Source: *SIRPant Immunotherapeutics, Inc.*

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SIRPant Immunotherapeutics Receives FDA Orphan Drug Designation for SIRPant-M for the Treatment of T-Cell Lymphoma

HUMMELSTOWN, Pa., Nov. 15, 2023 (GLOBE NEWSWIRE) -- SIRPant Immunotherapeutics Inc, a clinical-stage immuno-oncology company focusing on developing next-generation macrophage-based immunotherapies for the treatment of hematological malignancies and solid tumors, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for the Company's lead product candidate, SIRPant-M™, an autologous SIRPα^{low} activated macrophage therapy, for the treatment of T-cell lymphoma.

"Allowance of Orphan Drug Designation represents a significant milestone for the Company and is important recognition for the promise of our therapeutic platform," said Robert Towarnicki, CEO of SIRPant.

"Unlike B-cell lymphomas and classical Hodgkin Lymphoma, many T-cell lymphoma subtypes do not have a suitable drug target, and approved cellular immuno-therapy is currently unavailable in T-cell lymphoma," said Jelle Kijlstra, MD, CMO of SIRPant. "With its unique polyclonal mechanism of action, relying on tumor-specific neo-antigens, SIRPant-M is well positioned to reveal the therapeutic potential of macrophage cell-therapy in our recently opened clinical trial."

The FDA's Orphan Drug Designation program provides orphan status to drugs or biologics intended for the prevention, diagnosis, or treatment of diseases that affect fewer than 200,000 people in the United States. Sponsors of medicines that are granted Orphan Drug Designation are entitled to certain incentives and regulatory assistance, including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

About T-Cell Lymphoma

T-cell lymphoma is a group of rare blood cancers classified under non-Hodgkin's lymphoma and affect T-lymphocytes, a type of white blood cell critical to the immune system. T-cell lymphoma is a currently uncurable form of lymphoma, starting in the skin and often causing skin redness, rashes, and tumors.

About SIRPant M™

SIRPant M™ is an autologous cancer-agnostic macrophage cell therapy manufactured using PhagoAct™, an advanced non-genetic method to activate and educate patients' own macrophages for the recognition and elimination of cancerous cells. As a monotherapy or in combination with other immuno-stimulatory modalities such as radiotherapy and immune checkpoint inhibitors, SIRPant-M™ acts by directly attacking cancerous cells, stimulating cancer neoantigen-specific cytotoxic T cells and antibodies, reducing immunosuppressive elements, and perpetuating a pro-inflammatory tumor microenvironment that favors

cancer elimination. By mobilizing other immune cells and promoting a multi-prong attack on cancer, SIRPant-M™ targets established tumors and achieves persistent and durable immune memory that resists cancer relapse. SIRPant-M™ is currently being optimized for the treatment of relapsed or refractory non-Hodgkin's lymphoma (R/R NHL, SI-101).

About SIRPant Immunotherapeutics Inc.

SIRPant Immunpotherapeutics Inc is a clinical-stage immuno-oncology company specializing in the development of next-generation macrophage-based immunotherapies for the treatment of hematological malignancies and solid tumors. The cell therapy technology SIRPant employs is based on the reduction of SIRPα expression combined with activation of the patient's own macrophages. This population of SIRPαlow activated macrophages are designed to attack the tumor following injection by activating the patient's immune system to produce broad spectrum anti-tumor activity that utilizes patient T-cells and antibodies targeting cancer neoantigens. Because SIRPant does not genetically engineer its cell therapies, the company believes its product candidates will be easier and less expensive to manufacture, with reduced toxicities, compared to current engineered cell therapies in the clinic, and may provide patients with meaningful clinical benefit. As a result, SIRPant-M has a compelling product profile when compared to current gene-modified cell therapies. For more information, please visit www.sirpantimmunotx.com.

Forward-looking statements

This press release contains certain "forward-looking statements" concerning the development of SIRPant Immunotherapeutics products, the potential benefits and attributes of those products, and the company's expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. SIRPant Immunotherapeutics undertakes no obligation to update any forward-looking statements for any reason.

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