Insmed to Present Multiple Abstracts at the European Respiratory Society Congress 2025

—Data from Phase 2b Study of Treprostinil Palmitil Inhalation Powder in Patients with Pulmonary Arterial Hypertension to be Presented at Late-Breaking ALERT Session—

—New Analysis from Phase 3 ASPEN Trial Examines Efficacy and Safety of Brensocatib in Japanese Patients with Non-Cystic Fibrosis Bronchiectasis by Reduction of Exacerbation History—

BRIDGEWATER, N.J., Sept. 22, 2025 /PRNewswire/ -- Insmed 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 seven abstracts from across its late-stage portfolio at the European Respiratory Society (ERS) 2025 Congress, taking place September 27 – October 1, 2025, in Amsterdam.

Notably, data from the Phase 2 trial in treprostinil palmitil inhalation powder (TPIP) in patients with pulmonary arterial hypertension (PAH) will be highlighted in the Congress's Abstracts Leading to Evolution in Respiratory Medicine Trials (ALERT) session, which showcases important, late-breaking clinical data from all respiratory disease areas. In addition, presentations include three prespecified subgroup analyses from the Phase 3 ASPEN trial evaluating the efficacy and safety of brensocatib, including Japanese patient data, as well as Health Outcomes and Economic Research from The Health Improvement Network® (THIN) database in France and the United Kingdom in patients with non-cystic fibrosis bronchiectasis (NCFB).

"Our deep commitment to transforming care in serious respiratory and pulmonary diseases is evident in the recognition of our TPIP Phase 2b study in PAH as part of the prestigious ALERT session, along with the presentation of multiple analyses for brensocatib," said Martina Flammer, M.D., MBA, Chief Medical Officer of Insmed. "We are eager to showcase the strength and breadth of our data and the potential impact it may have for patients and the clinical community."

Presentations:

- **Oral Presentation Elicium 1,** Sunday, September 28, 15:50 – 15:55 PM CEST
  - **Presenting Author:** Michael Loebinger
    - Efficacy and Safety of Brensocatib in Patients with Non-Cystic Fibrosis Bronchiectasis by Exacerbation History: Analysis of the ASPEN Trial
- **Poster Session PS-30,** Monday, September 29, 12:30 – 14:00 PM CEST
  - **Presenting Author:** Takanori Asakura
    - Exacerbations Among Incident Cases of Bronchiectasis inJapan
- **Poster Session PS-29,** Tuesday, September 30, 8:00 – 9:30 AM CEST
  - **Presenting Author:** Kozo Morimoto
    - Efficacy and Safety of Brensocatib in Japanese Patients with Non-Cystic Fibrosis Bronchiectasis: Analysis of the ASPEN Trial
  - **Presenting Author**: Stefano Aliberti
    - Efficacy and safety of brensocatib in patients with non-cystic fibrosis bronchiectasis and Pseudomonas aeruginosa infection: Analysis of the ASPEN trial
- **ALERT 3 Session 436 /Clinical Trials Session 7A,** Tuesday, September 30, 8:30 – 10:00 AM CEST
  - **Presenting Author**: Ekkehard Grünig

        - A Randomized, Double-Blind, Placebo-Controlled Study of Treprostinil Palmitil Inhalation Powder (TPIP) in Patients with Pulmonary Arterial Hypertension (PAH)

- **Poster Session PS-29,** Tuesday, September 30, 12:30 – 14:00 PM CEST
    - **Presenting Author:** Pierre-Régis Burgel
        - Morbidity in Patients with NCFBE and Exacerbations in the THIN France Database
    - **Presenting Author:** Michael Loebinger
        - Morbidity in Patients with NCFBE and Exacerbations in the THIN UK Database

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 pulmonary arterial hypertension (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.

About the TPIP Phase 2b Study

The Phase 2b study of treprostinil palmitil inhalation powder (TPIP) in patients with pulmonary arterial hypertension (PAH) was a randomized, double-blind, multicenter, placebo-controlled study designed to evaluate the efficacy, safety, and pharmacokinetics of TPIP, administered once daily, in patients diagnosed with PAH (World Health Organization Group 1). The study was conducted at 44 sites and enrolled 102 adult participants. Patients started at a dose of 80 µg once daily (TPIP or matching placebo) and were titrated up to their maximum tolerated dose, or to the maximum allowable dose of 640 µg, once daily over a three-week period, with the possibility of a final dose increase occurring at Week 5. Patients self-administered TPIP or placebo using a capsule-based inhalation device. The primary endpoint was change from baseline in pulmonary vascular resistance (PVR) versus placebo at Week 16. Secondary endpoints were six-minute walk distance (6MWD), N-terminal pro b-type natriuretic peptide (NT-proBNP) concentrations, pharmacokinetics, and safety/tolerability. Patients who completed the study could enroll in a long-term open-label extension, with the option to titrate up to a maximum tolerated dose of 1,280 µg once daily.

About Pulmonary Arterial Hypertension

Pulmonary arterial hypertension (PAH) is a serious, progressive, rare disease in which the blood vessels in the lungs narrow or become obstructed, leading to high blood pressure in the pulmonary arteries. The most common symptoms include shortness of breath, chest pain, dizziness or fainting, fatigue, and weakness. It is estimated that approximately 35,000 patients in the U.S., 40,000 patients in the EU5 (France, Germany, Italy, Spain, and the UK), and 15,000 patients in Japan have been diagnosed with the disease. Untreated, PAH can be debilitating and often fatal.

About BRINSUPRI™ (brensocatib)

BRINSUPRI™ (brensocatib) is a small molecule, once-daily, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) indicated for the treatment of non-cystic fibrosis bronchiectasis (NCFB) in adult and pediatric patients 12 years of age or older. Brensocatib is designed to inhibit the activation of enzymes (neutrophil serine proteases) in neutrophils that are key drivers of chronic airway inflammation in bronchiectasis. Brensocatib is also being evaluated for its potential role in other neutrophil-mediated diseases.

About ASPEN

ASPEN was a global, randomized, double-blind, placebo-controlled Phase 3 study to assess the efficacy, safety, and tolerability of brensocatib in patients with non-cystic fibrosis bronchiectasis (NCFB). As part of the ASPEN study's conduct, more than 460 trial sites were engaged in nearly 40 countries. After excluding sites that did not enroll any patients and all sites in Ukraine, the total number of active sites in ASPEN was 391 sites in 35 countries. Adult patients (ages 18 to 85 years) were randomized 1:1:1 and adolescent patients (ages 12 to <18 years) were randomized 2:2:1 for treatment with brensocatib 10 mg, brensocatib 25 mg, or placebo once daily for 52 weeks, followed by 4 weeks off treatment. The primary efficacy analysis included data from 1,680 adult patients and 41 adolescent patients.

About Bronchiectasis

Bronchiectasis is a serious, chronic lung disease in which the bronchi become permanently dilated due to a cycle of infection, inflammation, and lung tissue damage. The condition is marked by frequent pulmonary exacerbations requiring antibiotic therapy and/or hospitalizations. Symptoms include chronic cough, excessive sputum production, shortness of breath, and repeated respiratory infections, which can worsen the underlying condition. Most bronchiectasis cases in adults are non-cystic

fibrosis bronchiectasis. Today, approximately 500,000 patients in the U.S., 600,000 patients in the EU5 (France, Germany, Italy, Spain, and UK), and 150,000 patients in Japan have been diagnosed with NCFB. Outside the U.S., there are currently no approved therapies specifically targeting bronchiectasis in these regions.

BRINSUPRI - IMPORTANT SAFETY INFORMATION

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.

Vaccinations
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 (incidence ≥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 52 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 1.4% 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 Prescribing Information.

INDICATION

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

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 throughoutthe United States, Europe, and Japan. Insmed is proud to be recognized as one of the best employers in the biopharmaceutical industry, including spending four 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: failure to successfully commercialize BRINSUPRI (brensocatib) in the U.S. and to maintain U.S. approval for BRINSUPRI; our inability to obtain, or delays in obtaining, approval of BRINSUPRI in Europe and Japan; failure to obtain, or delays in obtaining, regulatory approvals for brensocatib in other indications, or for TPIP in the U.S., Europe or Japan; failure to successfully commercialize our product candidates, if approved by applicable regulatory authorities, or to maintain applicable regulatory approvals for our product candidates, if approved; uncertainties or changes in the degree of market acceptance of BRINSUPRI or, if approved, TPIP, by physicians, patients, third-party payors and others in the healthcare community; our inability to obtain and maintain adequate reimbursement from government or third-party payors for BRINSUPRI or, if approved, TPIP, or acceptable prices for BRINSUPRI or, if approved, TPIP; inaccuracies in our estimates of the size of the potential markets for BRINSUPRI or TPIP or in data we have used to identify physicians, expected rates of patient uptake, duration of expected treatment, or expected patient adherence or discontinuation rates; failure of third parties on which the Company is dependent to manufacture sufficient quantities of BRINSUPRI or TPIP 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; the risks and uncertainties associated with, and the perceived benefits of, our secured senior loan with certain funds managed by Pharmakon Advisors LP and our 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 impact of the restrictions on our operations under these agreements; our inability to create or maintain an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of BRINSUPRI or TPIP if it is approved in the future; failure to successfully conduct future clinical trials for BRINSUPRI or TPIP and our potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval, among other things; development of unexpected safety or efficacy concerns related to BRINSUPRI or TPIP; 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; the 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, or that blinded data will not be predictive of unblinded data; risk that our competitors may obtain orphan drug exclusivity for a product that is essentially the same as a product we are developing for a particular indication; our inability to attract and retain key personnel or to effectively manage our growth; our inability to successfully integrate our recent acquisitions and appropriately manage the amount of management's time and attention devoted to integration activities; risks that our acquired technologies, products and product candidates will not be commercially successful; inability to adapt to our highly competitive and changing environment; inability to access, upgrade or expand our technology systems or difficulties in updating our existing technology or developing or implementing new technology; risk that we are unable to maintain our significant customers; risk that government healthcare reform materially increases our costs and damages our financial condition; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; risk that our current and potential future use of artificial intelligence and machine learning may not be successful; deterioration in general economic conditions in the U.S., Europe, Japan and globally, including the effect of prolonged periods of inflation, affecting us, our suppliers, third-party service providers and potential partners; the risk that we could become involved in costly intellectual property disputes, be unable to adequately protect our intellectual property rights or prevent disclosure of our trade secrets and other proprietary information, and incur costs associated with litigation or other proceedings related to such matters; restrictions or other obligations imposed on us by agreements related to BRINSUPRI or our product candidates, including our license agreements with PARI and AstraZeneca AB, and failure to comply with our obligations under such agreements; the cost and potential reputational damage resulting from litigation to which we are or may become a party, including product liability claims; risk that our operations are subject to a material disruption in the event of a cybersecurity attack or issue; our limited experience operating internationally; changes in laws and regulations applicable to our business,

including any pricing reform and laws that impact our ability to utilize certain third parties in the research, development or manufacture of our products or product candidates, and failure to comply with such laws and regulations; our history of operating losses, and the possibility that we never achieve or maintain profitability; goodwill impairment charges affecting our results of operations and financial condition; inability to repay our existing indebtedness and uncertainties with respect to our 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, 2024 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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