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CRISM Therapeutics Corporation
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("CRISM", "CRISM Therapeutics" or the "Company")

Submission of Orphan Drug Designation Application to the FDA for Irinotecan-ChemoSeed™ in Glioblastoma

CRISM Therapeutics Corporation (AIM: CRTX), a UK clinical-stage drug delivery company focused on the localised and sustained delivery of chemotherapy drugs, is pleased to announce that it has submitted an application to the US Food and Drug Administration ("FDA") seeking Orphan Drug Designation ("ODD") for its lead programme, irinotecan-ChemoSeed™, for the treatment of glioblastoma.

Glioblastoma is a rare and aggressive form of brain cancer with extremely limited treatment options and poor survival outcomes. The submission of this application marks another step in CRISM's strategy to advance irinotecan-ChemoSeed as a localised therapy for patients undergoing surgical resection of glioblastoma.

The FDA's Orphan Drug Designation programme is designed to encourage the development of medicines for rare diseases affecting fewer than 200,000 patients in the United States. If granted, ODD status would provide CRISM with potential benefits including: seven years of US market exclusivity following approval; tax credits for clinical research costs; waiver of FDA application fees; and enhanced regulatory support and guidance throughout development.

CRISM has already been awarded an Innovation Passport for irinotecan-ChemoSeed under the UK's Innovative Licensing and Access Pathway ("ILAP"), recognising the therapy's potential to address the critical unmet need in glioblastoma. ILAP provides access to enhanced regulatory collaboration and accelerated assessment pathways in the UK. In addition, CRISM is exploring participation in Project Orbis, the international regulatory collaboration led by the FDA to speed up access to promising cancer treatments across major global markets.

The submission of the ODD application follows recent regulatory and ethical approvals in the UK for CRISM's registration-grade Phase 2 clinical trial of irinotecan-ChemoSeed in surgically resectable glioblastoma, which is expected to begin dosing of patients in Q1 2026.

The Company's ODD application forms a key part of its global regulatory strategy designed to unlock accelerated development and early market access opportunities in both the US and UK.

Professor Chris McConville, **Chief Scientific Officer of CRISM Therapeutics, commented:**
"Submitting our Orphan Drug Designation application to the FDA represents another important step in CRISM's strategy. The US is the largest pharmaceutical market globally, and we believe this application will add further appeal to potential partners as we start to produce data from our Phase 2 clinical trial next year. Together with our Innovation Passport under ILAP and our potential alignment with Project Orbis, this application reflects a global regulatory strategy to bring ChemoSeed to patients faster, starting with glioblastoma."

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About CRISM Therapeutics Corporation

CRISM Therapeutics Corporation has developed an innovative drug delivery technology to improve the clinical performance of cancer treatments for solid tumours through the local delivery of chemotherapy drugs.

ChemoSeed, CRISM's lead product, can be implanted directly into the tumour or the resection margin following the removal of a tumour. This directs that therapeutic concentrations of chemotherapy drugs reach the deep-seated tumour tissue or cover the entire resection margin. In the case of treating glioblastoma, ChemoSeeds can be implanted during surgery thereby bypassing the blood brain barrier, which prevents other treatments from being able to reach the tumour and be effective.

CRISM will initiate its registration-grade Phase 2 clinical trial of irinotecan-ChemoSeed™ in patients with surgically resectable glioblastoma in Q1 2026.

For more information please visit: https://www.crismtherapeutics.com/

The Company's LEI is 213800XFW6MKVCHHPW88.

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