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Ovid Therapeutics Announces First Patient Randomized in Phase 1b/2a Clinical Trial of TAK-935/OV935 in Adults with Rare Epilepsies

- Cornerstone of Robust Clinical Development Strategy for Potential First-in-Class CH24H Modulator -

- Ovid's Clinical Pipeline of Rare Neurological Disorder Programs Advancing to Mid-Stage Trials -

NEW YORK, Aug. 21, 2017 (GLOBE NEWSWIRE) -- Ovid Therapeutics Inc. (NASDAQ:OVID), a biopharmaceutical company committed to developing medicines for patients with rare neurological disorders, today announced it has randomized the first patient in its Phase 1b/2a clinical trial of TAK-935, also known as OV935, in collaboration with Takeda Pharmaceutical Company Limited. This marks the second program Ovid has advanced into Phase 2 clinical development this year.

Takeda and Ovid formed a global collaboration focused on the clinical development and commercialization of TAK-935/OV935, a potent and highly selective cholesterol 24-hydroxylase (CH24H) inhibitor, being investigated in adults with developmental and/or epileptic encephalopathies in January 2017.

"We are excited to achieve this important milestone as this is the first clinical trial in our collaboration with Ovid and TAK-935/OV935 is the first CH24H inhibitor in clinical development," said Dr. Emiliangelo Ratti, head of Takeda's Central Nervous System Therapeutic Area Unit. "While there are many treatments available for epilepsy, few therapeutic options exist for patients with developmental and/or epileptic encephalopathies, which cause intractable seizures that are often associated with cognitive, neurologic and behavioral symptoms. Our collaboration with Ovid is geared to leverage each company's strengths to jointly develop this investigational medicine for people living with rare epilepsies."

“We believe that TAK-935/OV935 has the potential to target the increased pro-epileptic signaling that occurs in developmental and/or epileptic encephalopathies and provide a treatment for people with rare epilepsies who currently do not have sufficient options,” said Amit Rakhit, M.D., MBA, chief medical and portfolio management officer of Ovid Therapeutics. “This trial is the beginning of a planned broader development program for TAK-935/OV935. We intend to investigate TAK-935/OV935 in younger populations because rare epilepsies, such as Dravet syndrome, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex, are diagnosed early in life and this may provide an opportunity to intervene early in the disease course.”

Data from the Phase 1b/2a trial in adults with developmental and/or epileptic encephalopathies, which are types of rare epilepsies that share similar clinical manifestations, is anticipated in 2018. As part of the broader development program, Ovid and Takeda also plan to study the role of 24-S-hydroxycholesterol (24HC) as a peripheral biomarker that can inform future clinical trial designs and help clinicians individualize the use of this therapy.

TAK-935/OV935 has the potential to become a first-in-class CH24H inhibitor and is believed to modulate the N-Methyl-D-Aspartate (NMDA) receptor, which has been implicated in several neurologic disorders, including rare epilepsies. TAK-935/OV935 has been tested in four Phase 1 clinical trials involving 86 healthy volunteers and has been found to be well tolerated without clinically significant safety findings. Data from multiple preclinical models indicate that TAK-935/OV935 may affect both seizure intensity and frequency.

About the Phase 1b/2a Trial
The randomized, double-blind, placebo-controlled, dose-escalation Phase 1b/2a clinical trial will enroll approximately 20 adult patients with developmental and/or epileptic encephalopathies, including Dravet Syndrome, Lennox-Gastaut Syndrome and Tuberous Sclerosis Complex. The multicenter trial will include an initial one-month baseline period followed by a one-month double-blind, dose-escalation phase. Participants will have the option to continue for an additional two-month open-label extension phase. The primary endpoint of the study is to characterize the safety and tolerability of TAK-935/OV935. Secondary endpoints include assessment of standard safety laboratory values and evaluation of pharmacokinetics.

Learn more about the trial at http://www.clinicaltrials.gov (https://www.globenewswire.com/Tracker?data=wEU3ger3-QYbNV4P5mUqzAIzgMxn4CRQc08WV56zl_WMSyKPyqS8S6yM-m8z08CH_j6s7XPmOgV2KtWLrVCmFMJ6tWEMpSSrcPZmk41qBC5VQZz0oY6n3_S3ilxR3vEr).

About Rare Epilepsies
Developmental and/or epileptic encephalopathies are a group of rare epilepsies that cause significant morbidities for patients and their families beyond what might be expected from the underlying pathology alone and can worsen over time. Developmental and/or epileptic encephalopathies typically present early in life and are often associated with severe cognitive and developmental impairment in

addition to frequent seizures throughout the person's lifetime. These disorders vary in their age of onset, developmental outcome, etiologies, neuropsychological deficits, electroencephalographic (EEG) patterns, seizure types and prognosis.

Despite the availability of medicines for epilepsy, few treatment options are available for epileptic encephalopathies, and novel therapies are needed.

About TAK-935/OV935
TAK-935/OV935, which is being studied in rare epilepsies, is a potent, highly-selective, first-in-class inhibitor of the enzyme CH24H. CH24H is predominantly expressed in the brain, where it plays a central role in cholesterol homeostasis. CH24H converts cholesterol to 24HC, which then exits the brain into the blood plasma circulation. Glutamate is one of the main neurotransmitters in the brain and has been shown to play a role in the initiation and spread of seizure activity. Recent literature indicates CH24H is involved in over-activation of the glutamatergic pathway through modulation of the NMDA channel, implying its potential role in central nervous system diseases such as epilepsy. To Ovid's knowledge, TAK-935/OV935 is the only molecule with this mechanism of action in clinical development.

TAK-935/OV935 has been tested in preclinical models to provide data to support the advancement of the drug into human clinical studies in patients suffering from rare epilepsy syndromes. A novel proprietary PET ligand, developed by Takeda and Molecular Neuroimaging, LLC (MNI), has been used to determine target occupancy of TAK-935/OV935 in the brain. In addition, TAK-935/OV935's effect on CH24H enzyme activity in the brain has been assessed by following measurable reductions in the plasma concentration of 24HC.

TAK-935/OV935 has completed four Phase 1 clinical studies, which have assessed tolerability and target engagement at doses believed to be therapeutically relevant. TAK-935/OV935 is being co-developed by Ovid and Takeda Pharmaceutical Company Limited.

About Ovid Therapeutics
Ovid Therapeutics (NASDAQ:OVID) is a New York-based biopharmaceutical company using its BoldMedicine™ approach to develop therapies that transform the lives of patients with rare neurological disorders. Ovid's drug candidate, OV101, is currently in development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid has initiated the Phase 2 STARS trial of OV101 in adults with Angelman syndrome and a Phase 1 trial in adolescents with Angelman syndrome or Fragile X syndrome. Ovid is also developing OV935 in collaboration with Takeda Pharmaceutical Company Limited for the treatment of rare epileptic encephalopathies and has initiated a Phase 1b/2a trial of OV935.

For more information on Ovid, please visit http://www.ovidrx.com/ (https://www.globenewswire.com/Tracker?data=wEU3ger3-QYbNV4P5mUqzD_R8GuTfq2ZwSNbiuyCzQsWst5n_Ty6OKZmRNBCic3MEI6dltPccCK428WUd6EGdTpaoZb4CCGMzGUuB1Q_ytsQ8_zd7XJl4nArl3uEENoiYiH2KVe2Sry_wZ_MynY2JsztnVozTsnZVBMr3l6pMX1QuYC4CyvwhE59w-iorjs_eA_YtWjcJ8K3264GAxI85ZA4D4jS_wCk8akALHbSDMRZc6bRK9xWO8C_PqofNRfdviGp-YBhYZ4p2eL0X9gCsw==).

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding progress, timing, scope and results of clinical trials for Ovid’s product candidates, the reporting of clinical data regarding Ovid’s product candidates, and the potential use of TAK-935/OV935 to treat rare epilepsies. 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, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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.

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