# Ovid Therapeutics Reports Second Quarter 2019 Financial Results and Highlights Recent Progress

August 7, 2019

Phase 3 NEPTUNE Trial of OV101 in Angelman Syndrome on Track to Enroll the First Patients in the Third Quarter of 2019

Regulatory Authorities in the U.S. and Germany agree that NEPTUNE, if positive, could support the filings of an NDA and MAA for OV101

Interim Data from Open-Label ENDYMION Trial with OV935 for Individuals with DEE Expected in the Third Quarter of 2019

NEW YORK, Aug. 07, 2019 (GLOBE NEWSWIRE) -- Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today reported financial results for the second quarter ended June 30, 2019 and provided an overview of the company's recent progress.

"Our Phase 3 NEPTUNE clinical trial, if positive, has the potential to make OV101 the first drug approved specifically for patients with Angelman syndrome," said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "We expect to enroll the first patients in NEPTUNE during the coming weeks. In addition, we expect interim data from our open-label ENDYMION trial with OV935 (soticlestat) for individuals with rare developmental and epileptic encephalopathies to be available later this quarter. This is an exciting and productive time at Ovid as we continue to execute on our programs and corporate objectives."

**Recent Progress and Upcoming Milestones**

*OV101 (gaboxadol) for Angelman Syndrome*

- Based on Ovid's interactions with regulatory authorities in the U.S. and Germany regarding a Phase 3 program and registration path, Ovid, the U.S. Food and Drug Administration (FDA) and Germany's Federal Institute for Drugs and Medical Devices (BfArM) agree on the study design of the Phase 3 NEPTUNE trial, including the use of the Angelman syndrome-specific Clinical Global Impressions of Improvement (CGI-I-AS) as the primary efficacy outcome measure. Both the FDA and BfArM agreed that NEPTUNE, if positive, could support the filings of a New Drug Application (NDA) and Marketing Authorization Application (MAA), respectively.

- Ovid has initiated the pivotal Phase 3 NEPTUNE trial and plans to enroll the first Angelman syndrome patients in the third quarter of 2019. Topline results from the trial are expected in mid-2020.

- In July 2019, Ovid announced that the European Commission (EC) granted orphan drug designation (ODD) to OV101 for the treatment of Angelman syndrome based on the results of the Phase 2 STARS trial.

*OV101 (gaboxadol) for Fragile X Syndrome*

- The Phase 2 ROCKET trial continues to enroll patients and results are expected around year-end 2019 or early 2020.

*OV935 (soticlestat) for Rare Developmental and Epileptic Encephalopathies (DEE)*

- Interim data from the open-label extension ENDYMION trial for individuals with DEE who previously completed a clinical trial with OV935 are expected in the third quarter of 2019.

- The open-label Phase 2 ARCADE trial in individuals with Dup15q syndrome or CDKL5 Deficiency Disorder continues to enroll patients with data expected in the first quarter of 2020.

- The global Phase 2 ELEKTRA trial in children with Dravet syndrome or Lennox-Gastaut syndrome continues to enroll patients.

**Second Quarter 2019 Financial Results**

- As of June 30, 2019, cash and cash equivalents totaled $47.4 million.

- Research and development expenses were $9.1 million for the second quarter ended June 30, 2019, as compared to $8.1 million for the same period in 2018. The increase of $1.0 million was primarily due to an increase in clinical activities related to the Company's ongoing development programs.

- General and administrative expenses were $4.2 million for the second quarter ended June 30, 2019, as compared to $5.1 million for the same period in 2018. The decrease of $0.9 million was primarily due to a decrease in payroll and payroll-related expenses of $1.5 million offset by an increase in professional fees and general office expenses of $0.6 million.

- The Company reported a net loss of $13.1 million, or basic and diluted net loss per share attributable to common stockholders of $0.34, for the second quarter of 2019, as compared to a net loss of $12.9 million, or net loss per share attributable to common stockholders of $0.53, for the same period in 2018.

**About Ovid Therapeutics**

Ovid Therapeutics (NASDAQ: OVID) is a New York-based biopharmaceutical company using its BoldMedicine™ approach to develop medicines that transform the lives of patients with rare neurological disorders. Ovid has a broad pipeline of potential first-in-class medicines. The company's most advanced investigational medicine, OV101 (gaboxadol), is currently in clinical development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid is also developing OV935 (soticlestat) in collaboration with Takeda Pharmaceutical Company Limited for the potential treatment of rare developmental and epileptic encephalopathies (DEE).

For more information on Ovid, please visit http://www.ovidrx.com/.

**Forward-Looking Statements**

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding advancing Ovid's product candidates, progress, timing, scope and results of clinical trials for Ovid's product candidates, and the reporting of clinical data regarding Ovid's product candidates. You can identify forward-looking statements because they contain words such as "will," "believes" and "expects." Forward-looking statements are based on Ovid's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Ovid's filings with the Securities and Exchange Commission under the caption "Risk Factors". Ovid assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

**Condensed Consolidated Statements of Operations**

**(Unaudited)**

| | Three Months Ended June 30, 2019 | Three Months Ended June 30, 2018 | Six Months Ended June 30, 2019 | Six Months Ended June 30, 2018 |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | $ 9,117,495 | $ 8,116,385 | $ 18,454,804 | $ 16,590,942 |
| General and administrative | 4,204,771 | 5,093,311 | 8,920,999 | 10,048,615 |
| Total operating expenses | 13,322,266 | 13,209,696 | 27,375,803 | 26,639,557 |
| Loss from operations | (13,322,266) | (13,209,696) | (27,375,803) | (26,639,557) |
| Interest income | 264,999 | 274,556 | 518,341 | 521,662 |
| Net loss | $ (13,057,267) | $ (12,935,140) | $ (26,857,462) | $ (26,117,895) |
| Net loss attributable to common stockholders | $ (13,057,267) | $ (12,935,140) | $ (26,857,462) | $ (26,117,895) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.34) | $ (0.53) | $ (0.78) | $ (1.06) |
| Weighted-average common shares outstanding basic and diluted | 38,693,018 | 24,625,966 | 34,534,432 | 24,617,555 |

**Selected Condensed Balance Sheet Data**

**(Unaudited)**

| | June 30, 2019 | December 31, 2018 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 47,361,966 | $ 41,500,652 |
| Working capital[1] | $ 44,423,321 | $ 35,423,690 |
| Total assets | $ 54,908,278 | $ 47,649,602 |

| | | |
|---|---|---|
| Total stockholders' equity | $ 45,437,899 | $ 38,805,145 |

[1]Working capital defined as current assets less current liabilities

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