Currax Pharmaceuticals Announces First Patient Screened into the INFORMUS Cardiovascular Outcomes Trial

BRENTWOOD, TENNESSEE, UNITED STATES, January 25, 2024 /EINPresswire.com/ -- Currax Pharmaceuticals LLC (“Currax”) announces the first patient screened and accepted into the CONTRAVE® INFORMUS Cardiovascular Outcomes Trial (NB-CVOT3). The initiation of this study follows the October 2023 announcement of the favorable top-line results of the completed Cardiovascular Health Outcomes Analysis (HOA) where no evidence was found of excess cardiovascular risk and there was no statistically significant difference of major adverse cardiovascular events (MACE) between CONTRAVE and the active comparator group.

“We are thrilled to be commencing the INFORMUS trial for CONTRAVE,” said Michael Kyle, M.D., Currax SVP, Chief Medical Officer. “Over the past several years, we worked diligently with regulatory agencies to develop this study protocol. To reach agreement with the FDA and initiate patients into the trial is a significant milestone for this product, these patients, and this program.”

The HOA results substantiated the cardiovascular safety profile of CONTRAVE, and the initiation of the INFORMUS trial addresses regulatory post-marketing commitments. INFORMUS will further characterize long-term cardiovascular safety for patients taking CONTRAVE. The HOA study is completed and is expected to be published later this year.

“Our clinical team successfully achieved an on-time launch of the INFORMUS trial through strong collaboration and support from the FDA,” said Currax President and CEO George Hampton. “This is an important trial for patients, as CONTRAVE is now the number one prescribed branded oral medication for the treatment of obesity.”

About the INFORMUS Trial
The INFORMUS Trial (NB-CVOT3) is a Phase IV, multi-center, prospective, randomized, pragmatic, double-blinded, placebo controlled study intended to capture cardiovascular (CV) outcomes during real-world use of naltrexone/bupropion (CONTRAVE). Randomization will occur 1:1

between CONTRAVE and placebo. The primary endpoint includes comparison of major adverse cardiovascular events (MACE) between study subjects receiving CONTRAVE and subjects receiving placebo.

About CONTRAVE/MYSIMBA
CONTRAVE, also marketed as MYSIMBA® in the European Union and European Economic Area, is an extended-release fixed-dose combination of naltrexone and bupropion (naltrexone HCL/bupropion HCL) indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obese), or adults with a BMI of 27 kg/m2 or greater (overweight) with at least one weight-related medical problem such as high blood pressure, high cholesterol, or type 2 diabetes.

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