Bristol Myers Squibb Presents New Interim Long-Term Efficacy Data from the EMERGENT-4 Trial Evaluating KarXT in Schizophrenia at the 2024 Annual Congress of the Schizophrenia International Research Society

April 6, 2024

Long-term treatment with KarXT was associated with continued improvements in symptoms of schizophrenia across all efficacy measures at 52 weeks

More than 75% of participants achieved ≥30% improvement in symptoms from baseline, as measured by the Positive and Negative Syndrome Scale (PANSS) total score, at one year

Participants previously on placebo in acute trials experienced significant reduction of symptoms beginning at week two and maintained throughout treatment

PRINCETON, N.J.--(BUSINESS WIRE)-- Bristol Myers Squibb (NYSE: BMY) today announced new interim results from the Phase 3 EMERGENT-4 open-label extension trial evaluating the long-term efficacy, safety and tolerability of KarXT (xanomeline-trospium) in adults with schizophrenia. Long-term efficacy data from the trial were presented in a poster titled, “Maintenance of Efficacy of KarXT (Xanomeline and Trospium) in Schizophrenia” (Poster F264) at the Annual Congress of the Schizophrenia International Research Society (SIRS) being held April 3-7, 2024, in Florence, Italy.

“We are pleased to see a continued and consistent meaningful reduction in symptoms of schizophrenia across 52-weeks in an outpatient setting, beyond what was seen in the short-term, in-patient five-week trials (EMERGENT-2 and EMERGENT-3),” said Roland Chen, MD, senior vice president and head, Immunology, Cardiovascular and Neuroscience development, Bristol Myers Squibb. “We look forward to continued conversations with the FDA and to sharing additional data from the EMERGENT program later this year.”

EMERGENT-4 is a Phase 3, 52-week, outpatient, open-label extension study evaluating the long-term safety, tolerability, and efficacy of KarXT in adults with schizophrenia who previously completed the treatment period of one of the Phase 3, five-week, double-blind, placebo-controlled, efficacy and safety studies, EMERGENT-2 or EMERGENT-3. At the time of the data cutoff of April 17, 2023, 110 patients were part of the interim efficacy analysis, with 29 patients having completed 52 weeks of treatment.

In the interim analysis, KarXT was associated with significant improvement in symptoms of schizophrenia across all efficacy measures at 52 weeks. At the end of the open-label extension, more than 75% of participants achieved ≥30% improvement in symptoms, with an average reduction of 33.3-points from baseline (98.4), as measured by the Positive and Negative Syndrome Scale (PANSS) total score. In addition, participants had a mean 1.7-point change in Clinical Global Impression-Severity (CGI-S) score from baseline (5.2), representing an average shift from ‘markedly ill’ at baseline to ‘moderately’ or ‘mildly’ ill at one year.

Improvements in symptoms of schizophrenia continued throughout the 52-week trial regardless of whether participants were previously treated with KarXT or placebo during the acute trials. Prior to enrolling in the open-label extension, participants who previously received placebo in EMERGENT-2 and EMERGENT-3 had a significantly higher mean PANSS total score compared to those who received KarXT (placebo 86.5 vs. KarXT 76.1). When dosed with KarXT, the patients previously on placebo had significant improvements in symptoms within two weeks of treatment with KarXT. After four weeks, PANSS total scores were comparable between those who received KarXT or placebo in the acute trials.

“These interim data from EMERGENT-4 continue to validate the potential of KarXT in the long-term management of schizophrenia, with continued benefit across 52 weeks of treatment,” said Elan Cohen, Ph.D., principal investigator, CenExel Hassman Research Institute and investigator in the EMERGENT program. “The consistency of efficacy results across all EMERGENT clinical trial programs is encouraging and suggest KarXT could provide a differentiated treatment approach for people living with schizophrenia.”

In additional data presented at the congress, KarXT demonstrated a favorable impact on weight and long-term metabolic profile where most patients experienced stability or improvements on metabolic parameters over 52 weeks of treatment. In long-term trials, KarXT was generally well tolerated, with a side effect profile consistent with prior trials of KarXT in schizophrenia. KarXT was not associated with significant changes related to prolactin or clinically meaningful changes in movement disorder scale scores over 52 weeks (Oral Session: New Pharmacological Treatments and Assessments and Poster F74).

About KarXT

KarXT (xanomeline-trospium) is an investigational muscarinic antipsychotic in development for the treatment of schizophrenia and psychosis related to Alzheimer's disease. Through its novel mechanism of action, KarXT acts as a dual M1/M4 muscarinic acetylcholine receptor agonist in the central nervous system, which is thought to improve positive, negative, and cognitive symptoms of schizophrenia. Unlike existing treatments, KarXT does not

directly block dopamine receptors, representing a potential new approach to treating schizophrenia.

About Schizophrenia

Schizophrenia is a persistent and often disabling mental illness impacting how a person thinks, feels, and behaves, and affects nearly 24 million people worldwide, including 2.8 million people in the U.S. It is characterized by three symptom domains: positive symptoms (hallucinations and delusions), negative symptoms (difficulty enjoying life and withdrawal from others), and cognitive impairment (deficits in memory, concentration, and decision-making). In part due to limitations with current treatments, people living with schizophrenia often struggle to maintain employment, live independently, and manage relationships. While current treatments can be effective in managing select symptoms, approximately 30% of people do not respond to therapy, with an additional 50% experiencing only a partial improvement in symptoms or unacceptable side effects.

Bristol Myers Squibb: Delivering Breakthrough Science for Meaningful Interventions in Neuroscience

Neurological conditions represent some of the greatest challenges of our time because of their impact on society, including patients, caregivers, families and healthcare systems. At Bristol Myers Squibb, we are committed to advancing our robust pipeline of potential medicines for neurological disorders with the goal of modifying disease and improving quality of life. Leveraging genetics, biomarkers and predictive sciences, we target key pathways involved in the initiation and progression of neurological diseases to develop therapies with the potential to optimize patient outcomes.

About Bristol Myers Squibb

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

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This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that future study results may not be consistent with the results to date, that KarXT (xanomeline-trospium) may not achieve its primary study endpoints or receive regulatory approval for the indication described in this release in the currently anticipated timeline or at all, any marketing approvals, if granted, may have significant limitations on their use, and, if approved, whether KarXT for such indication described in this release will be commercially successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb’s business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2023, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

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