

PRESS RELEASE

Immunocore's tebentafusp demonstrates superior overall survival compared to investigator's choice in a Phase 3 clinical trial of patients with previously untreated metastatic uveal melanoma

The primary endpoint of Overall Survival favored tebentafusp with a Hazard Ratio = 0.51 (95% CI: 0.36, 0.71), $p < 0.0001$ at the first pre-planned interim analysis conducted by the independent Data Monitoring Committee

First positive Phase 3 clinical trial for any T cell receptor therapeutic and first for any bispecific in a solid tumor

Tebentafusp has the potential to be the first new therapy to improve OS in patients with metastatic uveal melanoma in 40 years

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 23 November 2020) Immunocore (the "Company"), a late-stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies designed to treat a broad range of diseases, including cancer, infectious and autoimmune, today announced that its Phase 3 IMCgp100-202 clinical trial of tebentafusp (IMCgp100) vs. investigator choice in metastatic uveal melanoma (mUM) has met the pre-defined boundaries for statistical significance of the primary endpoint of Overall Survival (OS) in its first pre-planned interim analysis conducted by the independent data monitoring committee. The OS Hazard Ratio (HR) in the intent-to-treat population favored tebentafusp, HR=0.51 (95% CI: 0.36, 0.71); $p < 0.0001$, over investigator's choice (82% pembrolizumab; 12% ipilimumab; 6% dacarbazine). Although not yet mature, the Kaplan-Meier estimates suggest a 1-year OS rate of approximately 73% vs 58%, respectively. The efficacy data confirm the promising OS observed in the phase 2 study IMCgp100-102 in previously treated mUM which will be presented next month at the ESMO Immuno-Oncology Virtual Congress 2020.

Bahija Jallal, Chief Executive Officer of Immunocore said: *"A positive survival benefit for tebentafusp represents a major step towards bringing a potential new treatment for cancer patients with a high unmet need. If approved, tebentafusp would be the first new therapy to improve overall survival in 40 years and to be specifically indicated for metastatic uveal melanoma, a disease with poor survival and where new therapies are urgently needed. We look forward to sharing these data with the medical community and Health Authorities in the near future."*

Tebentafusp is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector domain. It is engineered to specifically target gp100, a lineage antigen expressed in melanocytes and melanoma, and is the first molecule developed using Immunocore's ImmTAC technology platform designed to redirect and activate T cells to recognize and kill tumor cells. Tebentafusp has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) and has previously been granted orphan drug designation for uveal melanoma by the FDA and Promising Innovative Medicine designation under UK Early Access to Medicines Scheme.

“To our knowledge, this is the first survival benefit for any TCR therapeutic and for any bispecific in a solid tumor. The survival benefit observed in a randomized trial against checkpoint inhibitors validates our ImmTAC platform as we expand to study other cancers with high unmet need,” said David Berman, Head of R&D, “Uveal melanoma has one of the lowest tumor mutational burdens (TMB) and these results suggest our ImmTAC platform should be evaluated in tumors with low or high TMB status.”

The Phase 3 IMCgp100-202 clinical trial is designed to evaluate the OS of tebentafusp compared to investigator’s choice (either dacarbazine, ipilimumab or pembrolizumab) in patients with previously untreated mUM. 378 patients were randomized in a 2:1 ratio to either tebentafusp or investigator’s choice. Final results from IMCgp100-202 are expected to be presented at an upcoming scientific conference and to be submitted for publication in a peer-reviewed journal.

- Ends -

About Immunocore

Immunocore is a late-stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies called ImmTAX – Immune mobilizing monoclonal TCRs Against X disease – designed to treat a broad range of diseases, including cancer, infectious and autoimmune. Leveraging its proprietary, flexible, off-the-shelf ImmTAX platform, Immunocore is developing a deep pipeline in multiple therapeutic areas, including five clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs. Immunocore’s most advanced oncology therapeutic candidate, tebentafusp, has demonstrated monotherapy activity in a Phase 2 clinical trial in metastatic uveal melanoma, a cancer that has historically proven to be insensitive to other immunotherapies, and is currently being studied in an ongoing Phase 3 clinical trial. Collaboration partners include Genentech, GlaxoSmithKline, AstraZeneca, Eli Lilly and Company, and the Bill and Melinda Gates Foundation. Immunocore is headquartered at Milton Park, Oxfordshire, U.K., with offices in Conshohocken, Pennsylvania and Rockville, Maryland in the United States. For more information, please visit www.immunocore.com.

About ImmTAC® Molecules

Immunocore’s proprietary T cell receptor (TCR) technology generates a novel class of bispecific biologics called ImmTAC (Immune mobilising monoclonal TCRs Against Cancer) molecules that are designed to redirect the immune system to recognise and kill cancerous cells. ImmTAC molecules are soluble TCRs engineered to recognise intracellular cancer antigens with ultra-high affinity and selectively kill these cancer cells via an anti-CD3 immune-activating effector function. Based on the demonstrated mechanism of T cell infiltration into human tumours, the ImmTAC mechanism of action holds the potential to treat hematologic and solid tumours, regardless of mutational burden or immune infiltration, including immune “cold” low mutation rate tumours.

About Tebentafusp

Tebentafusp is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector function. Tebentafusp specifically targets gp100, a lineage antigen expressed in melanocytes and melanoma, and is the first molecule developed using Immunocore’s ImmTAC technology platform designed to redirect and activate T cells to recognise and kill tumour cells. Tebentafusp has been granted Fast Track Designation and orphan drug designation by the FDA in the United States and Promising

Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for metastatic uveal melanoma. For more information about enrolling tebentafusp clinical trials for metastatic uveal melanoma, please visit ClinicalTrials.gov (NCT03070392).

About Uveal Melanoma

Uveal melanoma is a rare and aggressive form of melanoma, which affects the eye. Metastatic uveal melanoma typically has a poor prognosis and has no currently accepted optimal management or treatment.[1],[2] Although it is the most common primary intraocular malignancy in adults, the diagnosis is rare, with approximately 8,000 new patients diagnosed globally each year (1,600-2,000 cases/year in the US).[3],[4],[5] Up to 50% of people with uveal melanoma will eventually develop metastatic disease.1,2 When the cancer spreads beyond the eye, only approximately half of patients will survive for one year.[6]

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