Insmed Presents New Data Across Three Pillars at American Thoracic Society 2022 International Conference

—Retrospective Cohort Study Shows Significant Reductions in All-Cause and Respiratory Disease-Related Hospitalizations in the 12 Months Following ARIKAYCE® (amikacin liposome inhalation suspension) Initiation in Real-World Settings—

—Post-Hoc Analysis of Phase 2 WILLOW Study in Adult Patients with Non-Cystic Fibrosis Bronchiectasis Supports Favorable Benefit-Risk Profile of Brensocatib—

BRIDGEWATER, N.J., May 17, 2022 /PRNewswire/ -- Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases, today reported data from seven presentations across three of its pillars—ARIKAYCE, brensocatib, and treprostinil palmitil inhalation powder (TPIP)—at the American Thoracic Society (ATS) 2022 International Conference.

"We were pleased to present a broad range of data at ATS from across our portfolio of programs, demonstrating our continued progress in addressing the needs of patients living with serious and rare diseases," said Martina Flammer, M.D., M.B.A, Chief Medical Officer of Insmed. "In particular, we were excited to share the first real-world data for ARIKAYCE, which showed significant reductions in hospitalizations in the 12 months after ARIKAYCE was initiated. These findings provide important information to better understand the impact of ARIKAYCE in the treatment paradigm for refractory MAC lung disease."

Summaries of these presentations are as follows:

ARIKAYCE

Poster: "Reduction in Hospitalizations Following Initiation of Amikacin Liposome Inhalation Suspension: A Retrospective Cohort Study of Patients in Real-world Settings"

Data were presented from a noninterventional retrospective cohort study to assess changes in hospitalizations among patients initiating ARIKAYCE in the real-world setting. The study used the All-Payer Claims Database – including health insurance claims data from more than 300 million unique U.S. patients – to identify patients receiving ARIKAYCE from October 2018 to April 2020. An analysis of 331 patients who were treated with ARIKAYCE in the real-world setting showed the following key findings:

- A significant reduction in the proportion of patients with all-cause hospitalizations was observed after 6 months of ARIKAYCE treatment, from 35.9% in the 6 months immediately before ARIKAYCE initiation to 26.6% (P=0.0033) in the first 6 months after ARIKAYCE initiation.
- These significant reductions in all-cause hospitalization continued during the follow-up period of 7 to 12 months after ARIKAYCE initiation, from 35.9% in the 6 months before ARIKAYCE initiation to 23.0% (P<0.0001) in the 7 to 12 months after ARIKAYCE initiation.
- The mean number of all-cause hospitalizations per person per 6 months decreased significantly from 1.2 ± 1.8 in the 6 months before ARIKAYCE initiation to 0.7 ± 1.2 (P=0.0002) and 0.7 ± 1.4 (P<0.0001) in the 0 to 6 months and 7 to 12 months after ARIKAYCE initiation, respectively.
- A significant reduction was observed in the proportion of patients with respiratory disease-related hospitalizations, from 26.9% in the 6 months immediately before ARIKAYCE initiation to 19.3% (P=0.0061) in the first 6 months after ARIKAYCE initiation and 15.4% (P<0.0001) in the 7 to 12 months after ARIKAYCE initiation.
- The mean number of respiratory disease-related hospitalizations per person per 6 months decreased

significantly from 1.0 ± 1.6 in the 6 months before ARIKAYCE initiation to 0.6 ± 1.0 (P=0.0002) and 0.6 ± 1.2 (P=0.0001) in the 0 to 6 months after ARIKAYCE initiation and in the 7 to 12 months after ARIKAYCE initiation, respectively.

Investigators concluded that both all-cause and respiratory disease-related hospitalizations were significantly reduced in the 12 months following ARIKAYCE initiation.

Poster: "The Hospitalization Burden Among Potentially Treatment-Refractory Nontuberculous Mycobacterial Lung Disease Patients in Japan"

Investigators presented data from a retrospective cohort study that used claims data to assess treatment patterns and healthcare resource utilization among patients with potentially treatment-refractory nontuberculous mycobacterial (NTM) lung disease in Japan. The study showed that most patients who were identified as having potentially refractory disease had a high hospitalization burden that consistently remained high over the 30-month study period, despite treatment of ≥18 months in contrast to patients who were identified as having potentially nonrefractory disease. Investigators concluded that refractory NTM lung disease has a substantial burden on patients in Japan.

Brensocatib

Mini Symposium: "Brensocatib for the Treatment of Non-Cystic Fibrosis Bronchiectasis (NCFBE): Number Needed to Treat (NNT) and Number Needed to Harm (NNH)"

Findings were presented from post-hoc analyses of clinical trial data to assess the NNT and NNH for brensocatib to provide further context for its risk-benefit profile. The analyses used data from the WILLOW study, a phase 2, randomized, double-blind, placebo-controlled study that assessed the efficacy, safety and tolerability, and pharmacokinetics of brensocatib in patients with non-cystic fibrosis bronchiectasis (NCFBE). As previously reported, the WILLOW study showed that brensocatib significantly prolonged time to first pulmonary exacerbation, the primary endpoint, over the 24-week treatment period versus placebo. Treatment with brensocatib also reduced the rate of pulmonary exacerbations, a key secondary endpoint.

The post-hoc analyses showed the following:

- The NNT for exacerbation prevention – which represents the average number of patients who would need to be treated to prevent one patient from having an exacerbation – was low, ranging from 6 to 7.
- When exacerbations were included, the NNH – which represents the number of patients who would need to be treated with brensocatib for one additional patient to experience one serious treatment-emergent adverse event (TEAE) vs. placebo – was negative, ranging from -9 to -11. A negative NNH suggests a lower risk of serious TEAEs for patients treated with brensocatib compared with placebo.
- When exacerbations were excluded, the NNH ranged from -25 to -55. Thus, the lower risk of serious TEAEs for patients receiving brensocatib compared with placebo was maintained when exacerbations were excluded from the analysis. Exacerbations that were captured as serious TEAEs were excluded from this analysis to provide a true measure of harm avoidance, since exacerbation incidence was the key outcome for the NNT analysis.

Investigators concluded that the low NNT and negative NNH suggest a potential favorable benefit-risk profile for brensocatib in patients with NCFBE.

Poster: "Pulmonary Exacerbations (PEx) and Hospitalizations in Commercially Insured Patients with Non-Cystic Fibrosis Bronchiectasis (NCFBE) Over 1- and 2-Year Follow-Up Periods"

Data were presented from a longitudinal retrospective insurance claims database study evaluating pulmonary exacerbation frequency and all-cause hospitalization frequency in patients with NCFBE over 1 and 2 years of follow-up. The study showed that most insured patients with NCFBE experience frequent exacerbations and increased hospitalization rates over 2 years of follow-up, and that the number of both exacerbations and hospitalizations increased from year 1 to year 2. Specifically, 67.4% of patients experienced at least one exacerbation during year 1 and 76.6% experienced at least one exacerbation in year 2 of follow-up. In addition, 41.04% of patients were hospitalized at least once during year 1, and 51.05% were hospitalized at least once during year 2. Notably, an occurrence of 2 or more exacerbations increased the likelihood of multiple subsequent exacerbations within 1 and 2 years of follow-up. Investigators concluded that in patients with NCFBE, pulmonary exacerbations result in an increased disease burden over time.

TPIP

Posters: "Treprostinil Exerts Anti-Fibrotic Effects via the Prostanoid Receptor Subtype EP_2 in Human Lung Fibroblast"; "Administration of Treprostinil to the Basolateral Surface, but Not the

Apical Surface of Human Bronchial Air-Liquid Interface Epithelial Cells Induces Release of Prostaglandin E_2"; and "Binding Affinity of Treprostinil to Rat Recombinant Prostanoid Receptors IP and EP_2"

Three treprostinil posters were presented at ATS showcasing preclinical data. The first showed that treprostinil exerts an anti-fibrotic effect by acting via prostanoid receptor subtype EP_2. The anti-fibrotic effects of treprostinil may also be enhanced by its ability to inhibit profibrotic cytokine secretion. The second study showed that treprostinil does not alter the integrity of the bronchial epithelium or induce an inflammatory response, and that prostaglandin E_2 release is caused by administering treprostinil on the basolateral but not the apical surface, suggesting a polarized distribution of the prostanoid receptors on the bronchial epithelium. Therefore, the scale and duration of treprostinil-induced vasodilation may be controlled by regulating the epithelial penetration of inhaled treprostinil. Lastly, the third study showed that the binding affinity of treprostinil to the rat prostanoid receptors was similar for the prostaglandin I_2 (IP) receptor compared with that in humans and about 7-fold higher for the EP_2 receptor compared with that in humans. Researchers concluded that these data may be useful in interpreting results from rat studies of treprostinil palmitil to inform dosage selection for studies in patients with pulmonary arterial hypertension (PAH).

About ARIKAYCE®

ARIKAYCE is approved in the United States as ARIKAYCE® (amikacin liposome inhalation suspension), in Europe as ARIKAYCE® Liposomal 590 mg Nebuliser Dispersion, and in Japan as ARIKAYCE® inhalation 590 mg (amikacin sulfate inhalation drug product). Current international treatment guidelines recommend the use of ARIKAYCE for appropriate patients. ARIKAYCE is a novel, inhaled, once-daily formulation of amikacin, an established antibiotic that was historically administered intravenously and associated with severe toxicity to hearing, balance, and kidney function. Insmed's proprietary PULMOVANCE® liposomal technology enables the delivery of amikacin directly to the lungs, where liposomal amikacin is taken up by lung macrophages where the infection resides, while limiting systemic exposure. ARIKAYCE is administered once daily using the Lamira® Nebulizer System manufactured by PARI Pharma GmbH (PARI).

About PARI Pharma and the Lamira® Nebulizer System

ARIKAYCE is delivered by a novel inhalation device, the Lamira® Nebulizer System, developed by PARI. Lamira® is a quiet, portable nebulizer that enables efficient aerosolization of ARIKAYCE via a vibrating, perforated membrane. Based on PARI's 100-year history working with aerosols, PARI is dedicated to advancing inhalation therapies by developing innovative delivery platforms to improve patient care.

About Brensocatib

Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) being developed by Insmed for the treatment of patients with bronchiectasis and other neutrophil-mediated diseases. DPP1 is an enzyme responsible for activating neutrophil serine proteases (NSPs), such as neutrophil elastase, in neutrophils when they are formed in the bone marrow. Neutrophils are the most common type of white blood cell and play an essential role in pathogen destruction and inflammatory mediation. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active NSPs that cause lung destruction and inflammation. Brensocatib may decrease the damaging effects of inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs. Brensocatib is an investigational drug product that has not been approved for any indication in any jurisdiction.

About TPIP

Treprostinil palmitil inhalation powder (TPIP) is a dry powder formulation of treprostinil palmitil, a treprostinil prodrug consisting of treprostinil linked by an ester bond to a 16-carbon chain. Developed entirely in Insmed's laboratories, TPIP is a potentially differentiated prostanoid being evaluated for the treatment of patients with PAH, pulmonary hypertension associated with interstitial lung disease (PH-ILD), and other rare and serious pulmonary disorders. TPIP is administered in a capsule-based inhalation device. TPIP is an investigational drug product that has not been approved for any indication in any jurisdiction.

IMPORTANT SAFETY INFORMATION FOR ARIKAYCE IN THE U.S.

WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS

ARIKAYCE has been associated with an increased risk of respiratory adverse reactions, including

hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

Hypersensitivity Pneumonitis has been reported with the use of ARIKAYCE in the clinical trials. Hypersensitivity pneumonitis (reported as allergic alveolitis, pneumonitis, interstitial lung disease, allergic reaction to ARIKAYCE) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (3.1%) compared to patients treated with a background regimen alone (0%). Most patients with hypersensitivity pneumonitis discontinued treatment with ARIKAYCE and received treatment with corticosteroids. If hypersensitivity pneumonitis occurs, discontinue ARIKAYCE and manage patients as medically appropriate.

Hemoptysis has been reported with the use of ARIKAYCE in the clinical trials. Hemoptysis was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (17.9%) compared to patients treated with a background regimen alone (12.5%). If hemoptysis occurs, manage patients as medically appropriate.

Bronchospasm has been reported with the use of ARIKAYCE in the clinical trials. Bronchospasm (reported as asthma, bronchial hyperreactivity, bronchospasm, dyspnea, dyspnea exertional, prolonged expiration, throat tightness, wheezing) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (28.7%) compared to patients treated with a background regimen alone (10.7%). If bronchospasm occurs during the use of ARIKAYCE, treat patients as medically appropriate.

Exacerbations of underlying pulmonary disease has been reported with the use of ARIKAYCE in the clinical trials. Exacerbations of underlying pulmonary disease (reported as chronic obstructive pulmonary disease (COPD), infective exacerbation of COPD, infective exacerbation of bronchiectasis) have been reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (14.8%) compared to patients treated with background regimen alone (9.8%). If exacerbations of underlying pulmonary disease occur during the use of ARIKAYCE, treat patients as medically appropriate.

Anaphylaxis and Hypersensitivity Reactions: Serious and potentially life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients taking ARIKAYCE. Signs and symptoms include acute onset of skin and mucosal tissue hypersensitivity reactions (hives, itching, flushing, swollen lips/tongue/uvula), respiratory difficulty (shortness of breath, wheezing, stridor, cough), gastrointestinal symptoms (nausea, vomiting, diarrhea, crampy abdominal pain), and cardiovascular signs and symptoms of anaphylaxis (tachycardia, low blood pressure, syncope, incontinence, dizziness). Before therapy with ARIKAYCE is instituted, evaluate for previous hypersensitivity reactions to aminoglycosides. If anaphylaxis or a hypersensitivity reaction occurs, discontinue ARIKAYCE and institute appropriate supportive measures.

Ototoxicity has been reported with the use of ARIKAYCE in the clinical trials. Ototoxicity (including deafness, dizziness, presyncope, tinnitus, and vertigo) were reported with a higher frequency in patients treated with ARIKAYCE plus background regimen (17%) compared to patients treated with background regimen alone (9.8%). This was primarily driven by tinnitus (7.6% in ARIKAYCE plus background regimen vs 0.9% in the background regimen alone arm) and dizziness (6.3% in ARIKAYCE plus background regimen vs 2.7% in the background regimen alone arm). Closely monitor patients with known or suspected auditory or vestibular dysfunction during treatment with ARIKAYCE. If ototoxicity occurs, manage patients as medically appropriate, including potentially discontinuing ARIKAYCE.

Nephrotoxicity was observed during the clinical trials of ARIKAYCE in patients with MAC lung disease but not at a higher frequency than background regimen alone. Nephrotoxicity has been associated with the aminoglycosides. Close monitoring of patients with known or suspected renal dysfunction may be needed when prescribing ARIKAYCE.

Neuromuscular Blockade: Patients with neuromuscular disorders were not enrolled in ARIKAYCE clinical trials. Patients with known or suspected neuromuscular disorders, such as myasthenia gravis, should be closely monitored since aminoglycosides may aggravate muscle weakness by blocking the release of acetylcholine at neuromuscular junctions.

Embryo-Fetal Toxicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides, including ARIKAYCE, may be associated with total, irreversible, bilateral congenital deafness in pediatric patients exposed *in utero*. Patients who use ARIKAYCE during pregnancy, or become pregnant while taking ARIKAYCE should be apprised of the potential hazard to the fetus.

Contraindications: ARIKAYCE is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Most Common Adverse Reactions: The most common adverse reactions in Trial 1 at an incidence ≥5% for

patients using ARIKAYCE plus background regimen compared to patients treated with background regimen alone were dysphonia (47% vs 1%), cough (39% vs 17%), bronchospasm (29% vs 11%), hemoptysis (18% vs 13%), ototoxicity (17% vs 10%), upper airway irritation (17% vs 2%), musculoskeletal pain (17% vs 8%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), pneumonia (10% vs 8%), headache (10% vs 5%), pyrexia (7% vs 5%), vomiting (7% vs 4%), rash (6% vs 2%), decreased weight (6% vs 1%), change in sputum (5% vs 1%), and chest discomfort (5% vs 3%).

Drug Interactions: Avoid concomitant use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of ARIKAYCE with ethacrynic acid, furosemide, urea, or intravenous mannitol.

Overdosage: Adverse reactions specifically associated with overdose of ARIKAYCE have not been identified. Acute toxicity should be treated with immediate withdrawal of ARIKAYCE, and baseline tests of renal function should be undertaken. Hemodialysis may be helpful in removing amikacin from the body. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment.

U.S. INDICATION

LIMITED POPULATION: ARIKAYCE® is indicated in adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

Patients are encouraged to report negative side effects of prescription drugs to the FDA.
Visit **www.fda.gov/medwatch**, or call 1–800–FDA–1088. You can also call the Company at 1-844-4-INSMED.

Please see Full Prescribing Information.

About Insmed

Insmed Incorporated is a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases. Insmed's first commercial product is a first-in-disease therapy approved in the United States, Europe, and Japan to treat a chronic, debilitating lung disease. The Company is also progressing a robust pipeline of investigational therapies targeting areas of serious unmet need, including neutrophil-mediated inflammatory diseases and rare pulmonary disorders. Insmed is headquartered in Bridgewater, New Jersey, with a footprint across Europe and in Japan. For more information, visit https://insmed.com/.

Forward-looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential," "continues," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) may identify forward-looking statements.

The forward-looking statements in this press release are based upon the Company's current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause the Company's actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timings discussed, projected, anticipated or indicated in any forward-looking statements. Such risks, uncertainties and other factors include, among others, the following: failure to

obtain, or delays in obtaining, regulatory approvals for ARIKAYCE outside the U.S., Europe or Japan, or for the Company's product candidates in the U.S., Europe, Japan or other markets, including regulatory approval for the Lamira® Nebulizer System and the drug delivery device for TPIP in each market and for each usage; failure to successfully commercialize ARIKAYCE, the Company's only approved product, in the U.S., Europe or Japan (amikacin liposome inhalation suspension, Liposomal 590 mg Nebuliser Dispersion, and amikacin sulfate inhalation drug product, respectively), or to maintain U.S., European or Japanese approval for ARIKAYCE; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; impact of the COVID-19 pandemic and efforts to reduce its spread on the Company's business, employees, including key personnel, patients, partners and suppliers; risk that brensocatib does not prove effective or safe for patients in ongoing and future clinical studies, including the ASPEN study; risk that TPIP does not prove to be effective or safe for patients in ongoing and future clinical studies; uncertainties in the degree of market acceptance of ARIKAYCE by physicians, patients, third-party payors and others in the healthcare community; the Company's inability to obtain full approval of ARIKAYCE from the U.S. Food and Drug Administration, including the risk that the Company will not successfully or in a timely manner complete the study to validate a patient reported outcome tool and the confirmatory post-marketing clinical trial required for full approval of ARIKAYCE; inability of the Company, PARI or the Company's other third-party manufacturers to comply with regulatory requirements related to ARIKAYCE or the Lamira® Nebulizer System; the Company's inability to obtain adequate reimbursement from government or third-party payors for ARIKAYCE or acceptable prices for ARIKAYCE; development of unexpected safety or efficacy concerns related to ARIKAYCE or the Company's product candidates; inaccuracies in the Company's estimates of the size of the potential markets for ARIKAYCE, brensocatib, TPIP or the Company's other product candidates or in data the Company has used to identify physicians, expected rates of patient uptake, duration of expected treatment, or expected patient adherence or discontinuation rates; the Company's inability to create an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of ARIKAYCE or any of the Company's product candidates that are approved in the future; failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population; risk that the Company's competitors may obtain orphan drug exclusivity for a product that is essentially the same as a product the Company is developing for a particular indication; failure to successfully predict the time and cost of development, regulatory approval and commercialization for novel gene therapy products; failure to successfully conduct future clinical trials for ARIKAYCE, brensocatib, TPIP and the Company's other product candidates due to the Company's limited experience in conducting preclinical development activities and clinical trials necessary for regulatory approval and its potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval, among other things; risks that the Company's clinical studies will be delayed or that serious side effects will be identified during drug development; failure of third parties on which the Company is dependent to manufacture sufficient quantities of ARIKAYCE or the Company's product candidates for commercial or clinical needs, to conduct the Company's clinical trials, or to comply with the Company's agreements or laws and regulations that impact the Company's business or agreements with the Company; the Company's inability to attract and retain key personnel or to effectively manage the Company's growth; the Company's inability to successfully integrate its recent acquisitions and appropriately manage the amount of management's time and attention devoted to integration activities; risks that the Company's acquired technologies, products and product candidates are not commercially successful; the Company's inability to adapt to its highly competitive and changing environment; risk that the Company is unable to maintain its significant customers; risk that government healthcare reform materially increases the Company's costs and damages its financial condition; the Company's inability to adequately protect its intellectual property rights or prevent disclosure of its trade secrets and other proprietary information and costs associated with litigation or other proceedings related to such matters; restrictions or other obligations imposed on the Company by agreements related to ARIKAYCE or the Company's product candidates, including its license agreements with PARI and AstraZeneca AB, and failure of the Company to comply with its obligations under such agreements; the cost and potential reputational damage resulting from litigation to which the Company is or may become a party, including product liability claims; risk that the Company's operations are subject to a material disruption in the event of a cybersecurity attack or issue; business disruptions or expenses related to the upgrade to the Company's enterprise resource planning system; the Company's limited experience operating internationally; changes in laws and regulations applicable to the Company's business, including any pricing reform, and failure to comply with such laws and regulations; the Company's history of operating losses, and the possibility that the Company may never achieve or maintain profitability; goodwill impairment charges affecting the Company's results of operations and financial condition; inability to repay the Company's existing indebtedness and uncertainties with respect to the Company's ability to access future capital; and delays in the execution of plans to build out an additional third-party manufacturing facility approved by the appropriate regulatory authorities and unexpected expenses associated with those plans.

The Company may not actually achieve the results, plans, intentions or expectations indicated by the Company's forward-looking statements because, by their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. For additional information about the risks and uncertainties that may affect the Company's business,

please see the factors discussed in Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 and any subsequent Company filings with the Securities and Exchange Commission (SEC).

The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date of this press release. The Company disclaims any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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