

January 6, 2023



Ligand's Partner Novan Submits New Drug Application to the U.S. FDA for Berdazimer Gel, 10.3% (SB206) for the Treatment of Molluscum Contagiosum

Potential FDA approval anticipated in the first quarter of 2024, assuming FDA filing acceptance and standard review timelines

Molluscum contagiosum is a viral skin infection that affects approximately 6 million people, mostly children

Berdazimer gel, 10.3% has the potential to be the first FDA-approved prescription product for molluscum

SAN DIEGO--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** announced that its partner Novan, Inc. (Nasdaq: NOVN) has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for berdazimer gel, 10.3% (SB206) for the topical treatment of molluscum contagiosum (molluscum). Assuming the filing is accepted by the FDA and given a typical 12-month review process, Novan anticipates a potential first quarter 2024 approval.

Under a development funding and royalties agreement with Novan for berdazimer gel, Ligand is entitled to receive up to \$20 million of milestone payments and tiered royalties of 7% to 10% on future worldwide sales of berdazimer gel.

"In 2019 Ligand provided funding to Novan for the clinical development of berdazimer gel in exchange for milestones and royalties. Today's announcement brings the Novan team one step closer to potentially marketing an important medicine and provides further validation of our strategy of expanding our royalty portfolio by providing development capital," said Todd Davis, CEO of Ligand. "As we look to the future, we will continue to seek similar investments in high quality assets led by highly capable teams."

"Today marks a significant milestone for Novan and the culmination of substantial efforts of the entire Novan team – the company's first NDA submission. I am extremely proud of our team and the progress thus far with berdazimer gel, 10.3%. Based on the robust data generated from our Phase 3 studies, we believe the product candidate is well-positioned to treat molluscum, which remains an unmet need. The NDA submission brings Novan closer to providing what could be the first FDA-approved prescription product for the treatment of this contagious viral skin infection," commented Paula Brown Stafford, President and CEO of Novan.

Berdazimer gel, 10.3% is poised to be a first-in-class topical treatment for molluscum. The

active ingredient, berdazimer sodium, is a new chemical entity that releases nitric oxide and has anti-viral activity. If approved, berdazimer gel, 10.3% would be the first topical treatment indicated for molluscum with the convenience of self-application.

According to Novan, results from the pivotal Phase 3 B-SIMPLE4, clinical study evaluating berdazimer gel, 10.3% for the treatment of molluscum (NCT04535531) demonstrated highly statistically significant improvement in primary clinical endpoint ($p < 0.0001$) in the largest cohort of molluscum patients ever studied, which results were recently published in JAMA Dermatology. Berdazimer gel, 10.3% was found to be well tolerated with mild application site pain and mild to moderate erythema reported as the most common adverse events.

“Many patients with molluscum go untreated due to a lack of FDA-approved therapeutic options. A topical gel applied by the patient or caregiver that has the potential to clear molluscum lesions and is well tolerated would likely be a significant change to clinical practice. Right now, we are limited to in-office procedures to treat this bothersome infection. I think caregivers and patients with molluscum would welcome berdazimer gel as a breakthrough in treatment. I look forward to the potential of having this option available for my patients,” said Adelaide Hebert, M.D., Chief of Pediatric Dermatology at McGovern School of Medicine and Children’s Memorial Hermann Hospital.

About Berdazimer

Berdazimer sodium, the active ingredient in berdazimer gel, 10.3% (SB206), is a new chemical entity. Berdazimer gel, 10.3% for the treatment of molluscum contagiosum is a potential first-in-class topical nitric oxide-releasing agent with positive Phase 3 data submitted to the FDA. Berdazimer gel, 3.4% (SB204), a topical monotherapy in Phase 3 clinical development for the treatment of acne, utilizes the same active ingredient as berdazimer gel, 10.3% and is formulated specifically to address acne.

About Molluscum

Molluscum contagiosum is a common, contagious skin viral infection caused by the *molluscipoxvirus*, affecting approximately six million people in the U.S., with the greatest incidence in children aged one to 14 years. Infected children typically present with 10 to 30 unsightly lesions, and in severe cases, they can have around 100 lesions, mostly clustering on the face, trunk, limbs and axillary areas. Over 70% of molluscum patients go untreated. There are no FDA-approved therapies for molluscum, with current treatments limited to potentially painful in-office, healthcare provider-administered physical procedures or cantharidin, or off-label prescriptions and over-the-counter products. Molluscum may take a long time to resolve, with lesions persisting 13 months to 5 years, and transmission of this highly-contagious virus is common, spreading to other children through direct skin contact or sharing contaminated objects like towels. In-household transmission to other children is reported around 41%. Despite the prevalence and high transmissibility, there is a significant unmet need in the molluscum treatment landscape.

About Ligand Pharmaceuticals

Ligand is a revenue-generating biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines. Our business model creates value for stockholders by providing a diversified portfolio of

biotech and pharmaceutical product revenue streams that are supported by an efficient and low corporate cost structure. Our goal is to offer investors an opportunity to participate in the promise of the biotech industry in a profitable, diversified and lower-risk business than a typical biotech company. Our business model is based on doing what we do best: drug discovery, early-stage drug development, product reformulation and partnering. We partner with other pharmaceutical companies to leverage what they do best (late-stage development, regulatory management and commercialization) ultimately to generate our revenue. Ligand's Captisol platform technology is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Ligand's Pelican Expression Technology is a robust, validated, cost-effective and scalable platform for recombinant protein production that is especially well-suited for complex, large-scale protein production where traditional systems are not. Ligand has established multiple alliances, licenses and other business relationships with the world's leading pharmaceutical companies including Amgen, Merck, Pfizer, Takeda, Gilead Sciences and Baxter International. For more information, please visit www.ligand.com.

Forward-Looking Statements

This news release contains forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand's judgment as of the date of this release. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to the timing of potential FDA acceptance and approval of the Novan's NDA for berdazimer gel, 10.3% (SB206) for molluscum contagiosum, the therapeutic value and benefits and safety of the Novan's technology and its product candidates, including berdazimer gel, 10.3% (SB206), the potential market opportunity for Novan's product candidates, the timing and amount of milestone payments and royalties Ligand expects to receive in connection with the commercialization of Novan's SB206, and the validation and success of Ligand's strategy of expanding its royalty portfolio by providing development capital. Actual events or results may differ from Ligand's expectations due to risks and uncertainties inherent in Ligand's business, including, without limitation: risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable, including the risk that the FDA will not agree with Novan's approach in its NDA submission for berdazimer gel, 10.3% (SB206) for molluscum contagiosum or any future NDA submissions, that Novan's product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that Novan may not obtain funding sufficient to extend its cash runway or to complete the regulatory or development process; changes in the size and nature of the market for Novan's product candidates and promoted products, including potential competition, patient and payer perceptions and reimbursement determinations; that any of Novan's product candidates, if approved, will continue to demonstrate requisite safety and efficacy following their commercial launch; Ligand is dependent on Novan for the development and commercialization of SB206; the COVID-19 pandemic has disrupted and may continue to disrupt Ligand's and its partners' business, including delaying manufacturing, preclinical studies and clinical trials and product sales, and impairing global economic activity, all of which could materially and adversely impact Ligand's results of operations and financial condition; Ligand or its partners may not be able to protect their intellectual property and patents covering certain products and technologies may be challenged or invalidated; Ligand's partners may terminate any of their agreements or development or

commercialization of any of their products; and other risks described in Ligand's prior press releases and filings with the Securities and Exchange Commission available at www.sec.gov. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20230106005095/en/>

Ligand Pharmaceuticals Incorporated

Simon Latimer

investors@ligand.com

(858) 550-7766

Twitter: @Ligand_LGND

LHA Investor Relations

Bruce Voss

bvoss@lhai.com

(310) 691-7100

Source: Ligand Pharmaceuticals Incorporated