IMMUNOCORE

Immunocore's tebentafusp granted Breakthrough Therapy Designation for unresectable or metastatic uveal melanoma from FDA

February 19, 2021

Submission of a Biologic License Application to FDA planned for Q3 2021

OXFORDSHIRE, England and CONSHOHOCKEN, Pa. and ROCKVILLE, Md., Feb. 19, 2021 (GLOBE NEWSWIRE) -- 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, today announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to tebentafusp (IMCgp100) for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM).

Bahija Jallal, Chief Executive Officer of Immunocore, said: *"We are delighted that the FDA has granted Breakthrough Therapy Designation for tebentafusp based on the survival benefit from our Phase 3 clinical trial announced in November 2020. There is an urgent need for an approved treatment for this rare and aggressive form of melanoma and we look forward to continuing to work with regulators to bring tebentafusp to patients as quickly as possible."*

In an initial pre-planned interim analysis of a randomized Phase 3 clinical trial (IMCgp100-202) in previously untreated metastatic uveal melanoma, a cancer that has historically proven to be insensitive to other immunotherapies, tebentafusp demonstrated superior overall survival (OS) benefit as a monotherapy. The primary endpoint was achieved when 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).

The Breakthrough Therapy Designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

Tebentafusp has also been granted Fast Track Designation and orphan drug designation from the FDA for uveal melanoma and Promising Innovative Medicine designation under the UK Early Access to Medicines Scheme. Immunocore will be working with the FDA to facilitate submission of a BLA for tebentafusp. If approved, Immunocore believes tebentafusp would be the first new therapy for the treatment of metastatic uveal melanoma in 40 years.

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 results, conduct, progress and timing of the Company's development programs including tebentafusp, the potential benefit of Breakthrough Therapy Designation for tebentafusp, estimates

regarding the planned submission a BLA for 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 in the Company's final prospectus dated February 4, 2021 filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) on February 8, 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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