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Mezzion Pharma announces positive results from FUEL trial

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In adolescents with single ventricle heart disease who have undergone the Fontan procedure

Mezzion Pharma Co. Ltd., a biotech company based in Korea, haas announced that top line data from the Phase 3 Fontan Udenafil Exercise Longitudinal (FUEL) trial, which was designed to evaluate the safety and efficacy of udenafil for the treatment of certain adolescents with congenital single ventricle heart disease (SVHD), had positive results for key parameters.

Although Mezzion is restricted in providing specific data results at the present time due to contractual obligation, the Company is looking forward to publication of the full results in a peer reviewed journal and the presentation of the clinical trial data at a major scientific meeting later this year.

The FUEL Trial is a study in 400 male and female adolescents with a single functional ventricle who had previously undergone Fontan surgical palliation. Study participants were drawn from a total of 30 Pediatric Heart Network http://www.pediatricheartnetwork.org/ (PHN) and auxiliary sites throughout the U.S., Canada, and Korea. The PHN is funded by the National Heart, Lung, and Blood Institute, part of the National Institutes of Health.

In view of these results from the FUEL trial and the safety data collected about the drug candidate over other clinical studies, Mezzion Pharma intends to submit a New Drug Application to the U.S. Food and Drug Administration to seek approval for the use of udenafil to treat adolescents with SVHD who have undergone Fontan palliation.

In addition to this FUEL trial, Mezzion continues forward in its clinical efforts with the FALD study, also conducted under the auspices of the PHN, which is measuring the ability of udenafil to impact the effects of Fontan Associated Liver Disease.