



ASX Announcement

Race appoints clinical and FDA regulatory strategy advisor

Friday 18th September - Race Oncology is pleased to announce that it has appointed the clinical and regulatory strategy advisor, CCS Associates (CCSA, California, USA) to advise on development options for Bisantrone as an inhibitor of the Fat mass and obesity-associated protein (FTO).

Recent preclinical studies by researchers at the City of Hope Hospital (ASX Announcement: 29 June 2020) has identified Bisantrone to be a highly potent FTO inhibitor at low, non-toxic concentrations¹. The FTO protein has been found to be a key driver of cancer progression in a wide range of cancers including breast, lung, kidney, pancreatic, melanoma, glioblastoma, cervical, ovarian, liver, gastric, as well as many leukaemias². This independent pre-clinical work has repositioned Bisantrone from a traditional chemotherapeutic agent to a targeted agent of wide possible utility across multiple cancer sub-types.

FTO is a key strategic opportunity for Race. The Race team will work closely with CCSA to identify the optimal means of translating this compelling pre-clinical research into clinical practice.

Race's CSO, Dr Daniel Tillett, commented, "The identification of FTO as a key driver of oncogenic RNA epigenetic change is one of the most interesting cancer discoveries of the last decade. We are excited by the potential of Bisantrone to specifically target FTO and look forward to working closely with CCSA on how to best unlock this opportunity."

In tandem with this work, CCSA will liaise with Race's current regulatory advisor to review Race's Investigational New Drug applications to be submitted to the US Food and Drug Administration (FDA), in line with our existing 5-path strategy. Race is seeking FDA IND approval to investigate Bisantrone for the treatment of Paediatric Acute Myeloid Leukemia (AML) and Adult AML Measurable Residual Disease (MRD). This review is not expected to delay Race's IND process which continues to be advanced by our team.

Race's CEO, Phillip Lynch commented, "CCSA has over 35 years' experience in providing integrated regulatory advice services and has long term relationships with the National Cancer Institute and FDA regulatory divisions. Their highly capable team and FDA insights around approval processes will help to ensure our clinical plans remain on track and are suitably optimised to drive commercial value for Bisantrone."

-ENDS-

¹ Su, R., Dong, L., Li, Y., Gao, M., Han, L., Wunderlich, M., et al. (2020). Targeting FTO Suppresses Cancer Stem Cell Maintenance and Immune Evasion. *Cancer Cell*, 38(1), 79–96.e11.

² Zhao, W., Qi, X., Liu, L., Ma, S., Liu, J., & Wu, J. (2020). Epigenetic Regulation of m6A Modifications in Human Cancer. *Molecular Therapy - Nucleic Acids*, 19, 405–412.



About Race Oncology (RAC: ASX)

Race Oncology (RAC) is a drug development biotech with a Phase II/III cancer drug called Bisantrene. RAC has compelling clinical data for Bisantrene in acute myeloid leukaemia (AML) as well as breast and ovarian cancer. RAC is pursuing an exciting '5-Path' clinical development strategy that involves parallel Israeli, US and Australian clinical trials in AML, breast and ovarian beginning in 2020.

About CCS Associates

Established by Dr. Caroline C. Sigman in 1985, CCSA is a scientific research consulting firm specializing in technical and support services for clinical research, design strategies for preclinical studies, chemical information sciences, and research and development support for translational science. We have been instrumental in bioinformatics, developing master databases of chemical information, and working with government and private industry clients to harness nonclinical and clinical data in support of pharmaceutical development. The professional staff of CCSA includes PhD-, MD-, MS-, MA-, BS-, and BA-level scientists with academic backgrounds and professional certifications in clinical research, pediatrics, organic chemistry, biochemistry, anatomy, physiology, genetics, carcinogenesis, pharmacology, immunology, toxicology, cell and molecular biology, biostatistics, and computer science.

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