Vision-DMD sponsor ReveraGen BioPharma Receives FDA Fast Track Designation for Vamorolone for the Treatment of Duchenne Muscular Dystrophy

ROCKVILLE, Maryland, March 24, 2017

ReveraGen BioPharma Inc, a privately held corporation, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for vamorolone (VBP15) for the treatment of patients with Duchenne muscular dystrophy. This designation can speed the review of efficacy and safety data for vamorolone in boys with DMD, potentially leading to more rapid regulatory approval. Vamorolone is under parallel guidance from the FDA and the European Medicines Agency (EMA).

By granting this designation, FDA acknowledges that the vamorolone program is directed towards development of a potential treatment for a serious condition, and addresses an unmet medical need. The VISION-DMD clinical trial program for vamorolone is currently enrolling boys with DMD into clinical trials in US, Canada, Australia, Sweden, UK, and Israel (open label Phase 2a, Phase 2a extension, and Long-term extension studies). Blinded, placebo- and glucocorticoid-controlled Phase 2b trials are expected to initiate enrollment later this year.

“We are excited about this new development in our discussions with FDA”, said Eric Hoffman, Ph.D., CEO of ReveraGen. “We hope that our innovative clinical program in DMD, with extensive use of pharmacodynamic biomarkers, will lead to a rapid read-out of drug effect”.

About vamorolone

Vamorolone is an oral, once-daily formulation with multiple mechanisms of action that are thought to target multiple aspects of DMD muscle pathology. It is a potent glucocorticoid receptor agonist that shows strong anti-inflammatory activity, but without many of the safety concerns seen with other steroidal immune modulators. Vamorolone is also a mineralocorticoid receptor antagonist, and has been shown to aid dystrophic heart function in mouse models of DMD. Finally, vamorolone stabilizes plasma membranes, and may counteract the membrane instability caused by dystrophin deficiency in DMD. The vamorolone DMD clinical program is supported by the National Institutes of Health (NIAMS, NINDS) and the European Community Horizons 2020 program.

About ReveraGen BioPharma

ReveraGen is a privately held, clinical-stage pharmaceutical company with vamorolone in DMD as the lead program. The vamorolone pre-clinical and clinical programs have been carried out in collaboration with international stake holder non-profit foundations and governments, and with Actelion

Pharmaceuticals through an initial milestone payment related to an option agreement for future vamorolone sales and distribution.

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See also http://vision-dmd.info/

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ReveraGen BioPharma www.reveragen.com

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