



Immunocore presents phase 3 data comparing tebentafusp with investigator's choice in the clinical trial plenary session at the American Association for Cancer Research 2021 Annual Meeting

April 12, 2021

PRESS RELEASE

Immunocore presents phase 3 data comparing tebentafusp with investigator's choice in the clinical trial plenary session at the American Association for Cancer Research 2021 Annual Meeting

Tebentafusp is the first investigational therapy to improve Overall Survival (OS) in patients with metastatic uveal melanoma

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

(OXFORDSHIRE, England & CONSHOHOCKEN, Penn. & ROCKVILLE, Md., US, 12 April 2021) [Immunocore](#) (Nasdaq: IMCR), a late-stage biotechnology company pioneering the development of a novel class of T cell receptor (TCR) bispecific immunotherapies designed to treat a broad range of diseases, including cancer, infectious and autoimmune disease, presented data from a phase 3 randomized trial comparing tebentafusp (IMCgp100) with investigator's choice in first-line metastatic uveal melanoma (mUM) in the clinical trial plenary session at the American Association for Cancer Research (AACR) Annual Meeting 2021.

Tebentafusp demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) as a first-line treatment in mUM. The OS Hazard Ratio (HR) in the intent-to-treat population favored tebentafusp, HR=0.51 (95% CI: 0.37, 0.71); $p < 0.0001$, over investigator's choice (82% pembrolizumab; 12% ipilimumab; 6% dacarbazine). Treatment-related adverse events were manageable and consistent with the proposed mechanism.

"This is the first investigational therapy to demonstrate improved OS in metastatic uveal melanoma," said Bahija Jallal, Chief Executive Officer of Immunocore. "We believe these data demonstrate that tebentafusp has the potential to provide a meaningful difference in the treatment of metastatic uveal melanoma, a highly aggressive disease for which there is no effective standard of care."

In a separate oral presentation on Monday April 12, Marcus O. Butler shared an analysis of previously treated uveal melanoma patients who had prolonged survival.

Two posters from the phase 2 IMCgp100-102 study are also available for on-demand viewing at the [AACR website](#). These analyses investigated the proposed mechanism of action (MoA), including inducing an increase in cytokines and T cell trafficking into the tumor.

Tebentafusp has been granted Breakthrough Therapy Designation, Fast Track designation and orphan drug designation by the U.S. Food and Drug Administration (FDA) and Promising Innovative Medicine (PIM) designation under the UK Early Access to Medicines Scheme for metastatic uveal melanoma. Immunocore will be working with the FDA to complete submission of a BLA for tebentafusp in the third quarter of 2021.

The Company will host a conference call for industry, health and investment professionals on Tuesday, April 13th at 7:30 am ET to discuss the phase 3 IMCgp100-202 trial. The webcast can be accessed directly through this [link](#). A replay of the webcast will be made available shortly after the conclusion of the call and archived on the Investor Relations section of the Company's website for at least 90 days.

PLENARY AND ORAL PRESENTATIONS

Title: *Phase 3 randomized trial comparing tebentafusp with investigator's choice in first line metastatic uveal melanoma*

- **Date and Time:** Plenary session presentation (CT002), Saturday April 10th at 11:30am - 1:30pm ET
- **Presenter:** Jessica C. Hassel (PI), University Hospital Heidelberg, Heidelberg, Germany
- **Abstract #:** [5342](#)
- **Session Title:** Phase III Clinical Trials

Title: *Kinetics of radiographic response for tebentafusp (tebe) in previously treated metastatic uveal melanoma (mUM) patients (pts) achieving prolonged survival*

- **Date and Time:** Oral presentation (CT038), Monday April 12th at 1:30pm – 3:15pm ET
- **Presenter:** Marcus O. Butler (PI), Princess Margaret Cancer Centre, Toronto, ON, Canada
- **Abstract #:** [5338](#)
- **Session Title:** Disease-Oriented Innovative Clinical Research and Trials

POSTER PRESENTATIONS

Title: *Tebentafusp induces transient systemic inflammation and modifies the micro-environment to sensitize uveal melanoma tumors to cytotoxic CD8 cells*

- **Poster #:** [517](#)
- **Presenter:** Marcus O. Butler (PI)

Title: *Uveal melanoma study patients with low CD163:CD3 ratio in tumor biopsy and low serum IL-6 showed enhanced tumor shrinkage (TS) and*

overall survival (OS) on tebentafusp

- **Poster #:** [1673](#)
- **Presenter:** Jessica Hassel (PI)

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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 an overall survival benefit in a randomized Phase 3 clinical trial in metastatic uveal melanoma, a cancer that has historically proven to be insensitive to other immunotherapies.

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 Breakthrough Therapy Designation, 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. 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 per year in the United States). Up to 50% of people with uveal melanoma will eventually develop metastatic disease. When the cancer spreads beyond the eye, only approximately half of patients will survive for one year.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but are not limited to, statements regarding the efficacy, safety and therapeutic potential of tebentafusp, the design, progress, timing, scope and results of the Company's clinical trials including IMCgp100-202, the anticipated timing of disclosure of results of clinical trials, plans for initiating future clinical trials and extension studies, the progress of the Company's development programs including tebentafusp, the potential benefit of Breakthrough Therapy Designation or Orphan Drug Designation for tebentafusp, the timing of regulatory filings including estimates regarding the planned submission a BLA for tebentafusp, the likelihood of obtaining regulatory approval of any of the Company's product candidates including tebentafusp, and the regulatory approval path for tebentafusp. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, many of which are beyond the Company's control. These risks and uncertainties include, but are not limited to, the impacts of the COVID-19 pandemic on the Company's business, clinical trials and financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; and the uncertainties and timing of the regulatory approval process. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 25, 2021, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information except as required by law.

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