



Antibiotic Pipeline Surveillance – 2010 to mid 2011
Cardinal Health Clinical Affairs
(Phase I and some early Phase II not included)

Generic name (Brand or Reference number)	Manufacturer	Status	Predicted Indication(s)	Doses Studied (assume in adults unless specified)	Product Presentation	Drug Class	Website / Additional Information
Amadacycline (PTK -796)	Novartis / Paratek	Phase II	CSSI	Once daily dosing	PO/IV	Aminomethycycline	http://www.novartis.com/downloads/research/planned-filings.pdf http://www.paratekpharm.com/pt_pipeline.html
Amikacin inhaled powder (NKTR-061 / BAY 41-6551)	Nektar/Bayer	Moving into Phase III	Gram negative pneumonia	400 mg every 12 -24 hours	INH	Aminoglycoside	http://www.nektar.com/product_pipeline/all_phases.html
Amikacin liposomal (Arikace®)	Transave Inhalational Biotherapeutic	Phase II	<i>Pseudomonas</i> infections in cystic fibrosis and non CF bronchiectasis	560mg once daily	INH	Aminoglycoside	http://www.transaveinc.com/products.shtml#amik
aztreonam lysine inhalation (Cayston®)	Gilead Sciences	FDA approved 2/13/2010.	Improve respiratory symptoms in cystic fibrosis patients with <i>Pseudomonas</i>	75 mg three times daily	INH	Monobactam	www.cayston.com
Ceftaroline	Cerexa/Forest	NDA submitted in late 2009	CSSI and hospitalized CAP	300-600 mg IV every 12 hours	IV	Cephalosporin with MRSA activity	http://www.frx.com/research/pipeline.aspx
ciprofloxacin inhaled powder (CIP, Cipro Inhale)	Nektar/Bayer	Phase II	Use in cystic fibrosis patients with recurrent <i>P. aeruginosa</i> infections	50 – 75mg Cipro PulmoSphere Inhalation powder BID x 28 days	INH	Fluoroquinolone	http://www.nektar.com/product_pipeline/all_phases.html
Clostridium difficile MAB [MDX-066 (CDA-1) + MDX-1388 (CDA2)]	Medarex/ BMS	Moving into Phase III	CDAD	10mg/kg each administered together	IV	Monoclonal Antibody	http://www.nature.com/nbt/journal/v27/n9/fig_tab/nbt0909-781_T1.html

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fidaxomicin previously Difimicin, (OPT-80) and PAR101	Optimer	Phase III (plans to submit NDA late 2010)	CDAD	200 mg every 12 hours	PO	Novel Macrocyclic Antibiotic	http://www.optimerpharma.com/pipeline.asp?pipeline=1
isavaconazole (BAL8557)	Basilea/Astellas	Phase III	Esophageal candidiasis, Aspergillus, Candidiasis	Various doses being studied	IV/PO	Triazole Antifungal	http://www.basilea.com/Development/Isavuconazole/
peramavir	Biocryst	Phase III (granted Emergency Use Access in 2009)	Influenza	600 mg IV daily for 5-10 days	IV (IM trial failed)	Neuraminidase inhibitor	http://www.biocryst.com/peramavir
pleconaril (VP 63843)	Schering- Plough / Merck	Phase II	Cold and asthma exacerbations (INH), neonatal enteroviral sepsis (PO)	Various regimens	PO/INH	Antiviral	http://www.merck.com/research/pipeline/SGP_Oct_Products-in-Development.pdf
prulifloxacin (OPT-99)	Optimer	Phase III	Infectious diarrhea/traveler diarrhea	600mg daily x 3 days	PO	Fluoroquinolone	http://www.optimerpharma.com/pipeline.asp?pipeline=2
ramoplanin	Nanotherapeutics	Phase III	CDAD	200 or 400 mg every 12 hours	PO	Glycolipodepsi- peptide	http://www.nanotherapeutics.com/products_pipeline_ramoplanin.php
razupenem (PTZ601)	Novartis	Phase II	CSSI and pneumonia	N/A	IV	Carbapenem with MRSA activity	http://www.novartis.com/downloads/research/planned-filings.pdf
Sulopenem	Pfizer	Phase II	CAP	Various regimens	PO/IV	Carbapenem	http://www.pfizer.com/files/research/pipeline/2009_0331/pipeline_2009_0331.pdf

Table Key:
CAP = community acquired pneumonia, CDAD= *Clostridium difficile*-associated disease, CIAB – Complicated intra-abdominal infections, CSSI = Complicated skin and structure Infection, HAP = Hospital acquired pneumonia, MAB= monoclonal antibody, UTI = Urinary tract infection, N/A = information not available. Information regarding future indications available at www.clinicaltrials.gov.

Investigational drugs to watch – HIV Antiviral

- Apricitabine – PO NRTI, Phase III, Avexa Pharmaceuticals, <http://www.avexa.com.au/projects/hiv/avx754>
- Bevirimat – Maturation inhibitor in Phase II for both treatment naïve and experienced HIV patients, Panacos, http://www.panacos.com/discovery_platforms.htm
- Dixelvucitabine (DFC, Formerly Reverset) - oral, once-daily cytidine nucleoside analog, Phase IIb studies revealed hyperlipasemia, a marker of pancreatic inflammation, <http://www.pharmasset.com/pipeline/dixelvucitabine.asp>
- Elvitegravir – oral integrase inhibitor, Phase III, Gilead, <http://www.gilead.com/research>
- GS 9190 – oral polymerase inhibitor, Phase II, Gilead, <http://www.gilead.com/research>
- IDX899 - NNRTI in Phase II, rights were bought from Idenix by GSK in Feb 2009
- IDX184 - once-daily, oral nucleotide prodrug, Phase IIa, Idenix Pharmaceuticals, <http://www.idenix.com/hepc/drug/>
- Racivir - oral, once-daily cytidine nucleoside analog, Phase II completed, Pharmasset, <http://www.pharmasset.com/pipeline/racivir.asp>
- Rilpivirine (TMC278) – NNRTI in Phase III for NNRTI-resistant HIV in patients who are treatment naïve and treatment experienced, Tibotec, http://www.tibotec.com/bgdisplay.jhtml?itemname=HIV_tmc278
- S/GSK 1349572 – integrase inhibitor in Phase II trials, ViiV healthcare, <http://www.viivhealthcare.com/en/r-and-d/our-pipeline.aspx>
- Vicriviroc PO HIV CCR5 entry inhibitor, Phase II HIV, Merck, http://www.merck.com/research/pipeline/SGP_Oct_Products-in-Development.pdf. Will only pursue treatment naïve indication after Phase III trials showed lack of efficacy in treatment experienced.

Investigational drugs to watch – Other Antiviral

- Albinterferon alfa-2b (Zalbin[®]) – SQ interferon in pPhase III for Hepatitis C combination with ribavirin, <http://www.hgsi.com/albuferona.html>
- Boceprevir – Hepatitis C, Phase III, http://www.merck.com/research/pipeline/SGP_Oct_Products-in-Development.pdf
- Fildabuvir- Pfizer Phase II for the treatment of Hepatitis C. http://media.pfizer.com/files/research/pipeline/2010_0127/pipeline_2010_0127.pdf
- Narlaprevavir (formerly SCH 900518) – Hepatitis C, Phase II, Merck product http://www.merck.com/research/pipeline/SGP_Oct_Products-in-Development.pdf
- RG7128 – HCV polymerase inhibitor currently in Phase II trials; Pharmasset, <http://www.pharmasset.com/pipeline/index.asp>
- Taribavirin – Nucleoside analog in Phase II for Hepatitis C in combination with ribavirin, <http://phx.corporate-ir.net/phoenix.zhtml?c=119269&p=irol-newsArticle&ID=1350053>
- Telaprevir – for HCV infection, Phase III, <http://www.vrtx.com/current-projects/drug-candidates/telaprevir-VX-950.html>

Investigational drugs to watch – Antifungal/Antibacterial

- Azithromycin/chloroquine (Pfizer) – combination product for malaria
- *Campylobacter jejuni* vaccine (ACE393)(BioSciences) – currently in phase II for prophylactic immunization of *C. jejuni* traveler's diarrhea, http://www.acebiosciences.com/index.php?option=com_content&view=article&id=55&Itemid=65
- Cethromycin (Restanza[®]) – Denied approval in June 2009 for CAP due to lack of efficacy but now being investigated for the prophylaxis and treatment of inhaled anthrax. <http://www.advancedlifesciences.com/product.php>
- Efungumab (Mycograb[®]) – Heat shock protein 90 developed by Neutek and sold to Novartis. Originally studied as adjuvant therapy for candidiasis and in Phase II for cryptococcal meningitis. Novartis plans on filing NDA in 2013. <http://www.pharma.novartis.com/research/pharmaceutical-product.shtml>
- E5564 (Eisai Pharmaceuticals) - synthetic antagonist of bacterial endotoxin (Toll receptor antagonist) Phase III trials for critical care-severe sepsis. <http://www.eisai.com/pipeline.asp?ID=173>

Investigational drugs to watch (continued)

- Fluidsomes Tobramycin – Axentis pharmaceuticals. Given orphan drug status in April 2009 for inhalational treatment of *P. aeruginosa* and *B. cepacia* in patients with cystic fibrosis. <http://www.axentispharma.com/>
- Iclaprim- Arpida pharmaceuticals. Dosed at 0.8 mg/kg- 1.6 mg/kg twice daily for sSSTI . Filed NDA but received negative recommendation from the FDA advisory board (11/20/2008). After European Union rejects Iclaprim, Arpida suspends iclaprim project and sold all rights of drug to Acino. http://www.acino-pharma.com/html/uploads/media/Icla_PressRel_En_091104.pdf
- Influenza Intradermal vaccine (Sanofi) – European Union approved in 2009 for influenza immunization
- Miconazole Lauriad (Oravig®), BioAlliance Pharma) – mucoadhesive buccal tablets; Phase III trial demonstrated comparable efficacy and safety profile to that of clotrimazole troches for oropharyngeal candidiasis. NDA filed summer 2009. – approved April 2010
- Moxidectin – Pfizer Phase III for Onchocerciasis (River Blindness). http://media.pfizer.com/files/research/pipeline/2010_0127/pipeline_2010_0127.pdf
- Oritavancin – Phase III IV glycopeptide with MRSA activity being studied for complicated skin and skin structure infection. FDA denied NDA in Dec 2008 and product was sold by Targanta to the Medicines Company which continues to pursue approval. http://www.themedicinescompany.com/products_oritavancin.shtml
- Posaconazole IV – Phase II, http://www.merck.com/research/pipeline/SGP_Oct_Products-in-Development.pdf
- Pafuramidine maleate (DB 289, Immtech) – Phase III PO for the treatment of PCP pneumonia in AIDS patients and African sleeping sickness. Research was placed on hold due to abnormal lab values found in volunteers of the study. (www.immtechpharma.com)
- Toraymyxin® cartridge (Spectral Diagnostics), a blood purification device that absorbs endotoxin from the bloodstream for treatment of sepsis
- Ravuconazole (Eisai Pharmaceutical) – Phase II antifungal. No additional information available.
- Raxibacumab – Monoclonal antibody for the treatment of inhaled anthrax. FDA issued a complete response letter to Human Genome Sciences requesting more info. See <http://www.hgsi.com/abthrax-raxibacumab.html>

Denials/Withdrawals

- Ceftobiprole
 - Dec 2009 - FDA rejects approval
 - FDA has requested additional information and recommended additional clinical studies be conducted in order to consider future approval
 - <http://www.fiercebiotech.com/press-releases/fda-issues-ceftobiprole-complete-response-letter>
- Cethromycin
 - June 2009- FDA rejects
 - Clevudine – oral nucleoside analog in Phase III trials for Hepatitis B was stopped in April 2009 for side effects like muscle weakness
 - Dalbavancin (Pfizer) – Sept 2008 Pfizer withdrew all marketing applications and returned product to phase III testing

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