



Jubilant Therapeutics Inc. announces US FDA clearance of IND for JBI-778, an Oral, Brain Penetrant and Selective PRMT5 Inhibitor, for treatment of solid tumors with brain metastases and primary brain tumors

Bedminster, New Jersey, USA – August 03, 2022 – Jubilant Therapeutics Inc., a biopharmaceutical Company advancing small molecule precision therapeutics to address unmet medical needs in oncology and autoimmune diseases, today announced U.S. Food and Drug Administration (US FDA) clearance of the Investigational New Drug application (IND) for JBI-778, an oral, brain penetrant and selective protein arginine methyl transferase 5 (PRMT5) inhibitor, for the treatment of solid tumors with brain metastases and primary brain tumors including high-grade glioma.

The Phase I/II trial is an open-label, two-part dose escalation and expansion study designed to define the safety profile, pharmacokinetics, optimal dosing and preliminary activity of JBI-778. The study population in the dose escalation phase will include patients with stable brain metastasis whose disease has failed prior standard therapy. Expansion cohorts will include patients with active brain metastases and high-grade gliomas.

Hari S Bhartia, Chairman, Jubilant Therapeutics Inc. shared on the announcement, “JBI-778 will be our second, highly selective oral drug candidate to enter clinical development following JBI-802. These two programs, along with several others partnered or in preclinical development, highlight Jubilant Therapeutics’ proven discovery engine and structure-based drug discovery expertise.”

Syed Kazmi, Chief Executive Officer, Jubilant Therapeutics Inc. said, “JBI-778 was engineered by our drug discovery team to be a PRMT5 substrate-competitive and brain penetrant drug candidate to address primary brain tumors and brain metastases which currently have limited treatment options. The incidence of brain metastasis is increasing due to improved therapies, increased imaging of neurologically asymptomatic patients and patients living longer. Our team has developed a unique capability to optimize brain penetration for precision oncology therapeutics. In addition to JBI-778, we are also advancing an oral brain penetrant PDL1 inhibitor, JBI 2174, which is on the IND-track to potentially treat primary CNS cancers among others.”

About JBI-778

JBI-778 is a potent and selective brain penetrant inhibitor of protein arginine methyl transferase 5 (PRMT5), which is overexpressed in many cancers. JBI-778 is in development for the treatment of patients with advanced cancer with brain metastasis, and patients with high-grade glioma all of whom have limited treatment options. It has a unique mechanism of action compared to existing PRMT5 inhibitors by being substrate-competitive and S-adenosylmethoinine (SAM) cooperative, combined with a high brain exposure that enables targeting of both primary brain tumors and CNS metastasis. The substrate competitive profile appears to provide enhanced selectivity in the biological system by not interfering with the functions of SAM and shows a good tolerability profile in toxicological studies.



About Jubilant Therapeutics Inc.

Jubilant Therapeutics Inc. is a clinical stage precision therapeutics Company advancing potent and selective small molecule modulators to address unmet medical needs in oncology and autoimmune diseases. Its advanced discovery engine integrates structure-based design and computational algorithms to discover and develop novel, precision therapeutics against both first-in-class and validated but intractable targets in genetically defined patient populations. The Company's advanced pipeline consists of a first in class dual epigenetic modifier, JBI-802, currently in a Phase I/II clinical trial to treat solid tumors, a novel brain-penetrant modulator of PRMT5 for which an IND has been accepted, a brain penetrant PDL1 inhibitor, as well as PAD4 inhibitors for oncology and inflammatory indications. The Company is headquartered in Bedminster, New Jersey and guided by globally renowned key opinion leaders and scientific advisory board members. For more: www.jubilanttx.com
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