Aduhelm™ (aducanumab-avwa) – Updated labeling

- On July 8, 2021, Biogen announced the FDA approval of updated labeling for Aduhelm (aducanumab-avwa), emphasizing that Aduhelm should be initiated in patients with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia.

- The update includes an addition to the *Indications and Usage* section of the label as seen below (*italics* to note updated language).

    — Aduhelm is indicated for the treatment of Alzheimer's disease. Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

- The update to the label is consistent with the patient population that was studied across the three Aduhelm clinical studies that supported approval.