PMX-30063
Defensin mimetic antibiotic

Information Package

September 2008

IMPORTANT INFORMATION

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The plans and projections in this information package represent the intended goals and objectives of PolyMedix with respect to the Company's PMX-30063 defensin mimetic antibiotic product candidate. The company will use its best efforts in working towards these objectives and in proceeding as efficiently and expeditiously as possible. However, all drug development is inherently risky. The actual pace of development may be substantially delayed and materially differ from these goals and projections.

This information package presents brief summaries of scientific information. It is not intended to convey detailed, comprehensive technical information.

PMX-30063 Defensin mimetic antibiotic

Summary

PolyMedix has developed novel non-peptide anti-infective small molecules and polymers. These compounds imitate nature and mimic the activity of host defense proteins. A Phase I clinical trial commenced in Canada in August 2008 under the Clinical Trial Application (or "CTA"). We believe PMX-30063 is the only systemic antibiotic being developed which mimics the host defense proteins, and thus has a completely different mechanism of action from other antibiotics: one that we believe makes bacterial resistance less likely to develop than with conventional drugs.

Based on pre-clinical laboratory studies conducted by PolyMedix and others to date, PMX-30063 and other PolyMedix antibiotics:

- Have a unique mechanism of action which we believe makes *resistance unlikely to develop.*
- Have activity against both Gram-positive and Gram-negative bacteria, with a first clinical program with an intravenous (i.v.) formulation to broadly target all *Staph* infections (pan-*Staph).*
- Are bactericidal, not simply bacteristatic like many other antibiotics
- Are faster acting than other antibiotics, *bactericidal in seconds to minutes*
- Are active against drug-resistant bacteria, including clinical isolates of multiple vancomycin resistant *Enterococcus (VRE)* and methicillin resistant *Staphylococcus aureus* (MRSA) strains
- Have shown excellent activity in animal studies, with comparable to superior efficacy compared to vancomycin.

Background

The recent stories in the press over the past months regarding outbreaks of drug resistant *Staph* (MRSA) infections serve as an ominous reminder of the growing problem of drug resistant bacterial infections. A publication by the *Infectious Disease Society of America* in the journal Clinical Infectious Diseases (2008; 46:155-164), published January 15, 2008, titled "The Epidemic of Antibiotic Resistant Infections" starkly describes the rapidly growing threat. The authors comment, "The ongoing explosion of antibiotic resistant infections continues to plague global and U.S. healthcare…..We are in the midst of an emerging crisis of antibiotic resistance for microbial pathogens in the United States and throughout the world. Epidemic antibiotic resistance has been described in numerous pathogens in varying contexts, including – but not limited to – a global pandemic of methicillin-resistant *Staphylococcus aureus* infection."

More and more bacterial infections are becoming resistant to current drug treatments. According to the Association of Professionals in Infection Control and Epidemiology (APIC), in a statement dated February 14, 2008, "*70% of infections may now be resistant to antibiotics*".

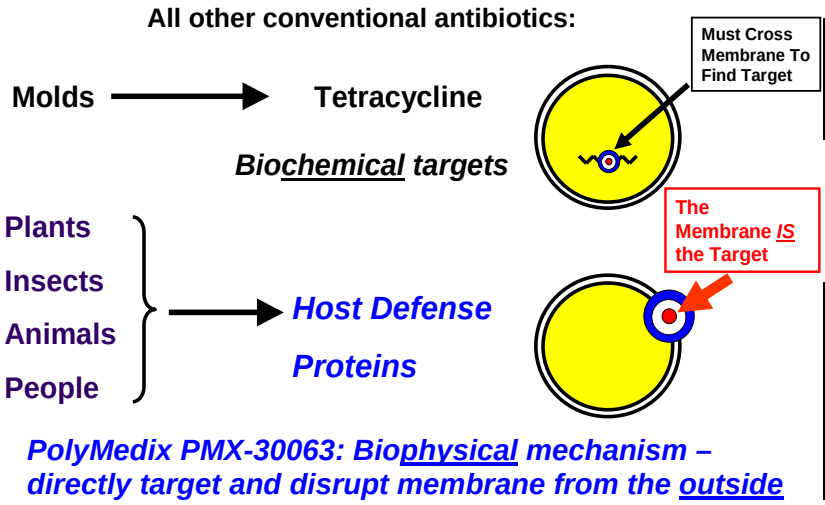
We believe PMX-30063 is unique among antibiotics in being the first small-molecule mimetic of host defense proteins being developed for systemic use. Because it attacks bacteria with a biophysical, rather than a biochemical, mechanism of action, we believe is unlikely that resistance will readily develop to PMX-30063. To the best of PolyMedix's knowledge, we are the only company currently working on antibiotic drugs of this nature. With bacterial infections currently ranking as the fourth leading cause of death in the U.S., and one of the fastest growing

causes of death (700% increase over the past ten years), we believe PMX-30063 represents a significant market opportunity and addresses a major medical need.

How PMX-30063 works:

Primitive life forms such as molds secrete compounds like penicillin to protect themselves from bacteria.

Higher forms of life produce host defense proteins as their first line of defense against bacterial attack.



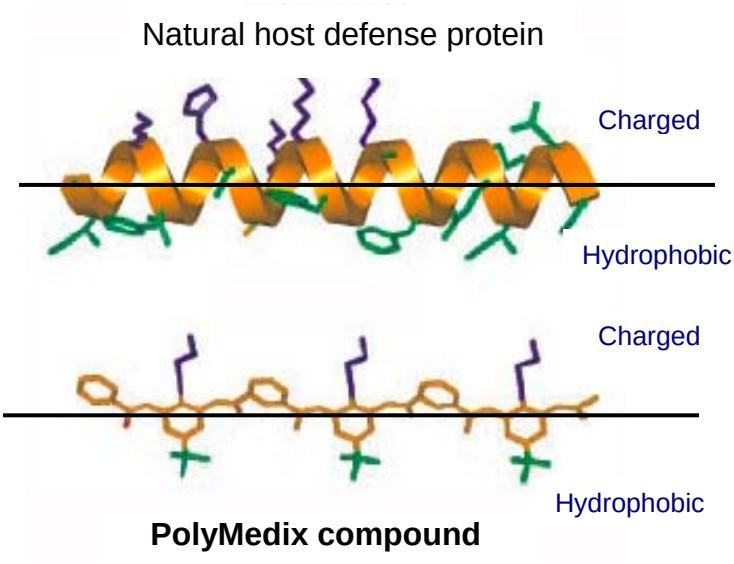
Many forms of life produce host defense proteins as their first line of defense against bacteria

Despite hundreds of millions of years of evolution, widespread bacterial resistance has not developed to the host defense proteins, validating this antimicrobial mechanism of action and target for the development of new antibiotic drugs

The host defense proteins, such as the magainins, cecropins, and defensins, are produced in all higher forms of life and provide a first line of defense against bacterial infections. These defense peptides are part of the nonhumoral response that keep humans from rapidly succumbing to infections. There are many different classes of natural host defense peptides, most with 20-40 amino acids. Although host defense peptides are composed of many different sequences, their physicochemical properties are very similar. These peptides are *amphiphilic*, having spatially separated hydrophobic and charged regions. Thus, they represent a "molecular Janus" having both a hydrophobic face and a spatially opposing hydrophilic face. This amphiphilic character, rather than the precise amino acid sequence, is believed to be responsible for their antimicrobial activity.

PolyMedix has thus learned from nature in mimicking one of the oldest and most effective immune system defenses, used by virtually all higher life forms as their first line of defense against bacterial infection.

These compounds have a highly unique mechanism of action: directly lysing (disrupting) bacterial cell membranes. The biophysical mechanism of action of PMX-30063 is completely different from the biochemical mechanism of action of other antibiotics. Thus, we believe it appears unlikely that bacterial resistance can easily develop to this mechanism and to PMX-30063.



Host-defense protein, showing amphiphilic structure

PolyMedix <u>non-peptide</u> antimicrobial compound, mimicking host-defense protein structure

Proof of Principle

Based on pre-clinical laboratory studies conducted by PolyMedix and others, PMX-30063 has demonstrated several critical characteristics which we believe fundamentally and significantly distinguish it from host defense proteins and other antibiotics. The following results have not been achieved with the host defense proteins, and demonstrate the utility of PolyMedix's PMX-30063:

- Systemically active in animal models – compound dosed intravenously achieves significant efficacy in multiple animal disease models
- Significant selectivity for bacteria vs. human cells – selectivity ratios of 100->10,000 compared with 10-20 for host defense proteins
- Well tolerated in animals – acute doses demonstrate Maximal No-Effect Doses with blood levels many times higher than bactericidal concentrations.
- Good drug like properties – pharmacokinetics, half-life, serum binding, and tolerability profiles characteristic of good drugs.
- Ease of synthesis – a true small molecule, only 5 step synthesis for PMX-30063 (unlike the 50-70+ steps for host defense proteins).

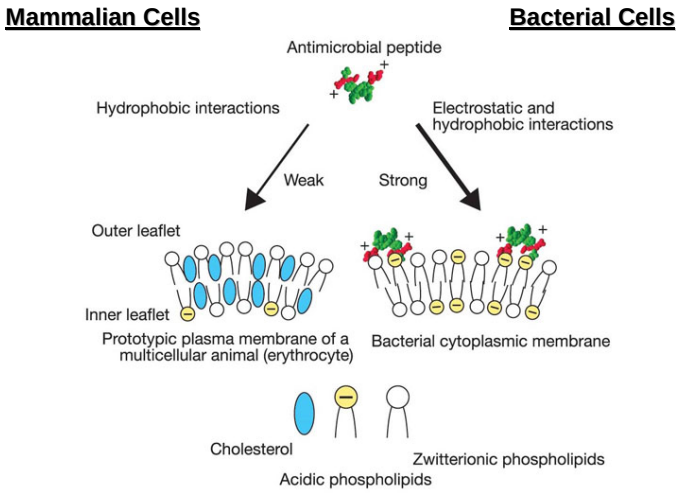
These results have not been demonstrated with host defense proteins, and were achieved in less than three years of research from program initiation.

We expect that the first application of PMX-30063 will be an injectable formulation for broad use against *Staph* infections (pan-*Staph* - many forms of *Staph,* not simply MRSA). The clinical indications for this include skin and soft tissue structure infections, respiratory tract infections, urinary tract infections, and complicated abdominal infections including gynecological.

Specificity for bacteria – do not harm mammalian cells

Antimicrobial peptides, and PMX-30063, take advantage of differences in the composition of bacteria versus mammalian cells to selectively bind to and attack their targets. Bacteria have more negatively charged groups on the outer surface of their membranes than mammalian cells. Bacterial membranes also lack cholesterol, an essential component of all mammalian

membranes. PolyMedix used *de novo* design to design non-peptidic compounds that home in on membranes that lack cholesterol and have a high degree of negative charged phospholipids – thus, they are specific and selective for bacterial cell membranes:



Moreover, PolyMedix's computational technology has allowed us to refine the Structure-Activity Relationship (SAR) of these compounds and produce small molecule compounds which are both more potent and more selective than natural host defense proteins. Selectivity studies have been done against several mammalian cell types, including mouse 3T3 cells, and human HepG2 (liver) and red blood cells, with excellent selectivity for a number of compounds. Representative data for the clinical leads are below:

Compound	**MIC_{100} (µg/mL)**	**Cytotoxicity**		**Selectivity**	
	Staph aureus	**3T3**	**HepG2**	**3T3**	**HepG2**
PMX-30063	0.098	430	1,031	4,388	10,520
PMX-30016	0.05	147	341	2,940	7,020
Host defense proteins	2 - 5	------- 20 – 50 ------		----- 10 – 20 --------	

Thus, compared with host defense proteins, PolyMedix's compounds are:

- Much smaller – 1/5 to 1/10 the molecular weight (500-950 vs. 6000)
- More potent – 50-100 times greater potency than natural host defense proteins
- Much more selective and less toxic – indices 100 - >10,000 vs. 10 – 20, about 1,000 more selective for bacteria vs. mammalian cells
- Are non-peptide small molecules vs. proteins – PolyMedix compounds are completely synthetic, and thus much easier and less expensive to synthesize
- PolyMedix compounds have good drug-like properties and are useful for systemic administration, unlike the host defense proteins

***In Vitro* Activity**

PMX-30063 has demonstrated robust and selective *in vitro* antibacterial activity. The bactericidal activity against some drug resistant strains of human clinical isolates is summarized below.

MIC100, µg/ml

Gram positive	**PMX-30016**	**PMX-30063**	**Vancomycin**
Enterococcus faecium	**1**	**1**	**1**
VR-Enterococcus faecium	**1**	**1**	**>128**
MR-Staphylococcus aureus	**0.5**	**0.5**	**1**
Staphylococcus epidermidis	**0.5**	**0.5**	**2**
Staphylococcus saprophyticus	**0.5**	**0.5**	**1**
Streptococcus pyogenes	**1**	**1**	**0.5**
Gram negative			
Escherichia coli	**2**	**1**	**>128**
Haemophilus influenzae	**8**	**4**	**>128**
Klebsiella pneumoniae	**2**	**1**	**>128**
Enterobacter cloacae	**2**	**2**	**>128**
Citrobacter species	**4**	**2**	**>128**
Acinetobacter species	**4**	**8**	**>128**
Anaerobes			
Clostridium difficile	**2**	**4**	**------**
P. acnes	**0.25**	**0.5**	**------**

The media often talks about “MRSA” or “drug resistant *Staph”.* In actuality, there are hundreds of different strains of *Staph* bacteria, and dozens of drug resistant forms. In our laboratory studies we have examined the activity of PMX-30063 against 148 different types of *Staph* bacteria, including multiple strains of*Staphylococcus aureus* (including MRSA)*, Staphylococcus epidermidis,* and *Staphylococcus hemolyticus.* We have tested activity of PMX-30063 against 89 different drug-resistant strains of *Staph.* The results are summarized below:

	Drug-suscept.	**OXA-R**	**VRSA/VISA OXA-R**	**LZD-NS OXA-R**	**DAP-NS OXA-R**	**VRSA/VISA DAP-NS OXA-R**
# of isolates	**59**	**69**	**7**	**5**	**5**	**3**
PMX-30063 MIC range	**0.25 - 1**	**0.25 - 2**	**0.5 - 1**	**0.5 - 1**	**0.5 - 2**	**0.5 - 1**
PMX-30016 MIC range	**0.25 - 1**	**0.25 - 1**	**1**	**1**	**1**	**1**

OXA-R: oxacillin-resistant
VISA: vancomycin intermediate S. aureus
VRSA: vancomycin resistant S. aureus
LZD-NS: linezolid resistant
DAP-NS: daptomycin resistant

MIC range = the concentration in *in vitro* (test tube) assays at which the compound is cidal against the bacteria

The data illustrated in the above table show that PMX-30063 (and a related compound, PMX-30016) are effective against resistant strains of *Staph* bacteria, and that the minimum inhibitory concentration (MIC) of both compounds remains constant at therapeutically relevant dose levels regardless of the resistance profile of the Staph bacteria strain. We believe these results both support our goal of initially developing PMX-30063 as a treatment for broad *Staph* infections, as well as demonstrate that the mechanisms by which *Staph* bacteria become resistant to conventional antibiotics do not seem to affect the activity of PMX-30063.

The antibiotic activity of PolyMedix's compounds has been replicated and confirmed by outside laboratories. These results from this set of experiments show the PolyMedix antimicrobial compounds have comparable potency to reference antibiotic drugs, and with superior activity against certain multi-drug-resistant bacterial strains such as methicillin-resistant *Staph. aureus* (MRSA) and vancomycin resistant *Enterococcus.*

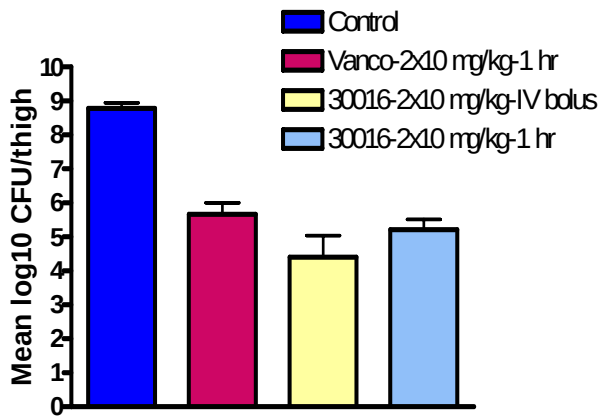
Animal Efficacy Studies

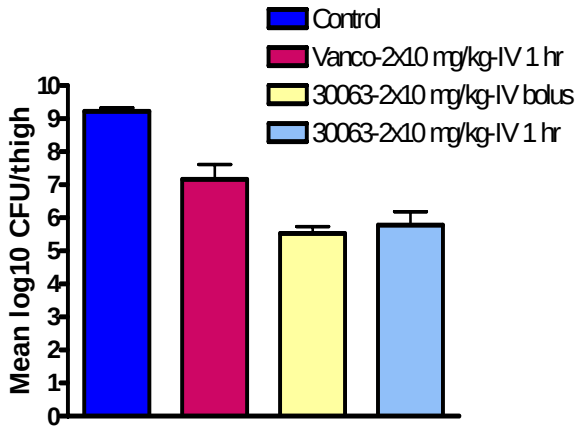
PMX-30063 has been tested for efficacy *in vivo* in mouse (dosing by i.v. bolus) and rat (dosing by i.v. infusion) thigh burden models, a widely used and accepted animal model for evaluating antibacterial activity of preclinical compounds.

Methods

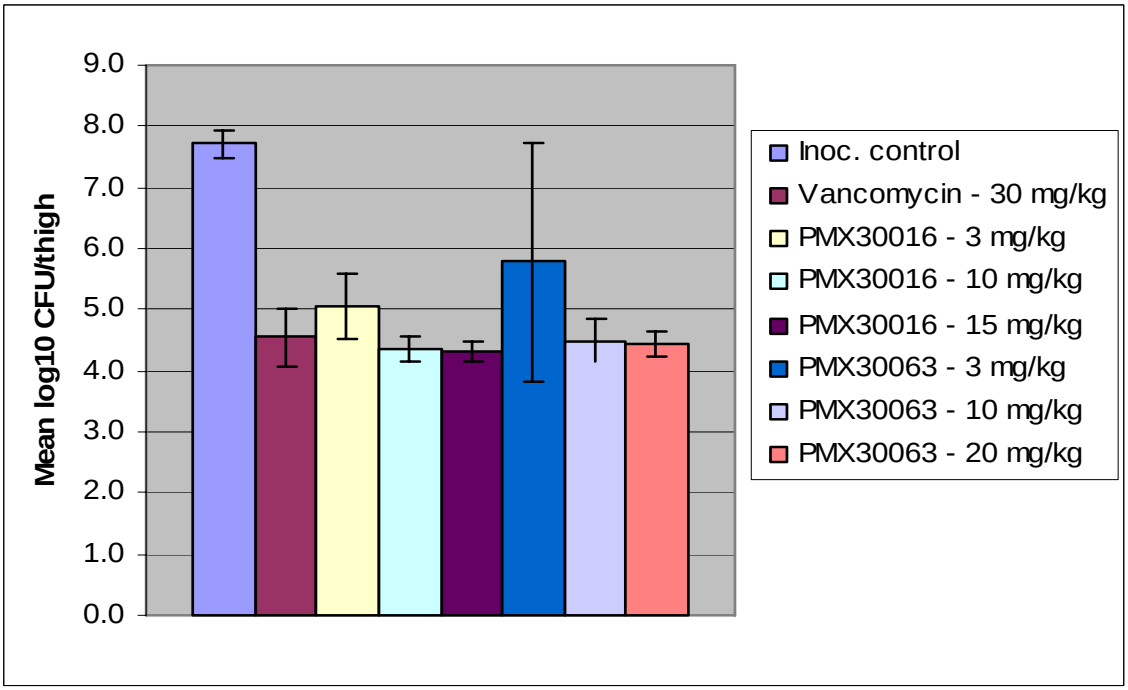
In the mouse model, neutropenic mice are inoculated in the posterior thigh muscles with *S. aureus* ATCC13709 (3×10^5 inoculum) and then treated with compound by single *i.v.* bolus administration. Bacterial quantitation is done at 4 or 24 hours post infection/treatment by aseptically removing the thigh muscles, homogenizing and plating serial dilutions of the homogenate. Vancomycin, dosed optimally (10 mg/kg, s.c.) is used as the positive control.

The antimicrobial activities of PMX-30063 in the mouse and rat model are robust at multiple time points. Studies (examples shown below) show that PMX-30063 (right) and PMX-30016 are comparably to more efficacious than vancomycin, with maximal efficacy of a 99.99%-99.999% reduction in bacterial counts with only two injections:



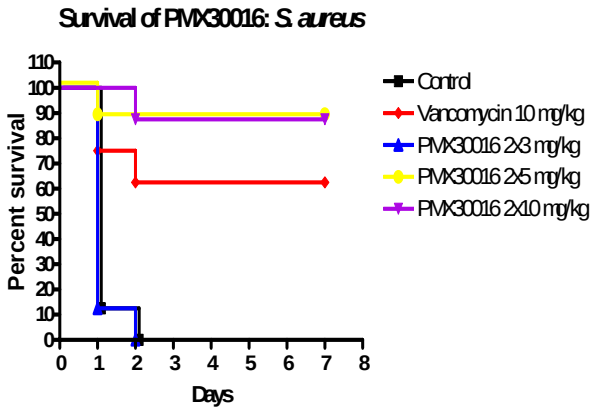


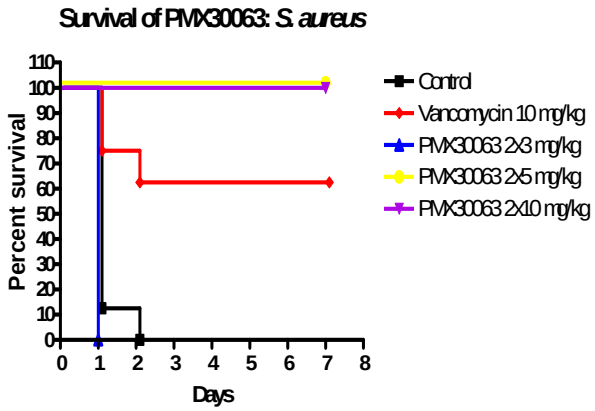
PMX-30063 has also been tested in animal models against MRSA, with comparable efficacy, as shown below:



Systemic infection: sepsis

In the following experiments, a systemic infection, *sepsis,* was produced in animals by administration of a lethal dose of *Staph aureus* by intraperitoneal (i.p.) injection. In this experiment two i.v. bolus doses of PMX-30063 or PMX-30016 were given, with the following representative results:





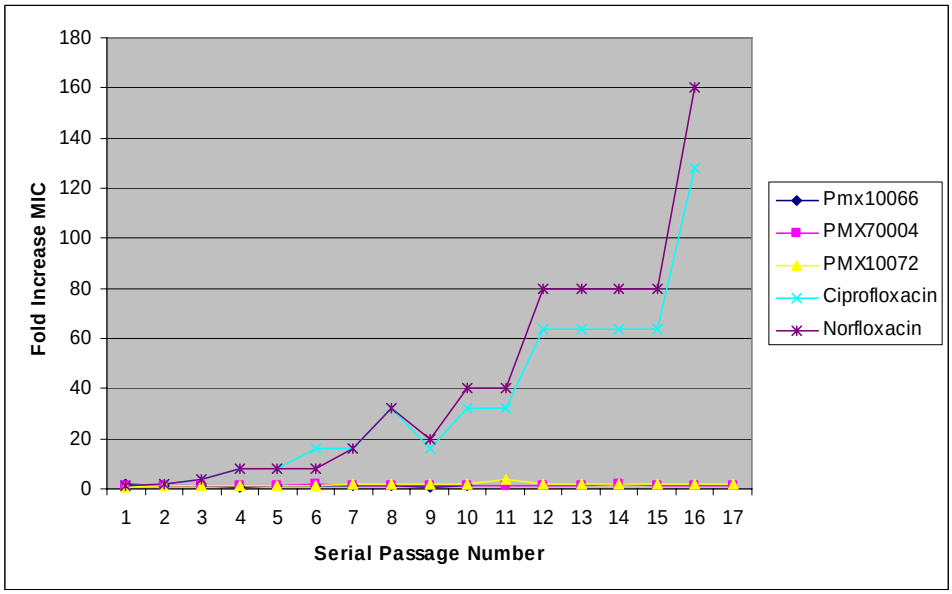
This sepsis model is considered a robust infection, as the bacteria spread throughout the body. This important result demonstrates that PMX-30063 is able to reach any compartment of the body wherever the bacteria may be resident, and was able to be completely effective against systemic sepsis infection with only two doses.

Experimental Data – Lack of Susceptibility to Bacterial Drug Resistance

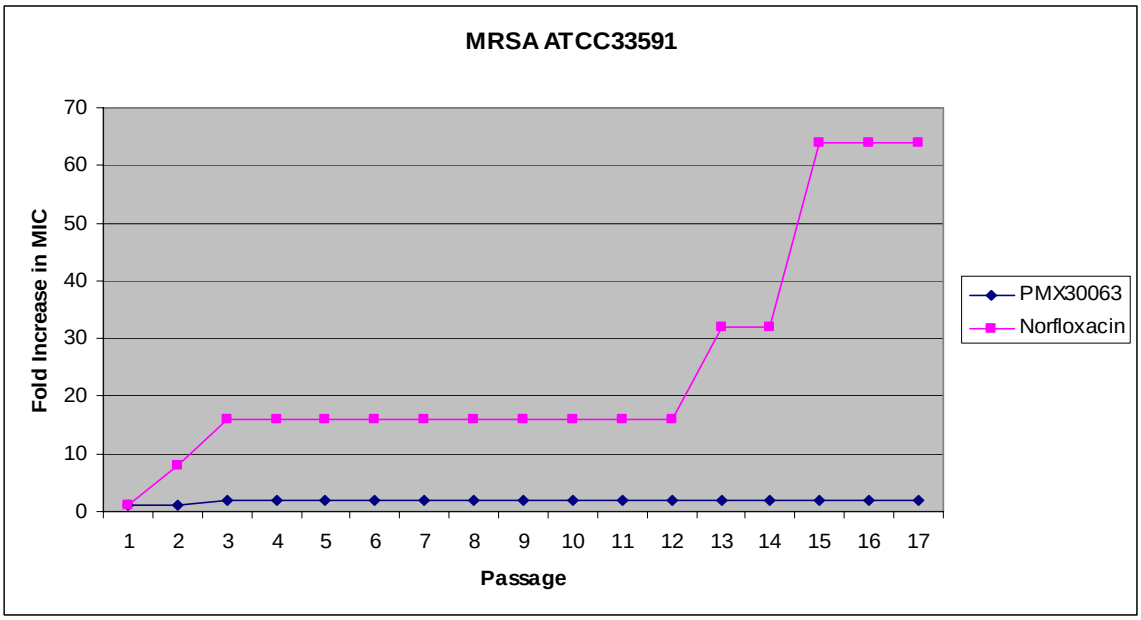
To experimentally measure the development of resistance (or the lack thereof) by bacteria to the antimicrobial activity of the PolyMedix antibiotic compounds, *Staph. aureus* has been exposed serially in the presence of sub-lethal concentrations of PMX-30063, as well as other related compounds PMX-30006, PMX-70004, PMX-10072, and PMX-10066. This is the so-called serial passage broth micro-dilution method that is a gold standard in the industry and is widely used to measure the development of resistance to many common antibiotics. As positive controls, two widely used fluoroquinolone antibiotic drugs were included in the assay, ciprofloxacin (Cipro) and norfloxacin. Bacteria, including *Staph. aureus*, readily develop resistance to conventional antibiotics in this experimental model.

The experiment is done by growing bacteria in the presence of increasing concentrations of an antibiotic drug (either a PolyMedix compound or a positive control). The culture tube containing the highest concentration of drug where bacterial growth is seen after 24 hours is selected and the bacteria are re-passaged with a fresh dilution series of compound. This process is repeated every 24 hours for 16 passages and the MIC (minimum inhibitory concentration, the lowest dose required to kill the bacteria) is noted at every passage. The development of resistance is indicated by a progressive increase in the MIC over time (passages). Conventional antibiotic drugs typically show significant bacterial resistance developing after 3-5 passages. The host defense proteins have been studied in this model and show no resistance even at up to 16 passages.

S. aureus was passaged in the presence of sub-MIC concentrations of the PolyMedix compounds and control antibiotics for 17 passages and the results are shown below. Resistance is readily observed for both ciprofloxacin and norfloxacin (as early as passage 3), with a greater than 100-fold increase in MIC, whereas no consistent increases in MIC values are apparent for the PolyMedix compounds. We believe these results are very encouraging, and experimentally demonstrate the low likelihood of resistance developing to our compounds. These results have now been replicated in two outside laboratories (in addition to PolyMedix's laboratories), with the experiments now having been done 14 times.



This serial passage study has also been performed specifically with PMX-30063 against MRSA, with the results shown below:



The lack of susceptibility to drug resistance of PMX-30063 directly addresses one of the most serious problems, and one of the greatest commercial opportunities, in medicine. We believe our antibiotic compounds may be the first for which bacterial resistance is unlikely to develop. These results have also been replicated by an outside academic collaborator, also demonstrating a lack of drug resistance when testing an oral pathogen, *Staphylococcus saprophyticus.*

Current Development Status

The GLP (Good Laboratory Practices) compliant toxicology, safety pharmacology and genotoxicity studies for PMX-30063 have been completed, which indicate that an effective therapeutic index for PMX-30063 may be achieved.

A Phase IA clinical study with PMX-30063 commenced in Canada in August 2008. The first Phase I studies will include -

(i) A single dose, dose-escalation study of healthy volunteers receiving PMX-30063 at various dose levels (Phase 1A), and

(ii) A multi-dose study of healthy volunteers who receive PMX-30063 at various dose levels (Phase 1B).

The primary endpoint for the two Phase 1 studies will be a safety assessment. Additional clinical and other studies will be required to obtain regulatory approval to commercially sell PMX-30063, and to obtain FDA approval in the U.S. and other countries.

Future Clinical Plans

The first formulation of PMX-30063 which is being developed is an intravenous form, for use in serious infections in hospitalized patients. The first clinical indication planned to be pursued for PMX-30063 is pan-*Staph* – that is, to broadly target *Staph* infections, including multiple strains of *Staphylococcus aureus, Staphylococcus epidermidis,* and *Staphylococcus hemolyticus. Staph* infections are one of the more common infections treated in hospitals, of a total estimated 7 million patients treated annually in hospitals for infections.

Staph infections can take a number of forms, including –

- Complex skin and soft tissue structure infections
- Respiratory infections, such as pneumonia and bronchitis
- Urinary tract
- Abdominal and gynecological

SBIR Grant Support

PolyMedix has received a total of four SBIR grants (out of four applied for – a 100% success rate) to support the development of these novel antibiotic agents: animal studies of biomimetic antibiotic agents; therapeutic development of biomimetic antibiotic agents; study of activity against biowarfare pathogens; and development of a sanitizing hand lotion.

The SBIR to support development of an antibiotic drug is an Advanced Technology SBIR, for which PolyMedix has received approximately $3 million to date. All grant objectives have been successfully completed, with all goals met.

Future Development

PolyMedix hopes to develop both PMX-30063 and other defensin-mimetic antibiotic compounds for additional uses, including:

- Ophthalmic formulation – PolyMedix has developed and tested an ophthalmic formulation of PMX-30063 for ocular (eye) infections. It is hoped to initiate clinical studies of this ophthalmic compound once additional financing is secured.

- Oral formulation – PolyMedix has started testing of an oral non-absorbed formulation of PMX-30063 for serious gastrointestinal infections such as *Clostridium difficile* and *Shigella*. It is hoped to continue testing and development of an oral formulation once additional financing is received.

- Antimicrobial polymers and oligomers for ***biomaterials*** applications. These polymer and oligomer biomaterials (PMX-50003, PMX-70004) are structurally distinct from PMX30063 but are amphiphilic and share the same basic mechanism of action as PMX-30063 drug. However they are easily synthesized and can be economically produced in large quantities. Advantages of the polymers and oligomers being used for biomaterial applications include:

- A unique mechanism of action which we believe makes *bacterial resistance unlikely to develop*
- Potent, broad spectrum activity against over 150 both Gram-positive and Gram-negative bacteria
- Rapidly bactericidal in minutes
- Polymer synthesis appears straightforward

- Active against drug-resistant bacteria, including clinical isolates of multiple *VRE* and *MRSA* strains
- Non-toxic to skin and eye in preliminary testing
- Long lasting antimicrobial effect
- Do not need to leech from material to exert their effects – makes the material itself inherently antimicrobial

Antimicrobial polymers can be used for *materials* applications to create self-sterilizing surfaces and develop bactericidal products, such as paints, plastics, personal care products, and textiles.

<u>Biomedical Applications:</u>

- i.v. tubes
- bandages
- catheters
- implantable joints, devices
- antiseptic lotions, wipes
- surgical gloves, masks

<u>Industrial Applications:</u>

- military uniforms & equipment
- paints
- paper
- marine antifouling coatings
- food preparation surfaces
- hospital surfaces

<u>Consumer Products</u>

- cosmetics & personal care
- bedding
- toilet seats
- towels
- toys
- carpeting

Antimicrobial plastics and other materials have been developed. Here, a bactericidal PolyMedix polymer was incorporated into medical grade PVC catheter tubing, which was then exposed to *E.coli*. Results show a robust antibacterial effect:

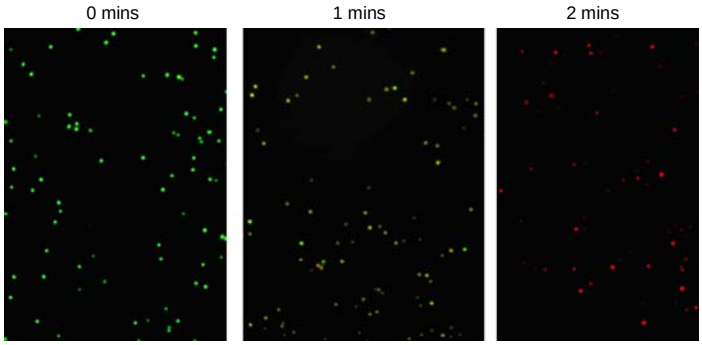
PVC tubing from medical catheter

Control

Treated with 1% PolyMedix polymer

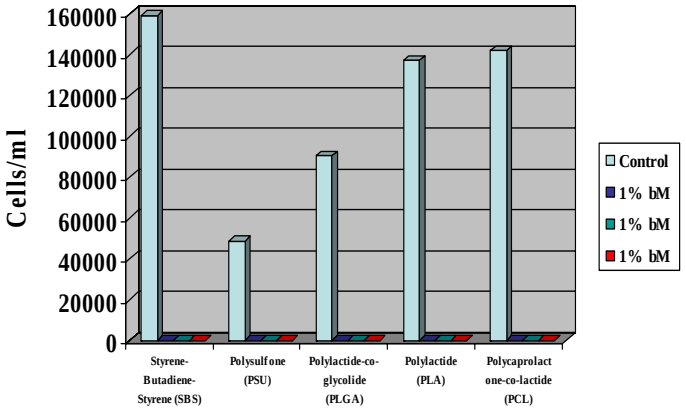
Experiments with polymer treated surfaces show complete bacterial killing within two minutes of exposure:

GREEN fluorescence is from live cells, **RED** fluorescence is from dead cells



Cells are killed in less than two minutes upon contact with the surface

Experiments show polymers can be successfully incorporated into many types of plastic, retaining antimicrobial activity:



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