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Pfizer announces positive Ph 3 results for long-acting human growth hormone

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Results demonstrated improved treatment burden with once-weekly injection

Pfizer Inc., an American multinational pharmaceutical corporation headquartered in New York City and OPKO Health Inc., a medical test and medication company focused on diagnostics and pharmaceuticals has announced that C0311002, a Phase 3, randomized, multicenter, open-label, crossover study evaluating somatrogon dosed once-weekly in children 3 to <18 years of age with growth hormone deficiency (GHD), met its primary endpoint of improved treatment burden compared to GENOTROPIN® (somatropin) for injection administered once-daily.

Top-line results from the study demonstrated that treatment with somatrogon once-weekly improved the mean overall Life Interference total score after 12 weeks of treatment (8.63) compared to treatment with somatropin administered once-daily (24.13). The point estimate of the treatment difference was -15.49 (-19.71, -11.27 (95% CI); $p<0.0001$) in favor of somatrogon at the nominal 0.05 level. In addition, key secondary endpoints showed an overall benefit in treatment experience with the somatrogon once-weekly dosing regimen compared to the somatropin once-daily dosing regimen.

No serious adverse events (SAEs) were reported during either of the treatment periods, and one participant discontinued use of somatrogon following a nonserious treatment-emergent adverse event (AE). The incidence of treatment-emergent AEs between the treatment arms were comparable and all AEs were mild to moderate in severity.

In 2014, Pfizer and OPKO entered into a worldwide agreement for the development and commercialization of somatrogon for the treatment of GHD. Under the agreement, OPKO is responsible for conducting the clinical program and Pfizer is responsible for registering and commercializing the product. The companies will evaluate the potential for additional pediatric and adult indications, as appropriate.