Oncolytics Biotech® Inc. Collaborators Present Data from Clinical Study in Multiple Myeloma

-- All Evaluable Patients to Date See Evidence of an Objective Response; Treatment Combination Associated with Statistically Significant Upregulation of PD-L1--

CALGARY, Sept. 25, 2015 /CNW/ - Oncolytics Biotech® Inc. (“Oncolytics”) (TSX:ONC) (NASDAQ:ONCY) today announced that Dr. D.W. Sborov and colleagues made a poster presentation at the 15th International Myeloma Workshop (IMW). The poster presentation, entitled “Combination Carfilzomib and the Viral Oncolytic Agent REOLYSIN® in Patients with Relapsed Multiple Myeloma: A Pilot Study Investigating Viral Proliferation,” discloses initial findings from a pilot study (NCI-9603) in patients with relapsed or refractory multiple myeloma treated using the combination of carfilzomib and REOLYSIN®. The IMW runs from September 23rd to 26th in Rome, Italy.

Highlights of the data presented include:

- 100% of patients (8 of 8) experienced an objective response as measured by changes in blood monoclonal protein. Of these, 2 patients had a very good partial response (VGPR), 3 patients had a partial response (PR) and 3 patients had a minor response (MR);
- Only one patient has progressed to date and five of eight remain on study;
- The combination of carfilzomib and REOLYSIN® produced a significant (p=0.005) increase in caspase-3, a marker associated with apoptotic (programmed) cell death; and
- The treatment combination was associated with an increased infiltration of CD8+ T-cells and the significant (p=0.005) upregulation of PD-L1, suggesting that the addition of a PD-1 or PD-L1 inhibitor may further optimize the treatment regimen.

“These findings demonstrate that the combination of carfilzomib and REOLYSIN® shows promise in hematological malignancies like multiple myeloma and provide compelling evidence that such drug combinations promote viral replication and cancer cell death,” said Dr. Matt Coffey, Chief Operating Officer of Oncolytics. “Based on these results, we intend to move into randomized studies in this indication.”

The investigators noted that this is the first time a REOLYSIN®-based combination has been tested in relapsed multiple myeloma patients. A previous single-agent study conducted by the collaborators in this patient population showed that REOLYSIN® was well tolerated. The collaborators and others were noted to have conducted preclinical investigations that demonstrated that the combination of REOLYSIN® and carfilzomib synergistically increased the killing of multiple myeloma cells. This provided the clinical rationale for this study. In this study, the combination of carfilzomib and REOLYSIN® produced a significant (p=0.005) increase in caspase-3, a marker associated with apoptotic cell death. The researchers also determined that the combination of REOLYSIN® and carfilzomib increases infiltration of CD8+ T-cells and significantly (p=0.005) upregulates PD-L1. The investigators concluded that these findings necessitate continued investigation, and suggest that the addition of a PD-1 or PD-L1 inhibitor may further optimize the REOLYSIN® and carfilzomib regimen.

“To this point, multiple myeloma has not responded to checkpoint inhibitor therapy,” said Dr. Brad Thompson, President and CEO of Oncolytics. “The combination of REOLYSIN® and carfilzomib upregulates PD-L1 and increases infiltration of CD8+ T-cells, which may make the tumor sensitive to anti-PD-L1 therapy. The follow-on randomized study we are currently planning is expected to have a patient group treated with the combination of REOLYSIN®, a standard of care chemotherapy, and a checkpoint inhibitor, as well as a patient group receiving REOLYSIN® and a standard of care chemotherapy.”

NCI-9603 is a U.S. National Cancer Institute sponsored single-arm, open-label study of intravenously administered REOLYSIN® with dexamethasone and carfilzomib to patients with relapsed or refractory multiple myeloma. Patients receive treatment on days 1, 2, 8, 9, 15 and 16 of a 28-day cycle, to be repeated in the absence of disease progression or unacceptable toxicity. Approximately 12 patients will be enrolled in the study. The primary outcomes include measuring reovirus replication, safety, and tolerability. Secondary outcomes include examining objective
response, duration of response, clinical benefit, progression-free survival, and time to progression. Other outcomes will include the measurement of immunologic correlative markers.

A copy of the poster will be available on the Oncolytics website at: http://www.oncolyticsbiotech.com/investors/presentations.

About Multiple Myeloma
Multiple Myeloma is a cancer of the plasma cells and the second most common hematological malignancy. The American Cancer Society estimates there will be 26,850 new cases diagnosed in the United States and 11,240 deaths from the disease in 2015.

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 Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's expectations related to the pilot single-arm clinical trial in multiple myeloma, future trials in this indication, and the Company's belief as to the potential of REOLYSIN® as a cancer therapeutic, 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. Such risks and uncertainties include, among others, 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, development and manufacturing of pharmaceuticals, changes in technology, general changes to the economic environment 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. Investors should consider statements that include the words "believes", "expects", "anticipates", "intends", "estimates", "plans", "projects", "should", or other expressions that are predictions of or indicate future events or trends, to be uncertain and forward-looking. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements, except as required by applicable laws.

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