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Insmmed to Present Data Across Its Respiratory Portfolio, Including Late-Breaking ARIKAYCE® Results from Phase 3b ENCORE Study, at the American Thoracic Society International Conference 2026

—New Data in Non-Cystic Fibrosis Bronchiectasis Further Define Impact of BRINSUPRI® on Respiratory Symptoms—

—Findings from a Pharmacokinetic Study Continue to Support Further Evaluation of Treprostinil Palmitil Inhalation Powder Phase 3 Development Program—

—Additionally, Insmmed Provides Independent Research Grant to the American Thoracic Society for a Landmark Quality Initiative to Improve Diagnosis of Bronchiectasis across the U.S.—

BRIDGEWATER, N.J., May 4, 2026 /PRNewswire/ -- Insmmed Incorporated (Nasdaq: INSM), a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases, today announced that it will present six abstracts from across its respiratory portfolio and pipeline at the American Thoracic Society International Conference 2026 (ATS 2026), taking place May 17–20 in Orlando, Florida.

Notably, data will be presented from the Phase 3b ENCORE study evaluating ARIKAYCE® (amikacin liposome inhalation suspension) with multidrug therapy (azithromycin 250 mg + ethambutol 15 mg/kg) once-daily versus placebo with multidrug therapy once-daily in diagnosed adult patients with a new occurrence of *Mycobacterium avium* complex (MAC) lung infection who had not received antibiotics. Additional presentations include a post-hoc analysis from the Phase 3 ASPEN trial of BRINSUPRI® (brensocaticib), real-world experience data in patients with non-cystic fibrosis bronchiectasis (NCFB), a pharmacokinetic analysis of investigational treprostinil palmitil inhalation powder (TPIP), and data highlighting disease burden in pulmonary hypertension associated with interstitial lung disease (PH-ILD).

"At Insmmed, our work in respiratory disease is guided by the experiences of people living with serious and rare pulmonary conditions, where meaningful treatment advances are still urgently needed," said Martina Flammer, M.D., MBA, Chief Medical Officer of Insmmed. "The research we're presenting at ATS 2026 reflects the strength of Insmmed's respiratory portfolio and pipeline, and our unwavering commitment to patients. Additionally, we're honored to present the Phase 3b ENCORE study findings as a late breaker, which will highlight compelling evidence of ARIKAYCE's potential use earlier in the treatment journey for patients living with *Mycobacterium avium* complex lung disease."

Presentations:

Late Breaking Science A71, Sunday, May 17, 11:30 AM – 1:15 PM EDT

- [Amikacin Liposome Inhalation Suspension for Newly Diagnosed Mycobacterium Avium Complex Lung Disease: Efficacy and Safety From a Phase 3b Study \(ENCORE\)](#)

Poster Session B45, Monday, May 18, 11:30 AM – 1:15 PM EDT

- [Effect of Brensocaticib on Patient-Reported Symptoms in Patients with Non-Cystic Fibrosis Bronchiectasis: A Post Hoc Analysis of QOL-B RSS Individual Items from the ASPEN Phase 3 Trial](#)

Poster Session B106, Monday, May 18, 2:15 – 4:15 PM EDT

- [Population Pharmacokinetics Analysis of Treprostinil Using Data From Phase 1 and 2 Studies of Treprostinil Palmitil Inhalation Powder](#)

Poster Session B107, Monday, May 18, 2:15 – 4:15 PM EDT

- [Patient and Caregiver Survey of Burden of Bronchiectasis in the US and Europe](#)

Poster Session C58, Tuesday, May 19, 11:30 AM – 1:15 PM EDT

- [Long-term Hospitalizations, Comorbidities, and Survival in Patients with Pulmonary Hypertension Associated With Interstitial Lung Disease in Real-World Settings Using the NorstellLinQ Claims Database](#)

Mini Symposium D92, Wednesday, May 20, 11:00 AM – 1:00 PM EDT

- [Exposure-response Relationships of Brensocatib in Adult and Adolescent Patients With Non-Cystic Fibrosis Bronchiectasis](#)

In addition to its scientific presentations, Insmmed will also host a Medical Affairs exhibit booth (location #937) at the ATS conference.

American Thoracic Society (ATS) Bronchiectasis Diagnosis Quality Initiative

As announced by the ATS, Insmmed is supporting the organization with an independent research grant for a landmark quality improvement initiative aimed at addressing the widespread underdiagnosis of bronchiectasis across the United States. Working with seven academic medical systems, the ATS will independently conduct a large-scale electronic health record study to identify patients misdiagnosed with asthma or COPD, pilot scalable diagnostic interventions, and disseminate findings nationally, with the goal of ensuring patients receive timely, accurate diagnoses and guideline-directed care.

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. Insmmed'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 BRINSUPRI

BRINSUPRI[®] (brensocatib) is a small molecule, once-daily, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1). BRINSUPRI (brensocatib 10 mg and 25 mg tablets) is indicated in the United States for the treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age or older. In the European Union, BRINSUPRI (brensocatib 25 mg tablets) is approved for the treatment of NCFB in patients 12 years of age and older with two or more exacerbations in the prior 12 months. Brensocatib is designed to inhibit the activation of enzymes (neutrophil serine proteases) in neutrophils that are key drivers of chronic airway inflammation in NCFB.

About TPIP

Treprostinil palmitil inhalation powder (TPIP) is an investigational 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 Insmmed's laboratories, TPIP is a potentially highly differentiated prostanoid being evaluated as once-daily therapy for the treatment of patients with pulmonary arterial hypertension (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 AND BOXED WARNING 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 $\geq 5\%$ 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](#).

BRINSUPRI® (brensocatib) U.S. INDICATION AND IMPORTANT SAFETY INFORMATION

Indication in the U.S.

BRINSUPRI is indicated for the treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age and older.

Important Safety Information in the U.S.

WARNINGS AND PRECAUTIONS

Dermatologic Adverse Reactions

Treatment with BRINSUPRI is associated with an increase in dermatologic adverse reactions, including rash, dry skin, and hyperkeratosis. Monitor patients for development of new rashes or skin conditions and refer patients to a dermatologist for evaluation of new dermatologic findings.

Gingival and Periodontal Adverse Reactions

Treatment with BRINSUPRI is associated with an increase in gingival and periodontal adverse reactions. Refer patients to dental care services for regular dental checkups while taking BRINSUPRI. Advise patients to perform routine dental hygiene.

Live Attenuated Vaccines

It is unknown whether administration of live attenuated vaccines during BRINSUPRI treatment will affect the safety or effectiveness of these vaccines. The use of live attenuated vaccines should be avoided in patients receiving BRINSUPRI.

ADVERSE REACTIONS

The most common adverse reactions $\geq 2\%$ in the ASPEN trial included upper respiratory tract infection, headache, rash, dry skin, hyperkeratosis, and hypertension. The safety profile for adult patients with NCFB in WILLOW was generally similar to ASPEN, except for a higher incidence of gingival and periodontal adverse reactions.

Less Common Adverse Reactions

Liver Function Test Elevations

In ASPEN, there was an increase from baseline in average ALT, AST, and alkaline phosphatase levels at all time points from Week 4 through Week 56 in both BRINSUPRI 10 mg and 25 mg arms compared to placebo. The incidence of ALT $>3X$ upper limit of normal (ULN) was 0%, 1.2%, and 0.9%; the incidence of AST $>3X$ ULN was 0.2%, 0.3%, and 0.5%; and the incidence of alkaline phosphatase $>1.5X$ ULN was 2.5%, 4.1%, and 4.0% in patients treated with placebo and BRINSUPRI 10 mg and 25 mg, respectively.

Skin Cancers

In ASPEN, the incidence of skin cancers among patients treated with BRINSUPRI 10 mg and 25 mg was 0.5% and 1.9%, respectively, compared to 1.1% in placebo-treated patients.

Alopecia

In ASPEN, the incidence of alopecia among patients treated with BRINSUPRI 10 mg and 25 mg was 1.5% and 1.6% respectively, compared to 0.4% in placebo-treated patients.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no clinical data on the use of BRINSUPRI in pregnant women.

Lactation: There is no information regarding the presence of BRINSUPRI and/or its metabolite(s) in human milk, the effects on

the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BRINSUPRI and any potential adverse effects on the breastfed child from BRINSUPRI or from the underlying maternal condition.

Pediatric use: The safety and effectiveness of BRINSUPRI for the treatment of NCFB have been established in pediatric patients aged 12 years and older. Common adverse reactions in pediatric patients aged 12 years and older enrolled in ASPEN were consistent with those in adults. The safety and effectiveness of BRINSUPRI have not been established in pediatric patients younger than 12 years of age.

Please see full [US Prescribing Information](#).

About Insmed

Insmed Incorporated is a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases. The Company is advancing a diverse portfolio of approved and mid- to late-stage investigational medicines as well as cutting-edge drug discovery focused on serving patient communities where the need is greatest. Insmed's most advanced programs are in pulmonary and inflammatory conditions, including two approved therapies to treat chronic, debilitating lung diseases. The Company's early-stage programs encompass a wide range of technologies and modalities, including gene therapy, AI-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

Headquartered in Bridgewater, New Jersey, Insmed has offices and research locations throughout the United States, Europe, and Japan. Insmed is proud to be recognized as one of the best employers in the biopharmaceutical industry, including spending five consecutive years as the No. 1 *Science* Top Employer. Visit www.insmed.com to learn more or follow us on [LinkedIn](#), [Instagram](#), [YouTube](#), and [X](#).

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: risk that interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or may be interpreted differently if additional data are disclosed; failure to successfully conduct future clinical trials for our marketed products or our product candidates and our potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval of our product candidates; development of unexpected safety or efficacy concerns related to our marketed products or our product candidates; risks that our clinical studies will be delayed, that serious side effects will be identified during drug development, or that any protocol amendments submitted will be rejected; our inability to obtain full approval of ARIKAYCE from the FDA or our failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population; failure to obtain, or delays in obtaining, regulatory approvals for our product candidates in the U.S., Europe or Japan, for ARIKAYCE outside the U.S., Europe or Japan, including separate regulatory approval for Lamira® in each market and for each usage, or for brensocatib in NCFB in Japan; and failure to successfully commercialize our marketed products and product candidates, if approved by applicable regulatory authorities, or to maintain applicable regulatory approvals for our marketed products and product candidates, if approved.

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, 2025 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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