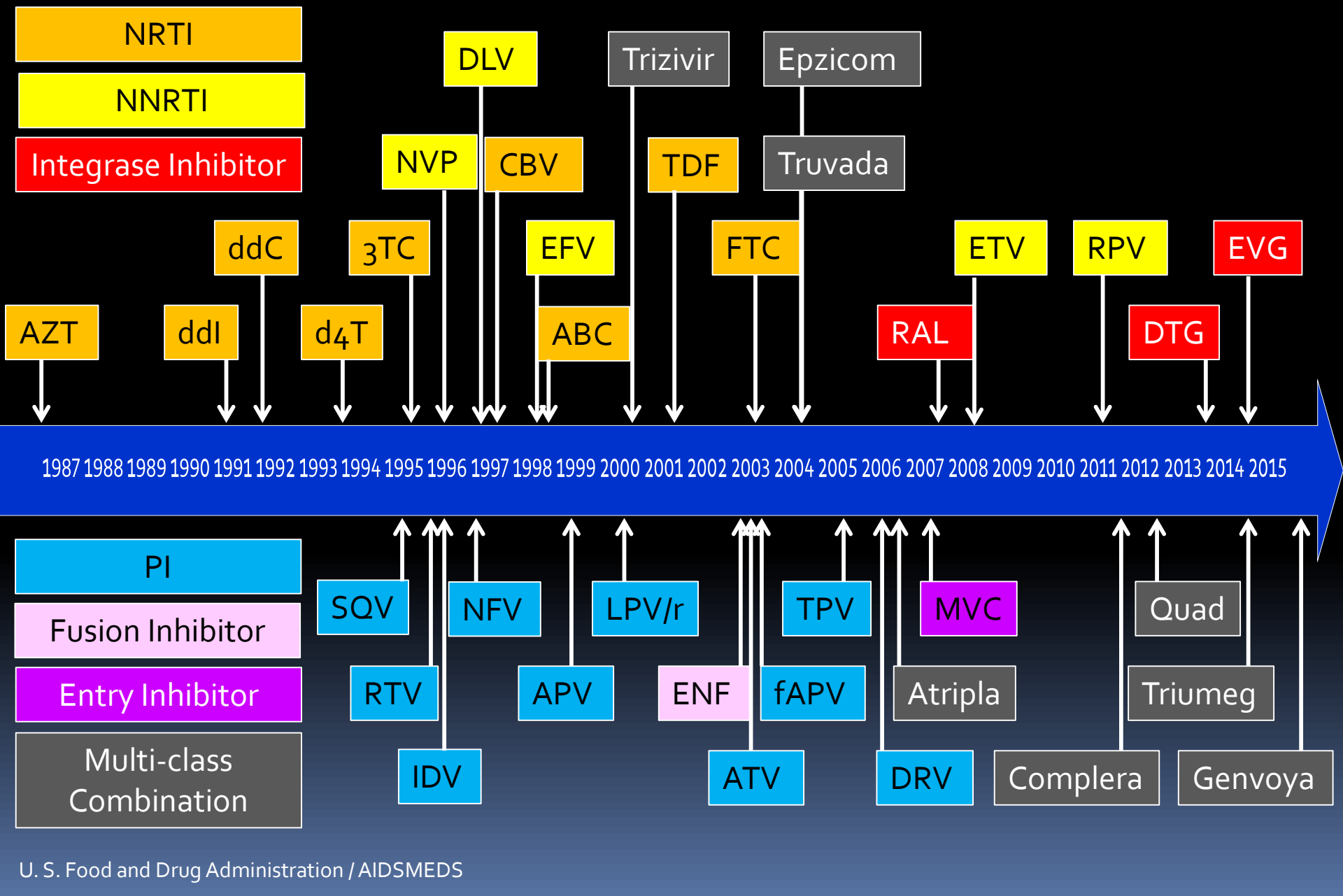
Antiretroviral Agents 1987-2015



U. S. Food and Drug Administration / AIDSMEDS

TaiMed Biologics (4147) R&D Status

	TMB-355 (Ibalizumab) IV infusion	TMB-355 (Ibalizumab) IM injection	TMB-360/365 (2nd generation TMB-355)	TMB-607 (HIV protease inhibitor)
Drug type	Monoclonal antibody			Small molecule
Status	2018 3/6 FDA approval	Phase I/II Completed	Pre-clinical	Phase I
Purpose	Multi-drug resistance salvage therapy	Therapeutic	Therapeutic and preventive	Therapeutic
Highlights	First-in-class First antibody and long-acting drug in HIV trials Orphan drug designation Breakthrough Therapy designation	Easier route of administration comparing to IV infusion	Broader spectrum, more potent efficacy and improved PK profiles comparing to TMB-355	Administered without booster. Nanoformulation of SC/IM injection has the potential for weekly/monthly dosing
Target Timeline	Q2, 2018 Drug launch	2019 Q1 FDA approval	mid of 2018 IND	US phase I

Milestones
Ibalizumab (TMB-355)

- The FDA granted approval of Trogarzo (trade name for ibalizumab) to TaiMed Biologics - 3/6/2018 (US time)
- Completed Pre-License Inspection (PLI) with no critical findings – 8/2/2017
- Granted Priority Review after BLA submission – 6/30/2017
- Completed BLA submission to US FDA- 5/3/2017
- Completed Phase III trial – 11/2016 (US, TW)
- Granted US FDA breakthrough designation therapy for MDR patients in IV dosage form – 2/2015
- Granted US FDA orphan drug designation for MDR patients – 10/2014
- Completed Phase II b -2011 (US, TW)

Phase III Results:

Achieved the Primary Endpoint

- 83% with $\geq$ 0.5 $\log_{10}$ (70% reduction) in viral load reduction after 7 days.
- Mean/median viral load reduction of 1.1 $\log_{10}$ (92% reduction) after 7 days.
    - (Presented these results at ID week 10/29/2016)

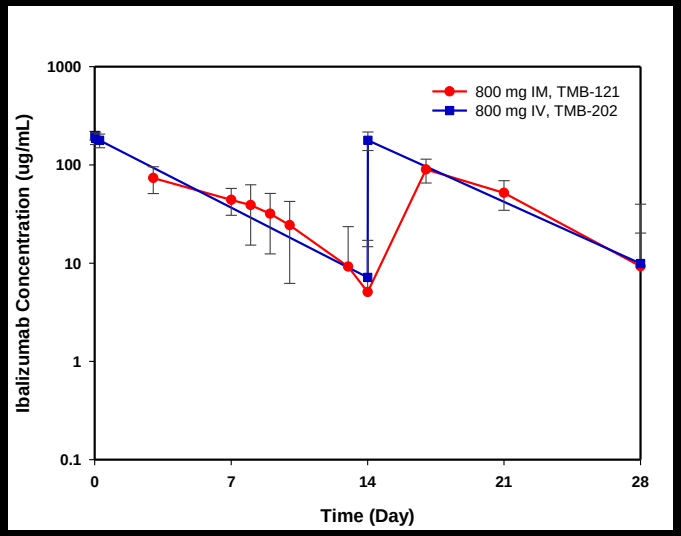
Significant Reduction of Viral Load over 24 Weeks

- Mean reduction in viral load was 1.6 $\log_{10}$ (97% reduction)
- 48% of patients had a reduction > 2.0 $\log_{10}$ (99% reduction)
- 43% of patients with undetectable viral load (HIV-1 <50 copies/mL) and mean viral load reduction was 3.1 $\log_{10}$ (99.92% reduction)
- The safety results in this Phase III trial are consistent with the Phase II b study
    - (Presented to CROI 2/14/2017)

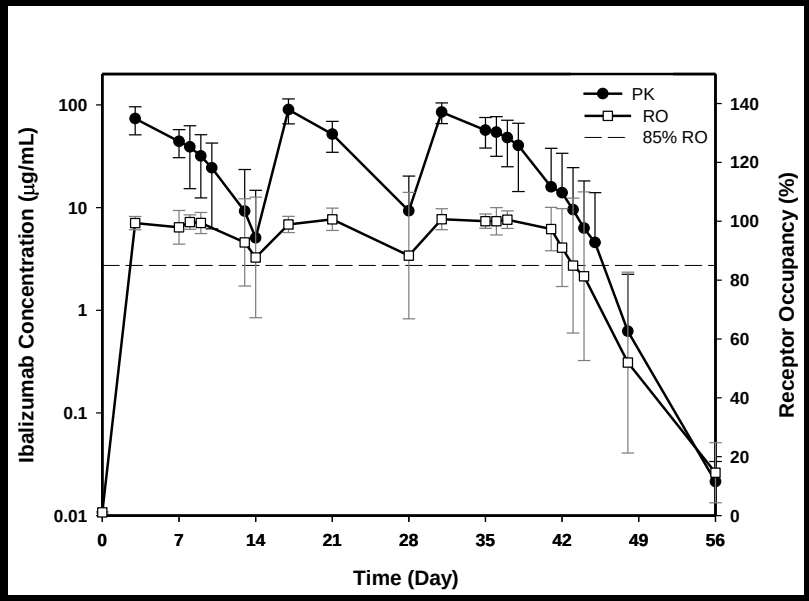
Development of Parenteral (SC/IM) Ibalizumab

- Completed Phase I/II trials in Taiwan

PK (800 mg IM vs. IV)



PK and RO (800 mg IM)



- Drug exposures of IV (TMB-202) 800 mg dosage are similar to same dosage of IM (TMB-121) treatment
- For the 800 mg IM dose, the mean RO was >85% during dosing period.

- label extension for IM
  - (Presented to CROI 2/15/2017)

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Clinical Supplies and Commercial Manufacturing Ibalizumab

- 2000L scale using disposable bioreactors at WuXi Pharma, China
- Three consecutive batches for process validation are completed and earmarked for commercial sale
- Completed eCTD for BLA submission on May 3, 2017
- Pre-approval inspection performed on July 17-Aug 2, 2017
- Commercial production from Q2, 2018

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Low Hanging Fruit - Fuzeon

- Fuzeon Product Profile
  - Twice daily subcutaneous administration
  - Major side effect profile: 98% reported injection site reactions
    - Low adherence!
  - Last resort for this patient population
- Current Rx/sales reflect ~500-1000 patients on Fuzeon in US
- Ibalizumab offers a no-brainer alternative
- Ibalizumab will command a price premium to Fuzeon (average whole sale price ~USD$4,098/month)
- The whole sale price for Trogarzo

  (USD$118,000 /per year per person)

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TMB-355 Marketing Contract

- Partner：Theratechnologies Inc., Canada public company
- Period：12 years from date of approval by countries
- Territory：North American and European Territory
- TaiMed responsibilities
  - ✓ All studies related to approval of the Product, except for Eueope
  - ✓ Manufacture and supply
- Theratechnologies resposibilities
  - ✓ Commercialization of the Product
  - ✓ All development and regulatory work in Canada and Europe
- Target Evaluation factors
  - ✓ Match with future business operation
  - ✓ New accounting principle adopted
  - ✓ International tax effect

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TMB-355 marketing contract terms

	North American Territory	European Territory
Upfront	$1M USD $1M Thera TSX common shares (issued on the date of launch)	$3M Thera TSX common shares 906,077 shares equivalent (within 30 days from the Execution Date)
Marketing Approval	$2M Thera TSX common shares (issued on the date of launch)	50% of all direct out-of-pocket Development costs mandated by the EMA to obtain Marketing Approval
Launch	$1M Thera TSX common shares $5.5M USD	$5M USD (one year after launch) $5M USD (one year after reaching sales of US$50M over 4Qs)
Development milesones	Bi-weekly IM - $3M USD Monthly SC/IM – up to $50M USD after negotiation	
Sales related milestones	Achieving $20M over 4Qs - $7M USD Annual sales of $200M - $10M USD Annual sales of $500M - $40M USD Annual sales of $1000M - $100M USD	Annual sales of $150M - $10M USD Annual sales of $500M - $20M USD Annual sales of $1000M - $50M USD
Transfer Price	52% of net selling price	52% of net selling price (within Annual sales of $50M) 57% of net selling price (sales above the US$50M threshold)

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Production Facility Planning

Investing US $35 million for 2,000 L disposable bioreactors production facility


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Ibalizumab Summary

- Monoclonal antibody HIV entry inhibitor
  - Unique, 1st-in-class mechanism of action blocks CD4-mediated entry
  - No cross-resistance with existing antiretrovirals
  - 1st long-acting ARV drug to offer alternative to daily regimen
- Phase 1a-2b studies completed with IV formulation
  - Well tolerated, safe, and effective
  - Ongoing compassionate use protocols
- Orphan drug
  - Smaller population, more "targeted" marketing effort
- Phase 3 completed (Nov. 2016)
- Rolling BLA submission starts with the CMC section - July 2016
- Completed eCTD for BLA – May 2017
- Launch for ibalizumab IV by Q2 2018
- Label extension for IM administration

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Making a Better (2nd Generation) Ibalizumab TMB-365

- Researched and developed by Aaron Diamond AIDS Research Center (David Ho)
  - WW Exclusive rights licensed to TaiMed Biologics
- Goals to generate ibalizumab-based antibody with markedly improved breadth, potency, stability and PK
  - Higher antiviral response rates
  - Improved viral load reductions
  - Decrease dose and or decrease frequency of administration achieving monthly dosing
- TMB-365 = glycan-modified ibalizumab variant with improved PK characteristics

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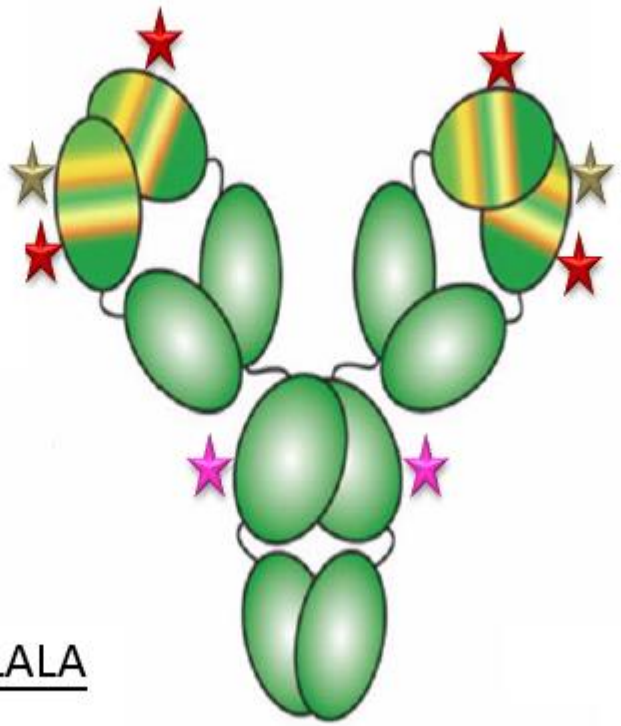
Advantages in 2nd Generation Ibalizumab TMB-365

Glycan modification

- *Broad virus neutralization against both ibalizumab susceptible and resistant HIV viruses*

Histidine switch

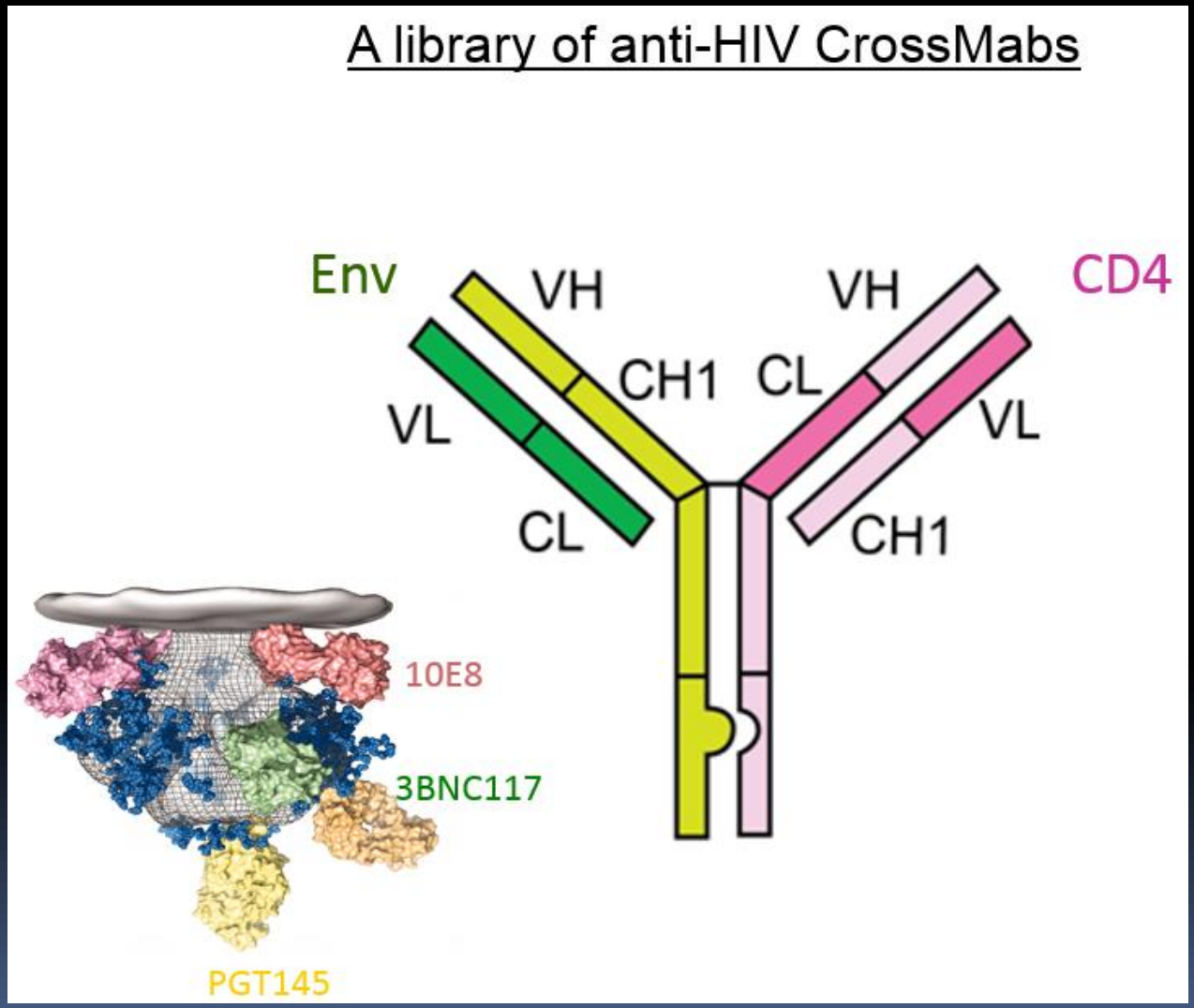
- *Improvement in receptor occupancy*
- *Improvement in half life*



Change IgG4 to IgG1-LALA

- *Improvement In stability*

The Third Generation Ibalizumab-based Bispecific Broadly Neutralizing Antibody



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TMB-607 (Protease Inhibitor)

- High genetic barrier to drug resistance
- Demonstrates better cross resistance profile than existing PIs
- Merck/Ambrilia already completed 2 phase 1 studies of an oral prodrug
- Phase 1 IM study with Dr. Jacobson at Temple University currently underway

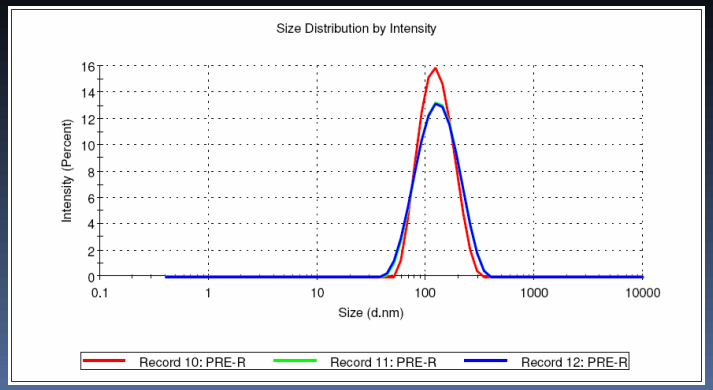
Long-acting TMB-607 Nanosuspension

Uses of such formulation could include

- once weekly/monthly injectable HAART
- maintenance of undetectable viral load
- prophylaxis

Infrequent parenteral dosing offers potential advantages over daily (oral) treatment:

- sustained concentrations of drug in plasma
- may improve adherence to therapy/prophylaxis
- may avoid gastro-intestinal adverse events
- may kill HIV virus in lymph nodes



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Thanks for Your Attention

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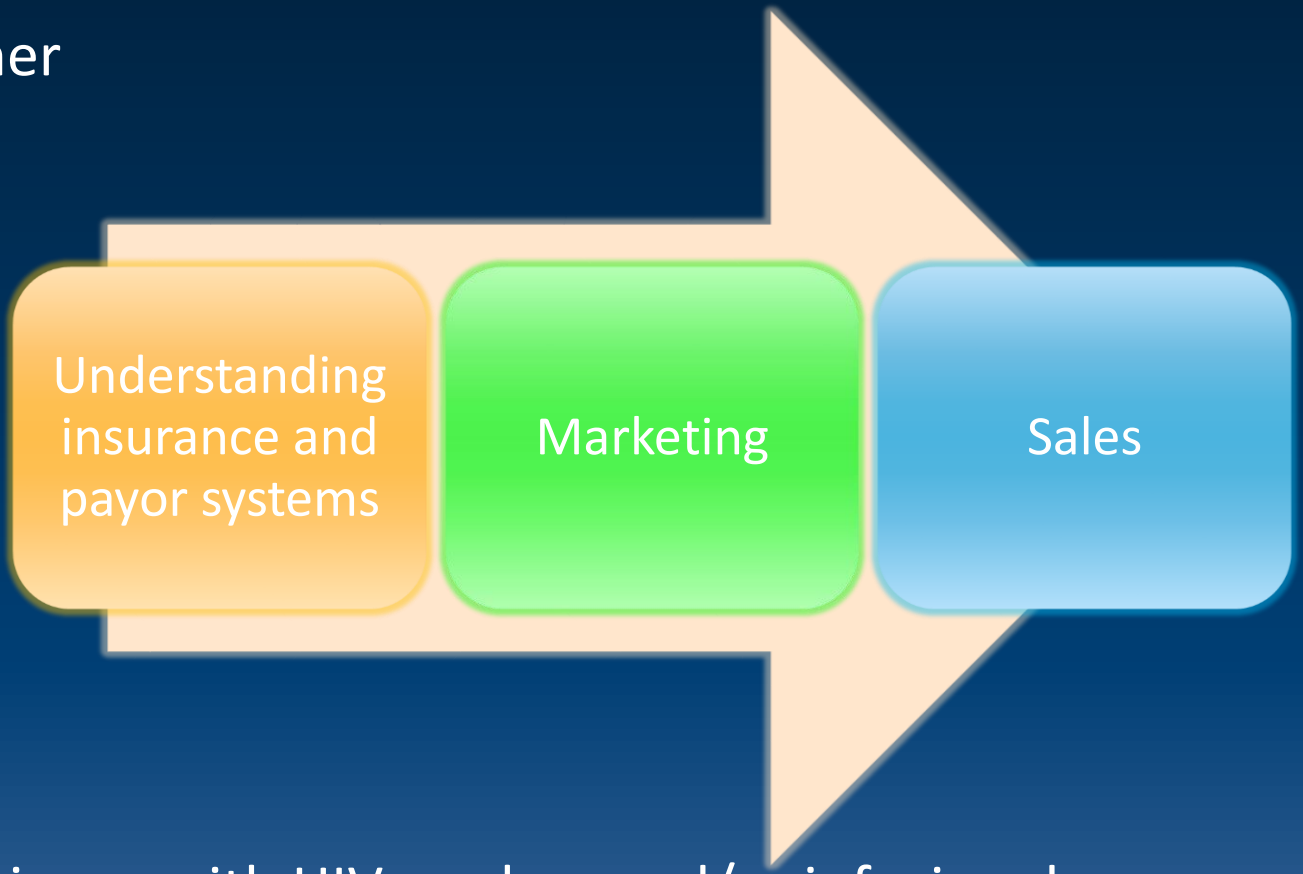
Partnering for Commercialization

- TMB will assume manufacturing and pharmacovigilance
- Partner



- Experience with HIV, orphan and/or infusion drugs

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TMB-301:
Achieved the Primary Endpoint in the Phase III

- 82.5% of patients enrolled in the phase III study (33/40, p-value <0.0001) have met the primary endpoint of a decrease of ≥ 0.5 log_{10} in viral load following a 7-day treatment period with ibalizumab.

- TaiMed presented these results at IDWeek 2016, a scientific conference on 29 October, 2016.

TMB-301

Ibalizumab Maintains Significant Reduction of Viral Load and Increases CD4+ T cells in Patients with Multi-Drug Resistant HIV-1 Over 24 Weeks.

- In the Phase III trial, after 24 weeks of treatment, the mean reduction in viral load was 1.6 log_{10} and a total of 48% of patients had a reduction in viral load of more than 2.0 log_{10} during this period. At the end of the treatment period using ibalizumab with optimized background regimen (OBR), the proportion of study participants with undetectable viral load (HIV-1 <50 copies/mL) was 43% (mean viral load reduction of 3.1 log_{10}) and 53% of patients had a viral load lower than 400 copies/mL.

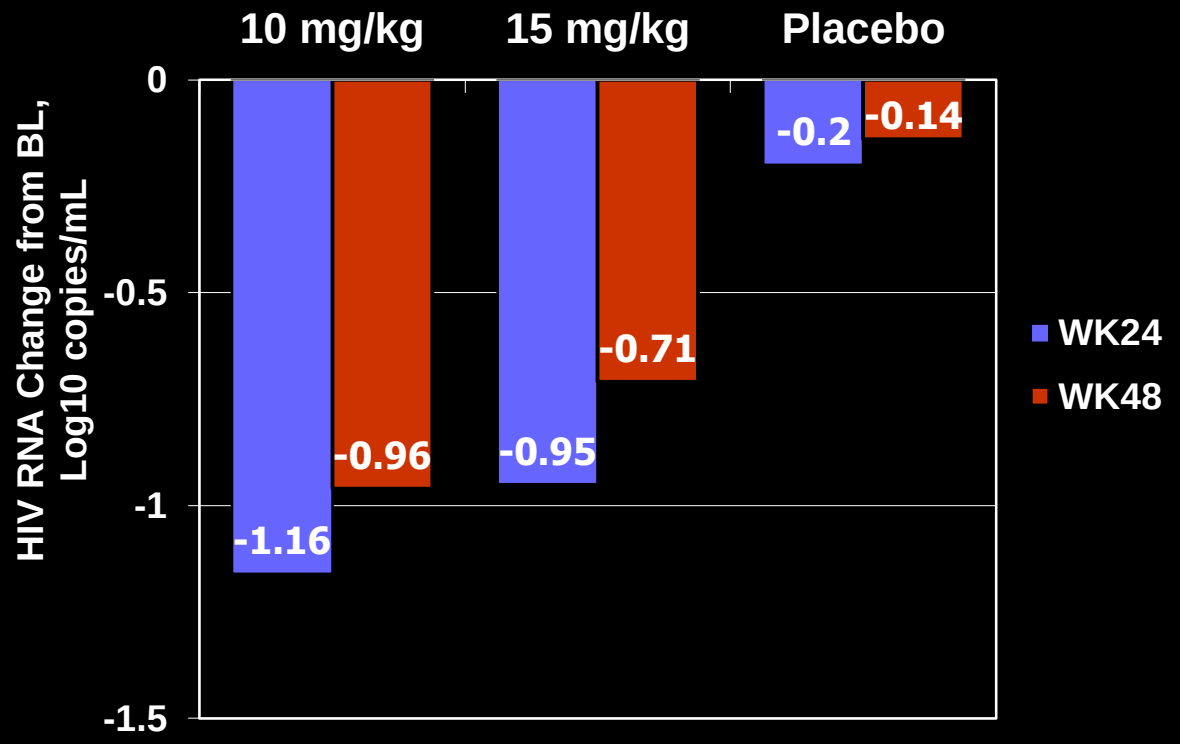
- a mean increase in CD4+ T cell of 48 cells/µL was observed. When subdivided by CD4+ cell count at baseline, Patients with a lower CD4+ T cell count at baseline those with the lowest count (<50 CD4+ T cells/µL, 17 patients) had an increase of 9, those with 50-200 CD4+ T cells/µL (10 patients) had an increase of 75 cells/µL and those with >200 CD4+ T cells/µL (13 patients) had an increase of 78 cells/ µL.

- The safety results in this Phase III trial are consistent with the ones previously observed in the Phase IIb study

Ibalizumab IM - Strategy

- TMB-121 underway in Taiwan
  - Tested 4 cohorts with various SC/IM doses
  - Arm E & F: Dosage will mirror IV – 800mg q2wk (n=8), 2000mg q4wk (n=6)
  - 6-8 week study; start in January 2016 and complete in H2, 2016.
- TMB-311
  - Expanded access program
  - Some patients have been on ibalizumab for >6.5 years
  - Will further test data in patients that switch to IM
- Label extension for IM may be available within 1 year after launch of IV
- Expands the market

Randomized, placebo controlled Phase 2a study with IV ibalizumab



- Combined with OBR for 24 weeks in treatment-experienced patients
- Statistically significant viral-load reduction
  - Significant increases in CD4+ cells
- Minimal side effects, comparable to placebo
  - No SAEs related to study drug, no infusion-site reactions

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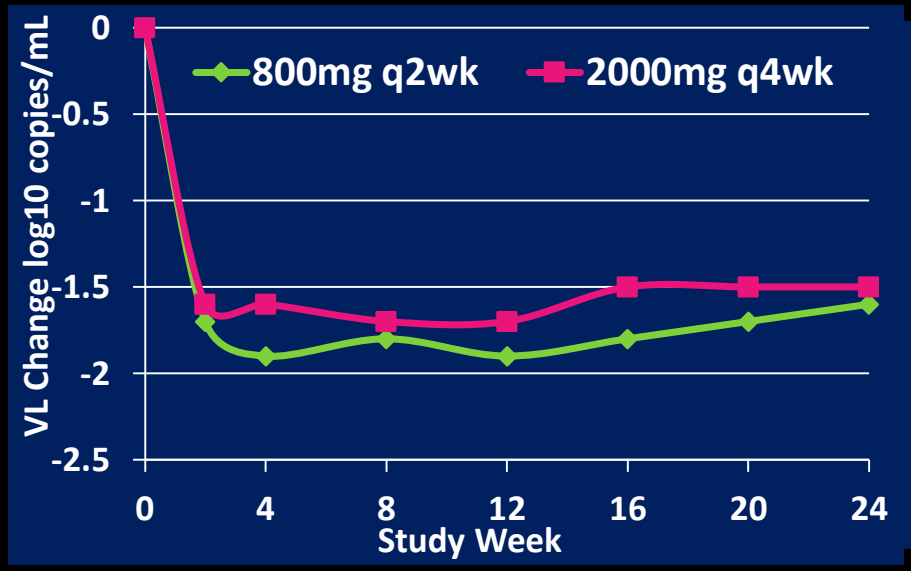
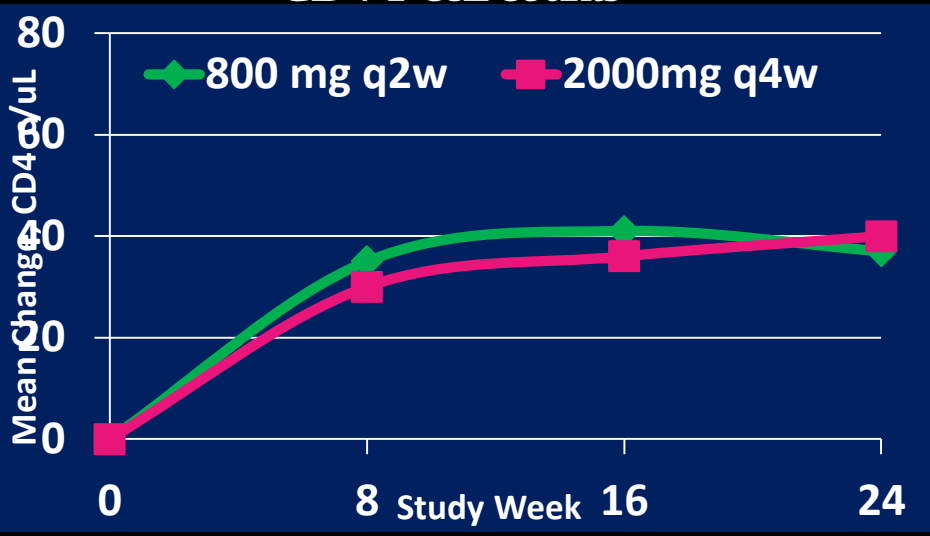
Ibalizumab IV Phase IIb -Summary of Efficacy Data

viral load



CD4 T cell counts



800 mg q2wk: -1.6 log 10 copies/mL

2000 mg q4wk, -1.5 log 10 copies/mL

patients with 1 log reduction

800mg q2wk: 63%;

2000mg q4wk: 57%

patients with <50 copies/mL at Week 24
800 mg q2wk: 44%
2000mg q4wk: 28%

Mean change in $CD4^+$ T-cells at Week 24

800 mg q2wk: +37 cells/µL

2000 mg q4wk :+40 cells/µL

Twenty-six percent (26%) of patients had baseline CD4 counts <20 cells/µL; reduced to 12 % at Week 24

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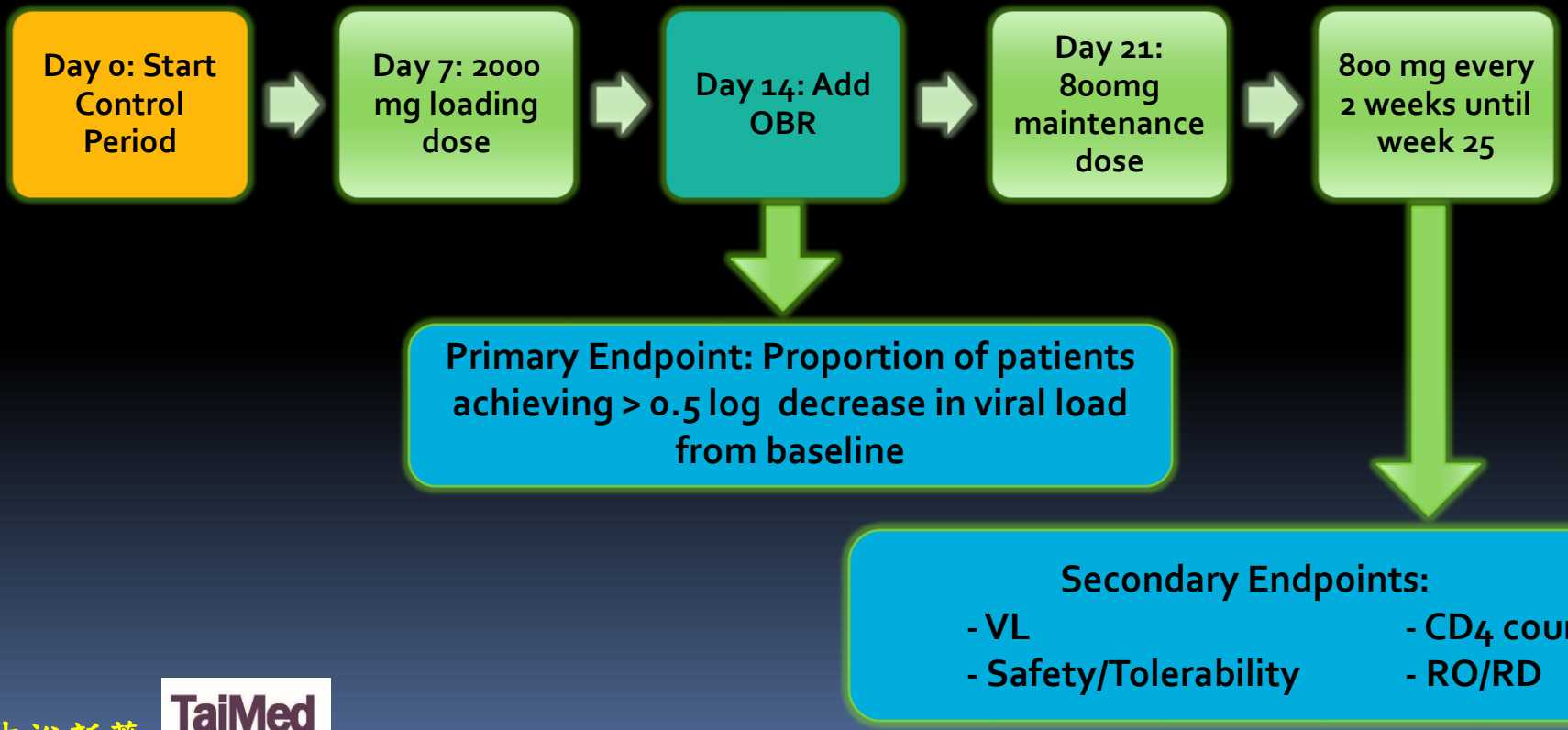
Differences between arms the were not statistically significant
ITT-MEF Intent to treat population with missing treated as failure

TMB-301: Phase 3 study in HIV+ with MDR

- 30-patient, Registrational trial for ibalizumab IV (initiated 8/2015 at 20+ sites in the U.S. and Taiwan)
- 2000mg loading dose, followed by 800mg maintenance doses every 2 weeks
- Completed enrollment of 40 patients (4/27/2016), of these US 36 and Taiwan 4

TMB-301 Study Design



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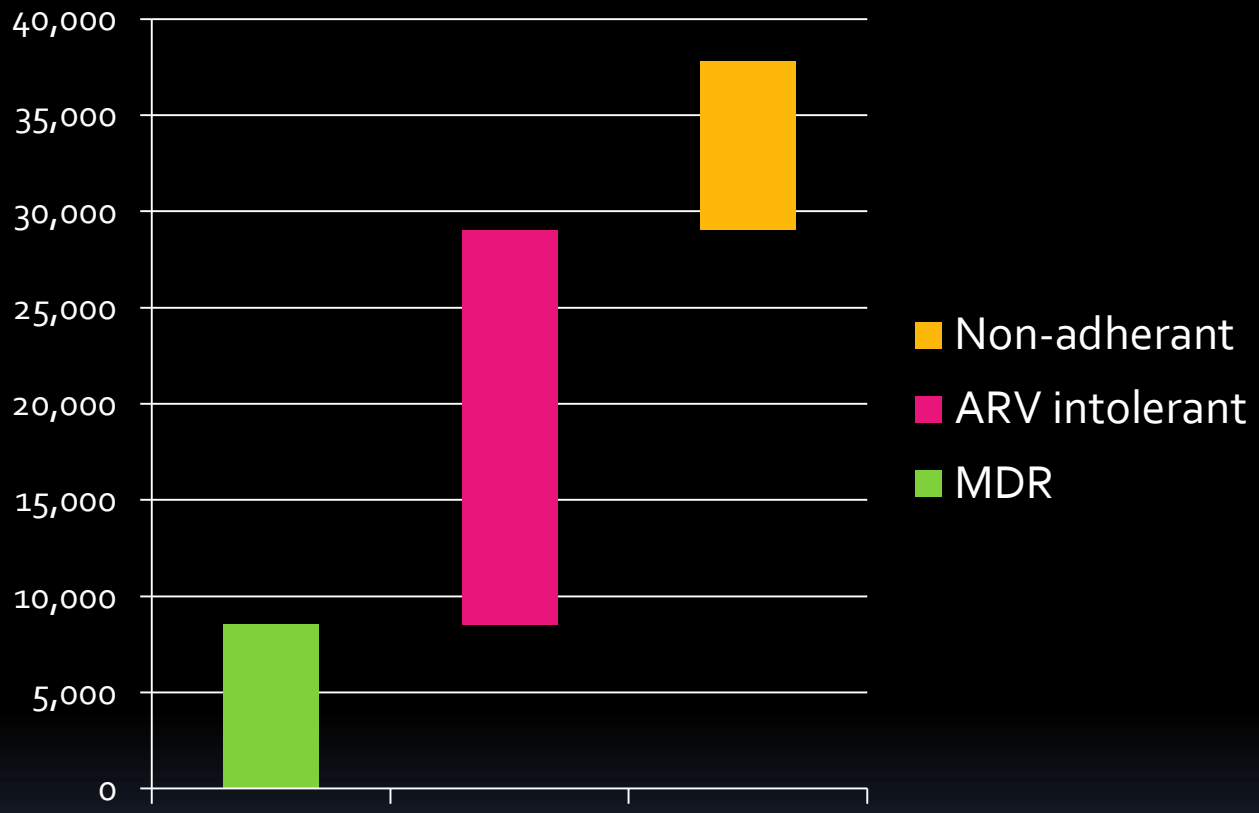
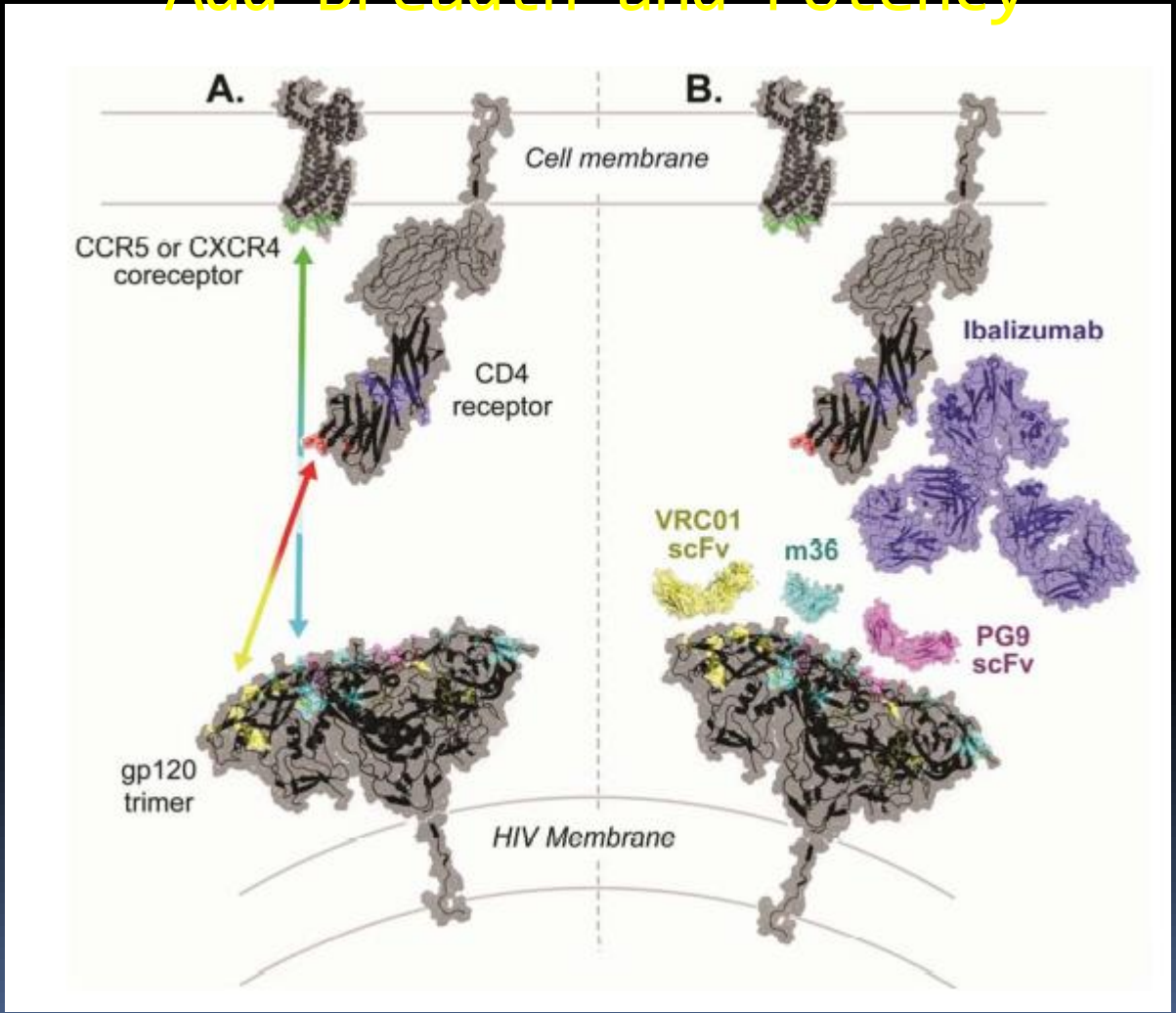
Orphan Drug Target Market



- Target population is approximately 38,000 patients in the US comprised of MDR/Salvage patients and those intolerant or non-adherent to ARV's
- New survey on October 2016 state that approximately 20,000 to 25,000 patients in the United States are currently infected with multi-drug resistant (MDR) HIV-1.

**Source: MMWR, 2011. As seen in our FDA Orphan drug application. Number vetted by US FDA*

Bispecific Antibody- The Third Generation Ibalizumab Multi-prong Attack on HIV Entry to Add Breadth and Potency



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