BREAK POINT

2015 - ISSUE 14

FROM THE NEWSLETTER EDITOR'S DESK

In line with the "New Drugs" focus of Breakpoint, this issue brings a summary of the pertinent features of Isavuconazole, a recent addition to the azole antifungal armamentarium, and its potential role in treating fungal infections in Australia, based on data available June 2015. A potential new antibiotic drug, and novel ways of harnessing antibacterials from mother nature, have been the target of much recent research – see "In the News". As always suggestions towards improving the Newsletter are very welcome.

Sharon Chen
ASA Breakpoint Editor

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IN THE NEWS

Teixobactin is a recently termed novel antibiotic produced by an as yet uncharacterized soil microorganism (provisionally, *Eleftheria terrae*). The discovery of Ling *et al*. published in early 2015, made through a "back-to-basics" approach, focused on a screen of 10,000 bacterial strains, cultured in their normal soil environment. This uncovered an antibiotic, named Teixobactin, with broad and potent activity, isolated with a new tool, the **iChip**, that allowed the environmental bacterium to grow and for the antibiotic it produced to be recovered and identified. Teixobactin has **activity against Gram-positive (but not**

IN THE NEWS CONT'D

Gram-negative) organisms and mycobacteria and because the compound targets lipid molecules, developing resistance is probably difficult. *In vitro* no mutants were obtained. Read on.....

Key references

1. Piddock LJ. Teixobactin, the first of a new class of antibiotics discovered by iChip technology? J Antimicrob Chemother. 2015 Jun 18. pii: dkv175.

2. Ling LL *et al*. A new antibiotic kills pathogens without detectable resistance. Nature 2015; 517: 455-9.

ISAVUCONAZOLE: A NEW KID ON THE BLOCK?

[1] Sharon Chen, [2] Tony Lai and Matthew O'Sullivan[1]

[1] Centre of Infectious Diseases and Microbiology, ICPMR and Westmead Hospital, Sydney;

[2] Antimicrobial Stewardship Pharmacist, Department of Pharmacy, Westmead Hospital, Sydney

Isavuconazole and azoles in Australia

Isavuconazole is a second-generation triazole antifungal with broad spectrum *in vitro* activity against fungal pathogens. It has been "on the horizon" for several years, yet as with many antifungals, has experienced a relatively long lag phase to approval for clinical use. Specifically, it was approved by the US Food and Drug Administration (FDA) in March 2015 to treat adults with invasive aspergillosis (IA) and invasive mucormycosis1. It has orphan drug status in the US for treatment of invasive candidiasis (IC) and has such similar status in Europe for IA and invasive mucormycosis[2].

In Australia, isavuconazole joins other azoles, including fluconazole, itraconazole, voriconazole and posaconazole in the azole armamentarium. New formulations of posaconazole have also arrived for clinical use. Neither isavuconazole, nor the tablet or intravenous (IV) formulation of posaconazole, are widely available. Here the salient features of isavuconazole in context of its potential clinical use is summarised.

The drug

Isavuconazole is derived from its prodrug **Isavuconazonium** (Cresemba[R]), the form that is marketed. Marketing is through either Basilea Pharmaceutica International Ltd or Astellas Pharma Inc., depending

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on geographic region. Development of the drug is managed by both companies. Isavuconazonium is water soluble and rapidly hydrolysed to the active entity, isavuconazole. It is available in an oral as well as IV formulation, enabling flexibility of use. As with other triazoles, it inhibits the P450 (CYP-) dependent enzyme, lanosterol 14-a-demethylase (CYP51), and hence synthesis of ergosterol, a key component of the fungal cell membrane. Main pharmacokinetic parameters are shown below in Table 1.

Table 1. Mean pharmacokinetic parameters of isavuconazole (adapted from Reference 3).

Parameter	Result(s)	Comment
Cmax (mg/L)	2.59/2.47	200 mg oral/IV
$t\ ^1/_2$ (h)	77.1/180.4	200 mg oral/IV
Protein binding	>99%	
Bioavailability	>95-98%	
t_{max} (h)	3.5	Steady state, 200 mg oral/IV
Renal excretion	<1% elimination	

Isavuconazole undergoes slow elimination allowing once daily dosing and has extensive tissue distribution. Drug clearance is decreased in liver disease and dose adjustments are required; at present, its use in severe hepatic disease should be avoided[3,4].

Recommended dosing schedules

The recommended dosages for the oral and IV formulation are identical, consisting of loading doses of 200 mg isavuconazole (equivalent to 372 mg of isavuconazonium) every 8 hours for six doses, followed by maintenance therapy with 200 mg (372 mg) one daily[1].

***In vitro* antifungal activity**

Similar to other triazoles, isavuconazole is fungistatic against yeasts, with a minimum fungicidal concentration within 2 dilutions of the minimum inhibitory concentration (MIC), but is fungicidal against *Aspergillus* spp. Interpretative clinical breakpoints are not yet established although wild type MIC distributions and epidemiological cuttoff values are published for *Aspergillus* and *Cryptococcus* spp.[5,6]. Table 2 shows MIC values for selected fungal pathogens (adapted from references 2 and 3).

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Table 2. *In vitro* susceptibility data (references 6-10).

Genus	MIC range (ug/ml)	MIC_{90} (ug/ml)
***Cryptococcus* spp.**	<0.004 - >64	</= 0.5
***Candida* spp. (including C. *glabrata* and *C. krusei*)**	<0.004 – 16	</= 2
***Trichosporon* spp.**		</= 0.5
***Pichia* spp.**		</=0.25
Aspergillus fumigatus	0.06 - >16	</= 2
Aspegillus flavus	0.06 – 4	</= 4
Aspergillus terreus	0.06 – 8	</= 4
Mucormycetes	<0.015 - >8	
Absidia	0.03 - >8	>/= 8
***Apophysomyces* spp.**	0.25 - 8	4
***Rhizopus* spp.**	0.12 – 8	2 - 8
***Mucor* spp.**	<0.015 - >200	>/= 8

In brief, isavuconazole displays good activity against most *Candida, Cryptococcus,* other yeast and *Aspergillus* spp. Against the Mucorales, isavuconazole has variable activity with wide MIC ranges (Table 2),[7-9] which are 4-16 fold higher than those for posaconazole and amphotericin B. However the lower end of the reported MIC ranges for these fungi are lower as compared with those for voriconazole. Identification of Mucorales to at least genus level is recommended.

Cross resistance of isavuconazole with other azoles has been observed where higher MIC values are seen with some fluconazole-resistant strains of *Candida* and MICs of >1µg/ml for many fluconazole-resistant *C. glabrata*[10,11]. In a recent study, two *A. fumigatus* isolates with pan-triazole resistance also displayed elevated MICs (8µg/ml) to isavuconazole (reviewed in reference 3).

In animal models of fungal infection, isavucoanzole displayed potent activity against *A. fumgiatus*, *Candida* spp. and *Rhizopus delemar*, reducing tissue burden and improving survival in immunocompromised mice[3].

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Clinical trials and studies

Phase III clinical trials evaluating isavuconazole for the treatment of systemic candidiasis, aspergillosis and invasive fungal disease caused by other moulds are currently under way, recently completed or available only in abstract form or in FDA briefing documents. Table 3 summarises the key studies[2,3].

Study	Comparator (s)	Indication (no. patients)	Phase and status	Main results
SECURE (RCT)	Voriconazole	Proven/probable IA and other IFD (527)	III, completed	Once daily isavuconazole (200 mg) was non-inferior to twice daily voriconazolea
VITAL (Open label)	None	Various infections: includes IA, mucormycosis, cryptococcosis, scedosporiosis, fusariosis	III, completed	Fewer adverse drug effects than voriconazole
ACTIVE (RCT)	Caspofungin followed by oral voriconazole	Invasive candidiasis	III, ongoing	Approximately 31-35% overall response rate depending on IFD
RCT	Fluconazole	Oesophageal candidiasis (≈160)	II, completed	Primary outcome: overall response (resolution of signs and symptoms, mycological eradication). Other outcomes: mycological response, all-cause mortality
	None	Antifungal prophylaxis in AML (23)	II, completed	Isavuconazole (three dosing strategies: 50 mg/d, 100 mg/d 400 mg weekly) non inferior to fluconazole; clinical cure 90-95% (14 days) and 90% (28 days), similar to fluconazole
				Safety and pharmacokinetics established[b].

Abbreviations: AML, acute myeloid leukemia; IA, invasive aspergillosis; IFD, invasive fungal disease; RCT, randomised controlled trial

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[a] Isavuconazole yielded similar results to voriconazole: day 42 all-cause mortality (19.6% vs. 23.3% for voriconazole); overall response at end of therapy (35% vs. 36.4%).

[b]See reference 12.

Isavucoanzole is well tolerated in humans and its safety profile appears to be favourable when compared with that of voriconazole[2,3]. As with all triazoles, clinicians should be vigilant for drug-drug interactions.

Comparative pricing of isavuconazole

As of June 2015, isavuconazole is currently available through the Special Access Scheme (SAS) or through compassionate use from the pharmaceutical company. There is a cost saving for IV isavuconazole compared to other antifungals given intravenously, but the same is not evident when comparing oral drug to the other azoles when given orally. Table 3 summarises the cost comparison of isavuconazole, posaconazole, voriconazole, fluconazole and liposomal amphotericin for the treatment of invasive fungal disease.

Table 3. Comparative pricing of isavuconazole (as of June 2015)

	Isavuconazole		Posaconazole			Voriconazole			Fluconazole		Liposomal Amphotericin
	Tablets	IV	Tablets	IV	Suspension	Tablets	Suspension	IV	PO	IV	IV
Dose	200 mg 8-hourly for 6 doses, then 200 mg daily		300 mg 12-hourly for 2 doses, then 300 mg daily		400 mg 12-hourly	400 mg 12-hourly for 2 doses, then 200 mg 12-hourly		6 mg/kg/dose 12-hourly for 2 doses, then 4 mg/kg/dose 12-hourly	800 mg/kg/day for 1 dose, then 400 mg/kg/day		3 - 5 mg/kg/day
Unit cost	$157 per 100 mg tablet	$538 per 200 mg vial	$35 per 100 mg tablet	$745 per 300 mg vial	$682 per 105 mL bottle	$38 per 200 mg tablet	$552 per 70 mL bottle	$226 per 200 mg vial	$1 per 200 mg capsule	$3.74 per 200 mg vial	$295 per 50 mg vial
Average cost per day[b]	$404	$692	$112	$798	$130	$81	$83	$936[a]	≈ $2	$8	$1475 - $2065[a]

[a] Using a body weight of 70 kg.

[b] Calculated over a 14 day period to cater for loading doses.

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Summary and current status

Isavuconazole is a broad spectrum antifungal that has advantages of high prodrug solubility (obviating the need for cyclodextrin), high oral bioavailability, predictable linear pharmacokinetics PKs with no relevant food effect. It displays good activity against *Candida*, including many fluconazole-resistant strains, *Aspergillus, Cryptococcus,* with variable activity against the Mucorales.

It provides a clinically useful alternative to voriconazole for treating invasive aspergillosis. It may also prove to be useful in the treatment of candidaemia and invasive mould infections. However these indications must await the results of further clinical trials and therapeutic drug studies.

The comparative cost of IV isavuconazole is less than IV posaconazole, IV voriconazole and IV liposomal amphotericin. However, there is a significant expense when oral isavuconazole is compared to the other licensed azoles. Changes in the price of acquisition of isavuconazole will likely occur when isavuconazole is licensed for use in Australia.

Conflicts of interest: None with respect to this report.

References

1. US Food and Drug Administration. FDA apporves new antifungal drug Cresemba. 2015. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437106.htm. Accessed 1 June 2015.
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5. Espinel-Ingorff A *et al*. Isavuconazole MIc distributions and epidemiological cuttoff values for the *Cryptococcus neoformans-Cryptococcus gattii* species complex by the CLSI broth microdilution method (M27-A3 document): a multicentre study. Antimicrob Agents Chemother 2014; doi. 10.1128/AAC.04055-14..

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7. Perkhofer S *et al*. *In vitro* activity of isavuconazole against *Aspergillus* species and zygomycetes according to the methodology of the European Committee on Antimicrobial Susceptibility Testing. Antimicrob Agents Chemother 2009; 53: 1645-1647.

8. Yamazaki T *et al*. *In vitro* activity of isavuconazole against 140 reference fungal strains and 165 clinically isolated yeasts from Japan. Int J Antimicrob Agents 2010; 36: 324-331.

9. Verweij PE *et al*. *In vitro* antifungal activity of isavuconazole against 345 mucorales isolates collected at study centres in eight countries. J Chemother 2009; 21: 272-281.

10. Thompson GR 3rd, Wiederhold NP. Isavuconazole: comprehensive review of spectrum of activity of a new triazole. Mycopathologia. 2010; 170: 291-313.

11. Pfaller MA *et al*. *In vitro* activities of isavuconazole and comparator antifungal agents tested against a global collection of opportunistic yeasts and moulds. J Clin Microbiol 2013; 51: 2608-2626.

12. Cornely O, *et al*. Safety and pharmacokinetics of isavuconazole as antifungal prophylaxis in acute myeloid leukemia patients with neutropenia: results of a phase 2, dose escalation study. Antimicrob Agents Chemother 2015; 59: 2078-2085.

ANTIMICROBIALS 2016

On behalf of the Australian Society for Antimicrobials I would like to invite you to the Society's 17th Annual Scientific Meeting "Antimicrobials 2016" to be held at the Melbourne Convention Exhibition Centre, Melbourne, on Thursday 25th - Saturday 27th February 2016.

I am pleased to announce Robin Patel, Mayo Clinic, USA; Neil Woodford, Imperial College London, UK; and Chris Baggoley (Chief Medical Officer) and Mark Schipp (Chief Veterinary Officer) will be participating at the meeting. Robin will be presenting the plenary "Biofilm Associated Implant Infections", and Neil will be presenting "Gram Negative Susceptibility/Resistance Epidemiology". Chris and Mark will be providing an update on the "Australian Response to the Antimicrobial Resistance Crisis" with particular reference to the recently released *"The Australian National Antimicrobial Resistance Strategy"* (www.health.gov.au/amr).

The 2016 Howard Florey Oration will be delivered by Lyn Gilbert from the Institute of Clinical Pathology and Medical Research, New South Wales. Lyn will be presenting the talk "Reflections on 50 Years of Antimicrobial Resistance – Will Science and Technology or Social Science win the Next 50 Years?"

The programme's symposia cover many different aspects on antimicrobials and sessions include "One Health", "Resistant Epidemics - KPCs", "ICU Related Infections: Does one Size Fit All?", "Infective Endocarditis" and *"Mycobacterium tuberculosis"*. In addition we have two pharmacy symposia on Saturday afternoon titled "Monitoring Outcomes of Antimicrobial Therapy" and "Using Antimicrobials Better". The scientific symposia it titled "Whole Genome Sequencing: Embracing New Technologies". Six proffered papers and two poster sessions are also planned for the meeting.

To promote discussion and interaction between delegates and the invited speakers the meeting's registration includes lunches, morning and afternoon teas and admission to the Howard Florey Reception and the Industry Reception. I am confident that you will find the meeting's programme both scientifically stimulating and informative and we look forward to meeting you in "Melbourne.

The meeting's website, Antimicrobials2016.com, will be available soon

IMPORTANT DATES

- Abstract Submission Deadline Friday 11th December 2015
- Abstract Notification Friday 18th December 2015
- Early Bird Registration Friday 8th January 2016

Kind regards

Thomas Gottlieb
President ASA

PROPOSED PROGRAM

THURSDAY 25 FEBRUARY	FRIDAY 26 FEBRUARY	SATURDAY 27 FEBRUARY	
INDUSTRY BREAKFAST SYMPOSIUM 0700 – 0845	**INDUSTRY BREAKFAST SYMPOSIUM** 0700 – 0845	**INDUSTRY BREAKFAST SYMPOSIUM** 0700 – 0845	
0900 – 0915 **Presentation of ASA Awards** Thomas Gottlieb ASA President	0900 – 1000 **Plenary 2** *Gram Negative Susceptibility/Resistance Epidemiology* Neil Woodford, Imperial College London, United Kingdom	0900 – 1000 **Plenary 3** *Biofilm Associated Implant Infections* Robin Patel, Mayo Clinic, USA	
0915 – 1015 **Plenary 1** *The Australian Response to the Antimicrobial Resistance Crisis* Chris Baggoley, Department of Health, Australian Capital Territory Mark Schipp, Department of Agriculture, Australian Capital Territory			
MORNING TEA 1015 – 1045	**MORNING TEA** 1000 – 1030	**MORNING TEA** 1000 – 1030	
1045 – 1245 **Symposium 1** **One Health** *Salmonella Zoonosis: Epidemiology and Source Tracking* Nigel French, Massey University, New Zealand *E. coli ST131* Darren Trott, Adelaide University, South Australia *Antimicrobial Resistance Surveillance: A Veterinary and Agriculture Perspective* David Jordan, Department of Primary Industries, New South Wales *Antimicrobial Stewardship: A Veterinary and Agriculture Perspective* Glenn Browning, Melbourne University, Victoria	1030 – 1200 **Symposium 3** **ICU Related Infections: Does one Size fit all?** *Sepsis Pathway: Have we got it Right and Implications for Antibiotic Use?* Simon Finfer, The George Institute for Global Health, New South Wales *What is the Role of MRO Screening in the 2016 ICU?* Allen Cheng, Alfred Hospital, Victoria *Topical Antiseptics in the ICU: Are we Hexed - What is the Role for Antiseptic and Disinfectant Use?* Caroline Marshall, Royal Melbourne Hospital, Victoria	1030 – 1230 **Symposium 5** **Mycobacterium tuberculosis** *Update on Mtb Treatment* Ivan Bastian, SA Pathology, South Australia *WGS for Tracking Mtb Transmission* Grant Hill-Cawthorne, University of Sydney, New South Wales *Susceptibility Testing: Beyond the Dark Ages* John Turnidge, Australian Commission on Safety and Quality in Health Care, New South Wales *Rapid Diagnostics: Practical Application of Resistance Gene Testing* Chris Coulter, Pathology Queensland, Queensland	
PROPOSED INDUSTRY LUNCH SYMPOSIUM 1245 – 1415	**PROPOSED INDUSTRY LUNCH SYMPOSIUM** 1200 – 1330	**LUNCH** 1230 – 1315	
1415 – 1545 **Proffered Paper Sessions 1 - 3** (Three concurrent sessions)	1330 – 1500 **Proffered Paper Sessions 4 - 6** (Three concurrent sessions)	1315 – 1445 **Scientific Symposium I** **WGS: Embracing New Technologies** *Current and Future WGS Platforms for the Diagnostic Laboratory* Robin Patel, Mayo Clinic, USA *Bioinformatic Tools for the Diagnostic Laboratory* Torsten Seemann, MDU, Doherty Institute, Victoria	1315 – 1445 **Pharmacy Symposium I** **Monitoring Outcomes of Antimicrobial Therapy** *Infection Biomarkers: Predictors of Clinical Response* Pat Charles, Austin Health, Victoria *Using the MIC in Predicting Clinical Outcomes of Antibiotic Treatment* Jason Roberts, University of Queensland, Queensland *AMS Programs: Measuring the Impact on Patient Care* Matthew Rawlins, Fiona Stanley Hospital, Western Australia
AFTERNOON TEA POSTER SESSION 1 (AUTHORS IN ATTENDANCE) 1545 – 1630	**AFTERNOON TEA POSTER SESSION 2 (AUTHORS IN ATTENDANCE)** 1500 – 1545	**AFTERNOON TEA** 1445 – 1500	
1630 – 1800 **Symposium 2** **Resistant Epidemics - KPCs** *Killer KPCs Worldwide* Neil Woodford, Imperial College London, United Kingdom *Victorian KPC Experience* Jason Kwong, MDU, Doherty Institute, Victoria *A Coordinated National Response* Mike Richards, The Royal Melbourne Hospital, Victoria	1545 – 1715 **Symposium 4** **Infective Endocarditis** *Laboratory Diagnosis* Robin Patel, Mayo Clinic, USA *Streptococcal/Enterocccal Infective Endocarditis* Eugene Athan, Melbourne University, Victoria *Is there a Role for TDM in Endocarditis?* Jason Roberts, University of Queensland, Queensland	1500 – 1630 **Scientific Symposium II** **WGS: Embracing New Technologies cont.** *Phenotype from Genotype* Neil Woodford, Imperial College London, United Kingdom *Using Genomics to Understand Resistance* Ben Howden, MDU, Doherty Institute, Victoria	1500 – 1630 **Pharmacy Symposium II** **Using Antimicrobials Better** *The National Antimicrobial Prescribing Survey: Are we Getting Better?* Karin Thursky, Melbourne University, Victoria *The Role of the Laboratory: Lessons from AMS* Sue Benson, PathWest Laboratory Medicine-WA, Western Australia *Hepatitis C: Changing Paradigm of Use of Direct Acting Antivirals* Joseph Torresi, Melbourne University, Victoria
1800 – 1845 **Howard Florey Oration** *Reflections on 50 Years of Antimicrobial Resistance – Will Science and Technology or Social Science win the next 50 Years?* Gwendolyn Gilbert, Institute of Clinical Pathology and Medical Research, New South Wales	1715 – 1745 **Annual General Meeting**		
1845 – 2015 **Howard Florey Reception**	1745 – 1915 **Industry Reception**		

2015 - 2016 MEETING CALENDAR

2015

ESCMID-SHEA Training Course in Hospital Epidemiology
20-24 July, Cairns, Australia
Website: www.escmid.org/

9th International Conference on Emerging Infectious Diseases
24-26 Aug, Atlanta, USA
Website: www.iceid.org/

***Clostridium difficile:* Practical Aspects Of Diagnosis And Comparative Genomics**
2-4 Sept, Maribor, Slovenia
Website: www.escmid.org/

STI and AIDS World Congress 2015
14-16 Sept, Brisbane, Australia
Website: www.worldsti2015.com/

BacPath13: Molecular Analysis of Bacterial Pathogens
27-30 Sept, Philip Island
Website: www.bacpath2015.org

55th ICAAC/ICC
18-21 Sept, San Diego, USA
Website: http://www.asm.org

ID week 2015
7-11 Oct, San Diego, CA
Website: www.idweekinternationa.com/

9th International Transplant Infectious Diseases Conference
13-15 Oct, Cancun, Mexico
Website: www.tts.org/

2016

ASA Annual Meeting - Antimicrobials 2016
25-27 February, Melbourne
Website: www.asainc.net.au

Pathology Update
26-28 February, Melbourne
Website: www.rcpa.edu.au

ASID
20-23 April, Launceston, Tasmania
Website: www.asid.net.au

26th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2015)
9-12 April 2016, Instanbul, Turkey
Website: http://escmid.org/dates_events/

***New ASM Microbe 2016 (Inaugural combined ASM general meeting with ICAAC)**
16-20 June 2016, Boston, MA
Website: www.asm.org/microbe2016

16th Asia Pacific Conference on Clinical Microbiology and Infection (APCCMI)
30 Nov-3 Dec, Melbourne, Australia
Website: http://www.asainc.net.au

21st International AIDS Conference
17-20 July, Durban, SA
Website: www.aids2016.org/

10th International Transplant Infectious Diseases Conference
Aug 17-19, Hong Kong, China
Website: www.tts.org/

In 2016, the ASM general meeting and ICAAC will be co-located in Boston, June 2016.