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Pelthos Therapeutics Launches ZELSUVMI™ (berdazimer) Topical Gel 10.3%, the First and Only FDA-Approved At-Home Treatment for Molluscum Contagiosum

- ZELSUVMI is now commercially available via prescription through retail pharmacies, ASPN pharmacy services and for at-home delivery through mail-order pharmacies
- Once-daily topical prescription medication can be applied by patients, parents and caregivers outside of a physician's office, at home or on the go
- Molluscum contagiosum is a highly contagious viral skin condition that afflicts an estimated 16.7 million people with up to 6 million new incidents per year in the United States, most of them children

DURHAM, N.C., July 10, 2025 (GLOBE NEWSWIRE) -- Pelthos Therapeutics Inc. (NYSE American: PTHS), a biopharmaceutical company committed to commercializing innovative therapeutic products for high unmet patient needs, today announced the launch of ZELSUVMI™ (berdazimer) topical gel, 10.3%, for the treatment of molluscum contagiosum (molluscum) in adults and pediatric patients one year of age and older.[i,ii] 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, a highly contagious viral skin condition.

“We believe that the commercial launch of ZELSUVMI marks a significant advancement for patients with molluscum and their caregivers, who previously lacked an at-home treatment option for this burdensome skin infection,” said Scott Plesha, CEO of Pelthos. “We are excited to make ZELSUVMI widely available for the millions of patients afflicted by this condition. Our commercial efforts will aim to provide stellar education and support for patients seeking effective treatment for their molluscum infections.”

ZELSUVMI is a novel, topical nitric oxide-releasing gel for the treatment of molluscum at the time of diagnosis. 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 infections on the body, including sensitive areas such as the face, groin, or underarms. ZELSUVMI was studied in the largest randomized clinical trial for the treatment of molluscum. The trial was a multicenter, randomized, double-blind, vehicle controlled, parallel-group, Phase 3 study of the efficacy and safety of ZELSUVMI in 891 patients. Complete clearance of molluscum

lesions was seen in nearly 33% of patients compared with 19.7% of patients who did not receive the active ingredient at the twelfth week. For many patients, ZELSUVMI demonstrated results within two weeks.[i,ii]

"Many parents delay seeking treatment for their children's uncomfortable lesions because current procedural treatments and frequent office visits can be inconvenient, while therapeutic options are limited. Untreated molluscum can spread throughout the child's body but also to other family members," said Nanette Silverberg, MD, Chief of Pediatric Dermatology at the Mount Sinai Health System. "A safe and effective topical gel for molluscum, like ZELSUVMI, which can be applied at home or on the go, would make a significant difference for this young patient population and address a serious, unmet medical need."

"We are launching our ZelsuvmiGo patient support program, which we expect to help onboard patients seamlessly and provide resources for caregivers," said Sai Rangarao, Chief Commercial Officer at Pelthos. "To ensure that ZELSUVMI reaches the people who need it quickly, we have hired 50 sales territory managers across the country to work with physicians who treat a high volume of patients with molluscum. We have also implemented extensive digital outreach and awareness efforts to ensure ZELSUVMI can be prescribed by any healthcare provider at any time. These patients have waited a long time for an at-home treatment option."

ZELSUVMI is now commercially available through retail pharmacies, ASPN pharmacy services and for at-home delivery through mail-order pharmacies via prescription. For more information about ZELSUVMI visit zelsuvmi.com.

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 every year in the United States, most of them children.[i,ii,iii] Individuals with compromised immune systems are at an elevated risk of contracting molluscum, with the condition impacting approximately 20% of HIV patients.[iv] 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.[v] Up to 73% of children with molluscum go untreated.[vi]

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%).

About Pelthos Therapeutics
Pelthos Therapeutics (NYSE American: PTHS) is a biopharmaceutical company committed to commercializing innovative, safe, and efficacious therapeutic products to help patients with unmet treatment burdens. The company's lead product ZELSUVMI™ (berdazimer) topical gel, 10.3%, for the treatment of *molluscum contagiosum*, was approved by the U.S. Food and Drug Administration in 2024. More information is available at www.pelthos.com. Follow Pelthos on LinkedIn and X.

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 commercial launch of ZELSUVMI marks a significant advancement for patients with molluscum and their caregivers, (ii) our commercial efforts will aim to provide stellar education and support for patients seeking effective treatment for their molluscum infections, (iii) our expectation that the launch of ZelsuvmiGo patient support program will help onboard patients seamlessly and provide resources for caregivers; and (iv) the timing of product launches, including ZELSUVMI. 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 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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