Insmed Presents Range of New Study Findings at American Thoracic Society 2023 International Conference

—Brensocatib Reduced Risk of Exacerbations Irrespective of Disease Severity in Patients with Non-Cystic Fibrosis Bronchiectasis (NCFBE) in Phase 2 WILLOW Subgroup Analysis—

—Real-World Cohort Study Shows Fewer Hospitalizations Among Patients with Chronic Obstructive Pulmonary Disease (COPD) Who Received Early Diagnosis of Nontuberculous Mycobacterial (NTM) Lung Disease vs. Patients in the Late-Diagnosis Group—

—Analysis of WILLOW Data Demonstrates Reduction in Azurocidin-1 (AZU1) Sputum Levels with Brensocatib Treatment—

BRIDGEWATER, N.J., May 22, 2023 /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 eight presentations across three of its pillars—ARIKAYCE® (amikacin liposome inhalation suspension), brensocatib, and treprostinil palmitil inhalation powder (TPIP)—at the American Thoracic Society (ATS) 2023 International Conference in Washington, D.C.

"We were pleased to share Insmed's breadth of new data with experts at this year's conference, including treatment-specific data and disease state findings that can help advance the care of patients with rare and serious diseases," said Martina Flammer, M.D., M.B.A, Chief Medical Officer of Insmed. "Data were presented on how early diagnosis of NTM lung disease in patients with COPD may be associated with a reduction in healthcare resource utilization, particularly all-cause and respiratory-related hospitalizations. In addition, we were excited to share the latest subgroup analyses from WILLOW, which showed a reduction of exacerbations in patients with NCFBE, regardless of baseline disease severity."

Summaries of these presentations follow:

Poster: "Outcomes of Patients With Bronchiectasis by Disease Severity: Subgroup Analysis From the Brensocatib WILLOW Study"
This subgroup analysis of the phase 2 WILLOW study (a randomized, double-blind, placebo-controlled trial of brensocatib in adults with NCFBE) compared patient characteristics and outcomes, as determined by the Bronchiectasis Severity Index (BSI), in mild (≤4), moderate (5–8), and severe (≥9) bronchiectasis subgroups.

- At baseline, mean (standard deviation [SD]) BSI score in all patients was 8.3 (4.4).
- Compared with placebo, brensocatib 10 mg and 25 mg (pooled data) reduced the risk of exacerbations across BSI subgroups during the study:
    - In the mild subgroup: 41.2% of placebo and 13.9% of brensocatib patients had ≥1 exacerbation.
    - In the moderate subgroup: 36.1% of placebo and 28.3% of brensocatib patients had ≥1 exacerbation.
    - In the severe subgroup: 64.7% of placebo and 43.8% of brensocatib patients had ≥1 exacerbation.
- Across all subgroups, compared with placebo, brensocatib was also associated with numerical reductions in rate of lung function decline.
- Both doses of brensocatib were well-tolerated. The most frequent AEs were headache, cough and sputum increased. No major differences were seen across BSI subgroups.
- Between-group statistical comparisons were not possible because this was a post hoc analysis. Effects should be interpreted with caution because the size of some patient subgroups was small.

Mini Symposium: "Long-term Hospitalization Burden Among Patients With Chronic Obstructive Pulmonary Disease With Possible Diagnostic Delays of Nontuberculous Mycobacterial Lung Disease"
This retrospective cohort study used US Medicare claims (2006–2017) to assess the association between possible diagnostic delay of nontuberculous mycobacterial (NTM) lung disease and hospitalization burden among patients with chronic obstructive pulmonary disease (COPD) over a five-year period. The study identified 2,122 patients with COPD who were predicted to have NTM lung disease and received a subsequent NTM lung disease diagnosis. These patients were grouped by the possible diagnostic delay (time from predicted NTM lung disease onset to date of NTM lung disease diagnosis): <2 years (early diagnosis), 2–3 years (intermediate diagnosis), and >3 years (late diagnosis).

- Patients who were diagnosed earlier showed a decrease in hospitalizations over the 5-year follow-up.
- Possible NTM lung disease diagnostic delay was found among a substantial proportion of patients with COPD, especially among those with more severe COPD and other respiratory comorbidities.
- By the 5th year following the predicted NTM lung disease onset, hospitalization burden was highest in the late-diagnosis group: the late-diagnosis group was 2.1 times (95% CI, 1.6–2.7) more likely to experience all cause hospitalizations and 3.1 times (95% CI,

2.3–4.2) more likely to experience respiratory-related hospitalizations compared with the early-diagnosis group, despite controlling for confounding factors such as patient characteristics, comorbidities, and COPD severity.
- Study authors concluded that early NTM lung disease diagnosis may be associated with reduced longer-term hospitalization burden.

Poster: "The Dipeptidyl Peptidase-1 Inhibitor Brensocatib Reduces Airway Azurocidin-1 Levels in Bronchiectasis"
In this post-hoc analysis from the WILLOW study, researchers sought to measure the effect of brensocatib on azurocidin-1 (AZU1), an inflammatory mediator that is structurally related to neutrophil elastase but lacks protease activity. Sputum samples of patients enrolled in the trial were assessed at Day 1, Day 29, Day 169, and Day 197 (29 days following cessation of brensocatib treatment). Measurements of AZU1 concentration in sputum by ELISA showed:

- At Day 1, median sputum AZU1 levels, µg/mL (95% CI) were comparable across groups: brensocatib 10 mg, 80.26 (57.59, 182.8); brensocatib 25 mg, 122.7 (73.89, 198.1); and placebo, 137.5 (74.91, 258.5).
- By Day 29, 51/134 (38%) in the combined brensocatib group compared with 5/86 (7%) in the placebo group had undetectable AZU1 ($P < 0.001$).
- This significant effect on AZU1 was maintained over the entire duration of the treatment period with levels returning to pre-treatment levels 29 days after brensocatib was stopped.
- These findings suggest a novel effect of brensocatib on the multifunctional inflammatory mediator AZU1. The role of AZU1 in the pathophysiology of bronchiectasis warrants further investigation.

Poster: "Association of Baseline and Subsequent Bronchiectasis Exacerbations in Patients From the US Bronchiectasis and NTM Research Registry (BRR)"
This retrospective cohort study utilized data from patients enrolled in the US Bronchiectasis and Nontuberculous Mycobacteria (NTM) Research Registry (BRR) to explore the association between the number of bronchiectasis exacerbations at baseline and follow-up over 4 years. Analyses of 520 patients were conducted at 3 time points in 2-year intervals: baseline (retrospective period of 2 years before enrollment), follow-up window 1 (years 1–2 after enrollment), and follow-up window 2 (years 3–4 after enrollment). Patients were categorized according to their baseline exacerbation status: 0 exacerbations or ≥1 exacerbation.

- Compared with patients with no exacerbations at baseline, patients with prior exacerbations had significantly more exacerbations in years 1–2 (60% vs. 71%, $P < 0.01$) and years 3–4 (53% vs. 75%,$P<0.0001$).
- Prior bronchiectasis exacerbations at baseline increased the odds of bronchiectasis exacerbations in the first 2 years by 1.5 times (95% CI, 1.1–2.3) and in the subsequent 4 years by 2.4 times (95% CI, 1.6–3.5).
- These findings suggest that prevention or improved control of bronchiectasis exacerbations is a potential unmet need in patients with bronchiectasis.

Poster: "A Qualitative Interview Study to Explore the Use of Adverse Event Mitigation Strategies Among Adults Receiving Amikacin Liposome Inhalation Suspension (ALIS) in Real World Settings"
This real-world study of adults in the United States with a self-reported, clinician-confirmed diagnosis of refractory*Mycobacterium avium* complex (MAC) lung disease provided insights on patient perspectives and practices used to mitigate adverse events (AEs) associated with ARIKAYCE (referred to as ALIS in this poster). Patients were recruited through Insmed's patient support program if they had received ARIKAYCE for ≥7 consecutive days; data were collected through one-on-one patient interviews.

- Patients described more than 40 unique AE mitigation strategies, which were grouped into three main categories: 1) prepare for treatment, 2) prevent increased emergence of AEs, and 3) persist on treatment by mitigating AEs.
- The most common mitigation strategies (≥ 50%) included taking lozenges to manage throat irritation (70%); soothing fluid intake (e.g., hot tea) (65%); and the use of educational materials to understand what to expect in advance of starting treatment (60%).
- The results of this real-world interview study identified a diverse set of AE mitigation strategies used by patients with MAC lung disease taking ARIKAYCE.

The following Insmed posters were also presented atATS 2023:

- Treatment Patterns and Adverse Events (AEs) Among Patients With Bronchiectasis (BE) Chronically Receiving Macrolides Over a 1-Year Follow-up Period
- Longitudinal Changes in Forced Expiratory Volume 1 (FEV1) According to Exacerbation Frequency in Patients From the US Bronchiectasis and NTM Research Registry (BRR)
- Treprostinil Palmitil Hydrolysis Is Facilitated by Lung Esterases

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 highly differentiated prostanoid being evaluated for the treatment of patients with PAH, 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 www.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 separate regulatory approval for the Lamira® Nebulizer System 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 or TPIP does not prove to be effective or safe for patients in ongoing and future clinical studies, including, for brensocatib, the ASPEN study; 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, brensocatib, TPIP or the Company's other 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 risks and uncertainties associated with, and the perceived benefits of, the Company's secured senior loan with certain funds managed by Pharmakon Advisors, LP and the Company's royalty financing with OrbiMed Royalty & Credit Opportunities IV, LP, including our ability to maintain compliance with the covenants in the agreements for the senior secured loan and royalty financing and the perceived impact of the restrictions on the Company's operations under these agreements; 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; deterioration in general economic conditions in the U.S., Europe, Japan and globally, including the effect of prolonged periods of inflation, affecting the Company, its suppliers, third-party service providers and potential partners; 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, 2022 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.

Contact:

Investors:

Bryan Dunn
Executive Director, Investor Relations
Insmed
(646) 812-4030
bryan.dunn@insmed.com

Eleanor Barisser

Associate Director, Investor Relations
Insmed
(718) 594-5332
eleanor.barisser@insmed.com

Media:

Mandy Fahey
Executive Director, Corporate Communications
Insmed
(732) 718-3621
amanda.fahey@insmed.com

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