Avadel Pharmaceuticals Receives New PDUFA Date for AV001 of December 15, 2019

August 8, 2019

PDUFA Action Extended 3 Months; Launch Remains on Track for 1Q 2020

DUBLIN, Ireland, Aug. 08, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for narcolepsy, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) Action Date relating to the New Drug Application (NDA) for AV001, a sterile injectable product designed for use in the hospital setting, by three months to December 15, 2019. The NDA for AV001 was originally accepted in May 2019 under the FDA's Priority Review program with a statutory six-month review.

This three-month extension relates to recent submissions Avadel made in response to FDA requests for additional analytical information. The FDA determined that these submissions constitute a major amendment and will require additional time to review.

"We have remained in contact with the FDA since filing the AV001 NDA and look forward to continuing our constructive dialog with the Agency," said Greg Divis, Chief Executive Officer of Avadel. "Should FDA approve AV001, the three-month extension does not impact our planned timeline for the U.S. launch, which we currently anticipate occurring in the first quarter of 2020. As such, all our operational and launch planning remain on-track."

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 Note Regarding Forward-Looking Statements

This press release contains "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements (which may be identified by words such as "will," "look forward," "should," "planned" and "anticipate") are not statements of historical facts regarding AV001, the FDA review process relating thereto including the expected timing of that process, and the possible commercial launch of AV001. All forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA may determine that there are deficiencies in the NDA for AV001 or may never approve the NDA for AV001, AV001 may not have the therapeutic benefits the Company anticipates, the commercial launch of AV001 could be delayed, AV001 may not achieve commercial acceptance, other companies may develop competing products which may receive FDA approval before AV001, and the other risks detailed in Avadel's filings with the SEC, including, without limitation, its Form 10-K, Forms 10-Q and other reports on Forms 8-K, all of which can be obtained on the SEC website at www.sec.gov. Avadel assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

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