Press Release

Jubilant Therapeutics Inc. receives Orphan Drug Designation for JBI-802 for Acute Myeloid Leukemia (AML) and Small Cell Lung Cancer (SCLC)

Bedminster, New Jersey, United States - January 05, 2023 - Jubilant Therapeutics Inc., a clinical stage biopharmaceutical company advancing small molecule precision therapeutics to address unmet medical needs in oncology and autoimmune diseases, today announced that the United States Food and Drug Administration (US FDA) has granted Orphan Drug Designation for JBI-802 for the treatment of small cell lung cancer (SCLC) and acute myeloid leukemia (AML).

JBI-802 is a dual epigenetic modulator engineered in a single pharmacophore to achieve optimal inhibition of the transcriptional regulator CoREST, which regulates the development of cellular lineages responsible for neuroendocrine tumors like SCLC and hematopoietic tumors like AML. This unique profile has shown synergistic anti-tumor activity and it is expected to overcome tolerability limitations of first-generation, single target epigenetic modulators.

"JBI-802 is the lead product candidate from our TIBEO (Therapeutic Index and Brain Exposure Optimization) Discovery Engine. It is our unique approach of structure-based drug design to generate novel pharmacophores with improved target product profile compared to existing agents. The Orphan Drug Designations (ODD) were supported by several relevant preclinical models. In SCLC, JBI-802 showed unique activity not just in normal neuroendocrine models but also in the 'variant' models driven by MYC amplification. This data also supports the ongoing Ph I/II clinical trial in neuroendocrine tumor patients. In AML the activity was uniquely seen in models of erythroleukemia, a subset of leukemia, with a unique erythroid phenotype and a very high unmet need based on its aggressive nature and limited therapy. This designation and emerging clinical data from the ongoing fist-in-human JBI-802 study will now underpin expansion of our clinical activities in thrombocythemia, leukemia and other erythroid tumors like MPN", **said Syed Kazmi, Chief Executive Officer, Jubilant Therapeutics Inc**.

The US FDA's Office of Orphan Products Development (OOPD) grants orphan designation status to a drug that is intended to treat a rare disease or condition that affects fewer than 200,000 persons in the United States.

About JBI-802

JBI-802 is an oral, potent and selective dual inhibitor of two epigenetic targets of the CoREST complex: LSD1 and HDAC6. It targets stem cell modulation by inhibiting LSD1 and modulates immune suppression with isoform selective HDAC6 inhibition. Preclinical research has demonstrated its synergistic anti-tumor activity, which is superior vs. either target alone inhibitors and has a favorable safety profile with no significant safety concerns or accumulation. It is being clinically evaluated in multiple neuroendocrine tumors including SCLC, with a goal to expand in to hematological cancers such as acute myelogenous leukemia, essential thrombocythemia, and other myeloproliferative cancers. Positive clinical data was recently reported for bomedemstat, a LSD1 only inhibitor, in essential thrombocythemia, thereby establishing a pivotal role of epigenetic modulators in hematological malignancies.

About Jubilant Therapeutics Inc.
Jubilant Therapeutics Inc. is a clinical stage biopharmaceutical company developing precision oral medicines with enhanced therapeutic index to address unmet medical needs in oncology and autoimmune diseases for genetically defined patients. Its advanced structure based discovery engine, TIBEO (Therapeutic Index and Brain Exposure Optimization), has been validated through successful partnerships including with Blueprint Medicines for a brain penetrant EGFR Exon-20 program. The Company's pipeline, consists of a first in class dual epigenetic modifier, JBI-802, currently in a Phase I/II clinical trial in multiple tumors, a novel brain-penetrant modulator of PRMT5 for which an IND has been accepted, brain penetrant and gut restrictive PDL1 inhibitors, as well as PAD4 inhibitors for oncology and inflammatory indications. The Company is headquartered in Bedminster, New Jersey and guided by globally renowned scientific advisors.

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