Press Release

For immediate release

Many red flags raised by the FDA approval of aducanumab
Health Canada must stick to science

Montreal, August 9, 2021. Researchers and clinicians from six leading Canadian organizations working in the dementia research and care field, came to the conclusion that aducanumab – the treatment (or disease-modifying therapy) for Alzheimer's disease (AD) recently approved conditionally by the FDA and undergoing evaluation at Health Canada – requires further testing before approval and widespread use in patients with AD in Canada. This group of eminent health research professionals produced a position statement that was presented to Health Canada and other Canadian health regulatory bodies; it has also been made available to the public. They also offered to form a working committee, which would provide guidance and advice to Health Canada on the approval of any treatment or disease-modifying therapies for neurocognitive disorders.

Alzheimer's disease, one of many causes of dementia, affects more than 650,000 Canadians, and this number is expected to double within the next ten years. The annual cost attributed to dementia care is estimated at 10 to 12 billion dollars in Canada. People with Alzheimer's disease show an increase of a protein called amyloid in their brain. Aducanumab is an anti-amyloid medication. However, presence of amyloid in the brain is not the only important factor in AD, and it is unclear if amyloid reduction leads to dementia reversal.

"As researchers, we are all very dedicated towards finding a cure for Alzheimer's disease; we know that there was no treatment breakthrough in the last 20 years for dementia", explained the Canadian Consortium on Neurodegeneration in Aging Scientific Director, Dr. Howard Chertkow. "Patients and advocacy groups quickly applauded the accelerated approval of this drug in the U.S. It was the first ray of hope for a cure in a very long while. But scientific evidence must prevail, and actually, there are too many red flags raised. People have to understand that introducing a medication which may not have clinically relevant benefits could have detrimental effects", Dr Chertkow added.

In their statement, health research professionals commented that the available evidence presented by Biogen, the pharmaceutical company that developed the medication, suggests that aducanumab (ADUHELM™) does not meet accepted criteria for clinical efficacy, safety, and risk benefit for a disease-

modifying therapy for AD that would justify regulatory approval in Canada. Moreover, major questions about costs and benefits were raised and must be evaluated thoroughly.

"The Canadian health care system is very different from its counterpart in the U.S., and the benefits of an expensive disease-modifying therapy will need to be balanced against other potential uses of limited public financial resources, said Dr Tarek Rajji, Executive Director of the Toronto Dementia Research Alliance (TDRA). "Adding new costs to an already overloaded health care system will just force the authorities to make difficult decisions. We know that preventable dementia risk factors (such as hypertension, smoking, diabetes, and untreated mid-life hearing loss) can be responsible for up to 40% of dementia cases. Investing more in highly effective prevention programs would turn out to be cost saving, and would reduce number of individuals with dementia" Dr Rajji added.

The position statement was prepared by members of the Canadian Consortium on Neurodegeneration in Aging (CCNA), the Consortium of Canadian Centres for Clinical Cognitive Research (C5R), the Canadian Academy of Geriatric Psychiatry (CAGP), the Canadian Geriatric Society (CGS), the Ontario Neurodegenerative Disease Research Initiative (ONDRI), and the Toronto Dementia Research Alliance (TDRA), and endorsed by those organizations. The complete statement, a summary, and the list of signatories are available at www.ccna-ccnv.ca/aducanumab.

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About the research organizations:

CCNA (Canadian Consortium on Neurodegeneration in Aging) is a Canadian national umbrella organization for research on dementia funded by CIHR and partners with 350 researchers across Canada. www.ccna-ccnv.ca @ccna_ccnv

C5R (Consortium of Canadian Centres for Clinical Cognitive Research) is a not-for-profit research network of 30 academic memory clinics and research sites across Canada that conduct clinical trials in the desire to research and develop treatments for patients with Mild Cognitive Impairment, Alzheimer's disease, as well as other forms of dementia.

CAGP (Canadian Academy of Geriatric Psychiatry) is a national organization of psychiatrists and health professionals dedicated to promoting mental health in the Canadian elderly population through the clinical, educational, research and advocacy activities of its membership.

CGS (Canadian Geriatric Society) is the professional society for Geriatric Medicine specialists and Care of the Elderly specialists, and has over 500 members representing such specialists, along with medical

students and residents, as well as other physicians and members of allied health professions with an interest in the health care of older adults. http://www.canadiangeriatrics.ca/

ONDRI (Ontario Neurodegenerative Disease Research Initiative) brings together Ontario's research scientists and clinicians to tackle the complexity of dementia by studying multiple diseases related to neurodegeneration. ONDRI is funded by the Ontario Brain Institute (OBI). www.ondri.ca @ONDRIStudy

TDRA (Toronto Dementia Research Alliance) is a University of Toronto collaboration of scientists and clinicians which aims to better understand, prevent, and treat dementia, and embed research into care. https://tdra.utoronto.ca/ @TorontoDementia https://www.linkedin.com/company/toronto-dementia-research-alliance/