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Bispecific Immunotherapy, The Basis For Oxis' Cancer Drug, Lauded As Promising Alternative To CAR-T Therapy

LOS ANGELES, March 22, 2016 /PRNewswire/ -- Oxis Biotech Inc., a wholly owned subsidiary of Oxis International Inc. [OTC: OXIS and Euronext Paris: OXI.PA], announced today that the bispecific cancer immunotherapy approach on which its leading drug is based was lauded as a promising alternative to expensive CAR-T therapy.

Bloomberg News and biotech trade website BioPharmaDive.com have reported recently that bispecifics are emerging as a strong rival to CAR-T therapy, which is being tested by such companies as Kite Pharma [KITE], Juno Therapeutics Inc. [Juno] and Novartis AG [NVS].

CAR-T involves extracting a patient's T-cells, reprogramming them and reintroducing them into the patient's body. A single treatment could cost as much as $1 million, by some estimates.

Oxis' leading drug is OXS-1550, a treatment for leukemia and non-Hodgkins lymphoma using the bispecific approach to target and destroy cancer cells.

Bloomberg News described bispecifics this way: "These treatments have two distinct arms to grab onto proteins on the surfaces of different cells. One end hooks onto the cancer and one end latches onto the immune cell. Once they're connected, the immune cell moves in for the kill."

Oxis Chief Executive Officer Anthony Cataldo said the news coverage of bispecifics is a sign that the company is on the right track as it pursues the next generation of cancer treatment.

"This clearly demonstrates that the bispecific approach we're taking with OXS-1550 is a positive alternative to CAR-T cell therapy solutions," Cataldo said. "It's effective. It's cost-effective. It's non-invasive. It's saves lives and it's associated with fewer adverse effects."

BioPharmaDive reported that CAR-T therapy "is lengthy and extremely costly." It reported that bispecific treatment "does not require the complex process needed by Kite, Juno and Novartis to produce their individualized CAR-T therapies."

Oxis recently received a Notice of Allowance from the United States Patent and Trademark

Office for its cancer drug, OXS-1550.

OXS-1550 is currently in a Phase 1/Phase 2 clinical trial at the University of Minnesota Masonic Cancer Center.

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 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/bispecific-immunotherapy-the-basis-for-oxis-cancer-drug-lauded-as-promising-alternative-to-car-t-therapy-300239316.html

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