



Quantum Leap Healthcare Collaborative Initiates Landmark Phase 2 RECAST DCIS Platform Trial to Evaluate Alternative DCIS Treatments with Atossa Therapeutics, Havah Therapeutics, and the Menarini Group

40-site U.S. trial enrolling more than 300 patients could significantly change the way DCIS is treated and reduce possibly unnecessary surgery

SAN FRANCISCO, October 30, 2023/PRNewswire/ —Quantum Leap Healthcare Collaborative (QLHC) announces the enrollment launch for the Re-Evaluating Conditions for Active Surveillance Suitability as Treatment: Ductal Carcinoma In Situ (RECAST DCIS), a Phase 2 platform study aimed at preventing the progression of DCIS to breast cancer. The study is evaluating three investigational endocrine therapy arms: (Z)-endoxifen, a selective estrogen receptor modulator (SERM) in development by Atossa Therapeutics (Nasdaq: ATOS); HAVAH T+Ai™, a proprietary combination of testosterone (T) and anastrozole (Ai) that targets the androgen and estrogen receptor pathways in development by Havah Therapeutics; and ORSERDU® (elacestrant), the only FDA approved oral selective estrogen receptor degrader (oSERD) in development by Stemline Therapeutics Inc. (Stemline), a wholly-owned subsidiary of the Menarini Group.

“DCIS indicates the very earliest, noninvasive stage of the disease, that’s why it is important for us to seek out alternative therapies for DCIS patients and find ways to reduce toxicity and unnecessary surgeries. We are excited to partner with three innovative companies to explore new treatments for this large and often over-treated patient population,” said Laura Esserman, MD, a lead investigator for the study and founder of QLHC.

Surgery is the current standard treatment for DCIS even though many patients never progress to breast cancer, which means that patients are often over-treated with invasive procedures. This new trial, sponsored and operated by QLHC, offers DCIS

patients up to six months of endocrine therapy with the intent to forego surgery and instead be monitored via long-term active surveillance, if appropriate. A key element in reducing overtreatment of DCIS is identifying biomarkers that reflect the risk of progression so that those with low-risk lesions are spared surgery. RECAST DCIS features the assessment of imaging and molecular-based biomarkers in addition to evaluating new investigational agents in this setting. The study is open to enrollment with each investigational agent arm expected to enroll up to 110 patients.

The three collaborators for this trial, Atossa Therapeutics, Havah Therapeutics, and Stemline, all aim to find alternative solutions for DCIS patients and are providing different agents for assessment.

Atossa's (Z)-endoxifen has the potential to mitigate breast cancer risk (by reducing the density of breast tissue); to reduce cancer cell activity before surgery; and to reduce the risk of recurrent or new breast cancer after the initial treatment. According to published studies, (Z)-endoxifen is a competitive inhibitor of ER α and represses ER α transcriptional activity (Z)-endoxifen is 100-fold more potent in anti-estrogen activity compared to other SERMs. (Z)-endoxifen also binds to and disrupts protein kinase C beta one function (PKC β 1, a known oncogenic protein). The National Cancer Institute (NCI) and others have studied (Z)-endoxifen and have demonstrated promising results in the treatment of breast cancer as well as for the treatment of other solid tumors. Treatment with (Z)-endoxifen may avoid off target effects of tamoxifen and remaining metabolites potentially increasing adherence by improving the safety profile.

Havah Therapeutics' HAVAH T+Ai™ combines T, the natural ligand for the androgen receptor and Ai, an inhibitor of T conversion to estradiol, to modulate the growth of abnormal breast tissues. HAVAH T+Ai™ is a proprietary combination subcutaneously delivered system to overcome hormonal symptoms by balancing hormonal irregularities in the breast, developed from more than 10 years of clinical research into hormonal regulation in women. Havah has extensive clinical experience using HAVAH T+Ai™ to address pre- and postmenopausal prevention of breast disease, and the company generated data from more than 1,000 Australian women with breast disease through an ongoing open label cohort study (more than 6,200 implants), with critical safety pharmacokinetic and early efficacy data already demonstrated.

Stemline's Elacestrant (ORSERDU), was approved by the U.S. Food & Drug Administration in January 2023 for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, HER2-negative, ESR-1 mutated advanced or metastatic breast cancer, following at least one line of endocrine therapy. For more information including full prescribing information and important safety information, please visit <https://www.orserdu.com/>

###

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative is a 501c(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate high-impact research with clinical processes and systems technology, resulting in improved data management and information systems, greater access to clinical trial matching and sponsorship, and greater benefit to providers, patients and researchers. Our goal is to improve and save lives. For more information, visit <https://www.quantumleaphealth.org/>.

About Atossa

Atossa Therapeutics is a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology. Atossa's current focus is on breast cancer. More information is available at atossatherapeutics.com.

About Havah Therapeutics

Havah Therapeutics is a biopharmaceutical company developing innovative, proprietary hormonal therapies that aim to improve quality of life for women. Havah brings together a world-class team passionate about helping women live lives free from the suffering caused by breast pain, debilitating menopausal symptoms and breast cancer. More information is available at www.havahtx.com.

About The Menarini Group

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over \$4.4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

About Stemline Therapeutics Inc.

Stemline Therapeutics, Inc. ("Stemline") a wholly-owned subsidiary of the Menarini Group, is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. Stemline commercializes ORSERDU® (elacestrant) in the United States, an oral endocrine therapy indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Stemline also commercializes ELZONRIS® (tagraxofusp-erzs), a novel targeted treatment directed to CD123 for patients with blastic

plasmacytoid dendritic cell neoplasm (BPDCN), an aggressive hematologic cancer, in the United States and Europe, which is the only approved treatment for BPDCN in the US and EU to date. Stemline also commercializes NEXPOVIO® in Europe, an XPO1 inhibitor for multiple myeloma. Stemline also has an extensive clinical pipeline of small molecules and biologics in various stages of development for a host of solid and hematologic cancers.

QLHC Media Contact:

Jacqueline Murray
Marketing and Communications Director
j.murray@quantumleaphealth.org
(415) 839-8082

Atossa Media Contact:

Eric Van Zanten
VP, Investor and Public Relations
eric.vanzanten@atossainc.com
(610) 529-6219

Havah Media Contact:

Matt Brewer
mb@havahtx.com

Danielle Clark-Brown
dcb@havahtx.com

Stemline Media Contact:

Cheya Pope
cpope@menarinistemline.com