Lumos Pharma Announces that the USPTO Has Granted Patent Protection for Novel Formulation of LUM-201, Extending Exclusivity to 2042

Mar 20, 2024

AUSTIN, Texas, March 20, 2024 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a biopharmaceutical company advancing an oral therapeutic candidate for Pediatric Growth Hormone Deficiency (PGHD) through Phase 2 clinical trials, announced that on Thursday, March 14, 2024, the Company received a Notice of Allowance from the US Patent and Trade Office (USPTO) for claims in its patent application number PCT/US22/050700 titled “Compactable Oral Formulations of Ibutamoren.” This patent contains claims directed to certain improved formulations of LUM-201 the Company intends to utilize in its Phase 3 trial and ultimately commercialize. This grant of this novel formulation patent extends intellectual property protection through November 2042 for these improved versions of LUM-201 drug product.

“We are excited to announce that LUM-201 has been granted a novel formulation patent by the USPTO, which is enabled by unique properties of this molecule achieved through our improved manufacturing processes,” said Rick Hawkins, Lumos Pharma’s Chairman and CEO. “Importantly, this new patent extends our exclusivity of LUM-201 through 2042, surpassing our current method of use patent expiration in 2036. This novel formulation of LUM-201 permits a capsule with mini-tablets, which should reduce dose variance and enable easier administration for younger children. We intend to employ this formulation in our upcoming Phase 3 trial evaluating oral LUM-201 in moderate pediatric growth hormone deficiency (PGHD) expected to start in Q4 2024, and eventually in the commercial setting following potential regulatory approval of LUM-201.”

About LUM-201

LUM-201 (ibutamoren) is an orally administered small molecule that promotes the secretion (secretagogue) of Growth Hormone (GH) from the pituitary gland.[1] LUM-201 acts as an agonist of the GH Secretagogue Receptor to stimulate GH release and to suppress the release of somatostatin.[2] LUM-201 has been observed to increase the amplitude of endogenous pulsatile GH secretion in humans, which mimics the natural pattern of GH secretion. [3,4] This therapeutic candidate has been studied in more than 1,300 patients, both adult and pediatric, and was generally well tolerated with the most commonly reported adverse events being digestive systems events, including appetite increase. Mild elevations in liver enzymes without accompanying changes in bilirubin were also reported. LUM-201 has received Orphan Drug Designation in both the US and EU.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. The Company was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma’s lead therapeutic candidate, LUM-201, is a novel, oral growth hormone (GH) secretagogue, seeking to transform the ~$4.7B global GH market from injectable to oral therapy. LUM-201 is currently being evaluated in multiple Phase 2 clinical studies in Pediatric Growth Hormone Deficiency (PGHD) and has received Orphan Drug Designation in both the US and EU. For more information, please visit https://lumos-pharma.com/.

[1] Patchett A.A., et al. Design and Biological Activities of L-163,191 (MK-0677): A Potent, Orally Active Growth Hormone Secretagogue, Proc Natl Acad Sci, 1995, 92:7001-7005.

[2] Howard A.D., et al. A Receptor in Pituitary and Hypothalamus that Functions in Growth Hormone Release, Science, 1996, 273:974-977.

[3] Nass R., et al. Effects of an Oral Ghrelin Mimetic on Body Composition and Clinical Outcomes in Healthy Older Adults, Ann Intern Med, 2008, 149:601-611.

[4] Chapman I.M., et al. Oral Administration of Growth Hormone (GH) Releasing Peptide-Mimetic MK-677 Stimulates the GH/Insulin-Like Growth Factor-I Axis in Selected GH-Deficient Adults, J Clin Endocrinol Metab, 1997, 82(10):3455-3463.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All such statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. A law that, in part, gives us the opportunity to share our outlook for the future without fear of litigation if it turns out our predictions were not correct.

We are passionate about our business - including LUM-201 and the potential it may have to help patients in the clinic. This passion feeds our optimism that our efforts will be successful and bring about meaningful change for patients. Please keep in mind that actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make.

We have attempted to identify forward-looking statements by using words such as “projected,” "upcoming," "will," “would,” “should,” "plan," “intend,” "anticipate," "approximate," "expect," “potential,” “imminent,” and similar references to future periods or the negative of these terms. Not all forward-looking statements contain these identifying words. Examples of forward-looking statements include, among others, statements we make regarding the advancement of oral LUM-201 to Phase 3, the potential for LUM-201 to be the first oral therapeutic for PGHD, and any other statements other than statements of historical fact.

We wish we were able to predict the future with 100% accuracy, but that just is not possible. Our forward-looking statements are neither historical facts nor assurances of future performance. You should not rely on any of these forward-looking statements and, to help you make your own risk determinations, we have provided an extensive discussion of risks that could cause actual results to differ materially from our forward-looking

statements including risks related to the continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 meeting with the FDA, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to structure our Phase 3 trial in an effective and timely manner, the ability to successfully develop our product candidate, the effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict and the Middle East conflict and other risks could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements including information in the "Risk Factors" section and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2023, as well as other reports filed with the SEC including our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. All of these documents are available on our website. Before making any decisions concerning our stock, you should read and understand those documents.

We anticipate that subsequent events and developments will cause our views to change. We may choose to update these forward-looking statements at some point in the future, however, we disclaim any obligation to do so. As a result, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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