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Insmed Reports Third-Quarter 2025 Financial Results and Provides Business Update

—BRINSUPRI™ (brensocatib) Approved by FDA as First and Only Treatment for Non-Cystic Fibrosis Bronchiectasis; Positive CHMP Opinion Adopted in the European Union and Application Accepted in Japan—

—BRINSUPRI Total Revenue of $28.1 Million for the Third Quarter of 2025—

—ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of $114.3 Million for the Third Quarter of 2025, Reflecting 22% Growth Over the Third Quarter of 2024—

—Company Raises 2025 Global ARIKAYCE Revenue Guidance Range to$420 Million to $430 Million, Reflecting Double-Digit Growth Compared to 2024—

—Topline Data Readout Anticipated for Phase2b BiRCh Study of Brensocatib in Patients with CRSsNPby Early January 2026—

—Phase 2b CEDAR Study of Brensocatib in Patients with HSNow Fully Enrolled, with Topline Data Anticipated in the First Half of 2026—

—PALM-ILD Phase 3 Study of TPIP for PH-ILD Expected to Initiate in the Fourth Quarter of 2025; Additional Phase 3 Studies Planned for PAH, PPF, and IPF in 2026—

BRIDGEWATER, N.J., Oct. 30, 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 reported financial results for the third quarter ended September 30, 2025 and provided a business update.

"The third quarter of 2025 celebrated the FDA approval of BRINSUPRI and the availability of our second commercial product, underscoring our team's dedication to bringing forward a first-in-disease therapy for patients with non-cystic fibrosis bronchiectasis. While still early in the U.S. BRINSUPRI launch, we are very encouraged by positive feedback received from both physicians and patients," said Will Lewis, Chair and Chief Executive Officer of Insmed. "This achievement is just the beginning of numerous commercial and clinical catalysts anticipated over the next 18 months across our late-stage programs – ARIKAYCE, brensocatib, and TPIP – and our growing clinical pipeline of first- or best-in-class therapies. With these opportunities ahead, our team is more dedicated than ever to transforming the lives of patients with serious diseases."

Recent Progress and Anticipated Milestones by Program:

ARIKAYCE

- ARIKAYCE global revenue grew 22% in the third quarter of 2025 compared to the third quarter of 2024, reflecting year-over-year growth across all geographic regions.
- The Company anticipates the topline readout of the Phase 3 ENCORE trial in the first half of 2026 in patients with newly diagnosed or recurrent *Mycobacterium avium* complex (MAC) lung disease who have not started antibiotics.
- Assuming successful results from the ENCORE trial, Insmed plans to submit a supplementary new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for ARIKAYCE in all patients with MAC lung disease in the U.S. in the second half of 2026.

Brensocatib

- In August 2025, the FDA approved the Company's New Drug Application (NDA) for brensocatib for patients with non-cystic fibrosis bronchiectasis (NCFB). BRINSUPRI™ (brensocatib 25mg and 10mg tablets) was subsequently launched commercially in the U.S.
- In October 2025, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the approval of BRINSUPRI (brensocatib 25mg tablets) for the treatment of NCFB in the European Union (EU).
- Regulatory submissions for brensocatib for patients with bronchiectasis in theUnited Kingdom (UK) and Japan have been accepted. Insmed anticipates commercial launches for the EU, UK, and Japan in 2026, pending approval in each territory.
- Insmed expects to report topline data from the Phase2b BiRCh study of brensocatib in patients with chronic rhinosinusitis without nasal polyps (CRSsNP) by early January 2026.
- In October 2025, Insmed completed enrollment in the Phase2b CEDAR study of brensocatib in patients with hidradenitis suppurativa (HS). Insmed now expects to report topline data from CEDAR in the first half of 2026.

TPIP

- Insmed anticipates initiating PALM-ILD, a Phase 3 study of treprostinil palmitil inhalation powder (TPIP) in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD), in the fourth quarter of 2025.
- Insmed plans to initiate a Phase 3 study of TPIP in patients with pulmonary arterial hypertension (PAH) in early 2026.
- The Company anticipates initiating additional Phase 3 studies of TPIP in progressive pulmonary fibrosis (PPF) and idiopathic pulmonary fibrosis (IPF) in the second half of 2026.

Gene Therapy

- Insmed completed dosing of the first cohort in the Phase 1 ASCEND clinical study of INS1201, an intrathecally-delivered gene therapy for patients with Duchenne muscular dystrophy (DMD).
- The Company's Investigational New Drug (IND) filing for INS1202, an intrathecally-delivered gene therapy for patients with Amyotrophic lateral

sclerosis (ALS), has been cleared by the FDA.
- Insmed's third gene therapy candidate targeting Stargardt disease is currently advancing toward the clinic, with an IND filing expected in the first half of 2026.

Pre-Clinical Programs

- Insmed's research efforts include more than 30 identified pre-clinical programs in development, all of which have the potential to become first-in-class or best-in-class therapies for the indications being pursued.
- The Company anticipates submitting an average of one to two INDs per year from its pre-clinical research programs.
- Insmed continues to anticipate that the totality of its pre-clinical research programs will comprise less than 20% of overall expenditures.

Corporate Updates

- In September 2025, Insmed presented seven abstracts from across its portfolio at the European Respiratory Society (ERS) Congress 2025.
- In October 2025, Insmed presented six abstracts from across its portfolio at the American College of Chest Physicians (CHEST) 2025 Annual Meeting.
- In October 2025, Insmed announced that it has earned the No. 1 ranking in*Science*'s 2025 Top Employers Survey, marking the fifth consecutive year in which Insmed achieved the top ranking. The annual survey polls employees in biotechnology, pharmaceutical, and related industries to determine the 20 best employers, as well as their driving characteristics.

Third-Quarter 2025 Financial Results

The following table summarizes Insmed's third-quarter and year-to-date 2025 and 2024 revenues and revenue growth across all commercial regions:

	Three Months Ended September 30,			***Nine Months Ended September 30,***		
(in millions)	**2025**	**2024**	**Growth**	**2025**	**2024**	**Growth**
ARIKAYCE						
U.S.	$ 74.0	$ 66.9	11 %	$ 206.9	$ 187.0	11 %
International	40.3	26.6	52 %	107.6	72.3	49 %
Total	$ 114.3	$ 93.4	22 %	$ 314.5	$ 259.3	21 %
BRINSUPRI						
U.S.	$ 28.1	$ -	N/A	$ 28.1	$ -	N/A
International	-	-	N/A	-	-	N/A
Total	$ 28.1	$ -	N/A	$ 28.1	$ -	N/A
Total Revenues						
U.S.	$ 102.0	$ 66.9	53 %	$ 235.0	$ 187.0	26 %
International	40.3	26.6	52 %	107.6	72.3	49 %
Total	$ 142.3	$ 93.4	52 %	$ 342.6	$ 259.3	32 %

- Cost of product revenues (excluding amortization of intangibles) was$29.4 million for the third quarter of 2025, compared to$21.2 million for the third quarter of 2024. The increase in cost of product revenues primarily reflects growth in ARIKAYCE sales and BRINSUPRI sales.
- Research and development (R&D) expenses were$186.4 million for the third quarter of 2025, compared to$150.8 million for the third quarter of 2024. The increase in R&D expenses was primarily related to increases in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount, as well as clinical development and research costs, and manufacturing costs.
- Selling, general and administrative (SG&A) expenses for the third quarter of 2025 were$186.4 million, compared to $118.9 million for the third quarter of 2024. The increase in SG&A expenses was primarily related to increases in professional fees and other external expenses, as well as increases in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount, both driven by commercial readiness and commercial activities for BRINSUPRI.
- For the third quarter of 2025, Insmed reported a net loss of$370.0 million, or $1.75 per share, compared to a net loss of$220.5 million, or $1.27 per share, for the third quarter of 2024.

Balance Sheet, Financial Guidance, and Planned Investments

- As of September 30, 2025, Insmed had cash, cash equivalents, and marketable securities totaling approximately$1.7 billion.
- Insmed is raising its full-year 2025 global ARIKAYCE revenue guidance to a range of$420 million to $430 million, from a range of $405 million to $425 million previously, representing a range of 15% to 18% year-over-year growth compared to 2024.
- The Company plans to continue to invest in the following key activities in 2025:

(i) commercialization and expansion of BRINSUPRI in the U.S., with advancement of regulatory submissions for brensocatib in Europe, the UK, and Japan;
(ii) commercialization and expansion of ARIKAYCE globally;
(iii) advancement of clinical trial programs for brensocatib, including the ongoing Phase 2b BiRCh study in patients with CRSsNP and the Phase 2b CEDAR study in patients with HS;
(iv) advancement of the Phase 3 ENCORE study for ARIKAYCE, which is intended to satisfy the post-marketing requirement for full approval of its current indication and potentially support label expansion to include all patients with a MAC lung disease;
(v) advancement of clinical development programs for TPIP, including the initiation of a Phase 3 study in patients with PH-ILD and preparations for separate Phase 3 studies in patients with PAH, PPF, and IPF;
(vi) advancement of the Phase 1 ASCEND study for INS1201 in DMD; and
(vii) continued development of its pre-clinical research programs.

Conference Call

Insmed will host a conference call beginning today,October 30, 2025, at 8:00 AM Eastern Time. Shareholders and other interested parties may participate

in the conference call by dialing (888) 210-2654 (U.S.) and (646) 960-0278 (international) and referencing access code 7862189. 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 1 hour after its completion through November 6, 2025, by dialing (800) 770-2030 (U.S.) and (609) 800-9909 (international) and referencing access code 7862189. 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**.

INSMED INCORPORATED
Consolidated Statements of Net Loss
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Product revenues, net	$ 142,342	$ 93,425	$ 342,580	$ 259,265
Operating expenses:				
Cost of product revenues (excluding amortization of intangible assets)	29,365	21,170	78,718	59,591
Research and development	186,415	150,809	516,182	418,640
Selling, general and administrative	186,376	118,930	488,684	318,601
Amortization of intangible assets	1,538	1,263	4,064	3,789
Change in fair value of deferred and contingent consideration liabilities	104,653	14,682	181,953	106,482
Total operating expenses	508,347	306,854	1,269,601	907,103
Operating loss	(366,005)	(213,429)	(927,021)	(647,838)
Investment income	18,289	16,982	45,420	36,050
Interest expense	(20,382)	(21,054)	(63,196)	(63,363)
Change in fair value of interest rate swap	-	(3,852)	-	(1,106)
Other (expense) income, net	(603)	1,843	(18)	474
Loss before income taxes	(368,701)	(219,510)	(944,815)	(675,783)
Provision for income taxes	1,320	1,014	3,475	2,441
Net loss	$ (370,021)	$ (220,524)	$ (948,290)	$ (678,224)
Basic and diluted net loss per share	$ (1.75)	$ (1.27)	$ (4.89)	$ (4.27)
Weighted average basic and diluted common shares outstanding	211,759	173,721	194,087	159,013

INSMED INCORPORATED
Consolidated Balance Sheets
(in thousands, except par value and share data)

	As of September 30, 2025 (unaudited)	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 334,764	$ 555,030
Marketable securities	1,345,222	878,796
Accounts receivable	65,259	52,012
Inventory	120,965	98,578
Prepaid expenses and other current assets	65,597	37,245
Total current assets	1,931,807	1,621,661
Fixed assets, net	89,671	80,052
Finance lease right-of-use assets	16,239	18,273
Operating lease right-of-use assets	10,708	17,257
Intangibles, net	84,588	58,652
Goodwill	136,110	136,110
Other assets	91,613	93,226
Total assets	$ 2,360,736	$ 2,025,231
Liabilities and shareholders' equity		
Current liabilities:		

Accounts payable and accrued liabilities	$ 409,835	$ 285,209
Finance lease liabilities	3,246	2,961
Operating lease liabilities	4,133	9,358
Total current liabilities	417,214	297,528
Debt, long-term	539,719	1,103,382
Royalty financing agreement	163,854	161,067
Contingent consideration	259,600	144,200
Finance lease liabilities, long-term	21,595	24,064
Operating lease liabilities, long-term	7,588	9,112
Other long-term liabilities	5,595	499
Total liabilities	1,415,165	1,739,852
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 212,583,015 and 179,382,635 issued and outstanding shares at September 30, 2025 and December 31, 2024, respectively	2,126	1,794
Additional paid-in capital	6,249,654	4,645,791
Accumulated deficit	(5,308,207)	(4,359,917)
Accumulated other comprehensive gain (loss)	1,998	(2,289)
Total shareholders' equity	945,571	285,379
Total liabilities and shareholders' equity	$ 2,360,736	$ 2,025,231

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 BRINSUPRI™ (brensocatib)

BRINSUPRI™ (brensocatib) is a small molecule, once-daily, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) and 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. 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 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 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.

About INS1201

INS1201 is an investigational micro-dystrophin adeno-associated virus gene replacement therapy that Insmed is developing as a potential treatment for patients with Duchenne muscular dystrophy (DMD). Administered intrathecally, this approach has the potential to target both skeletal and cardiac muscles at lower doses. INS1201 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 ≥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 ≥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 throughoutthe 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: failure to continue to successfully commercialize ARIKAYCE in the U.S., Europe or Japan or failure to successfully commercialize BRINSUPRI in the U.S., or to maintain U.S., European or Japanese approval for ARIKAYCE or U.S. approval for BRINSUPRI; our inability to obtain full approval of ARIKAYCE from the FDA, including the risk that we will not successfully or in a timely manner complete the confirmatory post-marketing clinical trial required for full approval of ARIKAYCE, 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 Europe or Japan; failure to successfully commercialize our product candidates, if approved by applicable regulatory authorities, or to maintain applicable regulatory approvals for such product candidates, if approved; uncertainties or changes in the degree of market acceptance of our marketed products or, if approved, our product candidates, 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 our marketed products or, if approved, our product candidates, or acceptable prices for our marketed products or, if approved, our product candidates; inaccuracies in our estimates of the size of the potential markets for our marketed products and our product candidates 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 we are dependent to manufacture sufficient quantities of our marketed products and our product candidates for commercial or clinical needs, as applicable, to conduct our clinical trials, or to comply with our agreements or laws and regulations that impact our business; the risks and uncertainties associated with, and the perceived benefits of, our senior secured 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 our marketed products or any of our product candidates that are approved in the future; 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 or to permit the use of ARIKAYCE in the broader population of patients with MAC lung disease, among other things; 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; failure to successfully predict the time and cost of development, regulatory approval and commercialization for novel gene therapy products; 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 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 AI 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 our marketed products 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 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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