

DNARx Awarded DARPA Contract for up to \$10.7 Million to Develop Non-Viral DNA-Encoded Gene Therapy to Protect Against Pandemic Influenza

DNARx's proprietary HEDGES™ non-viral gene therapy delivery platform promises rapid, reliable, low-cost and relatively simple manufacturing and delivery of gene vectors to treat a wide range of diseases, particularly as compared to currently-employed delivery of genes using viruses

SAN FRANCISCO, Aug. 06, 2019 (GLOBE NEWSWIRE) -- DNARx, the developer of the pioneering HEDGES™, non-viral gene therapy delivery platform, announced today that the Defense Advanced Research Projects Agency (DARPA) has awarded the company up to \$10.7 million for research and development of DNA-encoded gene-based therapeutics to protect against pandemic influenza. HEDGES enables the rapid, reliable, low-cost and relatively simple manufacturing and delivery of gene vectors for *in-vivo* production of therapeutic proteins in order to treat a wide range of diseases, particularly as compared to currently-employed delivery of genes using viruses.

“Our proprietary HEDGES platform has the potential to cause a sea change in gene therapy due to its non-viral, DNA-encoded, gene delivery approach,” said Robert Debs, M.D., chief executive officer of DNARx. “DNARx has already demonstrated proof of concept with the *in vivo* production of human G-CSF (Neupogen®), rituximab (Rituxan®) and mepolizumab (Nucala®) in small animal models. We were able to show durable gene expression and control of gene expression over a broad temporal range, without evidence of significant toxicity. We believe the studies conducted to date and the significant medical need to respond rapidly to the emergence of pandemic flu demonstrate the potential market. We are thankful for DARPA's support. We look forward to expanding the potential of HEDGES to address multiple diseases where we can save patient lives.”

This \$10.7 million contract will support research for up to four years to advance promising anti-pandemic influenza candidates into preclinical testing. The results may enable human clinical trials after the end of the DARPA contract. The contract is part of DARPA's PREPARE program: PReemptive Expression of Protective Alleles and Response Elements. The PREPARE program explores ways to better protect against biological, chemical, or radiological threats by temporarily and reversibly tuning gene expression to bolster the body's defenses against – or directly neutralize – a given threat. The ultimate objective of PREPARE is to develop a modular, threat-agnostic platform solution with common components and manufacturing architecture that can be readily adapted to diverse and emerging threats. By the end of the four-year program, DARPA aims for each funded team to submit at least one final product to the U.S. Food and Drug Administration (FDA) for regulatory review as an Investigational New Drug or for Emergency Use Authorization. For more information about PREPARE, visit <https://www.darpa.mil/program/preemptive-expression-of-protective-alleles-and-response-elements>.

About DNARx, Inc., and HEDGES™

DNARx is pioneering HEDGES™, an entirely new approach to delivering gene therapeutics that produces human proteins or antibodies inside patient cells. This revolutionary *in-*

vivoplatform has demonstrated the ability to overcome current drawbacks of currently-employed virus-administered gene therapies because HEDGES can be re-dosed without causing an adaptive immune response, HEDGES can deliver gene payloads that are many times the size of current limits, and HEDGES can express human proteins at therapeutic levels for prolonged periods. HEDGES can also be delivered safely without integrating into the human genome, thereby avoiding the risk of the patient developing cancers from integration into the genome. DNARx has established a broad intellectual property portfolio which covers HEDGES and its uses. The company plans both to develop and commercialize innovative DNA-based drugs and to enter into collaborations with other companies to bring life-saving therapies to patients. DNARx is a privately held company based in San Francisco, California. Visit www.dnarx.net to learn more.

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