Biosight Announces Initiation of Investigator Sponsored Phase 2 Clinical Trial of Aspacytarabine for Relapsed/Refractory AML and MDS with the Groupe Francophone des Myélodysplasies

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First Patient Enrolled to the Phase 2 Trial, which will Evaluate Single-Agent Aspacytarabine in Second Line Relapsed/Refractory AML and MDS

Study sponsored by Groupe Francophone des Myélodysplasies, the French Study Group of the European Myelodysplastic Syndromes Cooperative Group

AIRPORT CITY, Israel, Aug. 16, 2021 (GLOBE NEWSWIRE) -- Biosight Ltd., a pharmaceutical development company developing innovative therapeutics for hematological malignancies and disorders, today announced the initiation of a Phase 2 trial to evaluate aspacytarabine (BST-236), Biosight's proprietary antimetabolite, as a second line treatment for patients with relapsed or refractory myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML). The investigator sponsored trial will be led by Dr. Pierre Fenaux of the Groupe Francophone des Myélodysplasies (GFM), the French Study Group of the European Myelodysplastic Syndromes (MDS) Cooperative Group (EMSCO). GFM is a non-profit organization comprised of most French hematology centers that conducts and sponsors clinical trials and translational research and coordinates diagnostic and therapeutic guidelines for MDS.

"This new trial is an important step forward in expanding the reach of aspacytarabine to a broader patient population, addressing the unmet needs in the treatment of relapsed/refractory AML and MDS," said Dr. Ruth Ben Yakar, Chief Executive Officer of Biosight. "Initiating an additional trial furthers our clinical momentum, building on updated, encouraging data from our ongoing first-line Phase 2b study presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and the receipt of Orphan Medicinal Product Designation for the European Medicines Agency. GFM is an ideal partner to expand the clinical evaluation into MDS with their extensive network of hematology centers, including registered centers of excellence, and we look forward to applying their expertise in clinical trials, treatments and diagnostics as we advance this Phase 2 trial."

Professor Pierre Fenaux, M.D., Ph.D., Head of Hematology at Hospital Saint Louis in Paris, and founding member and Chairman of GFM, said, "The first-line Phase 2b data that were presented at ASCO, with demonstrated efficacy across key measures including encouraging complete remission and negative minimal residual disease rates, duration of response and overall survival, further increase my conviction that aspacytarabine may serve as a more tolerable, end effective standard of care treatment for patients with both AML and MDS. We are thrilled to be collaborating with Biosight to advance this potentially transformative treatment for relapsed or refractory MDS and AML patients who currently are faced with poor prognoses and no effective standard of care treatment."

About Aspacytarabine (BST-236)

Aspacytarabine is a novel proprietary anti-metabolite. It is composed of cytarabine covalently bound to asparagine, acting as a pro-drug of cytarabine. Cytarabine serves as the backbone of AML therapy for over 45 years due to its superior efficacy, however, it is associated with severe bone marrow, gastrointestinal, and neurological toxicities, which significantly limit its use, especially in older and medically compromised patients. Due to its unique pharmacokinetics and metabolism, aspacytarabine enables high-dose therapy with lower systemic exposure to free cytarabine and relative sparing of normal tissues. As such, aspacytarabine may serve as a new therapy for AML and other hematological malignancies and disorders, including for older adults who are unfit for intensive therapy.

Aspacytarabine was granted FDA Fast Track Designation for treatment of AML patients unfit for standard chemotherapy, and FDA and EMA Orphan Drug Designations, which entitle Biosight to seven and ten years of market exclusivity in the U.S. and Europe, respectively, upon aspacytarabine marketing approval for the treatment of AML in each territory.

Interim results from an ongoing Phase 2b study evaluating aspacytarabine as a single-agent first-line AML therapy demonstrate safety and single-agent activity, and additional studies are launched to evaluate aspacytarabine as a second line treatment for patients with relapsed or refractory MDS or AML. For more information regarding the Phase 2b clinical study of BST-236, please visit www.clinicaltrials.gov.

About Biosight Ltd.

Biosight is a private Phase 2 clinical stage biotech company developing innovative therapeutics for hematological malignancies and disorders. Biosight's investigational product, aspacytarabine (BST-236), is an innovative proprietary anti-metabolite which addresses unmet medical needs by enabling high-dose chemotherapy with reduced systemic toxicity. Aspacytarabine is currently being investigated as a single agent in a Phase 2b clinical trial, recently completed enrollment, for the first-line treatment of AML. Interim results demonstrate tolerability with promising efficacy in the challenging population of AML patients unfit for intensive standard-of-care chemotherapy. An additional Phase 2 study was initiated in patients with relapsed/refractory AML and MDS in collaboration with the European cooperative group, Groupe Francophone des Myélodysplasies (GFM). A similar Phase 2 study is to be initiated in the US in 2021. For additional information, please visit www.biosight-pharma.com.

About Groupe Francophone des Myélodysplasies

Groupe Francophone des Myélodysplasies (GFM) is a Study Group of the European Myelodysplastic Syndromes Cooperative Group (EMSCO), which was founded in 2013 upon an initiative of the European Leukemia Network (ELN), and serves as a platform to foster academic clinical research, cooperation and education in the field of myelodysplastic syndromes (MDS). GFM is a non-profit organization that includes most French hematology centers, several of them registered as centers of excellence of the International MDS Foundation. Amongst others, the group conducts and sponsors clinical trials and translational research, coordinates the online French registry of MDS since 2003 and updates diagnostic guidelines and therapeutic procedures.

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