Dennis E Hruby, J Antivir Antiretrovir 2014, 6:2
http://dx.doi.org/10.4172/1948-5964.S1.022

OMICS Group Conferences
Accelerating Scientific Discovery

4th World Congress on
Virology

October 06-08, 2014 Hilton San Antonio Airport, TX, USA

Developing a drug for a disease that doesn't exist: Arestvyr TM, a smallpox antiviral

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ArestvyrTM is a smallpox antiviral drug that is in late-stage development for use as a therapeutic for symptomatic patients, prophylactic in infected but non-symptomatic patients, and for concomitant administration with smallpox vaccines to improve their safety profiles. Arestvyr is an egress inhibitor which prevents the formation of the EEV forms of orthopoxviruses. It has demonstrated excellent post-exposure efficacy in a large number of animal species that included mouse, ground squirrel, prairie dog, rabbit, and NHP challenged with a variety of different pathogenic orthopoxviruses including vaccinia, cowpox, rabbitpox, ectromelia, monkeypox and variola. In clinical studies, the drug appears to be safe and well-tolerated. Once a day oral dosing provides blood exposure at or above that which has been shown to be protective in animal studies. Following robust and iterative discussions with the regulatory authorities, a clear and achievable pathway has been mapped out for the approval of the drug for use as a therapeutic for symptomatic patients, and SIGA and its federal partners are in the process of executing this plan. Based on the data obtained to date, the U.S. government has awarded a contract to SIGA for the acquisition of two million courses of Arestvyr to be added to the Strategic National Stockpile. Work continues on the development of additional Arestvyr formulations and towards approval of the drug for additional indications.

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