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Cleveland Clinic releases fourth installment of Alzheimer's Disease Drug Pipeline Report

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Cleveland Clinic's fourth annual analysis of Alzheimer's disease drug development found that the pipeline has grown in the number and variety of agents being tested over the past year, while highlighting several advances in the field including new clinical trial designs, more detailed criteria for making a research diagnosis, and an increased use of biological tests reflecting of the disease.

Based on the federal website ClinicalTrials.gov, the paper, Alzheimer's disease drug development: pipeline 2019, is Cleveland Clinic's fourth review of Alzheimer's disease drug development and appears as a July featured article in *Alzheimer's & Dementia: Translational Research & Clinical Trials Interventions* (TRCI), an open access journal of the Alzheimer's Association.

"Improvements to clinical trial design and new guidelines for a research diagnosis of Alzheimer's disease have allowed for accuracy in studies and precision in the staging of Alzheimer's disease, which are increasingly important in drug development," said Jeffrey Cummings, M.D., ScD, director emeritus of Cleveland Clinic Lou Ruvo Center for Brain Health, director of the Center for Neurodegeneration and Translational Neuroscience and research professor at the University of Nevada, Las Vegas department of Brain Health. "This progress is a result of key collaborations amongst stakeholders and has elevated us to an unprecedented stage of drug development. We've never seen more funding, more agents or more diversity in the pipeline."

At a time when scientists are now reexamining the role of therapies targeting amyloid, this year's pipeline shows a trend toward a more diverse approach in attacking Alzheimer's disease. These agents include, anti-tau, neuroprotective, anti-inflammatory, regenerative (stem cells) and metabolic interventions. Additional trends include a variety of approaches to deep brain stimulation as well as ribonucleic acid (RNA)-based therapies.

"It's been really disappointing to see these last couple of clinical trials fail. We were worried that this would have a devastating impact on Alzheimer's drug development, but when we surveyed the landscape, we were encouraged to see more, not fewer agents being developed," said Aaron Ritter, M.D., director of clinical trials at Cleveland Clinic Lou Ruvo Center for Brain Health. "Every drug failure is an opportunity for learning, and it is our hope that through this paper, the public will see the importance of clinical trial participation. The bottom line is that as the pipeline grows, so does the number of people needed to test these medications."

Drs. Cummings and Ritter, along with fellow authors Garam Lee, Pharma.D., a clinical research pharmacist at Cleveland Clinic Lou Ruvo Center for Brain Health; Marwan Sabbagh, M.D., director of Cleveland Clinic Lou Ruvo Center for Brain Health; and Kate Zhong, M.D., CEO of CNS Innovations examined all clinical trials from 2018 to 2019 to uncover the diversity in the pipeline as well as innovations utilized in current trials such as designs, outcomes, populations and biomarkers.

The authors note that several new clinical trial designs—including futility analyses and adaptive trial designs, as seen in the development of cancer and diabetes medications—increase the speed and sophistication of conducting Alzheimer's disease clinical trials. Another important trend in the field is a move toward testing medications in people either minimally effected or even before the onset of symptoms.

Several Alzheimer's prevention studies enrolling people based on their genetic predisposition to Alzheimer's disease are now being conducted. Moving forward, the authors' specific areas of interest include repurposed agents, immunotherapies, and novel mechanisms of action (MOA).

More information: Jeffrey Cummings et al. Alzheimer's disease drug development pipeline: 2019, *Alzheimer's & Dementia: Translational Research & Clinical Interventions* (2019). DOI: 10.1016/j.trci.2019.05.008

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