European Medicines Agency lägger till observationella data för vuxna med SMA i produktresumén för SPINRAZA® (nusinersen)

- Produktresumén har blivit uppdaterad för att inkludera observationella data som visade att behandling med NUSINERSEN ledde till kliniskt betydelsefulla förbättringar, stabilisering av motorisk funktion hos vuxna med spinal muskelatrofi (SMA) och bibehållen säkerhetsprofil
- Dessa observationella data ger ytterligare stöd för NUSINERSENs effekt och säkerhet, nästan fem år efter dess marknadsföringstillstånd i EU
- En annan uppdatering av produktresumén ger ytterligare vägledning om hur NUSINERSEN ska administreras vid missade eller försenade doser

Upplands Väsby – 11 februari 2022 – Biogen Inc (Nasdaq: BIIB) today announced that the European Medicines Agency (EMA) updated the Summary of Product Characteristics (SmPC) for SPINRAZA® (nusinersen) to include real-world data demonstrating clinically meaningful improvements and stabilization in motor function over time in adults with spinal muscular atrophy (SMA). These results build on the sustained efficacy and established safety profile of NUSINERSEN shown in Biogen's clinical development program encompassing 10 studies.

These real-world findings demonstrate that treatment with NUSINERSEN improved or stabilized motor function, upper limb function and walking ability in some adults with later-onset SMA (Types 2 and 3). Safety results in this adult patient population were consistent with the known profile of NUSINERSEN and with co-morbidities associated with the underlying disease of SMA. The effectiveness of NUSINERSEN in adults is further characterized by a recently published independent meta-analysis[1] that concluded improved motor function can be observed across a range of individuals with SMA Type 2 and Type 3 over a 10- to 14-month observation period.

In addition, new updates to the label instruct prescribing physicians on how to adjust the NUSINERSEN dosing schedule should a patient miss or need to delay treatment because of the impact of COVID-19 or real-life circumstances. Over the past two years, the COVID-19 pandemic has interfered with planned treatments for some SMA patients when hospitals made changes to their protocols and procedures.[2] The EMA added new language to the SmPC indicating that if a patient misses a loading or maintenance dose of NUSINERSEN, the dosing schedule should be adjusted in order to restore nusinersen levels to those expected without treatment interruption. The EMA also removed the black triangle from the NUSINERSEN label, in line with products that have shown consistent safety data over five years.

Om SPINRAZA (nusinersen)

SPINRAZA är avsett för behandling av spinal muskelatrofi av typ 5q. Hos patienter som behandlats med Spinraza genom lumbalpunktion har allvarlig infektion, såsom meningit, observerats. Det har även förekommit rapporter om kommunicerande hydrocefalus, aseptisk meningit och överkänslighet (t.ex. angioödem, urtikaria och hudutslag). För information om kontraindikationer, varningar och försiktighet, biverkningar, dosering och förpackningar se http://www.fass.se.

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About Spinal Muscular Atrophy (SMA)

SMA is a rare, genetic, neuromuscular disease that affects individuals of all ages. It is characterized by a loss of motor neurons in the spinal cord and lower brain stem, resulting in progressive muscle atrophy and weakness.[5] SMA is caused by a deficiency in the production of survival motor neuron (SMN) protein due to a damaged or missing *SMN1* gene, with a spectrum of disease severity.[5] Some individuals with SMA may never sit; some sit but never walk; and some walk but may lose that ability over time.[6] In the absence of treatment, children with the most severe form of SMA would not be expected to reach their second birthday.[5]

SMA impacts approximately 1 in 10,000 live births,[7-10] is a leading cause of genetic death among infants[11] and causes a range of disability in teenagers and adults.[6]

About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease (not approved in Sweden). Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the potential benefits, safety and efficacy of SPINRAZA; the results of certain real-world data and clinical studies of SPINRAZA; the identification and treatment of SMA; our research and development program for the treatment of SMA; the potential of our commercial business, including SPINRAZA; and risks and uncertainties associated with drug development and commercialization. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation unexpected concerns that may arise from additional data, analysis or results obtained during clinical studies; the occurrence of

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adverse safety events; risks of unexpected costs or delays; the risks of other unexpected hurdles; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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