

Press Release

Jubilant Therapeutics Inc. announces First Patient Dosing in Global Clinical Trials for JBI-802, a COREST Inhibitor and JBI-778, a PRMT5 Inhibitor

- JBI-802 is a first-in-class, orally administered, inhibitor of CoREST complex
- JBI-778 is a potential best-in-class, orally administered, brain penetrant inhibitor of PRMT5

Yardley, Pennsylvania, Oct 25, 2024 – Jubilant Therapeutics Inc., a biopharmaceutical company advancing small molecule precision therapeutics to address unmet medical needs in oncology and autoimmune diseases today announced the dosing of first patients in global clinical trials involving two pipeline programs: Phase I/II clinical trial of JBI-802 in heme-oncology and Phase I clinical trial for JBI-778 in solid tumors.

"We are excited to take this significant step forward in our mission to transform the lives of patients through the development of easy to administer precision oral medicines with enhanced safety and therapeutic efficacy," said Hari S Bhartia, Chairman, Jubilant Therapeutics Inc.

JBI-802 is a first-in-class, orally administered, small-molecule dual inhibitor of LSD1 (Lysine-specific histone demethylase 1A) and HDAC6 (Histone deacetylase 6) within the CoREST (Co-repressor of Repressor Element-1 Silencing Transcription) complex. In the earlier Phase I study conducted in advanced solid tumor patients, JBI-802 showed a dose-proportional increase in exposure across cohorts and a strong correlation between exposure and the on-target effect of platelet decrease. There were no reports of Dysgeusia and Anemia, typical adverse events seen with LSD1only inhibitors. The Phase I trial also showed anti-tumor activity in Non-Small Cell Lung Cancer (NSCLC) patients including a confirmed partial response. Overall, the study results provided human proof-of-principle for expanding the development of JBI-802 in Essential Thrombocythemia and Myelodysplastic Syndrome/Myeloproliferative Neoplasms (MDS/MPN) with thrombocytosis.

Essential Thrombocythemia is a chronic disease of excessive platelets with over 100,000 patients in the United States for whom the primary treatment is hydroxyurea, a therapy that poses sever limitations for patients in terms of both safety and efficacy.

The second clinical trial is to assess both safety and the recommended Phase II dose for JBI-778, an oral brain-penetrant inhibitor of PRMT5 (Protein arginine N-methyltransferase 5) in mEGFR Tyrosine Kinase Inhibitor (TKI) resistant NSCLC, IDH+ high-grade glioma (HGG) and Adenoid Cystic Carcinoma (ACC).

PRMT5, although a proven pathway for multiple cancers, has produced mixed results in terms of drug development due to safety concerns surrounding SAM competitive approach to PRMT5 inhibition and patient segment limitations of MTAP null tumor-focused approach PRMT5 inhibition. JBI-778 is a unique substrate competitive brain penetrant PRMT5 inhibitor that has shown no adverse effects in preclinical setting and can address both MTAP null and wild type tumors as well as brain tumors, catering to larger patient segment including those with brain metastases.



"The two most advanced novel drug candidates at Jubilant Therapeutics Inc. were discovered inhouse using 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 therapeutic index compared to existing agents. We are excited to advance both JBI-802 and JBI-778 in genetically-defined subsets of patients with select hematological and solid tumor indications with high unmet medical needs. Initial clinical data are expected to read out in 2025", said Syed Kazmi, Chief Executive officer, Jubilant Therapeutics Inc.

About JBI-802

JBI-802 is novel, 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 compared to either target alone and with a favorable safety profile. JBI-802 is under evaluation in both hematological cancers such as acute myeloid leukemia, myelodysplastic syndrome and other myeloproliferative cancers as well as solid tumors, such as non-small cell lung cancer and small cell lung cancer.

About JBI-778

JBI-778 is novel, oral, potent and brain penetrant inhibitor of PRMT5. JBI-778 targets the substrate site and stabilizes SAM bound to PRMT5, providing high biological selectivity and has shown a superior safety profile as seen in animals. Preclinical research has demonstrated significant activity in Tyrokinase-Inhibitor resistant cell lines, brain tumor and NSCLC. JBI-778 is under evaluation in solid tumors such as NSCLC, High Grade Glioma and Adenoid Cystic Carcinoma.

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. The Company's clinical pipeline consists of a first in class dual CoREST modifier, JBI-802, currently in a Phase I/II clinical trial in multiple tumors and a novel brain-penetrant modulator of PRMT5, currently in Phase I clinical trial. Additional pre-clinical programs include brain penetrant and gut restrictive PDL1 inhibitors, as well as PAD4 inhibitors for oncology and inflammatory indications. The Company is headquartered in Pennsylvania and guided by globally renowned scientific advisors. For more information, please visit www.jubilanttx.com or follow us on Twitter @JubilantTx and LinkedIn.

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