

## Press Release



### **Jubilant Therapeutics Inc. receives Orphan Drug Designation for the PRMT5 inhibitor - JBI-778 for the treatment of Glioblastoma Multiforme (GBM)**

**Bedminster, New Jersey, United States: February 13, 2023** – [Jubilant Therapeutics Inc.](https://www.jubilanttherapeutics.com), 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 (ODD) for JBI-778 for the treatment of Glioblastoma Multiforme (GBM). JBI-778 is an oral, brain penetrant and substrate-competitive protein arginine methyl transferase 5 (PRMT5) inhibitor for the treatment of tumors with brain metastases and primary brain tumors including high-grade glioma.

JBI-778 is the Company's second drug candidate to receive ODD along with JBI-802, which received ODD for the treatment of small cell lung cancer (SCLC) and acute myeloid leukemia (AML).

*"JBI-778 is our highly differentiated, substrate competitive PRMT5 inhibitor in development for both systemic and brain tumors with certain genetic signatures. It is the second clinical stage oral drug candidate that has emerged from the TIBEO discovery engine,"* said **Syed Kazmi, Chief Executive Officer, Jubilant Therapeutics Inc.** He further added, *"JBI-778's differentiated profile compared to other PRMT5 inhibitors in development addresses safety issues of first-generation PRMT5 inhibitors. It also enables a balanced exposure in brain and plasma - for the treatment of GBM and brain metastases along with the systemic disease. We have identified a novel synthetic lethality approach for prospective patient selection in target indications. JBI-778 has already been cleared by the US FDA to initiate clinical trials, which we anticipate to start during the second half of 2023."*

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-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 advanced cancers with specific genetic mutations, 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-adenosylmethionine (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. JBI-778 has a unique opportunity to address the unmet needs of patients with an enhanced therapeutic index.

#### **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 coREST 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.

For more: [www.jubilanttx.com](http://www.jubilanttx.com), Twitter @JubilantTx, LinkedIn

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