Therapeutics: Potential New Drugs and Drugs in Development

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Presenter Disclosures

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The following relationships with commercial interests existed during the past 24 months:

Company Name:	Nature of Relationship: Consultant, Speakers Bureau, Sponsored Research, Other
Grant support	Cidara, Gilead, F2G
Consultant	Basilea, F2G, Gilead, Merck, Pfizer, Scynexis, Sfunga
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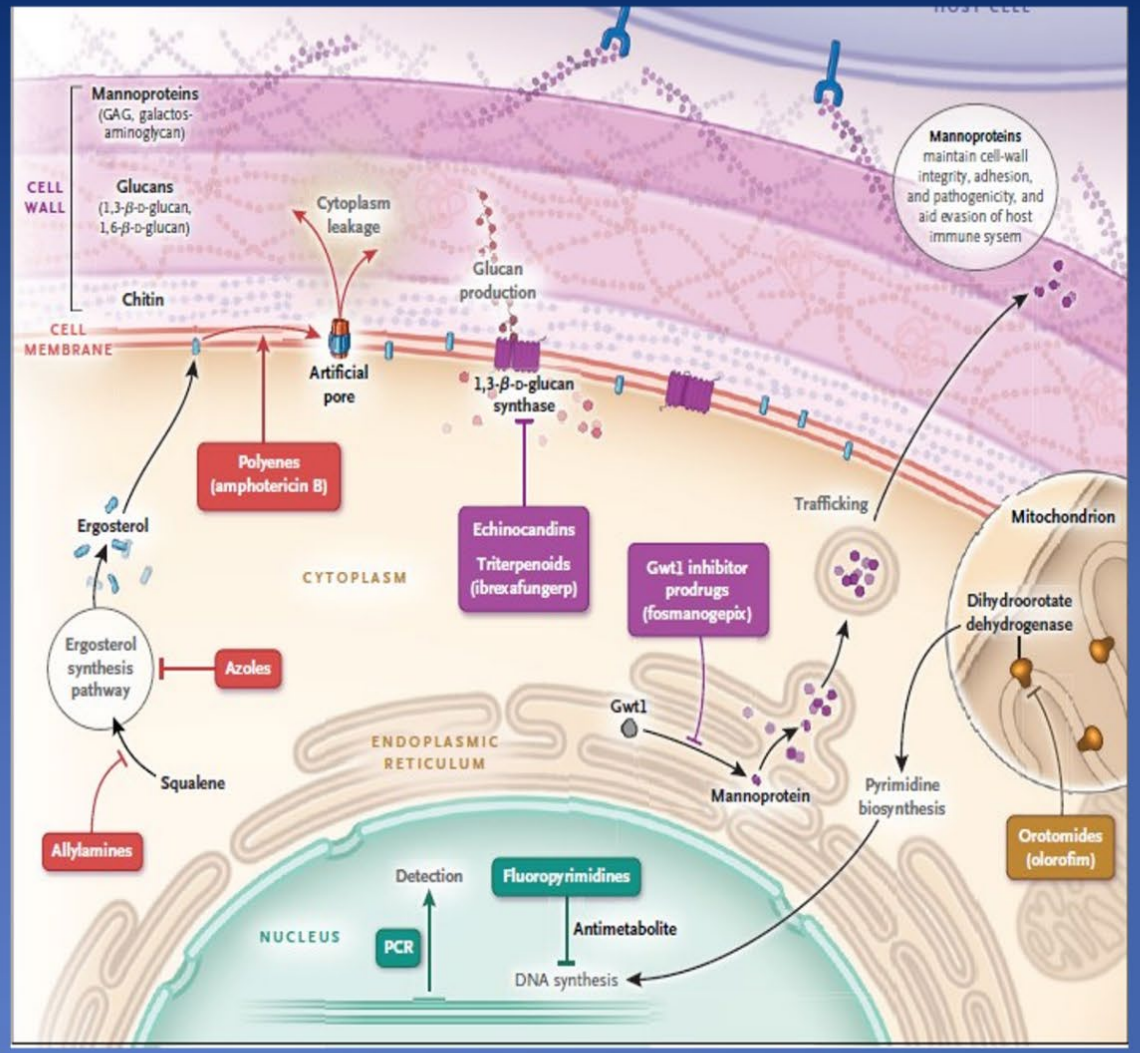
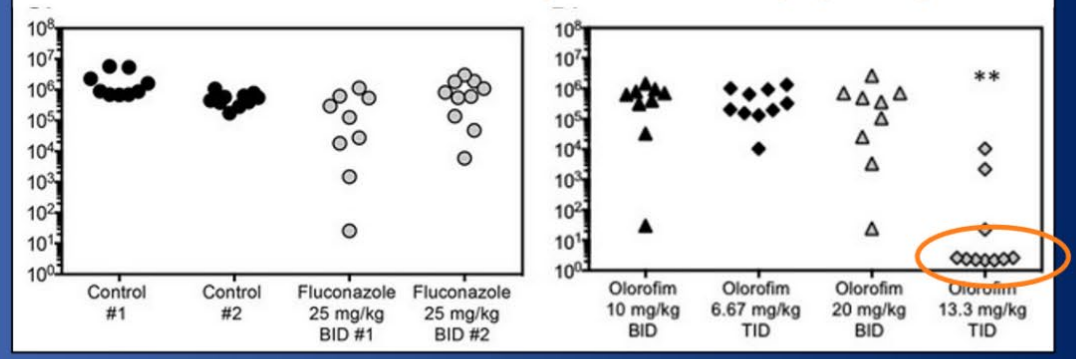
The Antifungal Pipeline: A Reality Check

Novel Agents



Drug	Target	MIC (µg/mL)
Olorofim	Dihydro-orotate dehydrogenase Pyrimidine synthesis	MIC_{50}/MIC_{90} ≤0.008/0.015
Ibrexafungerp	Glucan synthase New structure Cell wall	MIC range <0.125-0.25
Fosmanogepix	GPI synthesis inhibitor Cell wall	MEC range 0.002-0.016

Murine model: Olorofim x 7 days, then necropsy 7 days later



Culture negative in 7/10!

Thompson GR and Young JH. ***NEJM***. 2021; 385(16):1496-1509. Wiederhold et al. ***AntimicrobAgents Chemo*** 2018; 62(9):e00999-18

Slide courtesy George R Thompson III, MD; Thx! GR!

The Antifungal Armamentarium:
Key Questions for Coccidioidomycosis

- Unmet need: burden of infection; impact of resistance
- Newer clinical agents with activity in cocci
  - Isavuconazole
  - Posaconazole tablets/IV
  - SUBA-itraconazole
- Drugs with in vitro / in vivo activity in coccidioidomycosis
  - Nikkomycin Z (VFS-1)
  - Oteseconazole (VT-1161), VT-1598
  - Olorofim (F901318)
  - Fosmanogepix (AXP001)
  - Ibrexafungerp (SCY-078)
- Other drugs in the pipeline: unknown cocci activity
  - Amphotericin B cochleates
  - Glucan synthase inhibitors: rezafungin, others
  - Repurposed drugs: sertraline, aranofin, others

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Nikkomycin Z (VFS1)

(*Valley Fever Solutions)*

- **Nikkomycin Z (NikZ) is first in a new class of antifungal, chitin synthase inhibition**
  - Novel mechanism of action, significant unmet medical need
  - Activity against *Coccidioides, Blastomyces, Histoplasma, Aspergillus,* others
  - Selective to fungal cells - thus far no safety concerns in mammals
    - Efficacy in murine models
    - Efficacy in naturally occurring pulmonary coccidioidomycosis in dogs
  - May enhance other anti-fungal treatments in combination with other drugs
  - In 2014, GAIN Act QIDP designation—providing 7 and 5 years sequential market exclusivity after marketing approval.
  - Scaled up trial material in process, Phase IIa trials in clinical infection

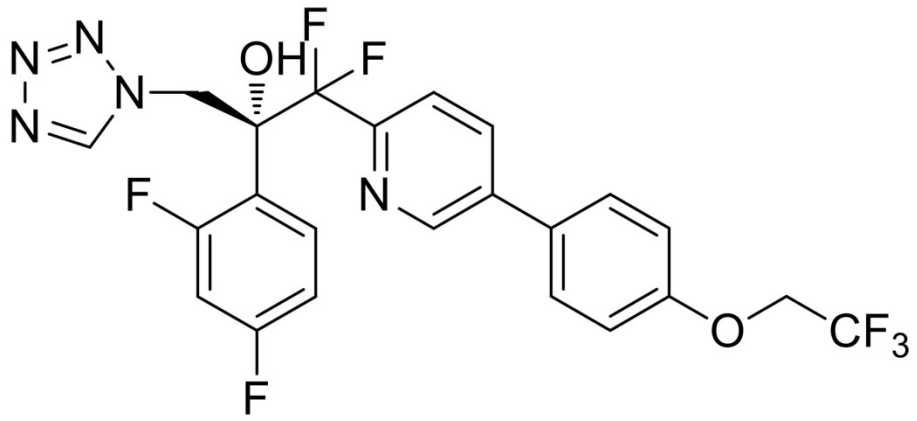
Shubitz LF, et al. *J Infect Dis* 2014;209:1949-54; Hector RF, et al. *Antimicrob Agents Chemother* 1990;34:587-93; Najvar LK, et al. ICAAC, 2015

http://valleyfeversolutions.com/

Novel Cyp51 Inhibitors VT-1161/1598

(Viamet; Mycovia Pharmaceuticals, Inc.)

- Investigational fungal Cyp51 inhibitors
- MOA similar to azoles
- Highly selective for fungal Cyp51 enzyme vs human Cyp450 enzymes (>2000 more so than the azoles)
  - *K_d against fungal Cyp51 ≤39 nM*
  - *Failed to inhibit human CYP450 at 50 µM*
- Oteseconazole exhibits minimal interactions with CYP51 and key drug metabolizing CYPs; along with high protein binding contributes to long half-life (~138 days)
  - **FDA approved: recurrent vulvovaginal candidiasis (NCT03561701 [VIOLET])**



VT-1161
(Oteseconazole)

Hoekstra WJ et al. *Bioorg Med Chem Lett* 2014;24:3455-8.
Warrilow AG et al. *Antimicrob Agents Chemother* 2014:58:7121-7.

Comparative In-Vitro Activity: VT-1161 (Oteseconazole)

		Minimum Inhibitory Concentration (µg/ml)[a] (MIC)					
	Fungal Species	**Oteseconazole**	**Fluconazole**	**Voriconazole**	**Posaconazole**	**Anidulafungin**	**Amphotericin**
Yeast MICs @ 50% inhibition	*Candida albicans*	0.001	0.2	≤0.008	0.03	0.015	0.5
	Azole-resistant *C. albicans*	0.15	20	0.32	0.20	[b]	[b]
	C. glabrata	0.16	2.0	0.06	0.25	0.06	1
	Echinocandin-res. *C. glabrata*	0.16	5.2	0.25	[b]	0.92	[b]
	C. auris	0.75	>64	0.70	0.035	0.12	1
	C. parapsilosis	0.033	0.44	≤0.008	0.06	2	0.5
	C. krusei	0.16	31	0.25	0.5	0.06	1
	Cryptococcus neoformans	0.03	2.0	0.03	0.12	>4	0.5
	C. gattii	0.06	1.9	0.12	0.12	>4	0.25
Endemic MICs @ 80% inhibition	*Coccidioides* spp.	1.4	8.3	0.11	0.14	0.11[a]	0.25
	Histoplasma capsulatum	0.43	2.0	0.06	0.47	0.40	0.25
	Blastomyces dermitiditis	1.0	2.5	≤0.03	0.62	0.55	0.12
Mold MICs @ 100% inhibition	*R. arrhizus* var. *arrhizus*	0.67	>64	8	1.0	>8	0.25

aAll MICs derived from studies conducted under CLSI protocols and represent either MIC50 or geomean values from collections of at least 10 clinical isolates (most studies having >50 isolates). Almost all oteseconazole values were from studies that used fluconazole as the comparator (and thus the fluconazole value is presented). Most other values were taken from the literature.

bNot in study found for other drugs; presumed to be fully sensitive.

Color codes: Green (Proven or Assumed Sensitive), Yellow (Proven or Assumed Intermediate), Red (Proven Resistant)

mycovia Pharmaceuticals

Slide courtesy Dr Ed Garvey; Thx! Ed

VT-1161 in Naturally Infected Dogs with Coccidioidomycosis

- Enrolled respiratory cases based on clinical signs, radiographs, serology, clinical pathology
- 60 days of medication: 14 days loading dose, followed by 46 days maintenance at ~5-fold lower dose

High dose – (29/6 mg/kg) – 12 dogs

- Mean entrance score: 13.3
- Mean exit score: 5.0
- Mean plasma concentration: 36 ±14 μg/ml*
- 9/12 dogs (75%) experienced 75%-100% reduction in clinical signs; 1 dog removed for progressive lung consolidation on day 35
- 66% of dogs had at least one dilution reduction in titer and 66% had reduction or resolution of CBC/serum chemistry abnormalities
- Radiographic improvement was mixed, ranging from no change to 90% improvement

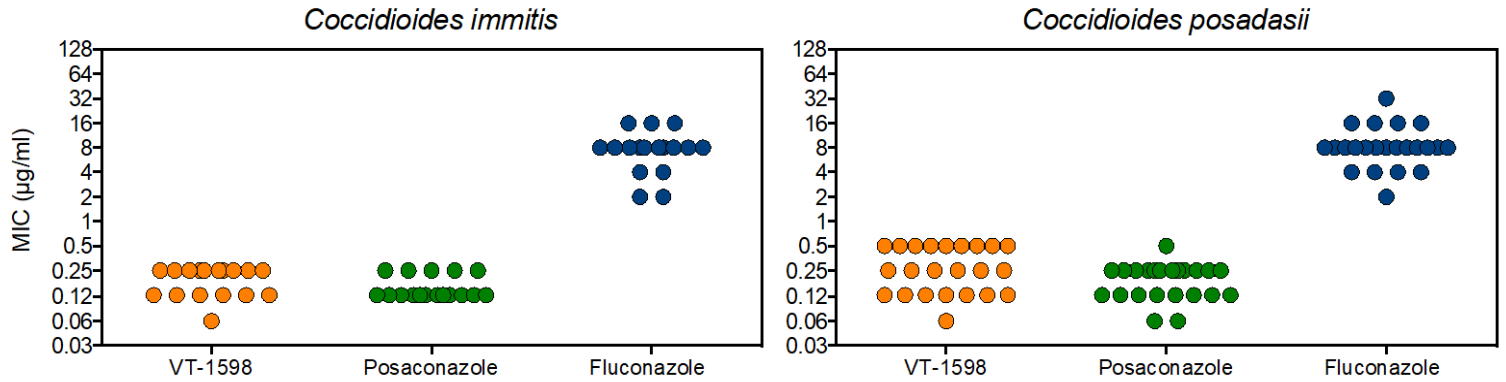
Low Dose (10/1.6 mg/kg) – 10 dogs

- Mean entrance score: 14.4
- Mean exit score: 4.7
- Mean plasma concentration: 19 ± 8 μg/ml*
- All 10 dogs experienced clinical improvement though 1 had radiographic progression and increased titer
- 60% of dogs had at least 1 dilution reduction in titer and 80% had reduction or resolution of CBC/serum chemistry abnormalities
- Radiographic improvement mixed, ranging from no change to 85% improvement

**In vitro* MIC90 and MIC range of 2 and 1-4 μg/ml for 52 clinical isolates of *Coccidioides*

Shubitz LF, *Antimicrob Agents Chemother* 2017;Apr 24;6(5).
Shubitz LF, et al. 60th CSG. Thanks! Lisa!

In vitro activity of VT-1598, Posaconazole, & Fluconazole against *C. immitis* & *C. posadasii*



Species	*Coccidioides immitis* (n = 17)			*Coccidioides posadasii* (n = 23)		
Antifungal	VT-1598	Posaconazole	Fluconazole	VT-1598	Posaconazole	Fluconazole
MIC range	0.06-0.25	0.12-0.25	2-16	0.06-0.5	0.06-0.5	2-32
MIC50	0.25	0.12	8	0.25	0.25	8
MIC90	0.25	0.25	16	0.5	0.25	16
GM MIC	0.180	0.153	7.08	0.250	0.179	8.00

Wiederhold NP, et al. *Microbe*. 2017.

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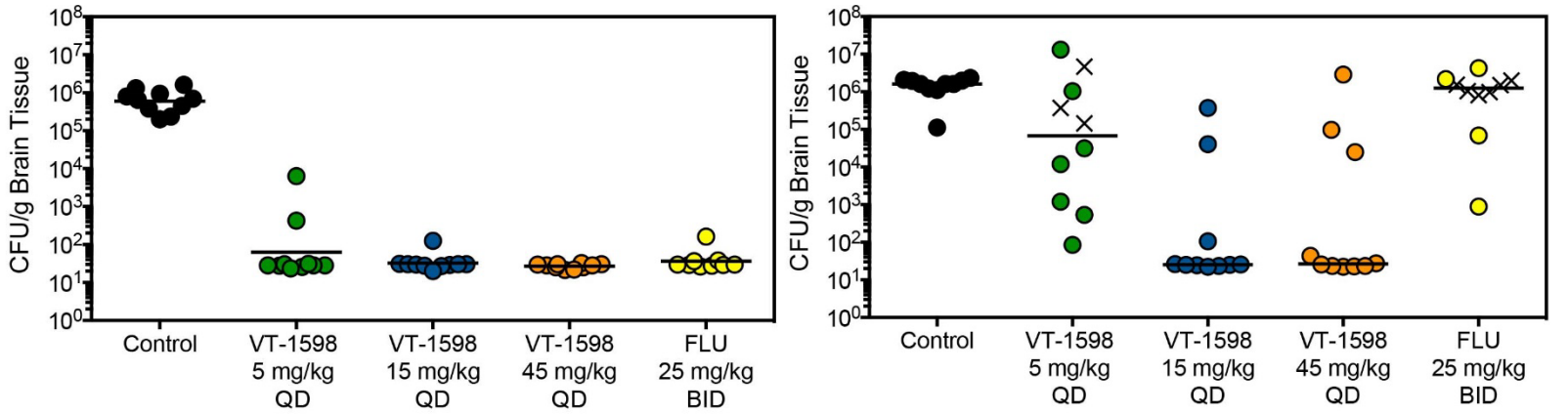
VT-1598 in Murine CNS Coccidioidomycosis: Tissue Fungal Burden



Group	Control	VT-1598 5 mg/kg QD	VT-1598 15 mg/kg QD	VT-1598 45 mg/kg QD	Fluconazole 25 mg/kg BID
Mean log CFU/g (SD) Day 9	5.77 (0.30)	1.80 (0.80) *p<0.0001	1.51 (0.21) *p<0.0001	1.43 (0.06) *p<0.0001	1.56 (0.25) *p<0.0001
Median log CFU/g (Range) Survival	6.21 (5.05 – 6.37)	4.83 (1.93 – 7.12)	1.40 (1.35 – 5.57) *p = 0.0005 **p = 0.0063	1.42 (1.35 – 6.46) *p = 0.0018 **p = 0.0193	6.10 (2.95 – 6.63)

*p-value vs. Control; **p-value vs. Fluconazole. X = mice in VT-1598 & Fluconazole groups that succumbed prior to day 30.

Tissue burden in fungal burden arm (day 9: A); and survival arm after 14 days of treatment wash-out (B). Lower Limit of Detection = 10 CFU/g.

Wiederhold NP, et al. *Antimicrob Agents Chemother*. 2018 Mar 27;62(4). pii: e02258-17

Orotomide: Olorofim (F901318) *(F2G)*

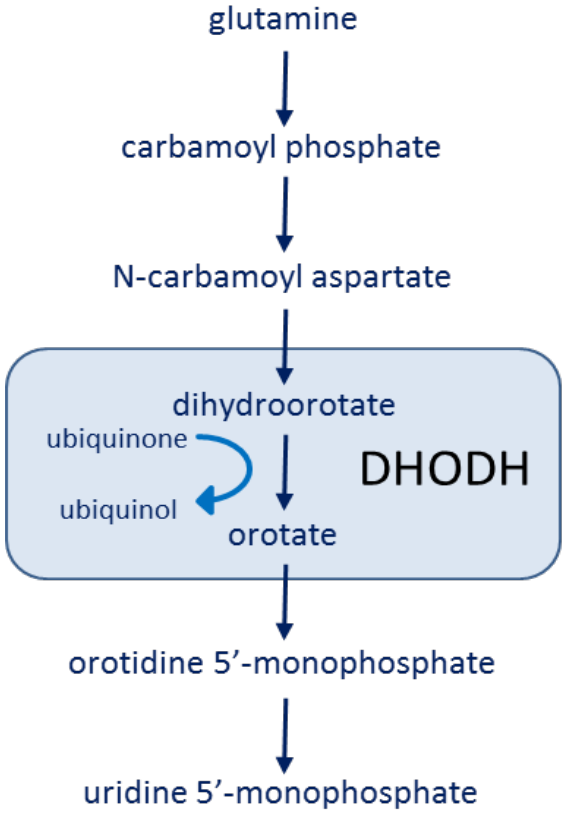
Mechanism of Action, Spectrum

- Olorofim is a potent inhibitor of *A. fumigatus* DHODH
  - DHODH (Dihydroorotate dehydrogenase) is a key enzyme involved in pyrimidine biosynthesis
- Mechanism was identified using genetic studies in *Aspergillus nidulans*
  - Confirmed by in vitro enzyme assays
- Humans also have this enzyme
  - But, > 2000-fold difference in IC_{50} between human and fungal enzymes
- Spectrum of activity: highly active against moulds/endemics
  - *Aspergillus (including resistant strains), Lomentospora, Scedosporium*
  - *Very potent vs endemic fungi: Coccidioides, Blastomyces, Histoplasma*
- Phase II clinical study for resistant/refractory mycoses completed

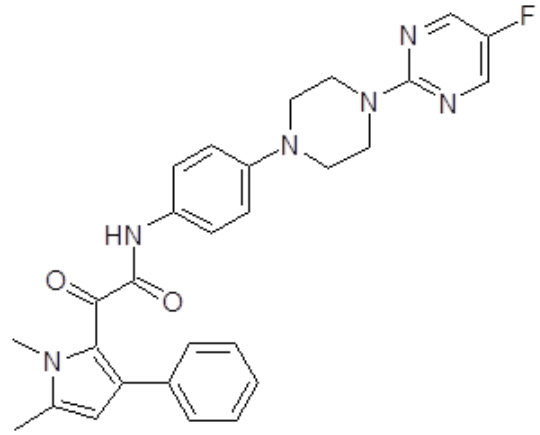
TABLE 1 MICs of olorofim and voriconazole against 59 *Coccidioides* species isolates

	All *Coccidioides* isolates (n = 59)		*Coccidioides immitis* (n = 21)		*Coccidioides posadasii* (n = 24)	
MIC parameter (μg/ml)[a]	Olorofim	Voriconazole	Olorofim	Voriconazole	Olorofim	Voriconazole
MIC range	≤0.008 to 0.06	≤0.03 to 0.25	≤0.008 to 0.015	≤0.03 to 0.25	≤0.008 to 0.015	≤0.03 to 0.25
MIC_{50}	≤0.008	0.125	≤0.008	0.06	≤0.008	0.125
MIC_{90}	0.015	0.25	0.015	0.125	0.015	0.125
GM MIC	0.011	0.113	0.009	0.072	0.009	0.103

[a]MICs were measured, after 48 to 72 h of incubation at 35°C, as the lowest concentration that resulted in 80% inhibition of growth, compared to the growth control. MIC_{50}, MIC at which 50% of isolates were inhibited; MIC_{90}, MIC at which 90% of isolates were inhibited; GM, geometric mean.

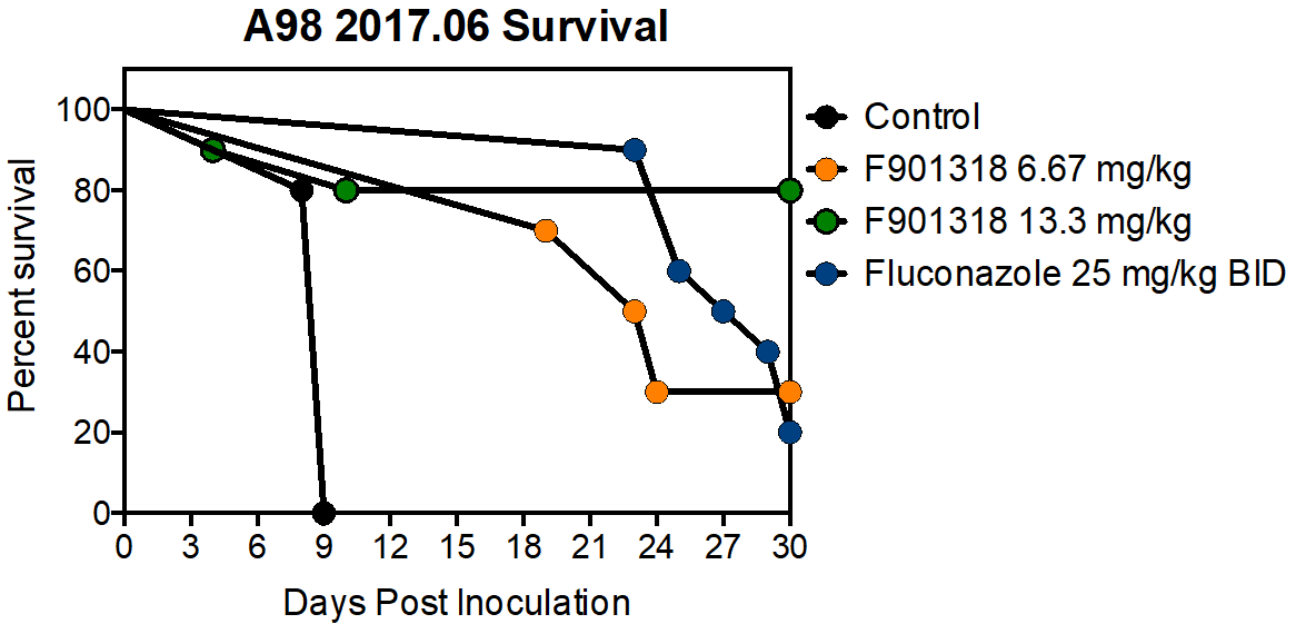


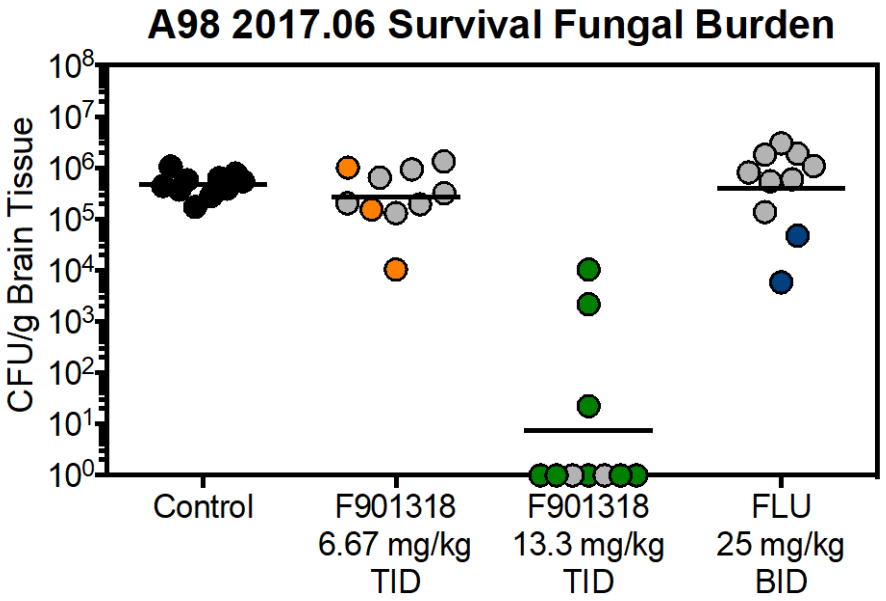
F901318 structure



Wiederhold NP, et al. *Antimicrob Agents Chemother* 2018;62(9): e00999-18

Olorofim in a Murine Model of CNS Coccidioidomycosis





Group	Control	F901318 6.67 mg/kg	F901318 13.3 mg/kg	Fluconazole 25 mg/kg
Mean $\log_{10}$ CFU/g (SD)	5.67 (0.22)	5.44 (0.62)	0.87 (1.55) *p < 0.0001	5.61 (0.84)
Mean $\log_{10}$ CFU/g (SD) (LLD)	5.67 (0.22)	5.44 (0.62)	1.13 (1.38) *p < 0.0001	5.61 (0.84)

*p-value vs. Control

Gray circles represent mice in treatment groups that succumbed prior to day 30

Wiederhold NP, et al. *Antimicrob Agents Chemother* 2018;62(9): e00999-18

Phase II Study for Resistant/Refractory Mycoses Completed: DRC-adjudicated response rate at Day 42 (mITT analysis set), *including stable disease as success*

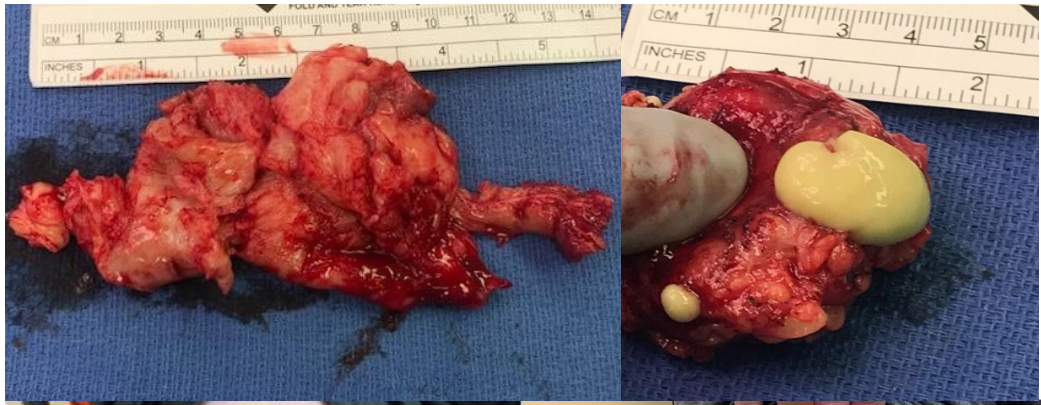
% success	DRC-adjudicated response rate[1] Day 42	
	Complete + partial	Complete + partial + stable
Overall (N = 100)	44%	69%
***Aspergillus* spp. (N = 53)**	47%	60%
***Lomentospora prolificans* (N = 17)**	53%	88%
***Scedosporium* spp. (N = 11)**	55%	82%
Other Olorofim-susceptible fungi (N = 8)	50%	87%
***Coccidioides* spp. (N = 11)**	0%	54%

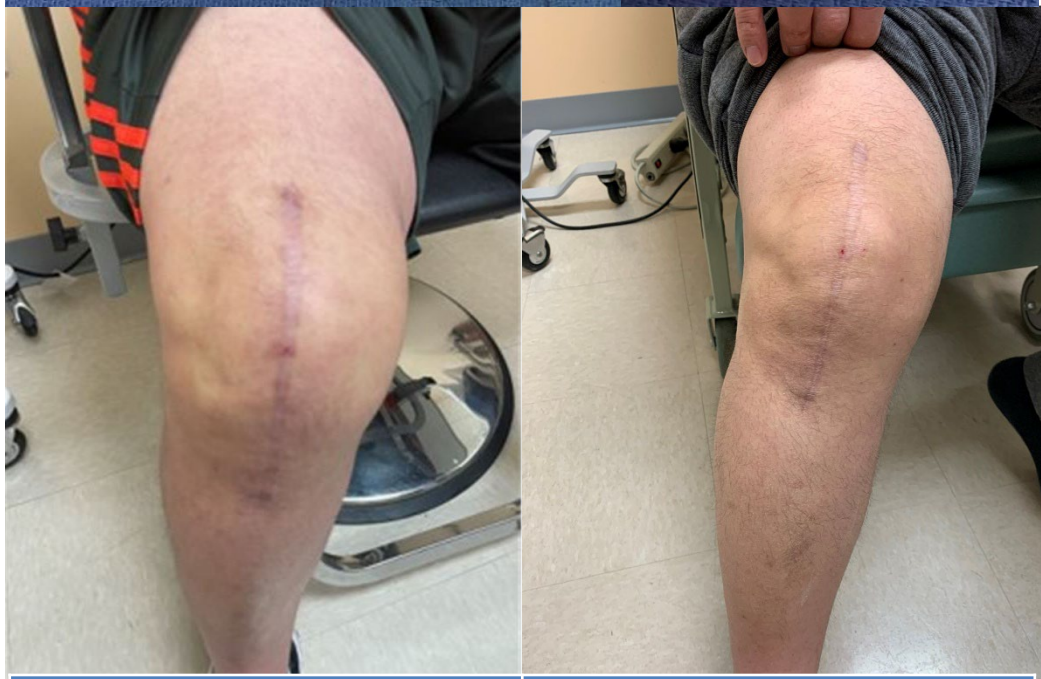
1. EORTC-MSG criteria per Segal 2008 CID

Maertens J, et al. IDWeek 2022

UTHSA Experience: Olorofim for Disseminated Coccidioidomycosis

- 49 yo Hispanic man oil field worker; 1/18 'CAP' unresponsive to abx, 7/18 knee swelling, serology pos cocci, treated flu no response & pseudohyperaldo; 9/19 Cocci IDCP 1:1024 debrided change itra (rash, pollakiuria, brain fog), posa (brain fog, fatigue, alopecia); 2/21 IDCF 1:16; olorofim 4/21 PRO 'best he's felt since initial dx' 10/22 clinically improved IDCF 1:8
- 52 yo woman refractory CNS cocci failed multiple azoles and intrathecal AmB; persistent headaches and csf abnormalities IDCF 1:16; tolerated Isavuconazole with minimal improvement 3/21 begun on olorofim + isavu; headaches resolved; 10/22 IDCF 1:8; pt reports significant clinical improvement
- 37 yo Cambodian man moved to TX from WA; developed CNS symptoms; CNS cocci dx made with pos serology treated with flu no response; readm for worse symptoms treated vori+L-AmB; presented to our hospital with C5 quadriplegia; csf pleocytosis; extensive leptomeningeal enhancement; CSF IDCF 1:256 restarted L-AmB+vori then Olorofim +vori; improvement in mental status and minimal arm movements csf titer dec to 1:8 by day 84 with improvement in CSF findings





June 2021 | 24 Jan 2022

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Coccidioidomycosis: External Controls

- Collaborated with Valley Fever Institute (VFI), Bakersfield, CA
- 3,184 VFI patients screened for cases similar to Study 32 patients
  - Extrapulmonary cocci, persistent symptoms, and at least 2 therapies.
  - Unless has died, at least 3 years follow-up
  - 29 comparable cases were identified
- Coccidioidomycosis HC cohort: Improvement to no symptoms was uncommon and slow
  - At average duration of observation of >4.5 years, 3% (1/29) had no symptoms
- Olorofim-treated patients: Complete Clinical response (No symptoms)
  - Day 42: 18% (2/11)
  - Day 120: 36% (4/11)
  - Similar pattern seen for partial response endpoint
- Net: Rapid and frequent complete resolution of symptoms that is unexpected relative to HC cohort

Maertens J, et al. IDWeek 2022

GPI Biosynthesis Inhibition – APX001 / Fosmanogepix

(Amplyx, Pfizer)

Fungal adhesion ligands derived from GPI-anchored proteins

- *Candida albicans* possess ~115 GPI-anchored proteins
- Als protein family members

GWT1 gene encodes Gwt1p

- *an inositol acyltransferase in early GPI biosynthesis pathway*

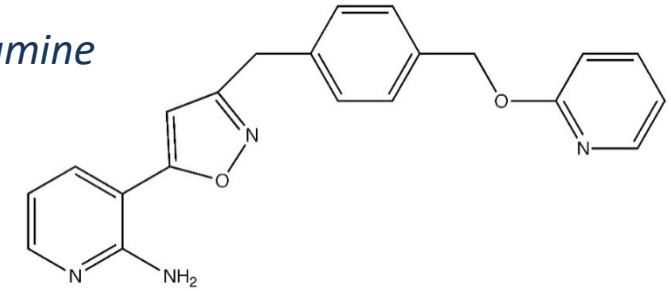
↓

1-(4-butylbenzyl)isoquinoline (BIQ)

↓

Manogepix (APX001a [E1210])

- *(3-(3-{4[(pyridin-2-yloxy)methyl]benzyl}isoxazol-5-yl)pyridin-2-amine*
- *Selectively inhibits fungal inositol acyltransferase*
- *Reduces expression of Als1p on C. albicans* cell surface



Umemura et al. *J Biol Chem* 2003; 278: 23639 – 47.
Watanabe et al. *Antimicrob Agents Chemother* 2012: 56: 960 – 71.

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Manogepix (APX001a[E1210]) In vitro Activity

Organism	Range	MIC50	MIC90
C. albicans (52)	≤ 0.008 – 0.016	≤ 0.008	≤ 0.008
C. glabrata (44)	≤ 0.008 – 0.06	0.06	0.06
C. tropicalis (23)	≤ 0.008 – 0.03	0.016	0.03
C. parapsilosis (26)	≤ 0.008 – 0.016	≤ 0.008	0.016
A. fumigatus (20)	0.03 – 0.13	0.06	0.13
A. terreus (23)	0.015 – 0.06	0.03	0.06
F. solani (23)	0.03 – 0.12	0.12	0.12
F. oxysporum (15)	0.03 – 0.25	0.06	0.12
S. prolificans (28)	0.03 – 0.25	0.06	0.12
S. apiospermum (28)	0.03 – 0.12	0.06	0.12
S. apiospermum (28)	0.03 – 0.12	0.06	0.12
C. immitis/posadasii (10)	0.002-0.016	0.004	0.004

*50% inhibition of growth for *Candida*; MEC endpoint for moulds/*Cocci* (static activity)
**Inactive against *C. krusei* and members of the Order Mucorales

Active against fluconazole-resistant *Candida* (MIC90 - 0.03 µg/mL)

Miyazaki et al. *AAC* 2011; 55: 4652 – 58; Castanhelra et al. *AAC* 2012; 56: 352 – 57; Pfaller et al. *AAC* 2011; 55: 5155 – 58; Wiederhold NP, et al. *AAC* 2015;59:690-2; Viriyakosol S, *AAC,* 2019;62(2): e01715-18

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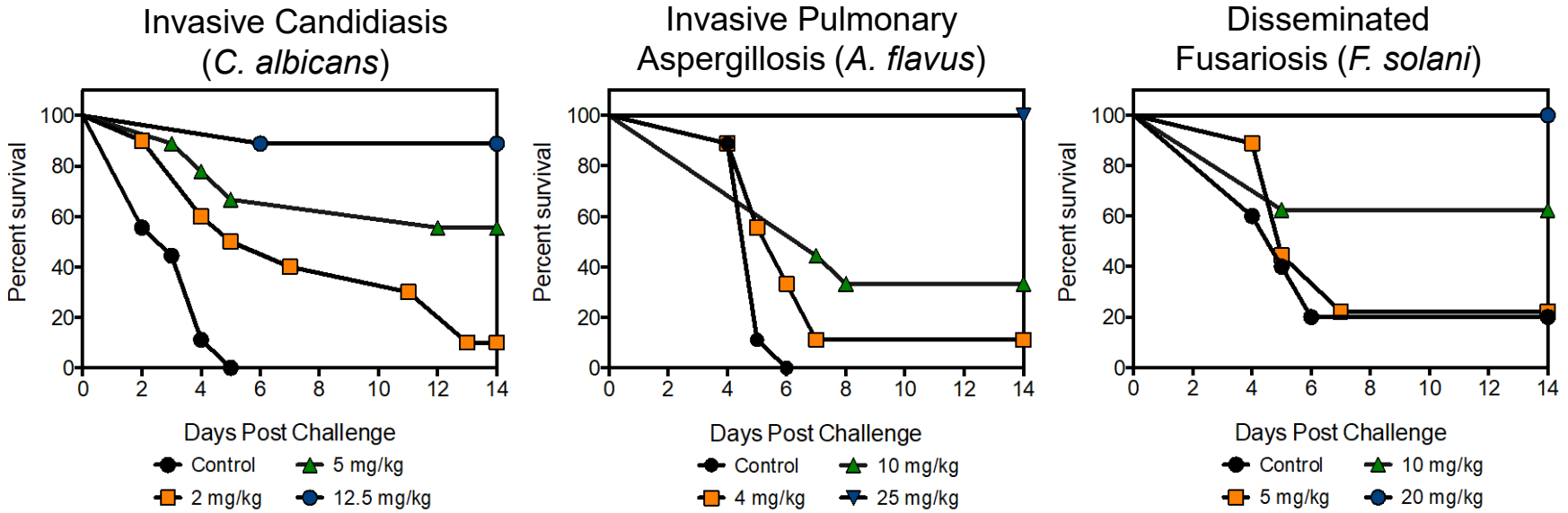
GPI Biosynthesis Inhibition *(Amplyx, Pfizer)*
Fosmanogepix (APX001[E1211]) – In vivo Efficacy

In vivo efficacy demonstrated in murine models of invasive fungal infections



PK parameter	Tmax	Bioavailability	Half-life
1 mg/kg PO X1	0.5 hours	57.5%	2.2 hours

- ✓ Efficacy in vitro and in vivo against resistant *C. albicans* & *C. auris*
- ✓ Phase 2 trials for *Candida* & moulds in progress

Hata et al. *Antimicrob Agents Chemother* 2011; 55: 4543 – 51;
Wiederhold NP, et al. *Antimicrob Agents Chemother* 2015;59:690-2.

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Efficacy of APX001/1a in vitro and in vivo against *Coccidioides*

- In vitro testing using agar dilution:

Strain	MEC (μg/ml), APX001A	MIC (μg/ml)[a]			
		APX001A	FLC	AMB	POS
C. immitis RS	0.002–0.004	8	>16	0.125	0.06–0.125
C. posadasii C735	0.004	0.03	>16	0.25	0.06–0.125
C. posadasii Silvera	0.008	8	>16	0.25	0.03

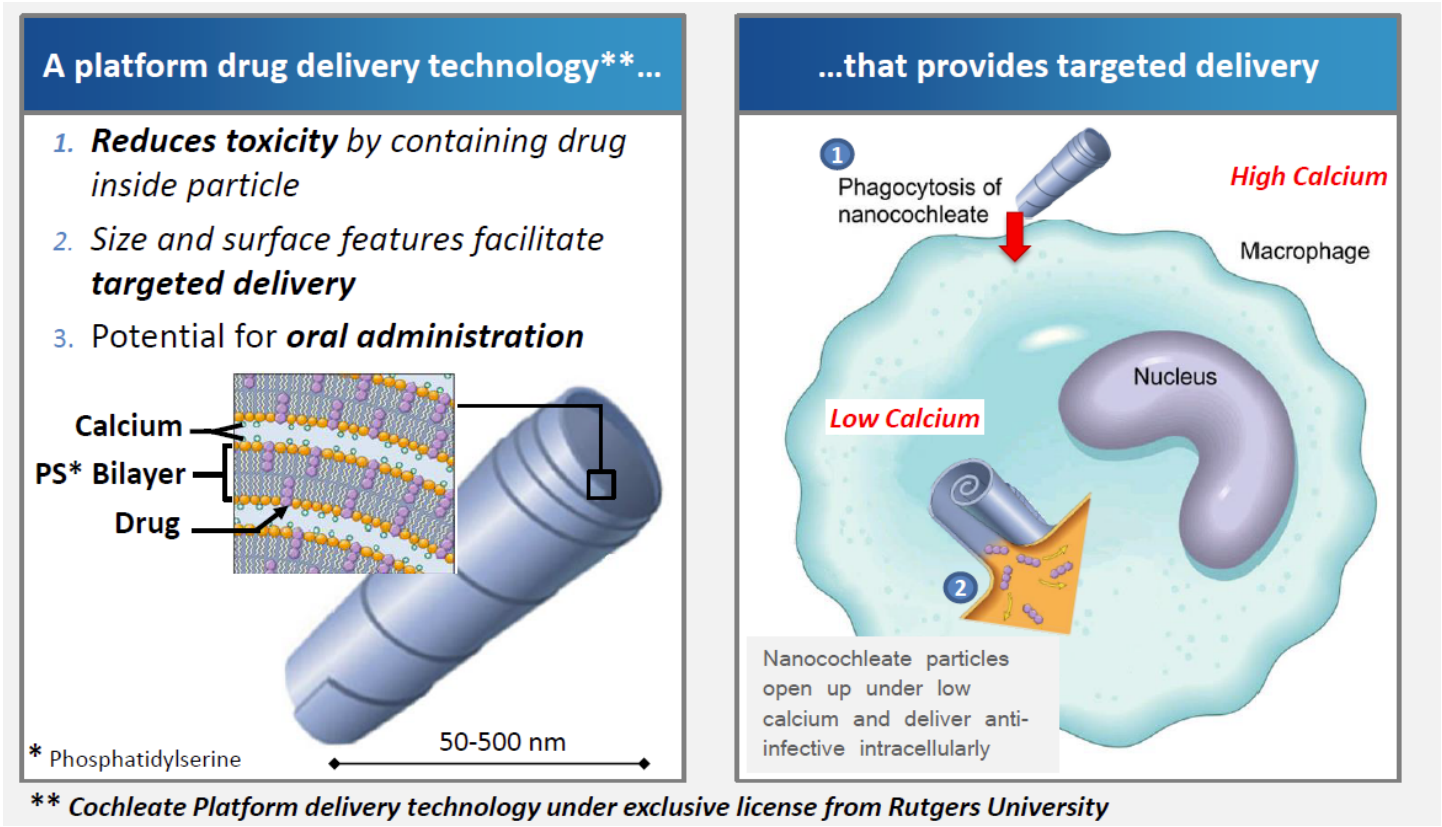
[a]The MIC value was read at 100% inhibition. FLC, fluconazole; AMB, amphotericin B; POS, posaconazole.

- Murine pulmonary coccidioidomycosis
  - 50 mg/kg bid + ABT starting d 7 and continuing for 5d
  - ~3-log reduction in lung CFU treated vs untreated controls
  - Reduced dissemination to spleen (1/10) vs controls (9/10); GM fungal burden 3.99 $\log_{10}$

Viriyakosol S, et al. *Antimicrob Agents Chemother* 2019;29:63(2):e01715-18.

AmB Cochleates (MAT2203) *(Matinas Biopharma)*

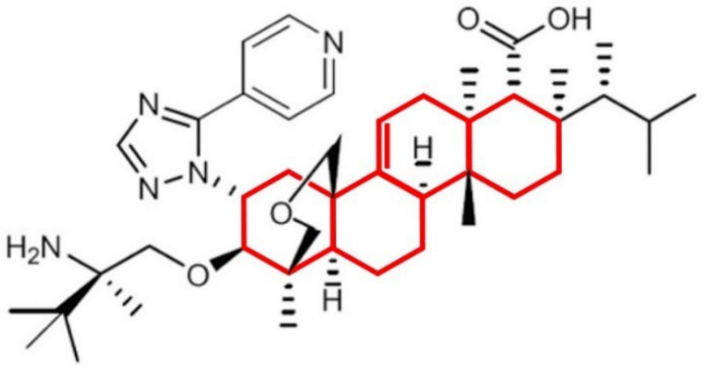
- Cochleate targeted nano-particle delivery
  - Reduced toxicity
  - Targeted delivery
  - Oral delivery
- MAT2203
  - Animal studies
  - Human Phase I tolerability
  - Phase 2 cryptococcal meningitis (EnACT) (NCT04031833)
    - Better tolerated than cAmB
    - Survival 90% vs 85% cAmB regimens
    - Good early fungicidal activity (EFA)



Atukunda M, et al. IDWeek 2022

Glucan Synthase Inhibitors: Ibrexafungerp – SCY-078 *(Scynexis)*

- Semi-synthetic derivative of natural product
  - New molecular class--triterpenoid
- Potent β 1,3 glucan synthesis inhibitor (GSI)
  - Same target as echinocandin antifungals Blocks synthesis of essential component of cell wall of pathogenic fungi
  - Unique target not in mammalian cells
- Excellent in vitro & in vivo activity against *Candida* (including *C. auris*), *Aspergillus, Pneumocystis, Coccidioides*
  - Active in vitro against azole & echinocandin resistant *Candida* strains
- Orally bioavailable/IV in development
- Extensive tissue distribution: kidney, lungs



•Phase I/II - generally well tolerated with good pharmacokinetics (QD); low drug-drug interactions

•Phase III trial *C. auris* (CARES) NCT03363841

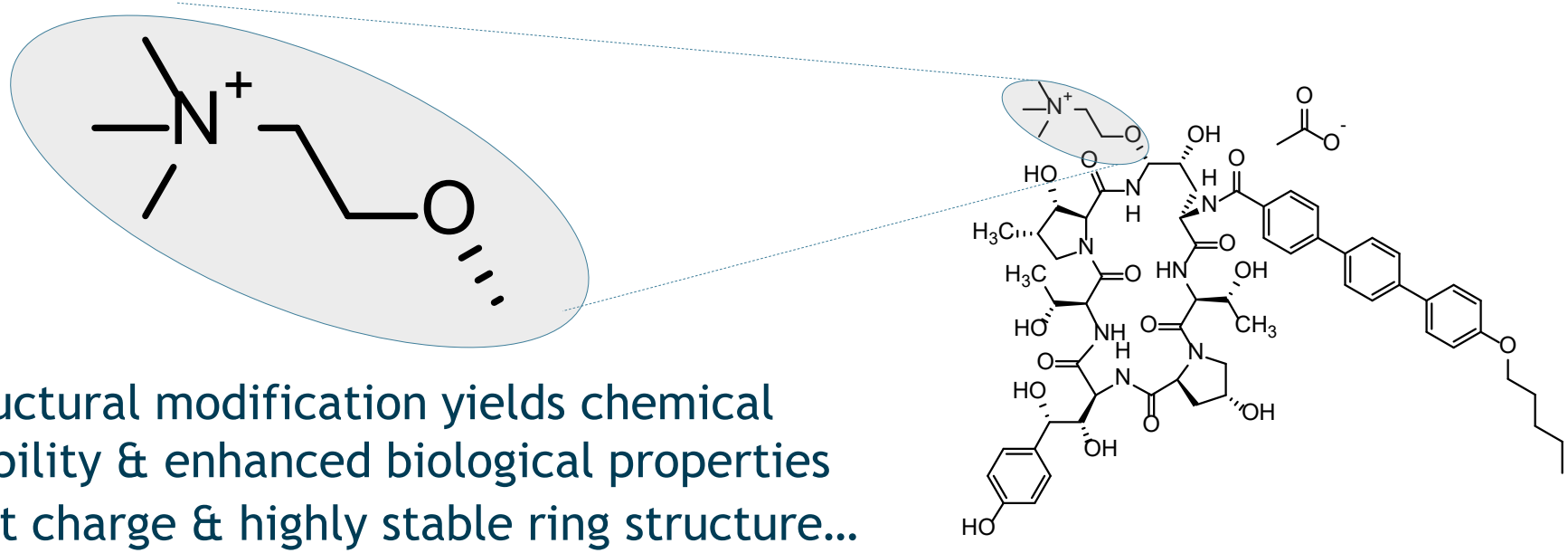
•Phase III trial IFI resistant/unresponsive to therapy (FURI) NCT03059992

•Includes coccidioidomycosis

•FDA Approved Acute Vaginal Candidiasis and Recurrent VVC (VANISH/CANDLE) NCT 03734991/NCT03987620

Wiederhold NP, et al. *J Antimicrob Chemother* 2018;73:448-51; Thompson GR, IDWeek 2022

Rezafungin (CD101)
A novel echinocandin antifungal *(Cidara)*



Structural modification yields chemical stability & enhanced biological properties

Permanent charge & highly stable ring structure…

- Prolongs PK: once weekly dosing
- Eliminates toxic degradation products: improved safety & dose range
- Allows high exposures: treats less susceptible pathogens
- Enables multiple formulations: systemic and topical

In vitro activity: *C. auris* including some echinocandin resistant strains
Aspergillus including azole resistant strains

✓ Phase 2/3 trials: candidemia vs caspo complete (STRIVE [NCT 02734862], RESTORE [NCT03667690])

Sofjan AK, et al. *J Glob Antimicrob Resist* 2018;Feb 24; Berkow EL, et al. *Diag Microbiol Antimicrob Resist* 2018;90:196-7; Wiederhold NP, et al. *J Antimicrob Chemother* 2018;doi:10.1093/jac/dky280; Thompson GR, et al. *Clin Infect Dis* 2021;73:e3647-66

CIDARA THERAPEUTICS

Sertraline

- Serotonin-reuptake inhibitor
  - Activity against other fungi (*Cryptococcus*)
- In vitro activity again *C. immitis* vs fluconazole and in combination

Drug	MIC (mcg/mL)			
fluconazole	4	8	16	32
sertraline	4	4	8	8
fluc + sert	4	2	4	4
	MFC (mcg/mL)			
fluconazole	4	16	16	32
sertraline	4	8	8	8
fluc + sert	2	4	4	4

- *Coccidioides* MIC (n=10): Flu 8-64 mcg/ml vs Sertraline 8 mcg/ml

Simon P et al. *Mycology* 2016;7(3):99-101; Fungus Testing Laboratory UTHSA; Personal communication: Thx! Nathan!

New Antifungals for Coccidioidomycosis: What Do We Need?

- Significant unmet medical needs: resistance, toxicity, drug interactions, oral bioavailability
- Many new potential targets and compounds under early & more advanced stages of investigation
  - New methods of delivery for old drugs
  - New uses for existing compounds
  - New agents in currently used classes
  - New compounds with novel mechanisms of action!

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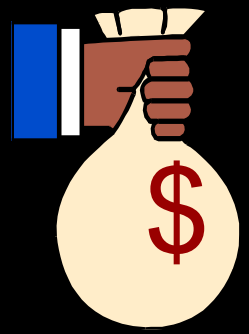

NIAID Grants/Contracts

AMoID/PCMID/In Vitro:

HHSN272010000038I
HHSN27200005 (A93)
HHSN27200006 (A98)
HSN272201000039I
HHSN27200004 (A20)
75N93019F00131 (A34)
75N93022F00001 (A65)
75N93019D00022
75N93012F00001(A13)

Grants:

U19AI166761 (Hung/López-Ribot)
R33/34AI140823 (López-Ribot)
R21AI140823 (López-Ribot)

S ◆ A ◆ C ◆ M ◆ M

San Antonio Center for Medical Mycology