Oxis Biotech Licenses Exclusive Worldwide Rights To Novel Cancer Therapy

TAMPA, Fla., Sept. 7, 2015 -- Oxis Biotech, Inc. (OXIS), a wholly owned subsidiary of Oxis International, Inc. (OTC: OXIS) and (Euronext Paris: OXI.PA) announced today the execution of an exclusive worldwide license agreement to further develop and commercialize DT2219ARL, a novel therapy for the treatment of various human B cell cancers, leukemias and lymphomas.

DT2219ARL is a bispecific scFv recombinant fusion protein-drug conjugate composed of the variable regions of the heavy and light chains of anti-CD19 and anti-CD22 antibodies and a modified form of diphtheria toxin as its cytotoxic drug payload. CD19 is a membrane glycoprotein present on the surface of all stages of B lymphocyte development, and is also expressed on most B-cell mature lymphoma cells and leukemia cells.[1] CD22 is a glycoprotein expressed on B-lineage lymphoid precursors, including precursor B acute lymphoblastic leukemia, and often is co-expressed with CD19 on mature B-cell malignancies such as lymphoma.[2]

DT2219ARL targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When DT2219ARL binds to cancer cells, the cancer cells internalize DT2219ARL and are killed due to the action of drug's cytotoxic payload. DT2219ARL has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia.

Twenty-five patients with advanced B-cell lymphoid malignancies expressing CD19 and/or CD22 were enrolled in a clinical study to evaluate DT2219ARL in a phase 1 FDA study. Patients were enrolled that had previous failed chemotherapy, immunotherapy, and/or hematopoietic (bone marrow or stem cell) transplantation. Patients received a single course of DT2219ARL according to study rules. Adverse events were successfully managed and included weight gain, low albumin, transaminitis, and fever were transient grade 1–2 and occurred in patients at the higher doses tested (>/=40µg/kg/day). Durable objective responses occurred in 2 patients at these higher doses. A complete response occurred in the only patient given a second cycle of therapy that had a 70% cancer reduction after the first cycle of therapy... The patient has been in remission for a year now. Correlative studies showed a surprisingly low incidence of neutralizing antibody (30%) production that could be related to the drug's ability to suppress antibody responses. For further information about the clinical trial, see Bachanova, V., *et. al.*, *Clin Cancer Res*; 21(6) March 15, 2015.

"We are pleased to have the opportunity to further develop DT2219ARL", said Anthony J. Cataldo, Chairman and CEO of Oxis Biotech. There were several other major companies interested in acquiring this technology and we are honored to be the partner selected for this. This cancer therapy along with our existing platform, puts us in the forefront of next generation therapy along side companies like Amgen Biologics (AMGN), Seattle Genetics, Inc. (SGEN). When I started Lion Biotechnologies, Inc. (LBIO) in February of 2011, I knew that cell therapy was the next wave of cancer therapies to come. Kite Pharma (KITE) and Juno Therapeutics (JUNO) followed and demonstrated this. Now the future is targeted immunotherapy and with DT2219ARL, we are poised to lead this effort. "We believe DT2219ARL holds great promise as a treatment for a number of B-cell malignancies", Mr. Cataldo further added.

"We are very excited to continue this work with Oxis Biotech, said Dr. Daniel A Vallera, professor, University of Minnesota Masonic Cancer Center. "A stellar commercialization partner is critical at this juncture since our FDA trial is scheduled to resume with a superior dose scheduling involving multiple cycles of therapy. We expect even better responses with more aggressive treatment and need to move forward quickly."

B-cell malignancies represent a diverse number of cancers of the blood cells, lymph nodes and other parts of the lymphatic system, including non-Hodgkin's lymphomas, certain types of leukemia, and myelomas. Examples include chronic lymphocytic leukemia, follicular lymphoma, mantle cell lymphoma and diffuse large B-cell lymphoma.[3]

According to the Leukemia and Lymphoma Society, an estimated 1,185,053 people in the U.S. are either living with or are in remission from leukemia, lymphoma or myeloma, and approximately every 10 minutes someone in the U.S. dies from a blood-related cancer.[4]

About Oxis Biotech, Inc.

Oxis Biotech develops innovative drugs focused on the treatment of cancer and other unmet medical needs. OXIS' lead drug candidate, DT2219ARL is a novel bispecific scFv recombinant fusion protein-drug conjugate composed of the variable regions of the heavy and light chains of anti-CD19 and anti-CD22 antibodies and a modified form of diphtheria toxin as its cytotoxic drug payload. DT2219ARL simultaneously targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When DT2219ARL binds to cancer cells, the cancer cells internalize DT2219ARL and are killed due to the action of drug's cytotoxic payload. DT2219ARL has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia. OXS-4235 is a small molecule therapeutic candidate targeting the treatment of multiple myeloma and associated osteolytic lesions. In *in vitro* and *in vivo* models of multiple myeloma and osteoporosis, OXS-4235 demonstrated the ability to kill multiple myeloma cells, and decrease osteolytic lesions in bone. OXIS' lead drug candidate, OXS-2175, is a small molecule therapeutic candidate targeting the treatment of triple-negative breast cancer (TNBC). In *in vitro* and *in vivo* models of TNBC, OXS-2175 demonstrated the ability to inhibit metastasis. For more information about Oxis Biotech, please visit http://www.oxis.com.

Forward-Looking Statements

Except for historical information contained herein, the statements in this release are forward-looking and made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently unreliable and actual results may differ materially. Examples of forward-looking statements in this news release include statements regarding the payment of dividends, marketing and distribution plans, development activities and anticipated operating results. Factors which could cause actual results to differ materially from these forward-looking statements include such factors as the Company's ability to accomplish its business initiatives, significant fluctuations in marketing expenses and ability to achieve and expand significant levels of revenues, or recognize net income, from the sale of its products and services, as well as the introduction of competing products, or management's ability to attract and maintain qualified personnel necessary for the development and commercialization of its planned products, and other information that may be detailed from time to time in the Company's filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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[1] Scheuermann RH, Racila E., *Leuk. Lymphoma* (1995) 18:385–97.

[2] Cesano A, Gayko U., *Semin. Oncol.* (2003) 30:253–7.

[3] National Comprehensive Cancer Network (2014).

[4] Leukemia and Lymphoma Society *FACTS 2014-2015*.

SOURCE Oxis Biotech, Inc.