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31 March 2025



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

Clinical Trial Update

CRISM Therapeutics Corporation (AIM: CRTX) the innovative UK drug delivery company focused on the localised delivery of chemotherapy drugs, provides a positive update regarding its clinical trial authorisation ("CTA") application to evaluate irinotecan ChemoSeed ("ChemoSeed") in patients with high grade glioma. CRISM has been working with the Medicines and Healthcare products Regulatory Agency ("MHRA") to finalise the design of the first in-human trial of ChemoSeed and is pleased to confirm it has received positive written scientific advice from the MHRA on the development, clinical trial programme and potential Market Authorisation Application for the commercialisation of ChemoSeed.

The written advice confirms that further preclinical toxicology studies will not be required, which will significantly reduce the cost and time of the development work. The Company had previously estimated a cost of approximately £400,000 to conduct the toxicology studies.

In addition, the MHRA agreed that there is a biological basis supporting the benefits of ChemoSeed and that more drugs and methods of delivery are needed for this disease. MHRA was supportive of CRISM's novel dose escalation study for ChemoSeed, confirming that the trial design was appropriate for a Phase 2 clinical trial. The MHRA provided recommendations to improve aspects of the clinical trial to make it more suited to achieving potential market authorisation. The Company is now progressing these recommendations, with support and advice from its contract research organisation, Aixial, and its medical advisers. The Company expects to finalise its CTA application for submission in H1 2025 and to begin clinical trials of ChemoSeed in Q4 2025, subject to MHRA and other external regulatory organisations meeting expected review times.

The Company has also appointed Ryan LLC, which has a specialisation in accessing grant funding, to assist CRISM secure grant funding specifically for this clinical trial. Ryan has an excellent track record in achieving successful grant applications and has already identified opportunities for which ChemoSeed is likely to qualify.

Commenting on the MHRA guidance, CRISM CEO Andrew Webb said: *We are pleased that the MHRA has confirmed that our trial design is appropriate for a Phase 2 clinical trial in patients with high grade glioma without the need for further toxicology studies. The MHRA confirmed the need for more drugs and methods of delivery in this disease where there remains a significant lack of treatment options. The written advice from the MHRA is well received, and we are working through the recommendations on ways to improve the trial design with our medical advisers and Aixial ahead of submitting our CTA. Additionally, we look forward to working with Ryan in order to secure grant funding for this trial.*

Dr. Valentina Zhukova-Harrill, Chief Medical Officer at Aixial, added: *We are proud to see Aixial's expertise playing a pivotal role in advancing the clinical strategy for ChemoSeed. This collaboration marks a critical step forward in addressing a significant unmet medical need, and we look forward to contributing to the upcoming Phase 2 study.*

-Ends-

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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 high-grade glioma, 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 is expects to submit a clinical trial application for ChemoSeed in high-grade glioma in H2 2025.

For more information please visit: <https://www.crisimtherapeutics.com/>

For more information about Aixial, please visit: <https://www.aixialgroup.com/>

For more information about Ryan, please visit: <https://ryan.com/europe/practice-areas/innovation-funding/>

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