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ModeX Therapeutics Secures \$35 Million BARDA Supplement to Develop COVID Multispecific Antibodies and \$16 Million to Initiate Influenza Program

- *Brings total awards from BARDA to \$110 million for development of broad SARS-CoV-2 and Influenza multispecifics, with potential funding of up to \$205 million if all options are executed*
- *Development work is based on ModeX proprietary MSTAR technology that incorporates multiple antibody binding sites into a single molecule*

WESTON, Mass., Oct. 07, 2024 (GLOBE NEWSWIRE) -- ModeX Therapeutics Inc., an OPKO Health, Inc. (NASDAQ: OPK) company, announces it has been awarded \$35 million of additional funding under an existing contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services (HHS).

This funding will support the development of a second novel multispecific antibody to SARS-CoV-2 from preclinical through Phase 1 trials, as well as preclinical work on gene-based expression of multispecific antibodies to SARS-CoV-2 including mRNA and/or DNA vectors. In addition, ModeX will begin development of influenza multispecifics with gene and/or protein delivery modalities by initiating the second phase of BARDA funding through activation of a \$16 million option.

The funding and advancement of these programs will further explore ModeX's proprietary MSTAR platform to prepare for outbreaks and respond rapidly to emerging viral threats. Together, this funding brings the total support awarded to ModeX to \$110 million out of \$205 million if all options are executed.

"A rapid response with broadly protective antibodies is crucial to effectively contain outbreaks of viruses like influenza or SARS-CoV-2. By design, our multispecific platform represents a potential countermeasure that could swiftly provide coverage against such public health threats," said Dr. Gary Nabel, President and Chief Executive Officer of ModeX.

MSTAR is a flexible multivalent, multispecific antibody design platform that allows the incorporation of multiple independent antibody binding sites into a single molecule, thus expanding their therapeutic potential while enabling rapid responses to emerging and re-emerging viral pathogens, including SARS-CoV-2 and influenza. These antibodies also have the potential to confer protection in immune-suppressed, cancer and other patients with suboptimal responses to vaccination.

Despite the seasonal availability of vaccines, influenza-related disease and COVID remain significant public health issues. Multispecific antibodies have the potential for wider breadth

of coverage to enable protection against multiple strains of a pathogen and be more resilient against pathogen evolution. Gene-based antibody expression represents a new method with potential to significantly reduce manufacturing costs and allow faster pivoting for new and emerging threats compared with conventional protein-based antibodies.

“Through our collaboration with BARDA, we are working to develop new medicines to protect the public from existing and emerging infectious disease pathogens,” added Dr. Elias Zerhouni, President of OPKO. “We are pleased with additional funding from BARDA. Cutting-edge technologies like those from ModeX have the potential to address pressing public health needs.”

The contract was originally [awarded to ModeX](#) in September of 2023, and it is supported through Project Next Gen efforts, which support development of next-generation COVID-19 vaccines and therapeutics, and through BARDA’s Flexible and Strategic Therapeutics (FASTx) program, which aims to transform antiviral therapy by developing rapidly adaptable platforms to combat viral threats.

This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00056.

About ModeX Therapeutics

ModeX Therapeutics is a clinical-stage biopharmaceutical company developing innovative multispecific biologics for cancer and infectious disease. Its platforms unite the power of multiple biologics in a single molecule to create multispecific antibodies and vaccines with unprecedented versatility and potency in fighting complex disease. The ModeX pipeline includes candidates against both solid and hematologic tumors, as well as several of the world’s most pressing viral threats. Its founding team includes globally recognized medical innovators with proven track records of delivering breakthroughs for patients. ModeX is an OPKO Health company based in Weston, Massachusetts. For more information, please visit www.modextx.com.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise, and novel and proprietary technologies. For more information, visit www.opko.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "could," "may," "anticipates," "believes," "should," "intends," "estimates" and other words of similar meaning. These statements concern, and these risks and uncertainties include, among others, product candidates being developed by ModeX and/or its collaborators or licensees and research and clinical programs now underway or planned, including without limitation ModeX’s

MSTAR technology, and its next-generation MSTAR multispecific antibody therapy intending to target known variants of SARS-CoV-2, as discussed in this press release; the feasibility and success of the MSTAR platform; whether additional funding of up to \$93 million will be granted to ModeX even if it were to achieve the specified milestones, the extent to which the results from the research and development programs conducted by ModeX and/or its collaborators may lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; uncertainty of the utilization, market acceptance, and commercial success of ModeX's product candidates and the impact of studies (whether conducted by ModeX or others) on any of the foregoing or any potential regulatory approval of ModeX's product candidates; safety issues resulting from the administration of ModeX's product candidates in patients; determinations by regulatory and administrative governmental authorities which may delay or restrict ModeX's ability to continue to develop or commercialize its product candidates; competing drugs and product candidates that may be superior to, or more cost effective than, ModeX's product candidates; the costs of developing products and any supply chain concerns; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on ModeX's business; the health need for ModeX's product candidates; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, as well as other non-historical statements, including statements about our expectations, products, beliefs or intentions regarding ModeX, projected future clinical developments, the potential for ModeX products and pipeline and any other statements regarding OPKO's and ModeX's future expectations, beliefs, plans, product candidates, objectives, financial conditions, assumptions or future events or performance. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other filings with the Securities and Exchange Commission, as well as liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, the success of our relationship with our commercial partners, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, and that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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