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Biopharma, Inc.

## **OXIS Biotech Announces Key U.S. Patent Issued for Its Cancer Drug, OXS-1550**

**LOS ANGELES, CA / ACCESSWIRE / June 21, 2016** /Oxis Biotech Inc., a wholly owned subsidiary of Oxis International, Inc. (OTCQB: OXIS and Euronext Paris: OXI.PA), announced today that a U.S. Patent has been issued for its cancer drug, OXS-1550. Oxis holds worldwide exclusive rights to develop and commercialize OXS-1550, a novel therapy for the treatment of various human cancers.

U.S. Patent No. 9,371,386 provides bi-specific targeting compositions including a cytotoxic agent conjugated to a targeting moiety and a binding fragment which targets CD19 or CD22. The patent also includes methods of treating humans having lymphoma or B-cell malignancies using the patented composition.

"We are pleased the USPTO has agreed that OXS-1550 is a patentable therapeutic composition. This is a significant milestone for Oxis and will attribute meaningful value to our existing IP portfolio," said Anthony J. Cataldo, Chairman and Chief Executive Officer of Oxis Biotech.

Dr. Daniel Vallera, the inventor of OXS-1550 and Director of the Section on Molecular Cancer Therapeutics at the University of Minnesota Masonic Cancer Center, said he believes OXS-1550 will play an important role in the treatment of cancer. The drug is designed to identify certain cancer cells and kill them, without damaging healthy cells.

"We believe OXS-1550 to be a powerful alternative to existing chemotherapies, since many patients fail chemotherapy or reach the toxic limits of their therapy," Vallera said.

The patent decision comes as OXS-1550 is being evaluated in a new Phase 1/Phase 2 clinical trial. The objective of the Phase 1 study is to identify the Maximum Tolerated Dose (MTD), and the optimized dose and regimen to be used in the Phase 2 study.

Enrollment of patients into the Phase 2 study will begin after the Phase 1 study is completed. The Phase 2 study is a two-stage, two-ARM design. Patients from the Phase 1 study plus an additional 9 patients will be enrolled in stage 1 of the Phase 2 study. If one patient enrolled in the Phase 2, stage 1 part of the study has a positive response, then an additional 8 patients will be enrolled in the Phase 2 stage of the study. At a maximum, up to 29 patients will be enrolled across both the Phase 1 and Phase 2 (stages 1 & 2) studies.

OXS-1550 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. 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.

OXS-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When OXS-1550 binds to cancer cells, the cancer cells internalize the drug and are killed due to the action of drug's cytotoxic payload. OXS-1550 has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia.

In an earlier Phase 1 clinical trial, twenty-five patients with mature or precursor B-cell lymphoid malignancies expressing CD19 and/or CD22 were enrolled. When the study allowed for an increase in the dose level (60 mg/kg) in the final 9 patients, durable objective responses occurred in 2 patients; one patient continues to be in complete remission after being administered 2 cycles of OXS-1550. For further information about the earlier Phase 1 clinical trial, see Bachanova, V., et. al., Clin Cancer Res; 21(6) March 15, 2015.

**About Oxis Biotech, Inc.:** Oxis Biotech Inc., a wholly owned subsidiary of Oxis International, Inc., is an immuno-oncology focused company developing innovative drugs focused on the treatment of cancer and other unmet medical needs. OXIS' lead drug candidate, OXS-1550 (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. OXS-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When OXS-2175 binds to cancer cells, the cancer cells internalize the drug and are killed due to the action of drug's cytotoxic payload. OXS-1550 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.

**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.

Company website: [www.oxis.com](http://www.oxis.com).

**SOURCE:** Oxis International, Inc.