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Development of Itraconazole Topical formulation in Skin Cancer Treatment

1. Overview: I, Praveen Kolimi, pursuing a first-year graduate program at the department of pharmaceuticals and drug delivery. This Graduate Student Council (GSC) grant proposal focus on topical application of Itraconazole (ICZ) in skin cancer treatment.

2. Intellectual Merit: 5.4 million skin cancer cases are reported each year in the United States. A study disclosed that one among five Americans are likely to develop skin cancer in their entire life⁹. Skin cancer can be distinguished into two types, malignant melanoma (MM) and non-melanoma skin cancer (NMSC)^{1,8}. NMSC further classified into squamous cell carcinoma (SCC) and basal cell carcinoma (BCC)^{8,10}. It was estimated that every year 2 million people are suffering from BCC and 80 per cent cases observed in NMSC⁴. Studies have demonstrated the hedgehog pathway is involved in BCC and melanoma development^{12,16}. Cyclopamine is a prototype drug which inhibits the hedgehog pathway in BCC and preclinical studies demonstrated cyclopamine as a potential drug for skin cancer treatment². However, cyclopamine was not effective in skin cancer clinically due to its low solubility and toxicity profile^{2,13}. Recently, cyclopamine derivatives vismodegib and sonidegib hedgehog pathway inhibitors have been approved by USFDA for skin cancer through the oral route of administration⁶. Studies have reported oral vismodegib, and sonidegib produced adverse effects, including muscle spasms, alopecia and weight loss¹¹. On the same lines, oral formulations are difficult to administer to unconscious patients, taste cannot be masked and they can be bulky making it difficult to ingest making oral formulations a discomfort to cancer patients. Topical anti-cancer drug treatment would be a better and effective option for topical (skin) cancer treatments. Topical products offer patient compliance which is of utmost importance especially to the cancer patients. As of now, in the market, only 5-fluoro uracil and imiquimod drugs are available for treating skin cancer through topical route⁷. Although 5-fluoro uracil and imiquimod are beneficial for treating skin cancer, these drugs exhibit adverse effects including skin irritation, hair loss, pain and changes in skin color. Recent clinical studies have demonstrated ICZ oral dose are effective in the treatment of BCC and proposed mechanism of action is hedgehog pathway inhibition. The ICZ is a high safety profile drug and extensively used as an anti-fungal agent for two decades. To our best knowledge, there is no effective topical formulation available for skin delivery of ICZ in skin cancer treatment, and therefore, it is required to develop ICZ topical formulation. The current study is designed to develop a topical formulation of ICZ and evaluate its potential effects in the treatment of skin cancer in athymic mice models.

3) External Opportunity:

Recently, many researchers are focusing on repurposing drugs, especially in cancer chemotherapy^{5,15}. Anti-fungal drugs, including ICZ and posaconazole, both drugs, were shown very positive results in skin cancer treatment^{5,14}. Here, we conduct studies of ICZ via the topical route of administration in skin cancer induced athymic nude mice. After executing studies, we will utilize this data and will write grant proposals to AAPS and other funding foundations.