

NEWS RELEASE

## Akamis Bio Highlights Data Showing Potential of its Adenovirus Vector Technology in Combination with Radiation to Treat Advanced Rectal Cancer

10/3/2023

I.V.-Delivered Vector Core to Akamis Bio T-SIGn® Therapeutics; Phase 1 Study Data to be Presented at the 2023 American Society for Radiation Oncology (ASTRO) Annual Meeting

CAMBRIDGE, Mass. & OXFORD, England--(BUSINESS WIRE)-- Akamis Bio, a clinical-stage oncology company using a proprietary Tumor-Specific Immuno-Gene (T-SIGn®) therapy platform to deliver novel immunotherapeutic proteins, biomolecules and transgene combinations to treat solid tumors, shared data today from a Phase 1 study of its adenovirus vector technology in combination with radiotherapy that showed improved response rates relative to expectations for radiation alone in patients with locally advanced rectal cancer.

The CEDAR study, sponsored by Cancer Research UK and Akamis Bio, found that Enadenotucirev (EnAd), a tumor selective, I.V.-administered oncolytic adenovirus (on which T-SIGn therapeutics are based), in combination with chemoradiotherapy, showed significantly higher response rates by MRI assessed tumor regression grade (mrTRG - 41.6%) and pCR/cCR (41.6%) than expected rates (~20%) for standard chemoradiation. In the two dose schedules with administration pre-CRT and post-CRT, mrTRG of 1 or 2 was observed in 5 out of 10 (50%) of the treated patients. Further, hexon staining of patient samples suggested EnAd localization in both the primary tumor and in metastatic sites. The combined therapy was well tolerated with an acceptable safety profile.

"These data are compelling given the higher-than-expected pCR/cCR rate, and the low adverse event rate highlights the ability to deliver the oncolytic virus concurrently with chemoradiation. This demonstrates the potential of a more reliable systemic administration compared to intratumoral injection," said Dr. Maria A. Hawkins, Chair of Radiation Oncology at University College in London and the principal investigator of the study. "We are further

encouraged by the potential of this systemic treatment to reach micro-metastatic cancer sites and we believe this approach should be pursued in additional studies as we look to improve the efficacy of chemoradiation for a wide range of solid tumors."

EnAd is a group B adenovirus designed for the systemic treatment of metastatic or advanced epithelial tumors. It is a precursor to Akamis Bio's clinical-stage Tumor-Specific Immuno-Gene (T-SIGn®) therapeutics platform, which selectively delivers multiple transgene combinations, such as cytokines, chemokines, and antibodies for expression by tumor cells.

The primary objective of the Phase 1 CEDAR study was to determine the optimal dose and frequency that EnAd can be administered with chemoradiation for rectal cancer, with secondary objectives focused on demonstrating the ability to deliver EnAd with chemoradiation and to measure the local response rate to combined therapy compared to pre-treatment status.

"These results are very encouraging as they demonstrate the acceptable safety profile and potent efficacy achievable with our first-generation adenovirus vector, EnAd," said Dr. Oliver Rosen, Akamis Bio's Chief Medical Officer. "As our T-SIGn therapeutics combine the EnAd backbone with an ability to selectively deliver transgenes to solid tumors, we look forward to building upon the clinical insights from the CEDAR study and demonstrating the potential of T-SIGn in conjunction with chemoradiation to positively impact the lives of patients living with rectal cancer and other solid tumors."

Data from the CEDAR study will be presented today at the 2023 American Society for Radiation Oncology Annual Meeting in San Diego, CA. Details of the presentation are as follows:

**Poster Presentation Title:** A Phase 1 Trial of the Safety, Tolerability, and Biological Effects of Intravenous Enadenotucirev (EnAd), a Novel Oncolytic Virus, in Combination with Chemoradiotherapy in Locally Advanced Rectal Cancer (CEDAR)

**Poster Session:** Gastrointestinal Cancer and Sarcoma

**Date and Time:** October 3 at 12:45 - 2:00 p.m. ET

**Presenter:** Dr Séan M. O'Cathail, MSc DPhil MRCPI FRCP FRCR, Senior Research Fellow, School of Cancer Sciences, University of Glasgow

## About T-SIGn

Akamis Bio's T-SIGn® therapeutics are based on a replication competent, chimeric group B adenovirus backbone which has been adapted via directed evolution to home specifically to both primary and metastatic epithelial-derived solid tumor tissue following intravenous delivery. Once at the tumor site, T-SIGn therapeutics can drive the

intratumoral expression of multiple transgene payloads, turning solid tumor cells into “drug factories” while leaving healthy tissue unaltered and intact. The intratumoral expression of immunologically active biomolecules and therapeutic proteins can result in the remodeling of the solid tumor microenvironment, triggering robust antitumor immune responses. T-SIGn therapeutics have the potential to be used in the monotherapy setting, as well as in combination with other immuno-oncology agents to target the key mechanisms that tumors use to evade the immune system.

## About Akamis Bio

Akamis Bio is a clinical-stage oncology company using a proprietary Tumor-Specific Immuno-Gene Therapy (T-SIGn®) platform to deliver novel immunotherapeutic proteins, biomolecules and transgene combinations to treat solid tumors. The company is developing a portfolio of solid tumor-targeted T-SIGn therapeutics which aim to enable a patient’s own immune system to recognize, attack, and clear their cancer. Akamis Bio has a growing pipeline of T-SIGn therapeutics anchored by its lead clinical-stage program, NG-350A (an immuno-stimulatory tumor gene therapy driving intratumoral expression of a CD40 agonist monoclonal antibody) being investigated in ongoing Phase 1 clinical studies in patients with metastatic or advanced epithelial tumors. In addition to internal pipeline development efforts, Akamis Bio has a number of T-SIGn platform-focused collaborations with leaders in the immuno-oncology field including BMS, Merck, and the Parker Institute for Cancer Immunotherapy (PICI). To learn more, please visit [www.akamisbio.com](http://www.akamisbio.com).

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