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Immunocore’s Lead Asset Tebentafusp Gains Fast Track Designation for Metastatic Uveal Melanoma

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(Oxford, UK and Conshohocken, US, 3 April 2019) Immunocore Limited, a leading T Cell Receptor (TCR) biotechnology company, today announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its development program, the investigation of tebentafusp (IMCgp100) for the treatment of patients who are HLA-A*0201-positive with previously untreated, metastatic uveal melanoma (mUM).

The pivotal study IMCgp100-202 is a 2:1 randomized study of tebentafusp compared with Investigator's Choice (dacarbazine, ipilimumab or pembrolizumab) in HLA-A*0201 positive adult patients with previously untreated mUM. The primary endpoint is a comparison of overall survival.

“For patients with metastatic uveal melanoma, the prognosis is poor and has not meaningfully changed in decades. Our goal is to test whether tebentafusp can prolong survival for these patients.” **comments David Berman, Head of R&D of Immunocore**. “We are delighted that tebentafusp has been granted Fast Track Designation.”

The FDA's Fast Track program is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. A drug granted Fast Track Designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if relevant criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a Biologics License Application (BLA) or New Drug Application (NDA).

Tebentafusp has previously been granted orphan drug designation for uveal melanoma by the US FDA and Promising Innovative Medicine designation under UK Early Access to Medicines Scheme.