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Introduction to the OyaGen Pipeline

OyaGen has its origins in the discovery and science of gene editing enzymes that affect the genetic readout of cells and viruses. The Company was founded in 2003 based on the academic work of Dr. Harold C. Smith, University of Rochester. The company and its founder are key opinion leaders on the APOBEC family of gene editing enzymes having published 147 peer-reviewed publications. Dr. Smith was the first faculty member at the University of Rochester to receive an individual Bill and Melinda Gates Foundation Grant for innovation in HIV research.

The mission of the Company is to address unmet needs for novel treatments that will prevent, treat and cure some of the world's most deadly viruses including HIV, COVID and Ebola. Our business model is to identify novel drug leads that act on antiviral targets and optimize these through preclinical development for licensing or partnering.

The company has two lead antiviral compounds in development, SN38 and OYA1.

SN38

Despite several FDA approved treatments, HIV remains a significant health care issue with >60 million people worldwide infected. Without a cure, viral rebound, the emergence of drug resistant HIV strains and the lack of access to antiretroviral therapy around the world continue to threaten the lives of patients. OyaGen has patented camptothecin derivatives as first-in-class HIV therapeutic based on their ability to inhibit HIV Vif-dependent degradation of the APOBEC host-defense mechanism (https://pubmed.ncbi.nlm.nih.gov/27825797/). OyaGen is the only company that has significant traction on drugging HIV Vif (https://pubmed.ncbi.nlm.nih.gov/29609878/). Oral formulation studies for extended release and delivery via the lymphatics enable long-acting drug delivery as shown in PK studies with two species rodents by the University of Southern Australia who are planning on conduct their own clinical trials with the formulation for rectal cancer. OyaGen has preliminary data in HIV from studies with HIV infected, humanized mice suggesting that oral dosing with this unique SN38 prodrug formulation can prevent HIV rebound associated with withdrawal of standard cART. Studies on the formulation and pharmacokinetics have been peer reviewed, published and patented by the University of Southern Australia.

OYA1

OyaGen developed OYA1 in collaboration with the federal government (NIH/NIAID) as a highly potent, broad-spectrum, antiviral compound that prevents the spread of infection of Coronaviruses, Ebola and Lassa viruses (https://pubmed.ncbi.nlm.nih.gov/34807849/) (https://pubmed.ncbi.nlm.nih.gov/37690700/). When dosed in combination with Remdesivir, OYA1 markedly improved the antiviral efficacy of Remdesivir enabling maximal virus stopping power with lower doses for both drugs. OYA1 has already been demonstrated to be safe in human clinical trials conducted by the NCI. OyaGen holds two patents for OYA1 as a therapeutic for COVID and Ebola. The Company has completed preIND discussions with the FDA for OYA1 treatment of COVID and is finalizing the studies that were requested.

OYA1 was discovered as an Ebola antiviral in collaboration with NIAID (https://pubmed.ncbi.nlm.nih.gov/33396288/). The unmet need is that protection through immunization takes 21 days, but the virus kills in 14 days. When an Ebola vaccine becomes available, it may prevent the spread of Ebola to those who are immunized but it will not prevent transmission or death of persons within the disease epicenter who are not immune. Mab production and distribution are costly and require special infrastructure. Clinical trials involving several therapeutic strategies showed that Mab therapy had the greatest therapeutic value in treating Ebola. To date, vaccination strategies for Ebola and Remdesivir were less effective for people infected with Ebola who already had symptoms. Our published data show that OYA1 is markedly more effective than Remdesivir and has significant virus stopping capability alone or in combination with Remdesivir. OYA1 will address the unmet need for highly active antiviral therapies. OYA1 as an antiviral for Ebola is patent protected.

The common antiviral mechanism of OYA1 that enables its broad-spectrum antiviral activity is its selective incorporation into viral genomes during their replication by the viral RNA-dependent, RNA polymerases. As such, it is predicted to have antiviral activity against Dengue, West Nile, Yellow Fever and Zika. Studies conducted with NIAID at Fort Detrick demonstrated antiviral efficacy against Pox viruses as well.

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