

December 4, 2025



Pelthos Therapeutics Signs Major Pharmacy Benefit Manager Agreement Expanding Patient Access to ZELSUVMI™ (berdazimer) Topical Gel, 10.3%

ZELSUVMI is the first and only FDA-approved at-home treatment for molluscum contagiosum, a highly contagious viral skin condition affecting an estimated 16.7 million people, with up to 6 million new incidents reported every year in the United States

DURHAM, N.C., Dec. 04, 2025 (GLOBE NEWSWIRE) -- Pelthos Therapeutics Inc. (NYSE American: PTHS), a biopharmaceutical company committed to commercializing innovative therapeutic products for unmet patient needs ("Pelthos"), today announced it has signed its first commercial agreement to expand patient access for [ZELSUVMI™](#) (berdazimer) topical gel, 10.3%, for the treatment of molluscum contagiosum in adults and pediatric patients one year of age and older ("ZELSUVMI").

Pelthos has entered into an agreement with a Group Purchasing Organization that collaborates with manufacturers on behalf of one of the largest Pharmacy Benefit Managers ("PBMs") in the United States. The PBM manages prescription drug benefits for more than 20 million covered lives, and the formulary inclusion updates for ZELSUVMI started on December 1, 2025.

"Partnering with a national pharmacy benefit manager is another important milestone in our efforts to achieve increased commercial coverage for ZELSUVMI," said Scott Plesha, CEO of Pelthos. "This new partnership will allow an important treatment option to be included in more coverage and distribution networks, thereby improving access for patients and caregivers who are seeking an at-home treatment for molluscum contagiosum."

Pelthos launched ZELSUVMI for the treatment of molluscum contagiosum in adults and pediatric patients one year of age and older in July 2025. ZELSUVMI is a novel, topical nitric oxide-releasing gel for the treatment of molluscum. The once-daily prescription medication is effective, well-tolerated, and convenient for at-home or on-the-go application and can be used to treat molluscum contagiosum infections on the body, including sensitive areas such as the face, groin, or underarms. ZELSUVMI received a Novel Drug designation from the U.S. Food and Drug Administration in January 2024 and is the first and only prescription therapy approved for use at home by patients, parents, and caregivers to treat molluscum infections.

“This PBM partnership supports our overall patient services plan for ZELSUVMI. We are committed to reducing barriers for patients and providing access to our novel medication ZELSUVMI for those patients suffering from molluscum,” said Sai Rangarao, Chief Commercial Officer at Pelthos.

About Molluscum Contagiosum

Molluscum is a poxvirus and one of the most common skin infections seen by dermatologists, pediatric dermatologists, and pediatricians. This highly contagious viral skin condition afflicts an estimated 16.7 million people, with up to 6 million new incidents reported every year in the United States, most of them in children.^{1,2,3} Individuals with compromised immune systems are at an elevated risk of contracting molluscum, with the condition impacting approximately 20% of HIV patients.⁴ Molluscum infections spread to others through contact with infected persons or contaminated objects like towels, toys, furniture, swimming pools, and other surfaces. Molluscum infections present with raised, flesh-colored or red bumps that can appear anywhere on the body, including the face, hands, trunk, genitals, back of the knees, armpits, and other sensitive areas. People with molluscum may suffer discomfort from itching, secondary bacterial infections from scratching, or atopic dermatitis, as well as immense social stigma from having visible molluscum lesions that may persist for months to years. It is estimated that 30% of children will have lesions that persist beyond 18 months.⁵ Up to 73% of children with molluscum go untreated.

About ZELSUVMI (berdazimer) topical gel, 10.3%

ZELSUVMI (berdazimer) topical gel, 10.3% is a nitric oxide (NO) releasing agent indicated for the topical treatment of *molluscum contagiosum* in adults and pediatric patients one year of age and older. ZELSUVMI received a novel drug designation from the U.S. Food and Drug Administration in 2024 and is the first and only approved topical prescription medication that can be applied by patients, parents, or caregivers at home, outside of a physician’s office, or other medical setting to treat this highly contagious viral skin infection. The product was developed using the proprietary nitric oxide-based technology platform, NITRICIL™, now owned by Ligand Pharmaceuticals Incorporated. Complete prescribing information and important safety information is available at www.zelsuvmi.com.

IMPORTANT SAFETY INFORMATION

Contraindications: None.

Warnings: Application site reactions, including, allergic contact dermatitis occurred. Discontinue ZELSUVMI and initiate appropriate therapy.

Adverse Reactions: The most commonly reported adverse reactions (1%) are application site reactions including pain such as burning or stinging sensations (18.7%), erythema (11.7%), pruritus (5.7%), exfoliation (5.0%), dermatitis (4.9%), swelling (3.5%), erosion (1.6%), discoloration (1.5%), vesicles (1.5%), irritation (1.2%), and infection (1.1%).

Forward-Looking Statements

This press release contains forward-looking statements, as defined in Section 21E of the Securities Exchange Act of 1934, regarding Pelthos’ current expectations. All statements, other than statements of historical fact, could be deemed to be forward-looking statements. In some instances, words such as “plans,” “believes,” “expects,” “anticipates,” and “will,” and similar expressions, are intended to identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect our good faith beliefs (or those of the indicated third parties) and speak only as of the date

hereof. These forward-looking statements include, without limitation, references to our expectations regarding (i) our belief that the new pharmacy benefit manager agreement will expand patient access to ZELSUVMI, (ii) our plans for continued commercial growth and increased coverage for ZELSUVMI, and (iii) the Company's future opportunities, strategy and plans in the market. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Factors that could cause actual results to differ materially from those set forth in such forward-looking statements include, but are not limited to, risks and uncertainties related to our reliance on third-party partners for market access and distribution; the possibility that ZELSUVMI may not achieve market acceptance or broad formulary coverage; our ability to maintain regulatory approvals; and changes in general economic conditions, including as a result of war, conflict, epidemic diseases, the implementation of tariffs, and ongoing or future litigation could expose us to significant liabilities and have a material adverse effect on us. These and other risks and uncertainties are described more fully in our filings with the U.S. Securities and Exchange Commission. The information in this press release is provided only as of the date of this press release, and we undertake no obligation to update any forward-looking statements contained in this press release based on new information, future events, or otherwise, except as required by law.

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¹ ZELSUVMI. Prescribing information. EPIH SPV, LLC. 2024.

² Browning JC, Enloe C, Cartwright M, et al. Efficacy and safety of topical nitric oxide-releasing berdazimer gel in patients with molluscum contagiosum: a phase 3 randomized clinical trial. *JAMA Dermatol.* 2022;158(8):871-878

³ Han H, Smythe C, Yousefian F, Berman B. Molluscum contagiosum virus evasion of immune surveillance: a review. *J Drugs Dermatol.* 2023;22(2):182-189.

⁴ Neal Bhatia, Adelaide A Hebert, James Q Del Rosso. Comprehensive Management of Molluscum Contagiosum: Assessment of Clinical Associations, Comorbidities, and Management Principles. *Journal of Clinical and Aesthetic Dermatology.* 2023 Aug;16(8 Suppl 1):S12–S17

⁵ Olsen JR, Gallacher J, Finlay A, Piguet V, Francis NA. Time to resolution and effect on quality of life of molluscum contagiosum in children in the UK: a prospective community cohort study. *Lancet Infect Dis.* 2015;15:190-195



Source: Pelthos Therapeutics, Inc.