Oncolytics Biotech® Inc. Announces Filing for Orphan Drug Designation with the U.S. FDA for High Grade Gliomas in Pediatric Patients

CALGARY, Feb. 9, 2015 /PRNewswire/ - Oncolytics Biotech Inc. (“Oncolytics”) (TSX:ONC, NASDAQ:ONCY) today announced that it has submitted an application for Orphan Drug Designation to the U.S. Food and Drug Administration (“FDA”) for REOLYSIN® for the treatment of high grade gliomas (HGG) in pediatric patients. Oncolytics has conducted three previous clinical studies in brain cancers including gliomas, and has found that REOLYSIN® can infect a variety of brain tumors when delivered intravenously.

"High grade gliomas are typically a very aggressive form of cancer. They remain difficult to treat, particularly in pediatric patients, and are associated with poor survival outcomes," said Dr. Brad Thompson, President and CEO of Oncolytics. "While surgical resection, radiotherapy and chemotherapy may be treatment options, REOLYSIN® may offer these patients an alternative, more targeted therapeutic approach to treatment."

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Orphan Drug Designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees. The receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval. For more information, please visit: http://www.fda.gov/forindustry/DevelopingProductsforrareDiseasesConditions/default.htm.

According to the US Central Brain Tumor Registry an estimated 4,620 new cases of primary malignant and non-malignant brain and central nervous system tumors will be diagnosed in pediatric and adolescent patients in 2015. In patients between zero and 19 years old, the overall total incidence of HGG (including anaplastic astrocytoma, anaplastic oligodendroglioma, glioblastoma, mixed glioma, and malignant glioma) is approximately 0.8 per 100,000.

About Oncolytics Biotech Inc.
Oncolytics is a Calgary-based biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. Oncolytics' clinical program includes a variety of later-stage, randomized human trials in various indications using REOLYSIN®, its proprietary formulation of the human reovirus. For further information about Oncolytics,
please visit: www.oncolyticsbiotech.com.

This press release contains forward-looking statements within the meaning of the U.S. Securities Act of 1933, as amended, and U.S. Securities Exchange Act of 1934, as amended, and forward-looking information within the meaning of Canadian securities laws. Statements, other than statements of historical facts, included in this press release that address activities, events or developments that Oncolytics expects or anticipates will or may occur in the future, including such things as, the Company’s expectations related to the granting of Orphan Drug Designation for REOLYSIN®, the Company’s belief as to the potential of REOLYSIN® as a cancer therapeutic, and other such matters are forward-looking statements and forward-looking information and involve known and unknown risks and uncertainties, which could cause the Company’s actual results to differ materially from those in the forward-looking statements and forward-looking information. Such risks and uncertainties include, among others, risks related to the statistical sufficiency of patient enrollment numbers in separate patient groups, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN® as a cancer treatment, the tolerability of REOLYSIN® outside a controlled test, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN®, uncertainties related to the research and development of pharmaceuticals and uncertainties related to the regulatory process. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements and forward-looking information. Investors are cautioned against placing undue reliance on forward-looking statements and forward-looking information. The Company does not undertake to update these forward-looking statements and forward-looking information, except as required by applicable laws.

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