

# HEROIN-KLH

THERAPEUTIC VACCINE FOR HEROIN ADDICTION

## Fact Sheet and Primer

### THE PROBLEM

Substance abuse and dependence are worldwide problems with significant health, economic, and societal impacts. Of the many illicit drugs of abuse, heroin is often considered the most highly addictive and dangerous. Long-term success rates for rehabilitation programs are generally only between 10-25% because current treatment modalities are inadequate and have measurable drawbacks. Psychotherapy and cognitive behavioral therapy, while helpful for some, are usually not sufficient alone and carry low compliance rates. Methadone or buprenorphine substitution therapy carries the risk inherent in continued opioid use and perpetuates dependence. Opioid receptor antagonist drugs, such as naltrexone, are associated with unpleasant symptoms, possible long-term side effects, and increased risk of fatal overdose with relapse.

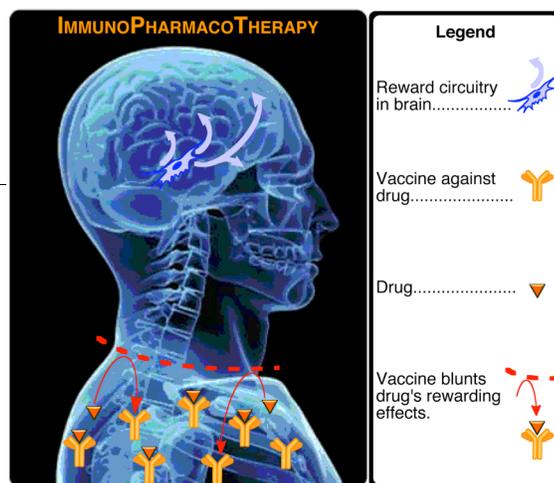
### THE SOLUTION

Researchers at The Scripps Research Institute (TSRI) have developed a therapeutic small molecule (“haptenic”) vaccine that has the potential to dramatically increase rehabilitation success for heroin abuse and addresses key deficiencies in past vaccine strategies. Importantly, the vaccine or what they term “immunopharmacotherapy” elicits a robust production of tightly binding antibodies that protect against even high doses of heroin in relevant animal models. In extensive rodent studies, the vaccine neutralized the effects of heroin and consequently extinguished drug seeking behavior. Instead of targeting heroin alone, the vaccine induces the patient to produce antibodies to breakdown products that also contribute to the psychoactive effects. However, the vaccine strategically spares several opioids, such that legitimate pain control may still be administered clinically if necessary. Since the vaccine does not target the opioid receptors directly, there is no impact on normal physiologic pain control function. Altogether, this novel vaccine represents a low-risk treatment that could confer substantial therapeutic benefit.

The inventor is Kim D. Janda, the Ely R. Callaway Professor of Chemistry at TSRI and considered the pioneer of creating vaccines against drugs of abuse and other small molecules.

### A PATH FORWARD

Further advancement of this promising vaccine into a Food and Drug Administration (FDA)-approved product will ultimately require some form of commercial partnering, as activity within TSRI is limited to basic science research. The outlook for such an endeavor appears promising given that there are no approved vaccines for heroin (or other drugs of abuse) and the potential need is substantial. There are up to 20 million people globally using heroin each year; and in the U.S., over \$20 billion is spent annually for heroin treatment, which does not include the economic impacts from productivity loss, the criminal justice system, and other effects. Given the known negative consequences of continued abuse and the lack of treatment alternatives, the barrier for FDA approval should be comparatively lower than treatments for other indications.



The anticipated path moving forward will require a measured strategy and plan generally comprising the following steps:

- Finishing Pre-clinical development “Humanizing” the vaccine
- Pre-clinical meeting with the FDA
- Production of vaccine under “current Good Manufacturing Practice (cGMP)” standards
- Animal toxicity studies (2 species)
- Demonstrate efficacy in an additional animal model (likely primate)
- IND filing with FDA prior to initiation of human trials

Although private funding will be necessary to initiate certain aspects of development, there are government grant opportunities available. The unique expertise that enabled the development of Heroin-KLH could moreover be directed towards the creation of novel vaccines for other targets such as nicotine, methamphetamine, cocaine and other opioids. The general technology has also shown efficacy for the treatment of drug overdose and could also be applied to numerous other small molecule targets which have been elusive for vaccine development, such as certain infectious diseases, obesity, and chemical warfare agents. In summary, a unique opportunity exists to develop a dynamic vaccine program for the treatment of substance abuse.