Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

16 December 2019

Communiqué

This Communiqué covers matters considered at the 18th video conference of the Gene Technology Technical Advisory Committee (16 December 2019)[1]

The Gene Technology Technical Advisory Committee (GTTAC) is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice to the Gene Technology Regulator (the Regulator) and the Legislative and Governance Forum on Gene Technology.

The Regulator seeks advice from GTTAC on licence applications to work with genetically modified organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared for applications. The purpose of this Communiqué is to provide a brief overview of GTTAC's consideration of applications and RARMPs and, in accordance with the Gene Technology Regulations 2001, to publish committee resolutions given to the Regulator. The Communiqué also provides an overview of any other deliberations of the committee. It does not include information which is treated as Confidential Commercial Information in accordance with the Act.

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO

The Regulator may seek GTTAC advice on RARMPs prepared for an application for Dealings Not involving an Intentional Release (DNIR) into the environment. DNIR licences include research work with GMOs undertaken in physical containment facilities (e.g. certified by the Regulator) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 606 – Clinical Study GO-004: An International Phase 1/2 Study of GRT-C901/GRT R902, a Neoantigen Cancer Vaccine, in Combination with Immune Checkpoint Blockade for Patients with Advanced Solid Tumors

The Peter MacCallum Cancer Centre has applied for a licence to conduct an open label Phase I/II clinical trial to assess the safety, immunogenicity and early clinical efficacy of a GM vaccine platform to generate a patient-specific and tumour-specific therapy.

GTTAC noted key points in the RARMP, including that it did not identify substantive risks associated with the proposed trial. The Committee discussed the exclusion criteria, work practices and control measures proposed for the trial, and agreed the resolutions outlined below.

[1] The video conference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Perth and Melbourne.

Resolutions

- The committee agrees with the overall conclusions of the RARMP
- The committee did not identify any additional information that should be considered
- The RARMP identifies all plausible risk scenarios
- The Regulator should further consider whether tumour samples should also be treated as per GMOs
- The Regulator should clarify whether clinical staff administering checkpoint blockade are required to be trained in accordance with licence conditions

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS

For all enquiries and to obtain copies of applications or RARMPs for Dealings involving the Intentional Release (DIR) of GMOs into the environment, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au. DIR RARMPs are also available on the OGTR website.