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FDA APPROVES IMLYGIC™ (TALIMOGENE LAHERPAREPVEC) AS FIRST ONCOLYTIC VIRAL THERAPY IN THE US

IMLYGIC Indicated for the Local Treatment of Unresectable Cutaneous, Subcutaneous and Nodal Lesions in Patients With Melanoma Recurrent After Initial Surgery.

Patients Treated With IMLYGIC Achieved a Significant Increase in Durable Response Rate in Pivotal Study.

PR Newswire, THOUSAND OAKS, Calif. (Oct. 27, 2015)

Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application for IMLYGIC™ (talimogene laherparepvec), a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery. IMLYGIC has not been shown to improve overall survival or have an effect on visceral metastases. IMLYGIC is the first oncolytic viral therapy approved by the FDA based on therapeutic benefit demonstrated in a pivotal study.

IMLYGIC is a genetically modified herpes simplex virus type 1 designed to replicate within tumors and produce an immunostimulatory protein called granulocyte-macrophage colony-stimulating factor (GM-CSF). IMLYGIC causes cell lysis, or death, which ruptures tumors, releasing tumor-derived antigens, which along with GM-CSF, may promote an anti-tumor immune response. However, the exact mechanism of action is unknown.

“IMLYGIC is the first clinical and regulatory validation of an oncolytic virus as a therapy, which Amgen is proud to bring to patients with a serious form of skin cancer. Not all melanoma patients currently benefit from available therapies, and IMLYGIC represents an important new option that can provide meaningful durable responses for patients with this aggressive and complex disease,” said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. “Immunotherapy is an exciting area for cancer research, and we are currently studying IMLYGIC in combination with other immunotherapies in advanced melanoma and other solid tumors.”

Metastatic melanoma continues to be one of the most difficult-to-treat cancers because it is often insensitive to chemotherapy, can be highly aggressive and can require several different types of treatment depending on the stage and location of the disease and health of the patient.^{4,5} Despite new therapeutic options, additional treatments are needed – particularly for patients with metastatic disease.

Amgen intends to make IMLYGIC available to patients in the U.S. within a week. Amgen anticipates the average cost of IMLYGIC therapy to be approximately \$65,000. Given that IMLYGIC represents a novel and first-in-class oncolytic viral therapy, Amgen expects variability of IMLYGIC dosing from patient to patient. Therefore, Amgen intends to work with the healthcare community to implement a program that helps limit the average cost of IMLYGIC therapy to \$65,000 for eligible participating institutions.

Amgen is committed to helping clinically appropriate patients access our medicines and will provide assistance for IMLYGIC in the U.S. in the following ways:

- Free medicines through The Safety Net Foundation are available to qualifying individuals with no or limited drug coverage.
- Co-pay coupon program for IMLYGIC through the Amgen FIRST STEP™ Program to help commercially insured patients meet their co-payment obligations; this program has no income requirement.

- Information about independent co-pay assistance foundations that give grants to qualifying patients who have difficulty paying out-of-pocket costs for medicines manufactured from across all of the industry.

About IMLYGIC (talimogene laherparepvec)

IMLYGIC is a genetically modified herpes simplex virus type 1 injected directly into tumors where it replicates inside tumors and produces GM-CSF, an immunostimulatory protein. IMLYGIC then causes the tumor to rupture and die in a process called lysis. The rupture of the tumor causes the release of tumor-derived antigens, which together with virally-derived GM-CSF may promote an anti-tumor immune response. However, the exact mechanism of action is unknown and being further investigated.

About the OPTiM Study

The most common adverse drug reactions in IMLYGIC treated patients were fatigue, chills, pyrexia, nausea, influenza-like illness and injection site pain. Most adverse reactions reported were mild or moderate in severity and generally resolved within 72 hours. The most common grade 3 or higher adverse reaction was cellulitis.

References

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