



## CORPORATE PROFILE

Headquartered in Beverly, Massachusetts, Cellceutix Corporation (Ticker: CTIX, application pending with NASDAQ) is a clinical stage biopharmaceutical company developing innovative therapies with oncology, dermatology and antimicrobial applications.

Cellceutix owns the rights to numerous drug compounds, including Kevetrin™, our lead anti-cancer compound; Brilacidin, our lead drug in a new class of compounds called defensin-mimetics; and Prurisol™, which is in development for psoriasis.



## KEY DEVELOPMENTS

Clinical trial of Kevetrin for advanced solid tumors; planned Phase 2 trial of ovarian cancer under Orphan Drug designation

Completed Phase 2b trial of Brilacidin demonstrating a single-dose of Brilacidin is safe and as effective as blockbuster antibiotic daptomycin in treating ABSSSI - Phase 3 trial under development

Enrollment complete in Phase 2 trial of Prurisol for psoriasis; top line data from trial expected in May 2016.

Phase 2 trial of Brilacidin-OM for the prevention and treatment of oral mucositis in head and neck cancer patients ongoing under FDA Fast Track designation.

Orphan Drug and Rare Pediatric Disease designations from FDA for Kevetrin for retinoblastoma; Orphan Drug designation for ovarian cancer and pancreatic cancer



## KEVETRIN, THE p53 COMPOUND

Kevetrin has demonstrated the potential for a major breakthrough in cancer research by inducing activation of p53, a protein often referred to as the “Guardian Angel of the Genome” due to its crucial role in controlling cell mutations. In nearly 100 percent of cancers, regardless of origin, the p53 pathway is muted from performing its anti-tumor functions. Extensive pre-clinical research demonstrated Kevetrin's unique mechanism of action to induce apoptosis, slow tumor progression and substantially reduce tumor volume in every cancer line tested, including, lung, breast, colon, prostate, squamous cell carcinoma and a leukemia tumor model.

A Phase 1 clinical trial is evaluating Kevetrin for advanced solid tumors at Harvard University's Dana-Farber Cancer Institute and partner Beth Israel Deaconess Medical Center.

More than forty patients have been enrolled with Kevetrin shown to be well-tolerated. Preliminary data indicates that the impact of Kevetrin on p53 is dose-dependent, with over 50% of treated patients showing an increase in the key biomarker p21. Signs of efficacy have also been suggested by tumor stabilization in certain patients.

A Phase 2 trial under a FDA Orphan Drug designation of Kevetrin for the treatment of ovarian cancer is planned to be initiated in the first half of 2016. The trial will evaluate Kevetrin as a monotherapy and in combination with docetaxel to treat patients with platinum-resistant ovarian cancer. The FDA has also awarded Orphan Drug and Rare Pediatric Disease designations for Kevetrin for retinoblastoma and Orphan Drug designation for pancreatic cancer.



## BRILACIDIN FOR INFECTIONS

Brilacidin is the most advanced drug candidate in our defensin-mimetic franchise. Defensin-mimetics, also called host defense protein (HDP)-mimetics, are a completely new class of antibacterial and anti-fungal small molecule compounds modeled after host defense proteins, which are the “front-line” of defense in the human immune system. Due to the fact that our non-peptidic, fully synthetic defensin-mimetics kill pathogens swiftly and thoroughly in the same manner as the human immune system, they can significantly reduce the risk of drug resistance developing, one of the greatest threats to society today. Based upon laboratory and clinical evidence, Cellceutix is developing Brilacidin as a single-dose or short-course therapy.

In September 2014, a Phase 2b trial was completed evaluating three different short-course regimens of Brilacidin (two single-dose and one three-dose). The data showed a single dose of Brilacidin to be comparable in safety and efficacy to the FDA-approved 7-day dosing regimen of daptomycin (brand name Cubicin™, 2014 sales: \$1.05 Billion) in the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI). The FDA has approved moving into a Phase 3 trial of Brilacidin for ABSSSI, which is planned to be initiated in the first half of 2016.

## Clinical Trials

(Jan. 2016)

Product	Indication	Phase 1	Phase 2	Phase 3
<b>Infectious Disease</b>				
<b>BRILACIDIN</b>	Skin Infections (ABSSSI) <sup>1</sup>			
<b>Cancer</b>				
<b>KEVETRIN</b>	Advanced Solid Tumors <sup>2</sup>			
<b>BRILACIDIN-OM</b>	Oral Mucositis <sup>3</sup>			
<b>Dermatology</b>				
<b>PRURISOL</b>	Psoriasis <sup>4</sup>			

1 Phase 2b trial completed Sept. 2014, Phase 3 planned 1H 2016

2 Studies at Harvard University's Dana-Farber Cancer Institute and BIDMC

3 Phase 2 trial enrollment commenced May 2015

4 Enrollment complete November 2015. Top-line data expected May 2016



## PRURISOL FOR PSORIASIS

Prurisol is a small molecule acting on the principles of immune modulation and PRINS reduction that has been found to be effective against psoriasis in animal models, both in induced psoriasis as well as a xenograft model with human psoriatic tissue. We have published images of mice on our website showing that Prurisol effectively eliminated virtually all signs of psoriatic tissue in studies compared with methotrexate, a standard of care today.

A Phase 1 trial in healthy humans was successfully completed in August 2014. A randomized, double-blind, placebo controlled Phase 2 trial of Prurisol to treat patients with mild to moderate plaque psoriasis completed enrollment ahead of schedule in November 2015. Top-line results are expected in Q2 2016.



## CAPITAL STRUCTURE

Shares Outstanding: **119 Million**

Insider Ownership: **34%**

Share Price (January 27, 2016): **\$1.18**

Market Capitalization: **\$140 Million**

52-Week High: **\$3.90**

52-Week Low: **\$0.94**



## CONTACT INFORMATION

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## BRILACIDIN-OM FOR ORAL MUCOSITIS

Oral mucositis, a common and often debilitating inflammation and ulceration that occurs in the mouth as a side-effect of certain cancer treatments, afflicts approximately 450,000 patients each year in the U.S., increasing treatment costs and affecting the course and outcome of cancer therapy. In animal models, Brilacidin-OM, an oral rinse formulation, has shown antibacterial, anti-biofilm and anti-inflammatory properties, which we believe can address a significant unmet medical need and pharmacoeconomic rationale to treat cancer patients with oral mucositis.

A multi-center, double blind, randomized Phase 2 trial in the U.S. evaluating the safety and efficacy of Brilacidin-OM compared to placebo for the prevention and treatment of oral mucositis began enrolling patients in May 2015. The FDA awarded a Fast Track designation to Brilacidin-OM for oral mucositis in November 2015.



## PRE-CLINICAL COMPOUNDS

Independently, and through collaborative relationships with leading universities and institutions supported by funding through government grants, Cellceutix is developing defensin-mimetics for a wide range of indications, including otic infections, diabetic foot infections, hidradenitis suppurativa and some of the most difficult to treat multi-drug resistant fungal infections (specifically *Candida albicans*) and bacterium ("superbugs") where there is a significant and growing medical need for new therapies.

Brilacidin-Otic has shown excellent results in laboratory testing of middle ear (otitis media) infection. Cellceutix intends to develop Brilacidin-Otic, currently undergoing ototoxicity testing in preparation for a clinical trial, as a topical solution to treat acute otitis media infections that drain into the external ear canal, including acute otitis externa and those that occur through a ruptured tympanic membrane or indwelling PE tube.

Cellceutix's researchers have identified a series of HDP-mimetic compounds that rapidly kill a variety of clinically-important Gram-negative pathogens. Cellceutix's compounds have been shown to be active with low toxicity against some of the most problematic pathogens, such as *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Escherichia coli* and *Acinetobacter baumannii* as well as highly multi-drug resistant ndm-1-producing *K. pneumoniae*. Data presented at the 2015 European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) Conference showcased study data demonstrating that Cellceutix's CC-1807 is potently active against clinical isolates of *E. coli*, *K. pneumoniae* and *E. cloacae*, including multi-drug resistant and carbapenem-resistant strains.

To the extent that statements in this fact sheet are not strictly historical, including statements as to revenue projections, business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's development, events conditioned on stockholder or other approval, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this release are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Factors that may impact Cellceutix's success are more fully disclosed in Cellceutix's most recent public filings with the U.S. Securities and Exchange Commission. Kevelin and Prurisol are trademarks belonging to Cellceutix Corporation.