Avadel Pharmaceuticals Announces FDA Acceptance of New Drug Application for AV001

May 22, 2019

AV001 granted Priority Review

PDUFA action date is September 15, 2019

DUBLIN, Ireland, May 22, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for the Company's fourth Hospital Product, AV001. It has been granted Priority Review status by the FDA resulting in a six-month review period. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 15, 2019.

"If approved, AV001 will be our fourth revenue producing Hospital Product," said Greg Divis, interim Chief Executive Officer of Avadel. "We are pleased that the FDA has granted AV001 an accelerated 6-month Priority Review. Subsequent to our NDA submission, the FDA granted an NDA approval for a parenteral product with the same Active Pharmaceutical Ingredient (API) as AV001. We will continue to monitor the marketplace as we work with FDA on our application and prepare for a successful launch of AV001."

About Avadel Pharmaceuticals plc

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company. Our primary focus is on the development and potential FDA approval for FT218 which is in a Phase III clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, we market three sterile injectable drugs used in the hospital setting which were developed under our "unapproved marketed drug" (UMD) program. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: *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. The words "will," "remain confident" and related or similar words and expressions, and (as applicable) the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on estimates and assumptions made within the bounds of our knowledge of our business and operations, 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. These risks include: (a) the risks that our NDA for AV001 may not receive FDA approval or, if AV001 does receive FDA approval; (b) risks relating to the development of our investigational "FT218" sodium oxybate product, including the risks that (i) we may need to obtain additional capital to complete the development of FT218, and such additional capital may not be available on attractive terms or at all; (ii) we may be unsuccessful in accelerating the pace of our clinical trial enrollment for the Phase 3 REST-ON clinical trial, or we could experience delay or failure in completing that clinical trial; and (iii) we could be unsuccessful in marketing the FT218 product in the event we obtain FDA approval for it; and (c) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2018, and our quarterly reports on Form 10-Q for the period ended March 31, 2019, in particular disclosures that may be set forth in under the captions "Forward-Looking Statements" and "Risk Factors." You should not place undue reliance on forward-looking statements, which speak only as of the date they are made and are not guarantees of future performance. We do not undertake any obligation to publicly update or revise these forward-looking statements.*

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