Bristol Myers Squibb Presents New Pooled Interim Long-Term Safety and Metabolic Outcomes Data from the EMERGENT Program Evaluating KarXT in Schizophrenia at the 2024 Annual Congress of the Schizophrenia International Research Society

April 6, 2024

KarXT demonstrated a favorable long-term metabolic profile where most patients experienced stability or improvements on metabolic parameters over 52 weeks of treatment

A majority of patients (65%) experienced reductions in weight over the course of the trial, with a mean weight decrease of 2.6kg observed at one year

Data show no significant changes related to prolactin or clinically meaningful changes in movement disorder scale scores over 52 weeks

KarXT was generally well tolerated, with a side effect profile consistent with prior trials of KarXT in schizophrenia

PRINCETON, N.J.--(BUSINESS WIRE)-- Bristol Myers Squibb (NYSE: BMY) today announced interim long-term safety, tolerability and metabolic outcomes data from its Phase 3 EMERGENT program evaluating KarXT (xanomeline-trospium) in adults with schizophrenia. These data were presented in a poster titled, “Long-Term Safety of KarXT (Xanomeline and Trospium) in Schizophrenia” (Poster F74) and in the Oral Session “Long-Term Metabolic Outcomes Associated With KarXT (Xanomeline and Trospium): Interim Results From Pooled, Long-Term Safety Studies EMERGENT-4 and EMERGENT-5” at the Annual Congress of the Schizophrenia International Research Society (SIRS) being held April 3-7, 2024, in Florence, Italy.

“These long-term safety results and metabolic outcomes from the EMERGENT program are extremely encouraging, allowing us to further understand the tolerability profile of KarXT in people living with schizophrenia,” said Roland Chen, MD, senior vice president and head, Immunology, Cardiovascular and Neuroscience development, Bristol Myers Squibb. “It is promising to see that over one year of treatment, KarXT was not associated with burdensome side effects, specifically weight gain and metabolic dysfunction, as well as extrapyramidal symptoms, which underscores its potential to provide a meaningful and differentiated option for people living with schizophrenia.”

Pooled Interim Long-Term Metabolic Outcomes Associated with KarXT (EMERGENT-4 and EMERGENT-5)

The EMERGENT-4 and EMERGENT-5 trials are Phase 3, outpatient, 52-week, open-label trials evaluating the safety, tolerability, and efficacy of KarXT in adults with schizophrenia. At the time of the data cutoff of August 18, 2023, the interim pooled data analysis included 718 patients who received at least one dose of KarXT, with 134 patients having completed one year of treatment.

In the pooled analysis, KarXT demonstrated a favorable impact on weight and long-term metabolic profile where most patients experienced stability or improvements on key metabolic parameters over 52 weeks of treatment. The majority of patients (65%) experienced an overall reduction in weight over the course of the trial, with more patients (18%) experiencing potentially clinically significant (≥7% change) decreases in weight vs. 4% of patients experiencing increases in weight (≥7% change). In patients who completed 52 weeks of treatment with KarXT, an average reduction in weight of 2.6kg was observed, with a larger mean reduction in weight of 4.1kg observed in clinically obese patients (BMI ≥ 30 kg/m^2). Total cholesterol, triglyceride and HbA1c levels did not meaningfully change over one year of treatment.

Interim Long-Term Pooled Safety Outcomes Associated with KarXT (EMERGENT-4 and EMERGENT-5)

In the long-term studies, KarXT was generally well-tolerated across 52 weeks of treatment, with a side effect profile consistent with prior trials of KarXT in schizophrenia. The overall discontinuation rate in the trial was 53% and primary reasons for discontinuation included withdrawn consent (19%), treatment-related adverse events (15%), participant lost to follow-up (8%), and participant failed to adhere to protocol requirements (7%).

Across the long-term EMERGENT trials, 62% of participants reported at least one treatment-related adverse event. The most common treatment-related adverse events (≥5%) were nausea, vomiting, constipation, dry mouth, dyspepsia, dizziness, hypertension, and diarrhea, of which nearly all were mild or moderate in severity and transient in nature.

KarXT was not associated with significant changes related to prolactin or clinically meaningful changes in movement disorder scale scores over 52 weeks.

“People living with schizophrenia and their care partners have long carried the burden of the condition, with a lack of treatment options that adequately treat the symptoms of schizophrenia without common debilitating side effects. To see that the long-term tolerability profile of KarXT remains consistent with earlier studies, where the cholinergic side effects of KarXT remained mainly mild or moderate in severity, and were transient and resolving with continued treatment is very encouraging,” said Rishi Kakar, M.D., chief scientific officer and medical director of Segal Trials and investigator in the EMERGENT program. “These results are extremely promising and add to the growing body of data which suggest that, if approved, KarXT could provide a long-desired, differentiated treatment option for people living with schizophrenia.”

In additional interim long-term data presented at the congress, KarXT was associated with significant improvements in symptoms of schizophrenia across all efficacy measures at 52 weeks in the EMERGENT-4 trial. Improvements in symptoms of schizophrenia continued throughout the open-label

extension regardless of whether participants were previously treated with KarXT or placebo during the acute trials, EMERGENT-2 or EMERGENT-3 (Poster F264).

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.

Cautionary Statement Regarding Forward-Looking Statements

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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