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PRESS RELEASE

CMS Proposed Decision Risks Driving Away Investment in Alzheimer's Disease

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Recent research published by the healthcare consultancy Vital Transformation shows that the proposed draft decision by CMS to only cover newly approved FDA monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD), under Coverage with Evidence Development (CED) exclusively for patients enrolled in CMS approved randomized controlled trials, could add three or more years to the process of approving new Alzheimer's therapies for coverage. This delay was found to have a profound impact on the financial viability of developing and commercializing those treatments successfully. According to this model, a three-year delay has the potential to reduce the number of therapies that will provide a return-on-investment by more than 80%.

Based on the delays in CMS coverage that are included in the draft CED, 42 of the 45 assets currently in development in Alzheimer's disease do not present a favorable Return on Investment (ROI) profile. Positive ROI is considered a key factor in determining the potential commercial success of an investigational asset for investors, whom would likely not support their continued development due to low likelihood of profitability. Companies would also be more likely to halt or pause existing Alzheimer's disease development programs, as they would no longer be profitable or sustainable.

By tracing available data from 551 clinical trials launched in Alzheimer's disease since 1995 until today, Vital Transformation has found that the average length of time to conduct a clinical development program is now approaching 12 years, from Phase 1 trial initiation to approval and launch.

According to Vital Transformation CEO Duane Schulthess, "We calculated the impact of the CMS proposed guidance on 45 clinical development programs that are currently active for Alzheimer's disease. We built a financial model similar to what investors use to determine if a therapy is a good or bad investment, and if its development should be terminated. When we added the delayassociated with the mandated clinical trial in CMS' draft CED proposal, investors and R&D directors would need to reduce their financial backing of these investigational therapies due to such a radical shift in the economic value of their portfolio, and would need to do so almost immediately."

Belgium office: Vital Transformation BVBA, 107 Leopold III Laan, Wezembeek-Oppem, Belgium 1970.
VAT BE 0535.674.580 **T** +32 2 306 8597
U.S. office: Vital Transformation LLC, 80 M Street SE, 1st Floor, Washington, DC 20003
E info@vitaltransformation.com **W** www.vitaltransformation.com

The proposed coverage decision by CMS also has implications beyond the class of drugs for which it is aimed. Even though the proposed CMS guidance applies specifically to amyloid-targeting antibodies, it introduces material risks to the ROI calculations for other assets in development, including other Alzheimer's treatments as well as for neurological disorders more broadly. It also brings into question the future sustainability of products approved under the accelerated approval pathway.

The entire neurological therapeutic area has seen a reduction in clinical trials by over 50% since reaching a peak in 2009, due to their associated scientific challenges and financial risks; this decline willbe amplified by the uncertainty created by this draft CMS decision. A key conclusion of the analysis is that removing the ROI from this class of therapeutics will likely drive an exodus from early stage investing, impacting the development of potential therapies in an area of high unmet need.

“We investigated 729 individual financing rounds and 287 deals in total, but the available data only allows for proxy measures for costs, and not for the quantification of the internal cost of R&D incurred by the lead sponsor of a clinical trial. In that sense, this research underestimates the total financial outlay required to successfully bring a product to market, and likely is conservative inits findings,” according to Dr. Harry Bowen, Vital Transformation’s consulting economist.

This research and analysis was commissioned and funded by Biogen, Inc.

About Vital Transformation:
Vital Transformation understands the implications of new medical procedures, technologies, and policies. We measure their impact on current clinical practices in close collaboration with health care professionals, researchers, and regulators. Through our web platform and client network, we are able to communicate our findings with international decision makers and stakeholders. Our Vital Transformation branded roundtables, webinars, and conferences are often oversubscribed, and are regularly presented in partnership with global thought-leaders and organizations.

The full research pack and underlying data is available for download at www.vitaltransformation.com.

Contact: info@vitaltransformation.com