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CRISM Therapeutics Corporation
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The information contained within this announcement is deemed to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014, as incorporated into UK law by the European Union (Withdrawal) Act 2018. Upon the publication of this announcement, this inside information is now considered to be in the public domain.

1 September 2025

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

Regulatory and Ethical Approval for Registration-Grade Phase 2 Trial of 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, today confirms that it has received both regulatory approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and favourable ethical opinion from a UK Research Ethics Committee (REC) to initiate its open label registration-grade Phase 2 clinical trial of irinotecan-ChemoSeed™ in patients with surgically resectable glioblastoma.

This dual approval marks a significant operational milestone and clears the Company to commence the trial across selected UK clinical sites in Q1 2026, as planned.

The approved study, titled *"An Open-label Phase 2 Safety and Efficacy Trial of Irinotecan ChemoSeed Administered Directly into the Resection Margin in Patients with Surgically Resectable Glioblastoma"*, is designed to assess the safety, tolerability, and efficacy of irinotecan-ChemoSeed, CRISM's proprietary, biodegradable implant technology delivering sustained-release irinotecan directly into the tumour resection margin following surgical removal of the glioblastoma tumour. The trial has been designed in alignment with regulatory expectations for future marketing authorisation submissions.

Key Highlights:

- Regulatory (MHRA) and Ethical (REC) approval received
- Trial confirmed to initiate in Q1 2026 at leading UK neuro-oncology centres
- Open-label format supports interim analysis, reporting of early results and potential for expedited regulatory approval
- ChemoSeed platform targets local recurrence with sustained, localised chemotherapy
- Registration-grade Phase 2 design supports pathway to marketing authorisation and commercialisation.

Professor Chris McConville, **Chief Scientific Officer of CRISM Therapeutics, commented:**
"We are delighted to have received both regulatory and ethical approval to begin our Phase 2 study. This is a critical inflection point for CRISM as we prepare to clinically validate our ChemoSeed platform in patients with glioblastoma, an area of immense unmet need. With these approvals secured, we are now in a position to move rapidly into trial activation and first patient dosing. We believe the data from this study could serve as a foundation for future regulatory submissions and commercial advancement."

Professor Garth Cruickshank, Emeritus Professor of Neurosurgery at the University of Birmingham, and scientific advisor to CRISM, added:"*This is a very exciting development in the drive to treat one of the most complex cancers. The technical innovation of putting the tumour killing drug irinotecan into the tumour site at*

the time of the surgery offers the very best chance to hit the tumour when it is at its smallest. The release process at least covers the time until radiotherapy and or temozolomide are introduced providing a much more powerful sustained antitumour assault. The local deposition of drug already known to attack glioblastoma, avoids systemic side effects, so no additional problems for patients. This approach safely enables high antitumour concentrations without evidence of associated neurotoxicity. Furthermore, the spectrum of patients likely to respond is greater than for any gene targeted or existing immunotherapy. Patients and surgeons will surely welcome such a pragmatic and truly practical step forward in treatment for glioblastoma."

CRISM is working with its CRO, Aixial Group, to activate the first site in the UK and start to enrol patients in Q1 of 2026. Further details of the trial are included in the Submission of Clinical Trial Authorisation application to the MHRA announcement on 01 July 2025.

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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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