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Session: P-58. Novel Agents

Background. Fox Chase Chemical Diversity Center (FCC) is developing non-peptide analogs of host defense proteins for the treatment of invasive fungal infections mainly caused by *Candida* (CAN) and *Aspergillus* (ASP). We evaluated the activity of 6 novel compounds and 2 comparators against 150 isolates from 15 fungal groups.

Methods. Susceptibility testing was performed per CLSI broth microdilution methods for investigational compounds and comparators against 70 CAN and 40 ASP isolates in addition to 10 *Cryptococcus* spp. (CRYP), 10 *Fusarium* spp. (FUS), 10 Mucorales, and 10 *Scedosporium* spp. (SCED) isolates from recent (2017-2019) clinical infections. MIC results were determined as ≥ 50% reduction at 24 and 72 hours for CAN and CRYP respectively, and 100% reduction at 24, 72, and 48 hours for Mucorales, SCED, and other moulds, respectively. CLSI clinical breakpoint (CBP) and epidemiological cutoff value (ECV) interpretive criteria were applied for comparators.

Results. Compounds FC10790, FC11083, FC11212, and FC11275 had MIC_{50} results at ≤ 0.015 mg/L and MIC_{90} results at ≤ 0.015 to 0.12 mg/L against CRYP, ASP, and FUS isolates. Compounds FC5096 and FC11022 were 2- to 4-fold less active while demonstrating MIC_{50} and MIC_{90} results of 0.03 to 0.5 mg/L against CAN, CRYP, ASP, and FUS isolates. The Mucorales isolate set showed the widest range of MIC results for FC compounds. FC10790 exhibited the greatest potency with a $MIC_{50/90}$ at 0.5/2 mg/L. FC compounds showed potent activity against SCED with MIC_{90} results of 0.03 to 0.25 mg/L. Fluconazole showed a wide range of MIC results, from 0.06 to >64 mg/L, but the highest results observed were for *Candida auris* ($MIC_{50/90}$, 64/ > 64 mg/L) and *Candida krusei* ($MIC_{50/90}$; 16/32 mg/L). Itraconazole was active against all ASP ($MIC_{50/90}$, 1/1 mg/L), but showed poor activity against FUS ($MIC_{50/90}$, > 8/ > 8 mg/L). Amphotericin B showed a narrow range of MIC results (0.5 to 2 mg/L) for all isolates except 1 ASP and most SCED.

Conclusion. Novel FCC compounds showed equal or greater activity than comparators against most CAN, ASP, SCED, and FUS. FC10790, FC11212, and FC11275 showed the greatest activity against all tested fungal isolates. development of this series of compounds for clinical studies.

Table 1

Compound	Organism group $MIC_{50/90}$ (mg/L)					
	Candida spp.	*Cryptococcus* spp.	*Aspergillus* spp.	*Fusarium* spp.	Mucorales	*Scedosporium* spp.
FC 5096	0.06/0.5	0.03/0.03	0.03/0.12	0.03/0.06	1/>8	0.12/0.25
FC 10790	≤0.015/1	≤0.015/≤0.015	≤0.015/0.06	≤0.015/≤0.015	0.5/2	0.03/0.03
FC 11022	0.06/0.25	0.03/0.03	0.06/0.12	0.06/0.06	2/8	0.25/0.25
FC 11083	≤0.015/8	≤0.015/≤0.015	≤0.015/0.12	≤0.015/0.03	>8/>8	0.12/0.12
FC 11212	≤0.015/1	≤0.015/≤0.015	≤0.015/0.06	≤0.015/0.03	2/>8	0.03/0.03
FC 11275	≤0.015/1	≤0.015/≤0.015	≤0.015/0.06	≤0.015/≤0.015	0.25/>8	0.03/0.06
Amphotericin B	1/1	0.5/1	1/2	2/2	1/1	4/>4
Fluconazole	0.25/64	2/4	--/--	--/--	--/--	--/--
Itraconazole	-- / --	-- / --	1/1	>8/>8	2/8	4/4

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1259. Activity of eravacycline against staphylococci isolated from periprosthetic joint infections

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Session: P-58. Novel Agents

Background. Perirosthetic joint infections (PJIs) are costly and difficult to treat. The most common causes of PJIs are *Staphylococcus aureus* and *Staphylococcus epidermidis*. Eravacycline is a newer tetracycline with promising activity against Gram-positive and negative bacteria which is approved for treatment of complicated intraabdominal infections. Here, the *in vitro* activity of eravacycline was assessed against bacteria associated with PJI.

Methods. 185 staphylococcal isolates, including 38 methicillin-resistant *S. aureus* (MRSA), 64 methicillin-susceptible *S. aureus* (MSSA), 62 methicillin-resistant *S. epidermidis* (MRSE) and 21 methicillin-susceptible *S. epidermidis* (MSSE) strains were studied. Minimum inhibitory concentrations (MICs) were determined according to Clinical and Laboratory Standards Institute guidelines (range of 0.06-64 µg/ml tested). Results were analyzed using susceptible breakpoints from EUCAST (≤0.25 µg/ml) and the FDA (≤0.06 µg/ml). Minimum biofilm bactericidal concentrations (MBBCs) were determined using a modification of the Calgary biofilm method. Briefly, biofilms were formed on pegged lids in trypticase soy broth, after which the pegged lids were rinsed in phosphate buffered saline (PBS), transferred to a plate containing dilutions of eravacycline in cation-adjusted Mueller Hinton broth (CAMHB) and incubated for 20-24h. Finally, the pegged lids were again rinsed in PBS and transferred to a plate containing CAMHB and incubated for 24h. The MBBC was the lowest concentration with no visible growth.

Results. $MIC_{50/90}$ (range) in µg/ml for MRSA, MSSA, MRSE, and MSSE were 0.125/0.125 (≤0.06-0.25), ≤0.06/0.125 (≤0.06-0.25). 0.125/1 (≤0.06-2), and 0.25/1 (≤0.06-1), respectively. Using the EUCAST susceptible breakpoint, 100% of isolates would be considered susceptible, whereas only 54% would be considered susceptible using the FDA breakpoint. $MBBC_{50/90}$ (range) in µg/ml for MRSA and MSSA were both 8/16 (4-16); for MRSE and MSSE, the values were 4/16 (2-32) and 8/16 (2-32), respectively.

Conclusion. Our data suggest that the FDA susceptible breakpoint may need re-evaluation. Eravacycline has low anti-staphylococcal biofilm activity.

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1260. Activity of Manogepix (APX001A) against 2,669 Fungal Isolates from the SENTRY Surveillance Program (2018-2019) Stratified by Infection Type

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Session: P-58. Novel Agents

Background. Existing antifungal agents are active against many common fungal pathogens; however, breakthrough fungal infections occur and often involve less frequently encountered yeast and mould isolates. These rarer isolates tend to exhibit diminished susceptibility to current agents. Manogepix (MGX, APX001A) is a novel inhibitor of the fungal Gwt1 enzyme. The prodrug (fosmanogepix), is being evaluated in Phase 2 clinical trials for invasive candidiasis/candidemia, *Candida auris* infections, and invasive aspergillosis. In this study, we evaluated the *in vitro* activity of MGX and comparators against 2,669 clinical fungal isolates collected worldwide (2018-2019) and stratified by infection type.

Methods. Fungal isolates were collected from medical centers located in North America (34 sites; 42.3%), Europe (30 sites; 37.9%), Asia-Pacific (11 sites; 12.3%), and Latin America (7 sites; 7.6%). Isolates were collected from bloodstream infections (BSI; 51.7%), pneumonia in hospitalized patients (PIHP; 21.1%), skin and skin structure infections (SSSI; 5.5%), urinary tract infections (UTI; 2.3%), intraabdominal infections (IAI; 1.9%), and other infection types (17.5%).

Results. MGX demonstrated potent *in vitro* activity against 1,887 *Candida* spp. isolates from BSI, PIHP, SSSI, and all infection types ($MIC_{50/90}$, 0.008/0.03-0.06 mg/L) outperforming all comparator agents (Table). Similarly, MGX was equally active against 578 *Aspergillus* spp. isolates ($MEC_{50/90}$, 0.015/0.03 mg/L), regardless of infection type. MGX was active against *Cryptococcus neoformans* var. *grubii* isolates from BSI and ALL infection types with $MIC_{50/90}$ values of 0.5/2 mg/L. *Scedosporium* spp. isolates from PIHP and all infection types were inhibited by low concentrations of MGX ($MEC_{50/90}$, 0.03/0.03 mg/L).

Table 1

	Manogepix $MIC_{50/90}$ or $MEC_{50/90}$ (mg/L) by Infection Type (no. tested)			
Organism	**All**	**BSI**	**PIHP**	**SSSI**
Candida spp.	0.008/0.06 (1,887)	0.008/0.06 (1,331)	0.008/0.06 (97)	0.008/0.03 (86)
C. albicans	0.004/0.008 (588)	0.004/0.008 (410)	0.008/0.008 (33)	0.008/0.015 (29)
C. auris	0.015/0.03 (11)	0.015/- (6)	-/- (1)	≤0.002/- (2)
C. dubliniensis	0.004/0.008 (65)	0.004/0.008 (37)	0.004/0.004 (10)	0.008/- (3)
C. glabrata	0.03/0.06 (460)	0.03/0.06 (336)	0.03/0.06 (25)	0.03/0.06 (16)
C. kefyr	0.12/0.25 (28)	0.12/0.25 (10)	0.12/- (2)	-/- (1)
C. lusitaniae	0.03/0.06 (52)	0.03/0.06 (35)	0.03/- (2)	0.03/- (4)
C. parapsilosis	0.008/0.015 (321)	0.008/0.015 (249)	0.008/- (6)	0.008/0.015 (15)
C. tropicalis	0.015/0.015 (225)	0.008/0.015 (154)	0.008/0.015 (12)	0.008/- (8)
Cryptococcus neoformans var. *grubii*	0.5/2 (49)	0.5/2 (27)	-/- (1)	-/- (1)
Aspergillus spp.	0.015/0.03 (578)	0.008/- (4)	0.015/0.03 (401)	0.015/0.03 (33)
Scedosporium spp.	0.03/0.03 (30)	-/- (0)	0.03/0.03 (23)	0.03/- (2)

[a] ALL includes BSI, PIHP, SSSI, IAI, UTI, and other infection types.

Conclusion: MGX demonstrated potent antifungal activity against *Candida* spp., *Aspergillus* spp., *C. neoformans* var. *grubii*, and non-*Aspergillus* moulds, including *Scedosporium* spp. isolates. Notable activity was seen against *C. auris,* echinocandin-resistant *Candida* spp., azole-resistant *Aspergillus*, and *Scedosporium* spp. isolates. Further clinical development of fosmanogepix in difficult-to-treat resistant fungal infections is warranted.

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1261. Antimicrobial Activity of Aztreonam-Avibactam against Gram-negative Bacteria Isolated from Patients Hospitalized with Pneumonia in Europe, Latin America, and Asia in 2019

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Session: P-58. Novel Agents

Background. Aztreonam (ATM) is a monobactam stable to hydrolysis by metallo-β-lactamases (MBL). Avibactam (AVI) is a non-β-lactam β-lactamase inhibitor that inhibits serine carbapenemases (CPEs), such as ESBLs, KPCs, AmpC, and some OXAs. ATM-AVI is under clinical development for treatment of serious infections caused by Gram-negative bacteria (GNB), including MBL-producers.

Methods. 2,582 GNB (1,630 *Enterobacterales* [ENT] and 952 nonfermentative-GNB) were consecutively collected (1/patient) from 56 medical centers located in Western Europe (W-EU; 22 centers in 10 nations), Eastern Europe (E-EU; 12 centers in 9 nations), Latin America (LATAM; 10 centers 6 nations), and the Asia-Pacific region (APAC; 12 centers in 8 nations) in 2019 and susceptibility (S) tested against ATM-AVI and comparators at a central laboratory by reference broth microdilution methods.

Results. Overall, 99.9% of ENT ($MIC_{50/90}$, 0.06/0.25 mg/L), including 99.1% of carbapenem-resistant ENT (CRE; $MIC_{50/90}$, 0.25/0.5 mg/L), were inhibited at an ATM-AVI MIC of ≤ 8 mg/L (Table). CRE rates were 1.4%, 23.7%, 6.3%, and 9.6% in W-EU, E-EU, LATAM, and APAC, respectively (6.9% overall). A CPE was identified in 95 of 113 CRE isolates (84.1%). These CPEs included NDM-like (31.0% of CRE), KPC-like (26.5%), OXA-48-like (24.8%), and VIM-like (7.1%). Six isolates produced 2 CPEs. The highest ATM-AVI MIC value among MBL-producers (n=43; $MIC_{50/90}$, 0.12/0.5 mg/L) was 4 mg/L. Among *P. aeruginosa*, 75.1% were inhibited at ≤ 8 mg/L of ATM-AVI; S to meropenem (MEM), piperacillin-tazobactam, and ceftazidime were 69.4%, 72.5%, and 75.7%, respectively, and ranged from 64.3% in E-EU to 82.0% in W-EU. MEM non-S *P. aeruginosa* varied from 22.2% in W-EU to 54.8% in E-EU. ATM-AVI was highly active against *S. maltophilia*, inhibiting 95.0%, 100.0%, 100.0%, and 90.0% of isolates from W-EU, E-EU, LATAM, and APAC, respectively, at ≤8 mg/L. *S. maltophilia* S to cotrimoxazole were 90.0%, 97.7%, 85.7%, and 100.0% in W-EU, E-EU, LATAM, and APAC, respectively. ATM-AVI also was very active against *Burkholderia* spp. (highest MIC, 8 mg/L).

Conclusion. Our results support clinical development of ATM-AVI to treat pneumonia caused by ENT (including MBL-producers), *P. aeruginosa*, *S. maltophilia*, and *Burkholderia* spp.

Table 1

Geographic	No. of isolates and cumulative % inhibited at ATM-AVI MIC (mg/L) of:												
Region (no.)	**≤0.03**	**0.06**	**0.12**	**0.25**	**0.5**	**1**	**2**	**4**	**8**	**16**	**>16**	**MIC_{50}**	**MIC_{90}**
Enterobacterales	756	446	228	123	53	16	4	1	1	1	1	0.06	0.25
(1,630)	46.4%	73.7%	87.7%	95.3%	98.5%	99.5%	99.8%	99.8%	99.9%	99.9%	100.0%		
CRE	7	10	27	44	17	5	1	1	0	0	1	0.25	0.5
(113)	6.2%	15.0%	38.9%	77.9%	92.9%	97.3%	98.2%	99.1%	99.1%	99.1%	100.0%		
MBL-producers	7	7	11	12	4	1	0	1				0.12	0.5
(43)	16.3%	32.6%	58.1%	86.0%	95.3%	97.7%	97.7%	100.0%					
P. aeruginosa	2	6	12	41	26	16	34	304	184	87	120	4	>16
(832)	0.2%	1.0%	2.4%	7.3%	10.5%	12.4%	16.5%	53.0%	75.1%	85.6%	100.0%		
S. maltophilia					1	6	56	38	5	1	3	2	4
(110)					0.9%	6.4%	57.3%	91.8%	96.4%	97.3%	100.0%		
Burkholderia spp.					1	0	6	1	2			2	8
(10)					10.0%	10.0%	70.0%	80.0%	100.0%				

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1262. Antimicrobial Activity of Gepotidacin against Clinical Isolates of Escherichia coli and Staphylococcus saprophyticus Collected Worldwide in 2019

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Session: P-58. Novel Agents

Background. Gepotidacin (GSK2140944) is a novel triazaacenaphthylene bacterial type II topoisomerase inhibitor in Phase 3 clinical development for the treatment of gonorrhea and uncomplicated urinary tract infections (UTI). This study reports on interim results from a global surveillance program to monitor the *in vitro*