Avadel Announces Sale of Hospital Sterile Injectable Drug Portfolio for $42.0 Million

July 1, 2020

DUBLIN, Ireland, July 01, 2020 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating excessive daytime sleepiness and cataplexy in patients with narcolepsy, today announced the sale of its portfolio of sterile injectable drugs used in the hospital setting, including three commercial products, Bloxiverz®, Vazculep®, and Akovaz®, as well as Nouress™, which is approved by the U.S. Food and Drug Administration, to Exela Sterile Medicines LLC for a total of $42.0 million.

"The sale of the sterile injectable drug portfolio is a significant milestone for the Company, as it further reflects our commitment to strategically focus on advancing FT218 through the regulatory review process and, if approved, bringing our once-nightly formulation of sodium oxybate to patients," said Greg Divis, Chief Executive Officer of Avadel. "By divesting our portfolio of sterile injectable drugs, we are now singularly focused on supporting the regulatory approval process, market planning and maximizing shareholder value for FT218."

Under the terms of the agreement, Avadel will receive $14.5 million upfront and the remaining $27.5 million will be paid out to Avadel over the next 13 months. The transaction closed on June 30, 2020.

About Avadel Pharmaceuticals plc
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is an emerging biopharmaceutical company. The Company's primary focus is the development and potential FDA approval of FT218, which has completed a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. For more information, please visit www.avadel.com.

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The Company recently completed the REST-ON study, a pivotal, double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

Cautionary Disclosure Regarding Forward-Looking Statements
This press release includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. Such forward-looking statements include, but are not limited to, the anticipated benefits of the sale of the Company's sterile injectable drug portfolio, the planned submission of the FT218 NDA to the FDA and the commercial launch of FT218, if approved. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "could," "believe," "expect," "look forward," "on track," "guidance," "anticipate," "estimate," "project," "next steps" and similar expressions, and the negatives thereof (if applicable).

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, our business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results of our research, development and commercialization activities and the results of our business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in our forward-looking statements include the risk that the impact of the current COVID-19 pandemic on our financial results and results of operations could be greater than we anticipate and the risks and uncertainties described in the "Risk Factors" section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, which we filed with the Securities and Exchange Commission (SEC) on March 16, 2020 and subsequent SEC filings.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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