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Oncolytics Biotech® Inc. Announces Receipt of Orphan Drug Designation from the U.S. FDA for Malignant Gliomas

CALGARY, April 17, 2015 /PRNewswire/ - Oncolytics Biotech Inc. ("Oncolytics") (TSX:ONC, NASDAQ:ONCY), a clinical-stage biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted an Orphan Drug Designation (ODD) for its lead product candidate, REOLYSIN®, for the treatment of malignant glioma. The Company applied for an ODD for pediatric high grade gliomas (HGG), however the FDA granted an ODD for the broader indication of malignant glioma in patients of all ages. In three previous brain cancer studies including gliomas, REOLYSIN® has been shown to infect a variety of brain tumors when delivered intravenously.

"The focus of our Orphan Drug submissions has been on difficult to treat cancers where patients have few effective treatment options," said Dr. Brad Thompson, President and CEO of Oncolytics. "Pediatric patients with high grade gliomas have particularly poor expected outcomes. We believe these patients, along with the adult population affected by malignant gliomas, would benefit from having additional treatment options."

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 Central Brain Tumor Registry of the United States (CBTRUS), in 2015, an estimated 68,470 new cases of primary malignant and non-malignant brain and central nervous system tumors will be diagnosed of which 23,180 estimated new cases will be primary malignant tumors and 4,620 estimated new cases will be diagnosed in pediatric and adolescent patients. The CBTRUS estimates that the broad category glioma represents approximately 80% of malignant tumors and in patients between zero and 19 years of age, 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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