Teva and MedinCell Announce FDA Approval of UZEDY™ (risperidone) Extended-Release Injectable Suspension, a Long-Acting Subcutaneous Atypical Antipsychotic Injection, for the Treatment of Schizophrenia in Adults

- ***This new treatment provides adults living with schizophrenia a long-acting formulation that offers flexible 1- and 2-month dosing intervals[1]***
- ***In a Phase 3 clinical trial, UZEDY demonstrated up to 80% reduction in risk of schizophrenia relapse versus placebo[1]***
- ***UZEDY is a subcutaneous injection from a pre-filled syringe with a 21-gauge needle***

PARSIPPANY, N.J., TEL AVIV & PARIS, April 28, 2023 – Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), and MedinCell (Euronext: MEDCL) announced today that the U.S. Food and Drug Administration (FDA) has approved UZEDY (risperidone) extended-release injectable suspension for the treatment of schizophrenia in adults. UZEDY is the first subcutaneous, long-acting formulation of risperidone that utilizes SteadyTeq™, a copolymer technology proprietary to MedinCell that controls the steady release of risperidone. Therapeutic blood concentrations are reached within 6-24 hours of a single dose.[1]

“UZEDY embodies Teva’s commitment to bringing innovative advances to patients and to providing people living with schizophrenia an important new treatment option that was designed to address certain treatment challenges and may decrease the risk of relapse,” said Richard Francis, President and CEO of Teva. “The approval of UZEDY is a culmination of a multidisciplinary effort across Teva and MedinCell to bring this important treatment to market. This milestone is a testament to advancing our robust biopharmaceutical pipeline of innovative medicines that aim to support more people living with mental health disorders and neurological diseases in the coming years.”

Approximately 80% of patients with schizophrenia experience multiple relapses over the first five years of treatment,[2] most commonly due to suboptimal adherence to treatment with oral antipsychotics. Each relapse carries a biological risk of loss of function, treatment refractoriness, and changes in brain morphology.[3,4]

Schizophrenia is a chronic, progressive and severely debilitating mental health disorder that affects how one thinks, feels and acts.[5] This approval is based on data from two Phase 3 trials evaluating UZEDY in patients with schizophrenia: TV46000-CNS-30072 (the RISE Study – The Risperidone Subcutaneous Extended-Release Study) and TV46000-CNS-30078 (the SHINE Study – A Study to Test TV-46000 for Maintenance Treatment of Schizophrenia).

"The approval of the first product formulated with our technology is a pivotal moment for MedinCell and for the many patients who will benefit,” said Christophe Douat, CEO of MedinCell. “We are committed to

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[1] UZEDY™ (risperidone) extended-release injectable suspension, for subcutaneous injection Current Prescribing Information. Parsippany, NJ. Teva Neuroscience, Inc.
[2] Emsley, R., & Kilian, S. (2018). Efficacy and safety profile of paliperidone palmitate injections in the management of patients with schizophrenia: an evidence-based review. Neuropsychiatric disease and treatment, 14, 205–223.
[3] Emsley, R., Chiliza, B., Asmal, L. et al. (2013) The nature of relapse in schizophrenia. BMC Psychiatry 13, 50.
[4] Andreasen, N. C., et al. (2013). Relapse duration, treatment intensity, and brain tissue loss in schizophrenia: a prospective longitudinal MRI study. The American journal of psychiatry, 170(6), 609–615.
[5] Patel, K. R., Cherian, J., Gohil, K., & Atkinson, D. (2014). Schizophrenia: overview and treatment options. P & T: a peer-reviewed journal for formulary management, 39(9), 638–645..

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supporting patients through innovative therapy options. It continues to be a wonderful journey with Teva, an ideal partner to harness the full potential of UZEDY. Our technology reaching commercial stage marks the start of an exciting new era for MedinCell and we are extremely proud to share this very special moment with all our employees and shareholders."

The use of novel SteadyTeq technology in UZEDY controls the release of risperidone over time. The initiation of treatment requires no loading dose or oral supplementation. Therapeutic blood concentrations are reached within 6-24 hours of a single dose.[1]

“Treatments for schizophrenia are largely prescribed as daily oral medications, which can present challenges with adherence due to missed doses. Lack of adherence to treatment with oral antipsychotics is the most common cause of relapse in schizophrenia,[6] so there’s a role for therapies that are dosed in one- or two-month dosing intervals to help prevent relapse,” said Christoph Correll, MD, professor of psychiatry at the Zucker School of Medicine, Hempstead, NY. “As a clinician, I am excited to now have a new treatment option that reduces the risk of relapse[1] for this complex disease and helps address some of the barriers around receiving schizophrenia treatment.”

The Wholesale Acquisition Cost (WAC or “list price”) for UZEDY ranges from $1,232 to $3,080 per month depending on dosage strength. Actual costs for individual patients are anticipated to be lower than WAC because WAC does not account for additional rebates and discounts that may apply. Teva is committed to helping patients who have been prescribed UZEDY access their medication and provide patient support specialists to help with access and reimbursement, prescription pull-through and patient assistance. Savings on out-of-pocket costs may vary depending on the patient’s insurance provider and eligibility for participation in the co-pay assistance program.

UZEDY will be available in the U.S. in the coming weeks.

UZEDY Clinical Trial Results

The RISE study[7] was a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy of risperidone extended-release injectable suspension for subcutaneous use as a treatment in patients (ages 13-65 years) with schizophrenia. 544 patients were randomized to receive a subcutaneous injection of TV-46000 once monthly (q1M), once every two months (q2M), or placebo in a 1:1:1 ratio. The primary endpoint was time to impending relapse.

The second of Teva’s Phase 3 studies – SHINE[8] – was designed to evaluate the use of TV-46000 subcutaneously administered q1M or q2M for up to 56 weeks in 336 patients (ages 13-65 years) with schizophrenia. The primary endpoint was the frequency of all adverse events, including serious adverse events. This study was completed in December 2021; results align with the findings of the RISE study.[9]

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[6] Kane JM, Correll CU. Optimizing treatment choices to improve adherence and outcomes in schizophrenia. J Clin Psychiatry. 2019;80(5):IN18031AH1C. doi:10.4088/JCP.IN18031AH1C.

[7] “A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Risperidone Extended-Release Injectable Suspension (TV-46000) for Subcutaneous Use as Maintenance Treatment in Adult and Adolescent Patients With Schizophrenia.” ClinicalTrials.gov, U.S. National Institutes of Health, 2018 (NCT03503318).

[8] “A Study to Evaluate the Safety, Tolerability, and Effect of Risperidone Extended-Release Injectable Suspension (TV-46000) for Subcutaneous Use as Maintenance Treatment in Adult and Adolescent Patients With Schizophrenia.” ClinicalTrials.gov, U.S. National Institutes of Health, 2019 (NCT03893825).

[9] Data on File. Parsippany, NJ: Teva Neuroscience, Inc.

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In a companion survey of study participants, 89% of patients and 92% of healthcare providers (HCPs) rated administration of UZEDY as easy when asked how easy or difficult it was to receive or administer the medication in its current form.[10] Further, 70% of patients agreed UZEDY provided a better injection experience than their previous long-acting injectables (LAIs); 30% of patients agreed they had a better injection experience with their prior LAI medication.[10] Moreover, given the choice between continuing to take the clinical trial medication or returning to their previous medication, 90% of patients opted to use UZEDY.[10]

Companion survey data were collected from 63 patients, 24 physicians, and 25 nurses in a prospective, cross-sectional companion survey assessing the perceptions regarding ease of use and satisfaction with UZEDY. The survey was conducted after a minimum of two experiences prescribing, administering, or receiving UZEDY.

About Schizophrenia

Schizophrenia is a chronic, progressive and severely debilitating mental disorder that affects how one thinks, feels and acts. Patients experience an array of symptoms, which may include delusions, hallucinations, disorganized speech or behavior and impaired cognitive ability. Approximately 1% of the world's population will develop schizophrenia in their lifetime, and 3.5 million people in the U.S. are currently diagnosed with the condition. Although schizophrenia can occur at any age, the average age of onset tends to be in the late teens to the early 20s for men, and the late 20s to early 30s for women. The long-term course of schizophrenia is marked by episodes of partial or full remission broken by relapses that often occur in the context of psychiatric emergency and require hospitalization. Approximately 80% of patients experience multiple relapses over the first five years of treatment, and each relapse carries a biological risk of loss of function, treatment refractoriness, and changes in brain morphology. Patients are often unaware of their illness and its consequences, contributing to treatment nonadherence, high discontinuation rates, and ultimately, significant direct and indirect healthcare costs from subsequent relapses and hospitalizations.

About UZEDY

UZEDY (risperidone) extended-release injectable suspension, for subcutaneous use rather than intramuscular use, is indicated for the treatment of schizophrenia in adults. In clinical trials, UZEDY reduced the risk of relapse by up to 80%. UZEDY administers risperidone through copolymer technology under license from MedinCell that allows for absorption and sustained release in the first subcutaneous injection. UZEDY is the only long-acting, subcutaneous formulation of risperidone available in both one- and two-month dosing intervals.[1] For full prescribing information, visit https://www.uzedy.com/globalassets/uzedy/prescribing-information.pdf.

[10] Robinson, D., Suett, M., Wilhelm, A. et al. (2023). Patient and Healthcare Professional Preferences for Characteristics of Long-Acting Injectable Antipsychotic Agents for the Treatment of Schizophrenia.doi.org/10.1007/s12325-023-02455-8.

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INDICATION AND USAGE

UZEDY (risperidone) extended-release injectable suspension for subcutaneous use is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. UZEDY is not approved for use in patients with dementia-related psychosis and has not been studied in this patient population.

CONTRAINDICATIONS: UZEDY is contraindicated in patients with a known hypersensitivity to risperidone, its metabolite, paliperidone, or to any of its components. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone or paliperidone.

WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions: In trials of elderly patients with dementia-related psychosis, there was a significantly higher incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, in patients treated with oral risperidone compared to placebo. UZEDY is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status including delirium, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If NMS is suspected, immediately discontinue UZEDY and provide symptomatic treatment and monitoring.

Tardive Dyskinesia (TD): TD, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients will develop the syndrome. Whether antipsychotic drug products differ in their potential to cause TD is unknown.

The risk of developing TD and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the cumulative dose. The syndrome can develop, after relatively brief treatment periods, even at low doses. It may also occur after discontinuation. TD may remit, partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment, itself, however, may suppress (or partially

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suppress) the signs and symptoms of the syndrome, possibly masking the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

If signs and symptoms of TD appear in a patient treated with UZEDY, drug discontinuation should be considered. However, some patients may require treatment with UZEDY despite the presence of the syndrome. In patients who do require chronic treatment, use the lowest dose and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia and diabetes mellitus (DM), in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, have been reported in patients treated with atypical antipsychotics, including risperidone. Patients with an established diagnosis of DM who are started on atypical antipsychotics, including UZEDY, should be monitored regularly for worsening of glucose control. Patients with risk factors for DM (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics, including UZEDY, should undergo fasting blood glucose (FBG) testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics, including UZEDY, should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics, including UZEDY, should undergo FBG testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic, including risperidone, was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of risperidone.

Dyslipidemia has been observed in patients treated with atypical antipsychotics.

Weight gain has been observed with atypical antipsychotic use. Monitoring weight is recommended.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

Orthostatic Hypotension and Syncope: UZEDY may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope. UZEDY should be used with particular caution in patients with known cardiovascular disease, cerebrovascular disease, and conditions which would predispose patients to hypotension and in the elderly and patients with renal or hepatic impairment.

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Monitoring of orthostatic vital signs should be considered in all such patients, and a dose reduction should be considered if hypotension occurs. Clinically significant hypotension has been observed with concomitant use of oral risperidone and antihypertensive medication.

Falls: Antipsychotics, including UZEDY, may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other fall-related injuries. Somnolence, postural hypotension, motor and sensory instability have been reported with the use of risperidone. For patients, particularly the elderly, with diseases, conditions, or medications that could exacerbate these effects, assess the risk of falls when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Leukopenia, Neutropenia, and Agranulocytosis have been reported with antipsychotic agents, including risperidone. In patients with a pre-existing history of a clinically significant low white blood cell count (WBC) or absolute neutrophil count (ANC) or a history of drug-induced leukopenia or neutropenia, perform a complete blood count (CBC) frequently during the first few months of therapy. In such patients, consider discontinuation of UZEDY at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue UZEDY in patients with ANC < 1000/mm^3) and follow their WBC until recovery.

Potential for Cognitive and Motor Impairment: UZEDY, like other antipsychotics, may cause somnolence and has the potential to impair judgement, thinking, and motor skills. Somnolence was a commonly reported adverse reaction associated with oral risperidone treatment. Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that treatment with UZEDY does not affect them adversely.

Seizures During premarketing studies of oral risperidone in adult patients with schizophrenia, seizures occurred in 0.3% of patients (9 out of 2,607 patients), two in association with hyponatremia. Use UZEDY cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Antipsychotic drugs, including UZEDY, should be used cautiously in patients at risk for aspiration.

Priapism has been reported during postmarketing surveillance for other risperidone products. A case of priapism was reported in premarket studies of UZEDY. Severe priapism may require surgical intervention.

Body temperature regulation. Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Both hyperthermia and hypothermia have been reported in association with oral risperidone use. Strenuous exercise, exposure to extreme heat, dehydration, and anticholinergic

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medications may contribute to an elevation in core body temperature; use UZEDY with caution in patients who experience these conditions.

ADVERSE REACTIONS

The most common adverse reactions with risperidone (≥5% and greater than placebo) were parkinsonism, akathisia, dystonia, tremor, sedation, dizziness, anxiety, blurred vision, nausea, vomiting, upper abdominal pain, stomach discomfort, dyspepsia, diarrhea, salivary hypersecretion, constipation, dry mouth, increased appetite, increased weight, fatigue, rash, nasal congestion, upper respiratory tract infection, nasopharyngitis, and pharyngolaryngeal pain.

The most common injection site reactions with UZEDY (≥5% and greater than placebo) were pruritus and nodule.**DRUG INTERACTIONS**

- Carbamazepine and other strong CYP3A4 inducers decrease plasma concentrations of risperidone.
- Fluoxetine, paroxetine, and other strong CYP2D6 inhibitors increase risperidone plasma concentration.
- Due to additive pharmacologic effects, the concomitant use of centrally-acting drugs, including alcohol, may increase nervous system disorders.
- UZEDY may enhance the hypotensive effects of other therapeutic agents with this potential.
- UZEDY may antagonize the pharmacologic effects of dopamine agonists.
- Concomitant use with methylphenidate, when there is change in dosage of either medication, may increase the risk of extrapyramidal symptoms (EPS)

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause EPS and/or withdrawal symptoms in neonates with third trimester exposure. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to atypical antipsychotics, including UZEDY, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Atypical Antipsychotics at 1-866-961-2388 or online at *http://womensmentalhealth.org/clinicaland-research-programs/pregnancyregistry/.*

Lactation: Infants exposed to risperidone through breastmilk should be monitored for excess sedation, failure to thrive, jitteriness, and EPS.

Fertility: UZEDY may cause a reversible reduction in fertility in females.

Pediatric Use: Safety and effectiveness of UZEDY have not been established in pediatric patients.

Renal or Hepatic Impairment: Carefully titrate on oral risperidone up to at least 2 mg daily before initiating treatment with UZEDY.

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Patients with Parkinson's disease or dementia with Lewy bodies can experience increased sensitivity to UZEDY. Manifestations and features are consistent with NMS.

Please see the full Prescribing Information for UZEDY, including Boxed WARNING.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic, biosimilar and innovative medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of innovative medicines and biopharmaceutical products. Learn more at www.tevapharm.com.

About MedinCell

MedinCell is an innovative pharmaceutical company with a portfolio of long-acting injectable products, from development to market, in various therapeutic areas. MedinCell proprietary technology BEPO® (licensed to Teva under the name SteadyTeq) makes it possible to control the delivery of a drug at a therapeutic dose for several days, weeks or months starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable. MedinCell collaborate with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities. www.medincell.com

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to:

- our ability to develop and commercialize UZEDY (risperidone) extended-release injectable suspension for the treatment schizophrenia;
- our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; concentration of our customer base and commercial alliances among our customers; delays in launches of new generic products; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; our ability to develop and commercialize biopharmaceutical products; competition for our innovative medicines, including AUSTEDO®, AJOVY® and COPAXONE®; our ability to achieve expected results from investments in our product pipeline; our ability to develop and commercialize additional pharmaceutical products; and the effectiveness of our patents and other measures to protect our intellectual property rights;
- our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit

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ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us;

- our business and operations in general, including: the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto; the widespread outbreak of an illness or any other communicable disease, or any other public health crisis; effectiveness of our optimization efforts; our ability to attract, hire, integrate and retain highly skilled personnel; manufacturing or quality control problems; interruptions in our supply chain; disruptions of information technology systems; breaches of our data security; variations in intellectual property laws; challenges associated with conducting business globally, including political or economic instability, major hostilities or terrorism; costs and delays resulting from the extensive pharmaceutical regulation to which we are subject;
- the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; significant sales to a limited number of customers; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; and our prospects and opportunities for growth if we sell assets;
- compliance, regulatory and litigation matters, including: failure to comply with complex legal and regulatory environments; increased legal and regulatory action in connection with public concern over the abuse of opioid medications and any delay in our ability to obtain sufficient participation of plaintiffs for the nationwide settlement of our opioid-related litigation in the United States; scrutiny from competition and pricing authorities around the world, including our ability to successfully defend against the U.S. Department of Justice criminal charges of Sherman Act violations; potential liability for intellectual property right infringement; product liability claims; failure to comply with complex Medicare and Medicaid reporting and payment obligations; compliance with anti-corruption, sanctions and trade control laws; environmental risks; and the impact of ESG issues;
- other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our long-lived assets; the impact of geopolitical conflicts including the ongoing conflict between Russia and Ukraine; potential significant increases in tax liabilities; and the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business;

and other factors discussed in this press release and in our Annual Report on Form 10-K for the year ended December 31, 2022, including in the sections captioned "Risk Factors" and "Forward Looking Statements." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

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