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AstraZeneca


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Co-Produced By
Division of Medicinal Chemistry
aaps American Association of Pharmaceutical Scientists

"Immunology: Lupus"

Laurence Menard, Senior Research Investigator, Bristol-Myers Squibb
Mary Struthers, Director Immunoscience, Bristol-Myers Squibb

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ACS Chemistry for Life®

Thursday, November 30, 2017

Treating Lupus: *SLE Pathogenesis and Targeted Therapies*
Session 10 of the 2017 Drug Design and Delivery Symposium

Laurence Menard, Senior Research Investigator, Bristol-Myers Squibb
Mary Struthers, Director Immunoscience, Bristol-Myers Squibb

Thursday, December, 7 2017

Painting a Brighter Future with Chemistry: *Innovating with Higher Performing and More Sustainable Pre-composite Polymers*
Session 11 of the 2017 Industrial Science Series

Jim Bohling, Dow Chemical Company

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Journal Scope
ACS Medicinal Chemistry Letters is interested in receiving manuscripts that discuss various aspects of medicinal chemistry. The journal will publish studies that pertain to a broad range of subject matter, including compound design and optimization, biological evaluation, drug delivery, imaging agents, and pharmacology of both small and large bioactive molecules.

Total Citations	Impact Factor	Articles Published
4,359	3.746	202

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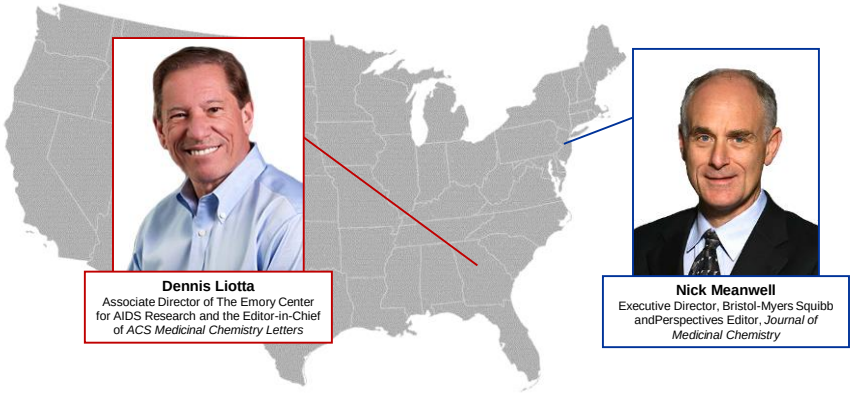
World AIDS Day and the Fight Against HIV:
Discovering and Developing Emtricitabine



Dennis Liotta
Associate Director of The Emory Center for AIDS Research and the Editor-in-Chief of *ACS Medicinal Chemistry Letters*

Nick Meanwell
Executive Director, Bristol-Myers Squibb andPerspectives Editor, *Journal of Medicinal Chemistry*

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DRIVE

INFECTIOUS INNOVATION

World AIDS Day and the Fight Against HIV:
Discovering and Developing Emtricitabine

Dennis Liotta, PhD, DSC, FTSE

New Structures are Needed to Support Discovery Research and Early Drug Development

DRIVE

New Models for Drug Discovery and Development

Changes in Pharma Industry Investment
- Big Pharma's rate of discovery and development is slowing
- R&D spending increasingly shifted to biotech M&A

Changes in Venture Capital Investment
- Increasingly investing in later stage technologies
- Large desire for breakthrough products

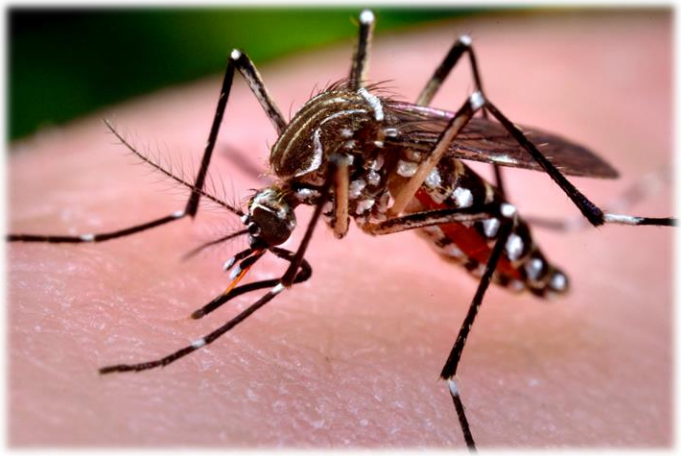
Changes in Public Funding Patterns
- Need for focus on a return for the public investment
- Increasing investment in translational research

Changes to Research University Models
- Success requires adapting to investment changes
- Winners will exploit strengths (creativity) and address weaknesses (focus, efficiency and lack of infrastructure)

Megatrends Forcing Change

2

Drugs for Neglected Diseases?



Aedes Aegypti is the vector that transmits, *inter alia*, Zika virus, Dengue Fever, Chikungunya

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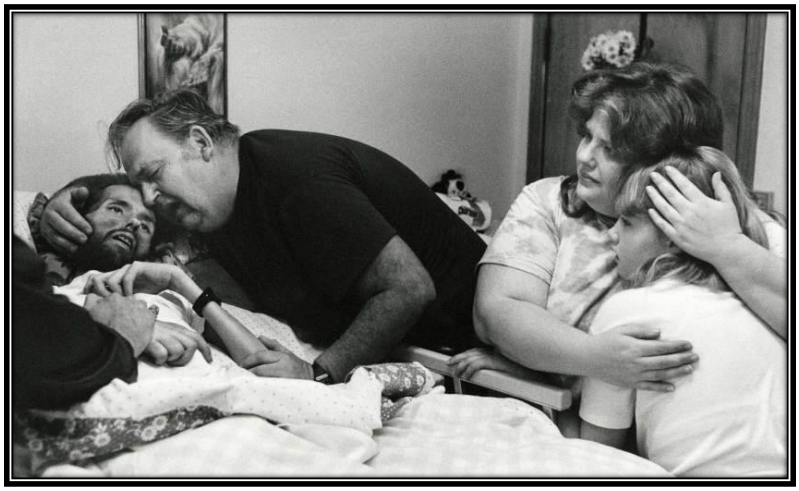
When AIDS Was A Neglected Disease



David Kirby on his deathbed, Ohio, 1990. Life Magazine.

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Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

In which year was the acronym AIDS created by the Centers for Disease Control and Prevention?

- 1979
- 1980
- 1981
- 1982
- 1983

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The Emergence of HIV/AIDS in the USA

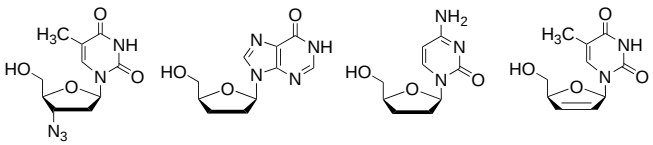
DRIVE

- The June 5, **1981** issue of the CDC's Morbidity and Mortality Weekly Report (MMWR) described five cases of a rare pneumonia, Pneumocystis carinii, usually only found in severely immune-compromised patients in five homosexual men. Three weeks later the MMWR reported 26 cases of Kaposi's sarcoma, a rare cancer, in homosexual men in New York and California.
- In **1982**, the CDC introduced the term **A**cquired **I**mmune **D**eficiency **S**yndrome (AIDS) and identified a broadened risk profile that included intravenous drug use, Haitian origin and hemophilia A.
- By **1984,** the etiologic agent for AIDS had been identified as a novel retrovirus, later named human immunodeficiency virus (HIV).
- In just ten years (**1991**) HIV infections had emerged in **51 countries**:
  - WHO reported that **10 million people** were infected with the virus **worldwide**;
  - CDC reported **one million Americans** were infected and that HIV/AIDS had become the 8th leading cause of death in the USA;
  - CDC predicted that AIDS would remain a global pandemic into the 21st century and **by the year 2000 forty million persons** would be infected;
  - The emerging pattern of infection indicated that **90% of these persons** would reside in developing countries in **sub-Saharan Africa, South and Southeast Asia, Latin America, and the Caribbean.**
- Sadly, these predictions proved to be an underestimate (**34.3 million living with HIV/AIDS and 18.8 million deaths**)

The HIV Epidemic: The First Ten Years, *Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report*, **June 07, 1991**, *40(22),* 357.

A Desperate Search for Antiretroviral Drugs

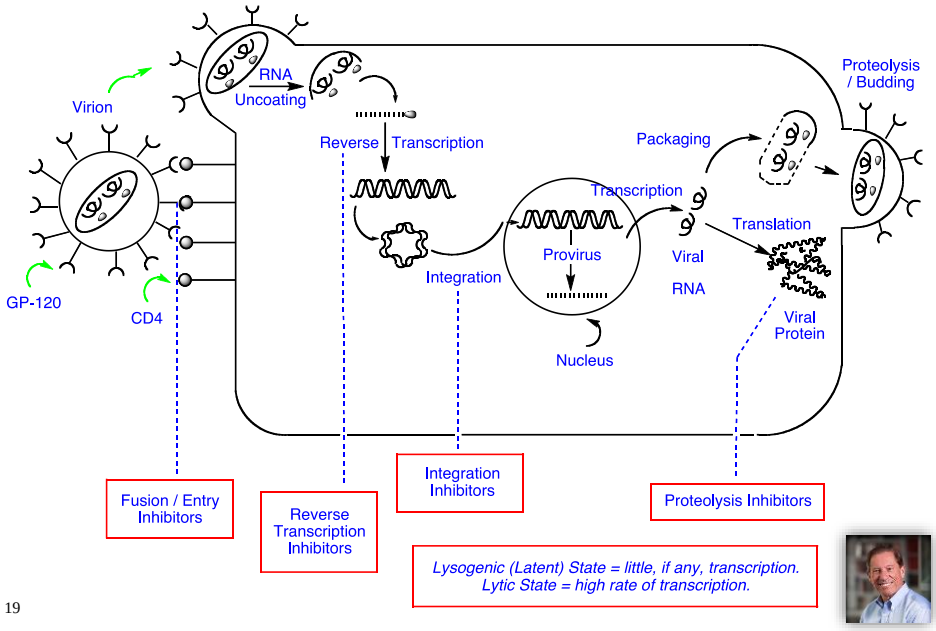
DRIVE



AZT (zidovudine) | **DDI (didanosine)** | **DDC (zalcitabine)** | **D4T (stavudine)**

- The search was carried out against a backdrop of little experience or success.
- The age of modern antiviral therapy had arguably only started in **1983** with the approval of acyclovir for the treatment of HSV infections.
- One company with a commitment to antiviral research was the Burroughs Wellcome Co., the company that discovered and developed acyclovir.
- Burroughs Wellcome Co., in collaboration with the National Cancer Institute (NCI) and the AZT Collaborative Working Group, developed the first anti-HIV drug, the nucleoside analog **azidothymidine** (AZT, retrovir®), which was approved by the FDA in **1987**.
- Two additional nucleoside analogs were subsequently approved, **diadanosine** in **1991** and **zalcitabine** in **1992**.
- Another nucleoside analog, **stavudine**, was approved in **1994**.
- All four drugs had significant clinical limitations due to toxicity and the development of viral resistance, but would remain the only treatment options through **1994**.

The HIV Replication Cycle



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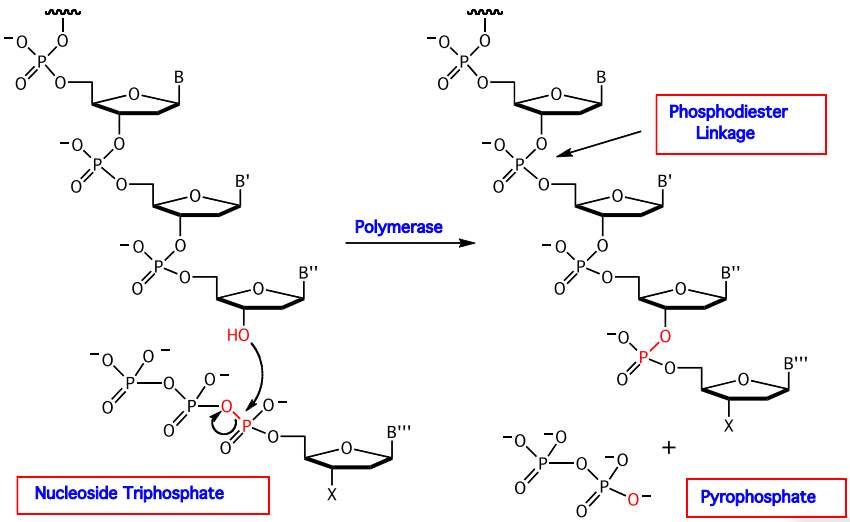
Obligate and Non-Obligate Chain Termination



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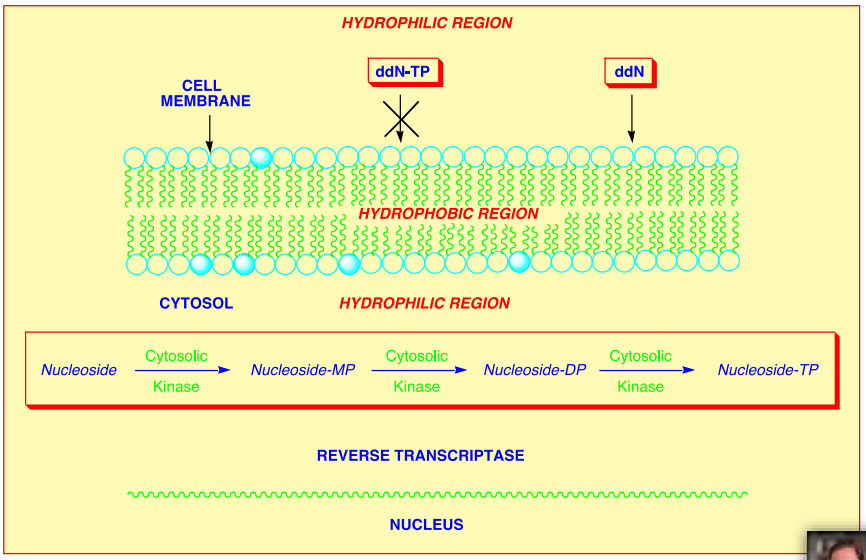
Passive Diffusion and Anabolism of Antiviral Nucleosides



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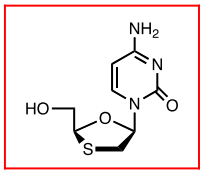
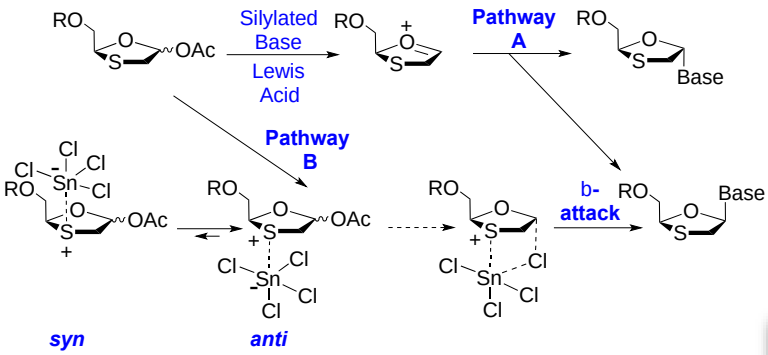
Oxathiolane Nucleosides

EMORY



BCH-189 (racemic)
IAF Biochemicals, Inc.



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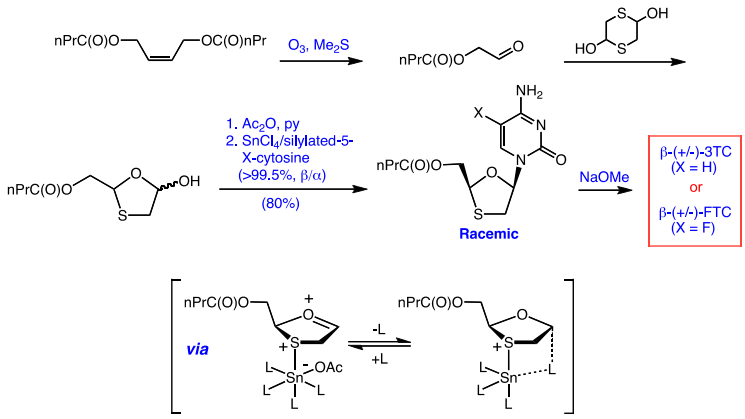
Oxathiolane Nucleoside Synthesis



Liotta, D.C. *et al. Bioorg. Med. Chem. Lett.* **1993**, *3*, 693; Chu, C.K. *et al. J. Med. Chem.* **1993**, 181; Liotta, D.C. *et al. Antimicrob. Agents Chemother.* **1992**, *36*, 2686; Liotta, D.C. *et al. JACS* **1991**, *113*, 9377; Liotta, D. C. *et al. J. Org. Chem.* **1992**, *57*, 5563

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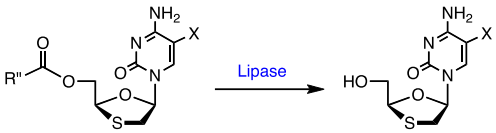
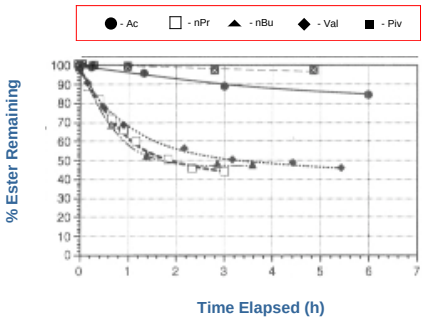
Enzymatic Resolution of Enantiomers



R" = alkyl, substituted alkyl; X = H, F, alkyl, halogen, *etc.*
Lipase = pig liver esterase, porcine pancreatic lipase, Amano PS-800, subtilisin, *etc.*



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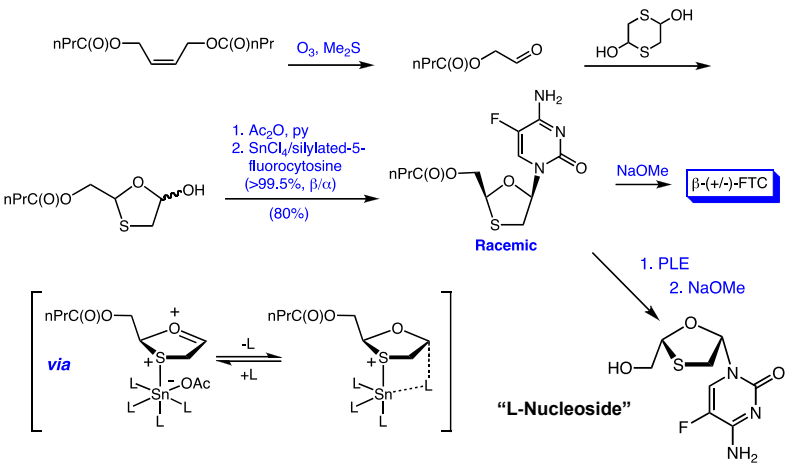
Enantioselective Synthesis of Oxathiolane Nucleosides



Liotta, D.C. *et al. Bioorg. Med. Chem. Lett.* **1993**, *3*, 693; Chu, C.K. *et al. J. Med. Chem.* **1993**, 181; Liotta, D.C. *et al. Antimicrob. Agents Chemother.* **1992**, *36*, 2686; Liotta, D.C. *et al. JACS* **1991**, *113*, 9377; Liotta, D. C. *et al. J. Org. Chem.* **1992**, *57*, 5563

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Emtricitabine: The Emory-Burroughs Wellcome Partnership

- Potent inhibitor of HIV-1 and HIV-2 with EC_{50} values ranging from 0.009 to 0.1 µM depending on viral strain and subtype and cell type
- Decreased extra and intra-cellular HBV DNA in a dose dependent fashion with an IC_{50} of 0.010µM
- Cytotoxicity was evaluated in multiple cell lines. CC_{50} values were all greater than 100 µM
- Inhibition of bone marrow progenitor cells occurred at significantly higher concentrations than those observed for AZT:
  - Granulocyte-macrophage colonies: IC_{50} = 300 ± 40 µM vs 10 ±3 µM for AZT
  - Erythroid colonies: IC_{50} = 200 ± 8 µM vs 0.30 ± 0.06 µM for AZT
- Showed high selectivity for the HIV encoded reverse transcriptase over human host polymerases α (SI=35)*, β (SI=100)* and γ (SI=35)*
- High oral bioavailability (79%)
- Long intracellular half life of its triphosphate (39 hrs.) supports once-a-day dosing
- Thirty day toxicity studies were conducted in rats and monkeys. In both species the NOAEL (No Observed Adverse Effect Level) was greater than 2000 mg/kg/day
- An IND application was submitted to the FDA in September of 1995 by Burroughs Wellcome Co. and a Phase I study was initiated the next month
- The drug was well tolerated by all subjects with no adverse events observed and its pharmacokinetics were linear with small inter-subject variability and no significant food effects
- The stage was set to begin Phase 2 of clinical development

*SI= K_i HIV RT/K_i human pol

Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

Since emtricitabine exhibited such an excellent profile, why couldn't it be used as a monotherapy to control HIV replication?

- A combination with any other anti-HIV drug will work better than a single drug
- Companies like to use multiple drugs so that they can charge more for the therapies
- Single antiviral drugs can rapidly develop resistance
- None of the above
- All of the above

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Antiviral Combination Therapies

DRIVE

- The clinical utility of drugs to treat HIV infection is limited by the ability of the virus to mutate and become drug resistance
- Resistant variants of HIV were quickly selected by passaging wild type strains of virus with the **oxathiolane nucleosides**, **emtricitabine** and **lamivudine**
- Tisdale *et al.* demonstrated that passaging of wild type virus with **AZT** and **emtricitabine** substantially delayed emergence of resistant virus
- Mathez *et al.* demonstrated in vitro that combinations of **AZT** and **emtricitabine**, and **AZT** and **lamivudine** were active against HIV variants harboring AZT-resistance mutations
- This data supported the idea that patients infected with wild type or AZT-resistant virus could be advantageously treated with a combination of **AZT** and an **oxathiolane nucleoside analog**
- The effectiveness of combination therapy with **AZT** and an **oxathiolane nucleoside** was subsequently demonstrated in a series of four clinical studies and led to the approval of **Combivir®**

Tisdale *et al*., *PNAS*, **1993**, *90*, 5653-5656.
Mathez *et al*., *Antimicrob. Agents Chemother.* **1993**, *37*, 2206 -2211.

A Changing Business Environment Impacts the Development of Emtricitabine

DRIVE %

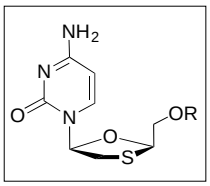
- The development of emtricitabine was interrupted by an unsolicited offer to purchase Wellcome PLC by Glaxo PLC on January 23, 1994
- The offer was for $14 billion and would rank among the top three largest deals in any industry at the time
- The merger of the two companies was part of a growing trend in the pharmaceutical sector driven by the need to maintain sales growth
- In addition to an immediate increase in market share, the merger was justified by synergies that would reduce operating costs, which was largely achieved by eliminating 7,105 jobs, including 1,953 jobs in R&D
- The acquisition of products and intellectual property from Wellcome PLC would make GlaxoWellcome the worlds leading antiviral company at the time
- The new company decided to stop the development of emtricitabine, a product that would be competitive to Glaxo's lamivudine (3TC)
- In 1996, virtually all of the former Burroughs Wellcome HIV group left GlaxoWellcome and formed the biotechnology company, Triangle Pharmaceuticals, Inc., which licensed the rights to develop emtricitabine from Emory University

Completion of the Clinical Development of Emtricitabine

DRIVE %

- A series of Phase II trials established the optimal dose of **emtricitabine** to be 200 mg/day for both HIV and HBV
- By 1998, the standard of care had evolved to be the administration of a cocktail of drugs in different mechanistic classes, a method of treatment also known as HAART (Highly Active Antiretroviral Therapy)
- As a consequence of HAART, emtricitabine's Phase III pivotal efficacy trials were run in combination with two approved antiviral drugs
  - **FTC-301:** emtricitabine + didanosine + efavirenz was compared to stavudine + didanosine + efavirenz for 48 weeks
  - **FTC-303:** switching from lamivudine twice daily to emtricitabine once daily, while maintaining all other antiretrovirals in a triple drug combination
- **Emtricitabine** met the two primary endpoints in both trials: a larger decrease in viremia expressed as HIV RNA copies/ml and an increase in immune function as evidenced by an increase in CD4+ T-cell count
- Based on these results, the FDA approved **emtricitabine** in combination with other antiretrovirals for the treatment of HIV infections on July 2, 2003

Epivir® (Lamivudine, 3TC)



- **Epivir** (oral, 300 mg, qd) (originally 150 mg, bid)
- **Combivir** (oral, 3TC, 150 mg + AZT, 300 mg, bid)
- **Tricivir** (oral, 3TC + AZT, 150 mg + ABC, 300 mg, bid)
- **Epivir-HBV** (oral, 100 mg, bid)

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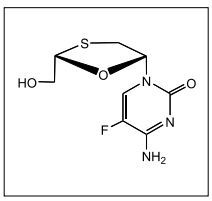
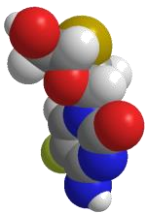
Emtriva® (Emtricitabine, FTC)





2003: FTC (Emtriva®), a low toxicity, once a day (qd) anti-HIV therapy, approved by the FDA.

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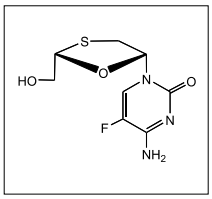
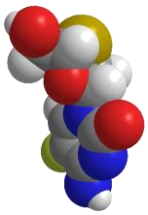
Emtriva® (Emtricitabine, FTC)

EMORY





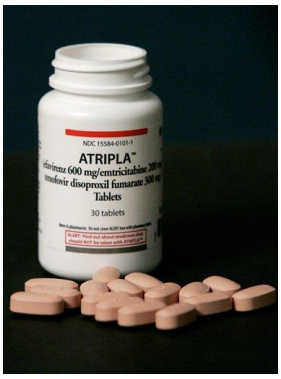
2003: FTC (Emtriva®), a low toxicity, once a day (qd) anti-HIV therapy, approved by the FDA.

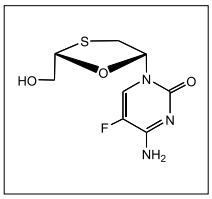
2004: Emtriva is one of the components of a binary, fixed dose combination called Truvada® (Viread®, oral 300 mg, Emtriva®, 200 mg, qd,) which received FDA approval.

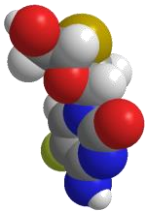
33

Emtriva® (Emtricitabine, FTC)

EMORY







2003: FTC (Emtriva®), a low toxicity, once a day (qd) anti-HIV therapy, approved by the FDA.

2004: Emtriva is one of the components of a binary, fixed dose combination called Truvada® (Viread®, oral 300 mg, Emtriva®, 200 mg, qd,) which received FDA approval.

2006: Atripla, a once-a-day fixed dose formulation containing 200 mg of Emtriva®, 300 mg of Viread® and 600 mg of the first-in-class NNRTI, Efavirenz (Sustiva®, Stocrin™) from Bristol-Myers Squibb / Merck.

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Clinical Agents From The Liotta Lab

EMORY

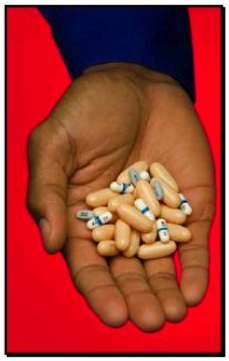
Product	Licensee	Preclinical	Phase 1	Phase II	Phase III	NDA	Market
Epivir®	GlaxoSmithKline/Shire						
Combivir®	GlaxoSmithKline/Shire						
Trizivir®	GlaxoSmithKline/Shire						
Epzicom®	GlaxoSmithKline/Shire						
Epivir-HBV®	GlaxoSmithKline/Shire						
Emtriva®	Gilead Sciences, Inc.						
Truvada®	Gilead Sciences, Inc.						
Atripla®	Gilead Sciences, Inc.						
Complera®	Gilead Sciences, Inc.						
Stribild™	Gilead Sciences, Inc.						
Genvoya®	Gilead Sciences, Inc.						
Descovy®	Gilead Sciences, Inc.						
Elvucitabine	Achillion Pharmaceuticals						
Q-122	Que Oncology						

Emtricitabine and Lamivudine

35

Consequences of a Three Drug, Fixed Dose Combination

EMORY



Atripla™
Single Tablet Regimen

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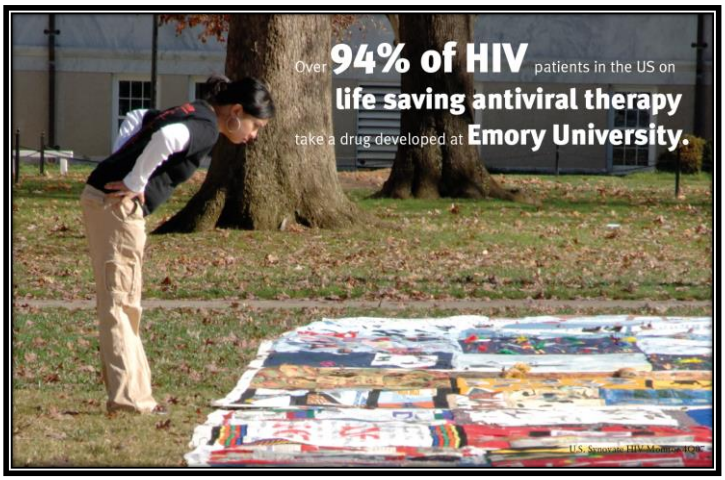
Consequences of a Three Drug, Fixed Dose Combination

EMORY



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Audience Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

Why did the development of emtricitabine take so much longer than lamivudine (13 years vs. 6-7 years)**?**

- Emtricitabine was harder to prepare than lamivudine
- Emtricitabine lacked sufficient intellectual property protection to be developed
- The development of emtricitabine was slowed down because of multiple litigations
- None of the above
- All of the above

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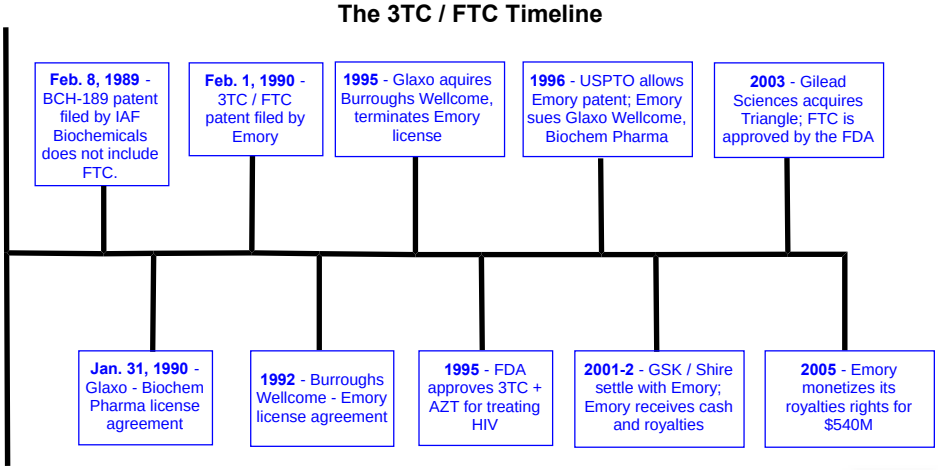
EMORY

Scientific vs. Legal / Business Considerations

The 3TC / FTC Timeline



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DRIVE INFECTIOUS INNOVATION

Drug Innovation Ventures at Emory

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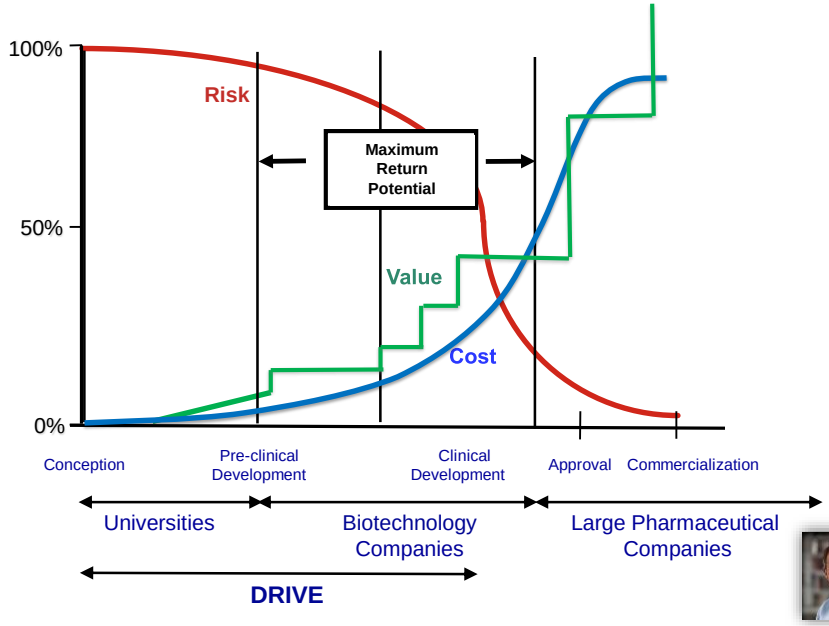
Drug Development Value Inflection Points



DRIVE: An Independent Biotechnology Company Operating in an Innovative University Environment

- **DRIVE**, LLC is an independently managed, non-profit drug development company, wholly owned by Emory University.
- **DRIVE** is managed by a highly experienced and successful management team and has a world class external advisory board.
- Founded in 2012, **DRIVE** was funded by a $20M investment from the Liotta discretionary funds.
- **DRIVE** can form its own for-profit spin-outs to accommodate private investment and can in- and out-license technologies. It is capable of advancing drugs candidates through Phase II clinical trials.
- **DRIVE's** ongoing funding is derived from government grants and contracts, as well as revenues from asset sales of major market disease therapeutics, which enables it to subsidize research on neglected (small market) diseases.
- Unlike traditional for-profit university spin-outs, **DRIVE** has ready access to the intellectual and physical assets of Emory.

Our Focus: Developing Therapeutics to Treat Viral Infections of Global Concern

DRIVE

- ***RNA viruses cause epidemic disease and are responsible for 80% of the viral disease burden worldwide.*** They are the major contributions to the pool of emerging and reemerging infectious diseases
- The vast majority of RNA viral disease is caused by two subgroups of RNA viruses, those carrying their genome as either negative (-) or positive (+) sense, single-stranded RNA
- ***There are no drugs available to prophylax against or treat infections due to the vast majority of these viruses.*** We are working to specifically address viruses in the following families (*NB: green indicates identified DRIVE lead compound*):

(+) Single-Stranded RNA Viruses

Flaviviradae: HCV, Dengue, West Nile, Zika
Togaviridae: EEEV, VEEV, WEEV, CHIKV
Coronaviridae: SARs and MERS – coronaviruses

(-) Single-Stranded RNA Viruses

Paramyxoviridae: Respiratory syncytial virus (RSV), Human parainfluenza viruses
Orthomyxoviridae: Influenza A & B
Bunyaviridae: Hantaviruses, Rift Valley fever virus

Hepatitis B Virus: New small molecule that potentially eliminates HBV cccDNA and produces a sustained virologic response (SVR)

DRIVE's Current Spin-off Pipeline

DRIVE

EIDD-1931 for the treatment of emerging/reemerging viral diseases and biodefense

- The only active small molecule to date against Alphavirus infections - Venezuelan Equine Encephalitis virus (VEEV - biodefense) and Chikungunya (emerging infection).
- The most active small molecule to date in murine models of Ebola infection
- The compound is in late stage pre-clinical development and on track for IND submission Q2, 2018
  - EIDD-1931 is orally bioavailable in rats
  - The compound is efficiently anabolized to its active 5'-triphosphate in multiple tissues important in the pathogenesis of Alphavirus infection, including the brain
  - The cytotoxicity profile of EIDD-1931 is acceptable with selectivity indices ranging from 8 to 232
- To date $15M support and commitments from DTRA and NIAID
- Interest from at least one mid-cap biotech company (Emergent Biosolutions)

EIDD-2023 for the treatment of picornavirus infections

- EIDD-2023 is active against rhinoviruses and enteroviruses - testing underway vs. polio virus
- EIDD-2023 was developed to pre-IND status for another indication
- EIDD-2023 has extensive and positive safety data (12 week GLP - tox studies in two species showing favorable toxicity profile)

Drusco, Inc.: DRIVE's First Spin-off

EIDD-2173 - A Novel Low Risk Opportunity for the Treatment of Hepatitis B Virus Infections

- Clevudine has shown potent anti-HBV activity in multiple clinical studies but its development and use were hampered by reversible skeletal muscle myopathy in a limited number of patients possibly due to systemic exposure
- Clevudine-5'-phosphoramidate conjugates have been designed by DRIVE to deliver the 5'-monophosphate to the liver thereby reducing systemic exposure to clevudine and minimizing the possibility of skeletal muscle myopathy
- Oral administration the clevudine phosphoramidate conjugate of EIDD-2173 significantly reduces systemic exposure to clevudine in rats, including muscle
- The phosphoramidate moiety was successfully metabolized to clevudine-5'-monophosphate and converted to active 5'-triphosphate in rat liver, thereby significantly decreasing non-liver organ exposure to clevudine and its 5'-triphosphate in rats
- When administered at equimolar doses, clevudine and EIDD-2173 generated similar levels of active 5'-triphosphate in the liver
- Selective targeting of the liver by EIDD-2173 could lead to a decrease in the off-target effects observed with long term dosing of clevudine in humans
- Eliminating the off-target effects of clevudine, while retaining the unique anti-HBV activity of clevudine 5'-triphosphate, could lead to combination therapies with approved NRTIs resulting in better SVR rates in chronically infected HBV patients

DRIVE's Major Milestones

- A recently completed research and out-licensing agreement with AbbVie to develop a compound to treat hepatitis C (HCV) infections brought **$24M** into DRIVE/Emory. The upfront payment for this was five times larger than Emory's previous record holder
- A four year, **$10.3M** contract from the Defense Threat Reduction Agency (DTRA) to file an IND for EIDD-1931, a potential treatment for systemic and aerosol infections with Venezuelan Equine Encephalitis Virus (VEEV). VEEV not only poses a serious public health threat in the Americas, but also can be used as a biological warfare agent
- A three year, **$3.5M** contract from NIAID to demonstrate the efficacy of EIDD-1931 in animal models of Chikungunya (CHKV) infection, a devastating polyarthritic disease that has spread around the world at an alarming rate. Based on new DRIVE data, the contract has been expanded to include Zika and Ebola **(**EIDD-1931 is the most potent compound found to date against Ebola**)**
- Georgia Research Alliance (GRA) funding for multiple DRIVE programs including HBV, RSV, Zika and Dengue and a preferred relationship for DRIVE spin-off companies (demonstrating broad support for DRIVE at the highest state funding levels)
- Spin-off company, Drusco, Inc., formed to develop EIDD-2173 for HBV, **$9-12M** committed Series A funding (among the largest Series A rounds in Emory and Georgia history)
- Development of a DRIVE discovery compound, EIDD-2023, for the treatment of rhinovirus (the primary cause of the common cold) and enterovirus infections; EIDD-2023 has shown a high level of safety in 90-day chronic toxicology studies
- DRIVE/EIDD has trained over 14 post-docs and interns in various aspects of drug discovery and development ranging from bench science to interaction with the venture financing community

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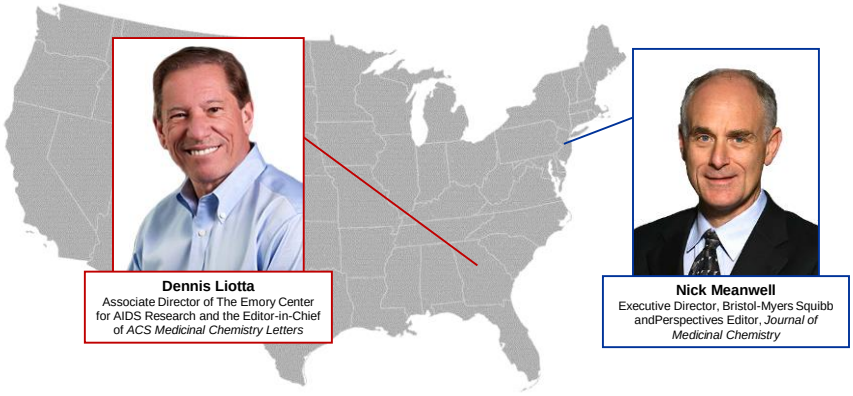

Dennis Liotta
Associate Director of The Emory Center for AIDS Research and the Editor-in-Chief of *ACS Medicinal Chemistry Letters*

Nick Meanwell
Executive Director, Bristol-Myers Squibb andPerspectives Editor, *Journal of Medicinal Chemistry*

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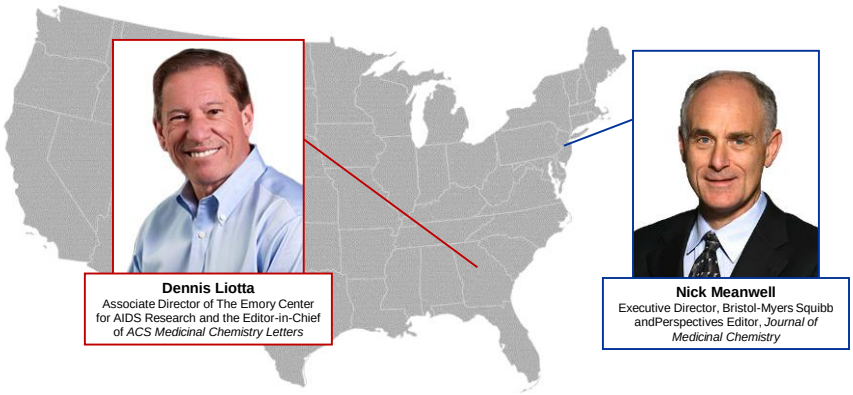

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