**INTRODUCTION AND PURPOSE**

Oral ulcerative mucositis (OM) is a common, painful, dose-limiting toxicity of drug and radiation therapy for cancer (Gylden 2008). The severity and frequency of OM have been significantly high among cancer patients, and frequently occurs in the formation of ulcerative lesions. In granulocytopenic patients, the ulcers that develop can be severe enough to interfere for entry of indigenous oral bacteria leading to sepsis or bacteremia (Donnelly 2012).

Mucositis occurs to some degree in more than one third of patients receiving anti-neoplastic drug therapy (Soni 2004). The frequency and severity are significantly greater among patients who are treated with chemotherapy for leukemia than for individuals treated for bone marrow transplant (Varo-Lichter 2012). Among the individuals, moderate to severe mucositis is not unusual in more than three-quarters of patients.

Moderate to severe mucositis occurs in virtually all patients who receive radiation therapy for tumors of the head and neck. It typically begins with cumulative exposures of 15 Gy and then worsens as total doses of 40 Gy or more are reached (Soni 2004, Sonis 2007). Host defense proteins (HDPs) form part of the innate immune system, and serve as the first line of defense against microbial infections in many species. HDPs can also perform many activities related to innate immunity and inflammation. Examples of cytokine production and inhibition of pro-inflammatory responses of host cells to bacterial components, Brilacidin (PNU-100640), is a synthetic form of host Defense Protein (HDP), with both antimicrobial and immunomodulatory properties. Brilacidin completed a successful Phase 2 clinical trial as an anti-inflammatory agent for treatment of acute skin and soft tissue infections. Studies (ASSIGD) (ECMID-2690).

**METHODS**

Based on the key-to-clinical models and its immunomodulatory activity, brilacidin is being tested in Phase 2 trial for chemotherapy induced oral mucositis.

**REFERENCES**


**RESULTS**

**Antimicrobial activity of brilacidin**

**Phase 2 clinical trial of oral mucosal activity**

Based on the very promising results of the pre-clinical oral mucosal models, antimicrobial studies, and immunomodulatory studies, brilacidin is being assessed for the prevention of oral mucositis induced by chemotherapy regimens used for the treatment of cancers of the head and neck.

The Phase 2 study is randomized, double-blind, placebo-controlled, 2-arm parallel trial in patients with oral mucositis due to chemotherapy for various cancers of the oral cavity and pharynx. Eligible patients will be randomized to receive 4xQD of brilacidin or placebo for 7 treatment days. Alternatively, the phase 2 clinical trial in radiation induced mucositis is ongoing.

**CONCLUSIONS**

Oral ulcerative mucositis (OM) is a common, pain-limiting toxicity of drug and radiation therapy for cancer. The existence of minimal treatment options is well documented and a growing body of evidence suggests that brilacidin has a promising role in the treatment of OM.

**For further information**

Please contact Cellceutix Corporation at 855-258-0200. Further information on clinical and preclinical results can be obtained at www.cellceutix.com.