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FDA Approves BRINSUPRI™ (brensocatib) as the First and Only Treatment for Non-Cystic Fibrosis Bronchiectasis, a Serious, Chronic Lung Disease

— Approximately 500,000 U.S. Patients Are Diagnosed with Non-Cystic Fibrosis Bronchiectasis (NCFB), a Progressive Disease That Can Lead to Permanent Lung Damage —

— BRINSUPRI 10 mg and 25 mg Doses Approved for the Treatment of NCFB —

— BRINSUPRI, a First-in-Class DPP1 Inhibitor Targeting Neutrophilic Inflammation, Is Available by Prescription Through a Comprehensive Specialty Pharmacy Network —

— Insmmed to Host Investor Conference Call Today at 12:00 PM ET —

BRIDGEWATER, N.J., Aug. 12, 2025 /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 the U.S. Food and Drug Administration (FDA) has approved first-in-class BRINSUPRI™ (brensocatib 10 mg and 25 mg tablets), an oral, once-daily treatment for non-cystic fibrosis bronchiectasis (NCFB) in adults and children 12 years and older. BRINSUPRI is the first and only FDA-approved treatment for NCFB, giving hundreds of thousands of patients and clinicians across the U.S. an option to manage this chronic and progressive disease that can lead to permanent lung damage and lung function decline.

This press release features multimedia. View the full release here: <https://www.multivu.com/insmed/9347351-en-fda-approves-brinsupri-brensocatib>

"This FDA approval represents a potential paradigm shift in how we approach non-cystic fibrosis bronchiectasis," said Doreen Addrizzo-Harris, M.D., FCCP, the Fiona and Stanley Druckenmiller Professor of Pulmonary, Critical Care and Sleep Medicine at NYU Grossman School of Medicine and Director of the NYU Langone Health Bronchiectasis and NTM Program, and ASPEN investigator. "For the first time, we have a treatment that directly targets neutrophilic inflammation and addresses a root cause of bronchiectasis exacerbations. Based on the strength of the data and the impact we've seen in patients, I believe this could become the new standard in non-cystic fibrosis bronchiectasis care."

There are approximately 500,000 people in the U.S. diagnosed with NCFB, and it is estimated that millions more are living with this disease globally. Unlike other respiratory diseases that are characterized by airway narrowing, bronchiectasis causes airways to permanently widen, making it harder to clear mucus and bacteria, leading to persistent inflammation and infection. A hallmark of bronchiectasis is frequent exacerbations, or flares, when symptoms worsen, such as coughing, increased mucus, shortness of breath and fatigue.

"Non-cystic fibrosis bronchiectasis deeply affects the lives of people living with this chronic lung condition, impacting both their physical health and emotional well-being," added Elisha Malanga, Executive Director of the Bronchiectasis and NTM Association. "Many patients experience frequent flares, which can disrupt daily life and potentially lead to disease progression. The FDA approval of brensocatib represents a significant and long-awaited advancement as the first approved therapy for non-cystic fibrosis bronchiectasis. Our hope is that treatments like this will enable people with bronchiectasis to manage their condition."

This approval is based on data from the Phase 3 ASPEN and Phase 2 WILLOW studies, which were both published in the *New England Journal of Medicine*. In ASPEN, patients taking BRINSUPRI 10 mg or 25 mg had a 21.1% and 19.4% reduction in annual rate of exacerbations respectively, as compared to placebo. Both dosage strengths of BRINSUPRI also met several exacerbation-related secondary endpoints, including significantly prolonging the time to first exacerbation and significantly increasing the proportion of patients remaining exacerbation-free over the treatment period. Patients who received BRINSUPRI 25 mg experienced statistically significant less decline in lung function, as measured by forced expiratory volume in one second (FEV₁) after using a bronchodilator, at week 52. The safety of BRINSUPRI was also evaluated in both studies. The most common adverse reactions ≥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 in WILLOW.

"The FDA approval of the first-ever treatment for non-cystic fibrosis bronchiectasis is a historic milestone for patients and for Insmed," said Martina Flammer, M.D., MBA, Chief Medical Officer of Insmed. "By keeping patients at the center of everything we do, we have once again delivered a first-in-class medicine for a disease with no prior approved treatments. This is an incredible achievement in medicine. We're deeply grateful to the patients, providers, and advocates who made this possible – this is just the beginning of what we can accomplish together for this community."

BRINSUPRI is a first-in-class dipeptidyl peptidase 1 (DPP1) inhibitor, designed to inhibit the activation of enzymes (neutrophil serine proteases) in neutrophils that are key drivers of chronic airway inflammation in NCFB. BRINSUPRI is the first approved therapy to address the underlying inflammatory process of NCFB.

In parallel, applications for brensocatib with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) have been accepted, and the Company plans to file in Japan in 2025. Commercial launches are anticipated in 2026, pending approval in each territory.

BRINSUPRI is now available in the U.S. by prescription through a comprehensive specialty pharmacy network.

Conference Call Information

Insmed will host a conference call today at 12:00 PM Eastern Time to discuss the FDA approval. The call can be accessed by dialing (888) 210-2654 (U.S. and Canada) or (646) 960-0278 (international) and entering the conference ID number 6364918. The call will also be webcast live on the Company's website at www.insmed.com.

A replay of the conference call will be accessible approximately two hours after its completion through August 19, 2025, by dialing (800) 770-2030 (domestic) or (609) 800-9909 (international) and referencing conference ID number 6364918. A webcast of the call will also be archived for 90 days under the Investor Relations section of the Company's website at www.insmed.com.

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 NCFB. Brensocatib is also being evaluated for its potential role in other neutrophil-mediated diseases.

About InLighten Patient Support Program

Insmed is committed to providing access to its products by providing eligible patients with financial assistance options. Patients using Insmed products may also enroll to receive ongoing education and support through its InLighten Patient Support Program.

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 WILLOW

WILLOW was a randomized, double-blind, placebo-controlled, parallel-group, multi-center, multi-national, Phase 2 study to assess the efficacy, safety and tolerability, and pharmacokinetics of brensocatib administered once daily for 24 weeks in patients with non-cystic fibrosis bronchiectasis (NCFB). WILLOW was conducted at 116 sites and enrolled 256 adult patients diagnosed with NCFB who had at least two documented pulmonary exacerbations in the 12 months prior to screening. Patients were randomized 1:1:1 to receive either 10 mg or 25 mg of brensocatib or matching placebo. The primary efficacy endpoint was the time to first pulmonary exacerbation over the 24-week treatment period in the brensocatib arms compared to the placebo arm.

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.

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.

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 $>3\text{X}$ upper limit of normal (ULN) was 0%, 1.2%, and 0.9%; the incidence of AST $>3\text{X}$ ULN was 0.2%, 0.3%, and 0.5%; and the incidence of alkaline phosphatase $>1.5\text{X}$ 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 [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. Insmmed'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, Insmmed has offices and research locations throughout the United States, Europe, and Japan. Insmmed 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 in the U.S. or to maintain U.S. approval for BRINSUPRI; failure to obtain, or delays in obtaining, regulatory approvals for BRINSUPRI in Europe or Japan, including the risk that any regulatory approvals, if granted, may be subject to significant limitations on use or subject to withdrawal or other adverse actions by the applicable regulatory authority; uncertainties in the degree of market acceptance of BRINSUPRI by physicians, patients, third-party payors and others in the healthcare community; inaccuracies in the Company's estimates of the size of the potential markets for BRINSUPRI 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 obtain adequate reimbursement from government or third-party payors for BRINSUPRI or acceptable prices for BRINSUPRI; development of unexpected safety or efficacy concerns related to BRINSUPRI, including the risk that data generated in further clinical trials of brensocatic may not be consistent with the results of the ASPEN study, which may result in changes to the product label and may adversely affect sales, or result in withdrawal of BRINSUPRI from the market; failure by us to comply with agreements related to brensocatic, including our license agreement with AstraZeneca AB; failure to successfully conduct future clinical trials for brensocatic, including due to the Company's potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval, among other things; failure to obtain regulatory approval for potential future brensocatic indications; and failure of third parties on which the Company is dependent to manufacture sufficient quantities of brensocatic 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 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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