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FDA Grants Priority Review to Insmmed's Brensocatib for Treatment of Bronchiectasis with PDUFA Target Action Date Set for August 12, 2025

—Brensocatib Would be the First and Only Available Treatment for Bronchiectasis and First DPP1 Inhibitor, if Approved—

BRIDGEWATER, N.J., Feb. 6, 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 accepted the Company's New Drug Application (NDA) for brensocatib for patients with non-cystic fibrosis bronchiectasis. In its Day 60 communication to Insmmed, the FDA granted Priority Review to the NDA and set a target action date of August 12, 2025, under the Prescription Drug User Fee Act (PDUFA). At present, the FDA has not indicated whether an advisory committee will be convened to discuss the application. Brensocatib has the potential to become the first and only approved treatment for bronchiectasis and the first in a new class of medicines called dipeptidyl peptidase 1 (DPP1) inhibitors for the treatment of neutrophil-mediated diseases.

"Bronchiectasis is a chronic, progressive disease with no approved treatments, leaving hundreds of thousands of people in the U.S. without an effective way to reduce the pulmonary exacerbations that can lead to serious consequences," said Martina Flammer, M.D., MBA, Chief Medical Officer of Insmmed. "Brensocatib has the potential to transform the treatment landscape for bronchiectasis and we were pleased to receive the FDA acceptance of our NDA with Priority Review even earlier than anticipated. We look forward to working with the FDA throughout the review process and, pending approval, bringing the first ever bronchiectasis treatment to patients as quickly as possible."

This NDA is based on data from the landmark Phase 3 ASPEN study, which met its primary endpoint with both dosage strengths of brensocatib achieving statistical and clinical significance for the reduction in the annualized rate of pulmonary exacerbations versus placebo over the 52-week treatment period. Both dosage strengths also met several prespecified exacerbation-related secondary endpoints, including significantly prolonging the time to first exacerbation and significantly increasing the odds of remaining exacerbation-free over the treatment period. Patients treated with brensocatib 25 mg also showed significantly lower lung function decline at week 52 as measured by post-bronchodilator forced expiratory volume over one second.

Brensocatib was well-tolerated in the study. Treatment-emergent adverse events occurring in at least 5.0% of patients treated with either dose of brensocatib and more frequently than in placebo were COVID-19 (15.8%, 20.9%, 15.8%), nasopharyngitis (7.7%, 6.3%, 7.6%), cough (7.0%, 6.1%, 6.4%), and headache (6.7%, 8.5%, and 6.9%) for brensocatib 10 mg, brensocatib 25 mg, and placebo, respectively.

The FDA grants Priority Review to applications for medicines that, if approved, would provide a significant improvement in safety or effectiveness in the treatment of a serious condition. The FDA had previously granted brensocatib Breakthrough Therapy Designation, which is designed to expedite the development and review of therapies that are intended to treat a serious or life-threatening condition, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on a clinically significant endpoint.

Insmmed plans to file regulatory submissions for brensocatib in the EU, UK, and Japan in 2025, with commercial launches anticipated in 2026, pending approval in each territory.

About ASPEN

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. 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 bronchiectasis, and there are currently no approved therapies specifically targeting bronchiectasis in these regions.

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, chronic rhinosinusitis without nasal polyps, hidradenitis suppurativa, 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 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 a therapy approved in the United States, Europe, and Japan to treat a chronic, debilitating lung disease. The Company's early-stage research 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 four consecutive years as the No. 1 *Science* Top Employer. Visit www.insmed.com to learn more.

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: the risk that the full data set from the ASPEN study or data generated in further clinical trials of brensocatib will not be consistent with the topline results of the ASPEN study or any additional results of the ASPEN study; failure to obtain, or delays in obtaining, regulatory approvals for brensocatib in the U.S., Europe or Japan; failure to successfully commercialize brensocatib, if approved by applicable regulatory authorities, in the U.S., Europe or Japan, or to maintain U.S., European or Japanese approval for brensocatib once approved; uncertainties in the degree of market acceptance of brensocatib 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 brensocatib 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; inability of the Company, Esteve Química, S.A., Thermo Fisher Scientific, Inc. or the Company's other third-party manufacturers to comply with regulatory requirements related to brensocatib; the Company's inability to obtain adequate reimbursement from government or third-party payors for brensocatib or acceptable prices for brensocatib; development of unexpected safety or efficacy concerns related to brensocatib; failure to obtain regulatory approval for potential future brensocatib indications; restrictions or other obligations imposed on us by agreements related to brensocatib, including our license agreement with AstraZeneca AB, and failure to comply with our obligations under such agreements; failure to successfully conduct future clinical trials for brensocatib, 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; 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 brensocatib 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 strength and enforceability of the Company's intellectual property rights or the rights of third parties; the cost and potential reputational damage resulting from litigation to

which the Company may become a party, including product liability claims; changes in laws and regulations applicable to the Company's business and failure to comply with such laws and regulations; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; and inability to repay the Company's existing indebtedness and uncertainties with respect to the Company's need and ability to access future capital.

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, 2023 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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