TECHNOLOGY

Use of EM 1412 as a vaginal microbicide for HIV, HPV and HSV transmission

OVERVIEW

Cervical dysplasia is the existence of abnormal cells in the cervix, which may indicate a pre-cancerous condition. In the United States, 250,000 to 1 million women are diagnosed with cervical dysplasia annually in which 30% to 50% possibly progressing to invasive cancer without treatment. In order to address this issue, UMB inventors have developed a nano-vesicle, water-based formulation to target intraepithelial neoplasia or dysplasia utilizing a plant-derived small molecule, tetramethyl nordihydroguaiaretic acid (Terameprocol, EM 1412). Terameprocol has demonstrated both anti-viral and anti-cancer properties in a previous petroleum-based formulation with early results in animal models demonstrating efficacy using topical treatments of lesions caused by papilloma virus. The compound has proven clinically safe in human Phase I/II trials in both healthy women and women with HPV-linked cervical intraepithelial neoplasia. In addition, Terameprocol has shown excellent antiviral activity and is believed highly useful as a vaginal microbicide in reducing transmission of viruses such as HIV, HPV, and HSV.

APPLICATIONS

Though the initiation of the HPV vaccination programs in 2006 will decrease cervical cancer rates for years to come, there remains a critical need to develop novel therapies in the chemoprevention of cervical and anal cancer. In particular, adult patients who are already infected with HPV and at risk for developing precancers and cancer and are not eligible for the HPV vaccine. Each year, about 12,000 women get cervical cancer in the U.S. Of the more than one million people living with HIV in the United States (with about 56,000 new infections each year), the incidence of certain cancers such as cervical and anal cancer are significantly higher than in the general population, and rates of these diseases are expected to rise further. Prevention of new infections by HIV and HPV through use of microbicides can also help prevent the cancers associated with these viruses.

ADVANTAGES

Excellent safety profile: proven clinically safe in human Phase I/II trials in both healthy women and women with HPV-linked cervical intraepithelial neoplasia

No other chemotherapeutic treatment currently available.

STAGE OF DEVELOPMENT

The water-based formulation has progressed to animal studies, by NIAID contract laboratories.

LICENSING POTENTIAL

UM seeks to develop and commercialize by an exclusive or non-exclusive license agreement and/or sponsored research with a company active in the area.

CONTACT INFO

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Additional Information

INSTITUTION

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PATENT STATUS

US patent 8,440,648 B2, Issued 5/14/13.

CATEGORIES

- Therapeutics
- Repurpose Drug
- Natural Compounds

INVESTIGATOR(S)

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EXTERNAL RESOURCES

- Phase I clinical trial of repeat dose terameprocol vaginal ointment in healthy female volunteers.
- Phase I/II clinical safety studies of terameprocol vaginal ointment.
- Genital dysplasia in women infected with human immunodeficiency virus.
- Treating cervical dysplasia: why does it matter?

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