Avadel to Present New Data on Once-Nightly Sodium Oxybate at SLEEP 2019 Conference

June 4, 2019

DUBLIN, Ireland, June 04, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for narcolepsy, today announced it will present two posters at the 33rd Annual Meeting of the Associated Professional Sleep Societies being held in San Antonio, Texas, from June 8-12, 2019. The posters highlight pharmacokinetic (PK) data for its investigational, once-nightly controlled-release sodium oxybate (FT218), including a head-to-head PK comparison to twice-nightly sodium oxybate and dose proportionality across three doses.

“Our once-nightly controlled-release sodium oxybate demonstrated lower overall peak plasma concentrations (C_{max}) and similar total exposures (AUC), compared to twice-nightly sodium oxybate in a head-to-head study,” said Jordan Dubow, MD, Chief Medical Officer of Avadel Pharmaceuticals. “Furthermore, results from our dose proportionality study showed that FT218 exhibits predictable increases in plasma levels with increasing doses, consistent with the PK profile desired for a once-nightly sodium oxybate formulation. We are excited about the potential benefits of our once-nightly formulation and look forward to completion of the Phase 3 REST-ON trial, which is nearly two-thirds complete.”

Poster Presentations:

Poster 0609, presented Sunday, June 9, 5:15 – 7:15 p.m. CDT
“Pharmacokinetics and Formulation Selection of FT218, an Investigational Controlled-Release Sodium Oxybate Formulation Designed for Once-Nightly Dosing”

Poster 0610, presented Sunday, June 9, 5:15 – 7:15 p.m. CDT
“Pharmacokinetics and Dose Proportionality of FT218, an Investigational Controlled-Release Sodium Oxybate Formulation Designed for Once-Nightly Dosing”

The pharmacokinetics and formulation selection pilot study was designed as a four-way crossover study in 16 healthy volunteers, evaluating three proprietary once-nightly formulations of Micropump™ controlled-release (CR) sodium oxybate (FT218) versus twice-nightly immediate-release (IR) sodium oxybate at a nightly dose of 4.5g (two doses of 2.25g for IR sodium oxybate). Each subject consumed a standard meal two hours prior to dosing. Subjects receiving the twice-nightly IR sodium oxybate, were administered the second dose 4 hours after the first dose. Two subjects dropped out of the study prior to the completion. The key data for the 14 evaluable subjects demonstrates:

- FT218 exhibited rapid initial absorption comparable to twice-nightly IR sodium oxybate
- FT218 demonstrated a lower overall C_{max} than twice-nightly IR sodium oxybate
- FT218 mean blood concentrations (ug/ml) at 8 hours were similar to that of twice-nightly IR sodium oxybate
- Safety and tolerability were similar across administrations

The dose proportionality study was an open-label, single-dose, three-sequential-period study in 20 healthy volunteers. Subjects received three separate single-dose administrations of FT218 at bedtime, two hours post-evening meal, in a sequential order of 4.5g, 7.5g and 9g with a minimum 7-day washout between doses. PK profiles were assessed for dose proportionality across the three doses and the results demonstrated:

- FT218, at each dose, exhibited PK profiles consistent with those desired for once-nightly dosing
- Dose proportionality was maintained for C_{max} across the dosage range
- Safety profile was consistent with what is known for sodium oxybate

The safety and efficacy of FT218 for the once-nightly treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy is currently being evaluated in the Phase 3, multi-centered, double-blind, placebo-controlled REST-ON trial, which is expected to complete enrollment in 2020. Poster reprints and REST-ON information will be available at Avadel’s Booth #1027 in the Exhibit Hall during the SLEEP 2019 conference.

About Avadel Pharmaceuticals plc:

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company. The Company’s primary focus is on the development and potential FDA approval for FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel develops and markets a portfolio of sterile injectable drugs used in the hospital setting. For more information, please visit www.avadel.com.

Cautionary Disclosure Regarding Forward-Looking Statements

This press release may include “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. In some cases, forward-looking statements can be identified by the use of words or phrases such as “will,” “as we continue,” “objective,” “future success,” “potential, “opportunity” 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 (i) the risk that we could experience failure or delay in completing the Phase 3 “REST-ON” clinical trial for our FT218 product, or that if the FDA ultimately approves such product, the approval may not include any period of market exclusivity; (ii) the risk that, even if we successfully complete the development of FT218 and begin its commercialization, it may not receive market acceptance, or new, announced alternative products in development may be approved and may be viewed as more effective than FT218 or otherwise receive greater market acceptance; (iii) the risk that servicing our $143.75 million Exchangeable Senior Notes due 2023 may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of such 2023 Notes in cash, repay the 2023 Notes at maturity, or repurchase the 2023 Notes as required following a “fundamental change” event described in the indenture governing the 2023 Notes; and (iv) the other 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, 2018 which we filed with the Securities and Exchange Commission on March 15, 2019.

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 the forward-looking statements contained in this press release.

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